National Guideline
and Operational Manual for Tuberculosis

Sixth Edition
October 2021

World Health Organization
Bangladesh

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Message

Tuberculosis (TB) is a communicable disease which causes major health problem globally. About 85% of people with TB disease can be successfully treated with a 6 month durg regimen and get benefit of curtailing onward transmission of infection. Since 2000, TB treatment has averted more than 60 million deaths. Despite being a preventable and curable disease, TB is one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent. To achieve The End TB Strategybe 2035, National Tuberculosis control program (NTP), Bangladesh is working hard for case findings and their treatment outcomes under DOTs through GO-NGO collaborating approach. Preventive treatment is available for people with TB infaction. But still TB remains a major public health problem and Bangladesh is one of the high TB burden countries. Many cases have missed out on diagnosis and care.

To face the challenges and to adopt the WHO recommended new policies in relation to TB diagnosis, management and TB preventive therapy, NTP felt the need of revising the existing guidelines. I am delighted to say that with valuable contribution from all stakeholders working in the field of TB control NTP has updated the guideline and is being published as 6th edition.

On behalf of NTP Bangladesh, I would like to express my heartfelt thanks to the working group consisting of experts form NTP and the partners for their contribution in this regards. I also thankfully acknowledge the support form our technical and development partners e.g. WHO, USAID, GFATM for extending the TB control efforts in Bangladesh.

I hope that this revised guideline will be helpful for all health care professionals and at the same time any suggestion and recommendation for its further improvement would be highly appreciated.

Lokman Hossain Miah

Director General
Directorate General of Health Services
Mohakhali, Dhaka.

Message

Tuberculosis is an ancient disease, which is still a major public health challenge in Bangladesh and remains in the 30 TB high-burden countries. The problem is aggravated by the increasing population density, rapid urbanization, poverty and illiteracy.

Since the introduction of DOTS strategy in 1993, The National Tuberculosis Control Programme (NTP) has achieved a remarkable success in terms of TB treatment coverage for both pulmonary and extrapulmonary TB and their treatment outcomes. The programme has been maintaining a high (>95%) treatment success over the last decade.

The most cost-effective public health measure for the control of tuberculosis is early detection and successful treatment of infectious patients. However, NTP, Bangladesh has also given emphasis on diagnosis and treatment of all types of TB including drug resistant TB, child TB and TB/HIV co-infection in the light of end TB strategy.

The access to rapid diagnostics has been ensured below subdistrict level, the number of GeneXpert machines increased up to 470 in 2021 from 52 in 2018. New treatment options, preventive treatment and people-centered services have successfully commenced. NTP is committed to ensure human rights and stigma-free TB services to every person including migrants, prisoners, children, the elderly and other high-risk populations.

I sincerely acknowledge and appreciate the support and contribution of the National Tuberculosis Control Programme and its implementing partners in updating this crucial document. I would also like to express my earnest thanks to all development and technical partners for their support in this regard.

Prof. Dr. Abul Bashar Mohammad Khurshid Alam

Line Director TBL & ASP
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Message

Despite the encouraging progress, global tuberculosis burden is still enormous with an estimated 9.9 million incident TB cases and 1.3 million TB deaths in 2020. Bangladesh is one of the high burden countries for TB in the world with annual incidence of 360,000 TB cases 44,000 death each year. But there are significant improvements also, the National TB Control Programme has attained more than 95% treatment success and showed a rapid increase in case detection.

Bangladesh successfully achieved the END TB death reduction target of 2020 but still the challenge remains with the static incidence rate. Bangladesh also met the United Nations High-Level Meeting (UNHLM) target of TB and MDR TB case notification in 2018 and 2019. NTP is working hard along with partners to meet the targets of child TB and TB preventive treatment.

To face the challenges and to achieve universal access to quality TB care for all people affected with TB, NTP has given special emphasis on those specific areas in the light of End TB strategy. Under this situation revision of the National Guidelines and Operational Manual for Tuberculosis Control was demand of the time. I am glad to announce that now this is on board.

The revision of this national guidelines has been done through a series of consultative participatory process involving key stakeholders working in the field of TB control. This revised 6th edition has been enriched through adopting the WHO's new recommendations regarding case diagnosis, case definition, and case management and follow up. I trust from my heart that this document will be instrumental for all professionals of the public and private health care providers involved in the National Tuberculosis Control Programme.

I do hope with the cooperation and support from all concerns, NTP, Bangladesh will be able to achieve its goal by following this revised guidelines.

Dr. Md. Khurshid Alam

Dr. Bardan Jung Rana
WHO Representative to Bangladesh

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Message

Globally, countries have made substantial progress in the fight against tuberculosis (TB) to reduce the prevalence, enhance specialized care and raise public awareness of this preventable and curable disease. Through a multisectoral strategic approach which includes the involvement of highlevel representatives, the World Health Organization (WHO) has been closely working with countries, partners and civil society all around the world in scaling up the TB response and translate commitments into actions.

Much has been achieved in recent decades to end the tuberculosis epidemic. Global efforts to combat TB have saved an estimated 63 million lives since the year 2000. However, TB remains a public health threat, affecting vulnerable populations and killing almost 4 000 people a day. Tuberculosis occurs in every part of the world, but over 95% of cases and deaths are registered in developing countries. In 2019, 87% of new TB cases occurred in the 30 high TB burden countries, with eight countries accounted for two thirds of the new TB cases, including Bangladesh.

There has been significant progress in testing, detection and treatment of TB. The global TB report in 2020 revealed that the TB treatment coverage was 81% in 2019 in comparison to 76% during the previous year with a high treatment success rate. WHO is honored to be associated with the Government of Bangladesh through the Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MOHFW) to address unreached populations with early diagnosis and offer appropriate treatment to patients suffering from various forms of TB.

WHO is committed to providing necessary technical guidance and assistance to the government in translating these guidelines into quality services for the patients and continue evidence generation through surveillance and research for future refinement of the policies and strategies to align with the growing global evidences. We will also continue to work with all stakeholders and implementing partners in order to fight against TB.

I expect that this Revised National Guidelines and Operational Manual for Tuberculosis Control will be strengthen the capacity of all health care professionals involved in the National Tuberculosis Control Programme of Bangladesh who provides tuberculosis care at the central or peripheral level health care facilities both in public and private sector, envisioning a world free of tuberculosis.

Dr Bardan Jung Rana

Abbreviation and Acronyms

ACSM	Advocacy, Communication, and Social Mobilization
ACF	Active Case Finding
ACH	Air Changes per Hour
ADR	Adverse Drug Reaction
AFB	Acid-fast bacillus
AIC	Airborne Infection Control
AIDS	Acquired Immune Deficiency Syndrome
AMC	Annual Maintenance Contract
AMK	Amikacin
ART	Antiretroviral Therapy
ATT	Anti-tubercular Treatment
BCAP	Bedaquiline Conditional Access Programme
BCG	Bacille Calmette-Guerin
BDQ	Bedaquiline
BMI	Body Mass Index
BSC	Biological Safety Cabinet
C&DST	Culture and Drug Susceptibility Testing
CB-NAAT	Cartridge-based Nucleic Acid Amplification Test
CHW	Community Health Worker
CFZ	Clofazimine
CI	Contact Investigation
CME	Continuing Medical Education
CPT	Cotrimoxazole Preventive Therapy
CSO	Civil Society Organization
CXR	Chest X-Ray
DLM	Delamanid
DM	Diabetes mellitus
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy, Short-course
DR-TB	Drug Resistant Tuberculosis
DRS	Drug Resistance Surveillance
DST	Drug Susceptibility Testing
DS-TB	Drug-Sensitive Tuberculosis
DQA	Data Quality Assurance
E	Ethambutol
EPTB	Extrapulmonary Tuberculosis
EQA	External Quality Assurance

FDC	Fixed-dose Combination
FLD	First-line Drugs
FQ	Fluoroquinolone
GDF	Global Drug Facility
GFATM	Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
H	Isoniazid
HA	Health Assistant
HBC	High Burden Countries
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HR	Human Resources
HS	Health Systems
HSS	Health Systems Strengthening
IC	Infection Control
ICF	Intensified Case Finding
ICT	Information and Communication Technologies
IEC	Information, Education, and Communication
IGRA	Interferon-Gamma Release Assay
INH	Isoniazid
IPC	Infection Prevention and Control
JMM	Joint Monitoring Mission
KPI	Key Performance Indicator
LFX	Levofloxacin
LPA	Line Probe Assay
LT	Laboratory Technician
LTBI	Latent Tuberculosis Infection
LTFU	Lost To Follow Up
LZD	Linezolid
M&E	Monitoring and Evaluation
MDG	Millennium Development Goal
MDR	Multidrug Resistance
MDR-TB	Multidrug Resistant Tuberculosis
MFX	Moxifloxacin
MGIT	Mycobacteria Growth Indicator Tube
MTB	Mycobacterium Tuberculosis
NCD	Noncommunicable Disease
NGO	Non-governmental Organization
NGS	Next-Generation Sequencing
NTRL	National TB Reference Laboratory
NSP	National Strategic Plan

NTM	Non-Tuberculous Mycobacteria
NTP	National Tuberculosis Control Programme
OR	Operational Research
PCR	Polymerase Chain Reaction
PICT	Provider Initiated Counseling and Testing
PLHIV	People Living with HIV/AIDS
PP	Private Practitioner
PPM	Public-Private Mix
PTB	Pulmonary Tuberculosis
QA	Quality Assurance
R (or RIF)	Rifampicin
RR-TB	Rifampicin-Resistant Tuberculosis
RTRL	Regional TB Reference Laboratory
SDG	Sustainable Development Goals
SEARO	South East Asia Regional Office
SLD	Second-line Drugs
SL-DST	Second-line Drug Susceptibility Testing
SLI	Second-line Injectable Drugs
SNRL	Supra National Reference Laboratory
TA	Technical Assistance
TAT	Turnaround Times
TALF	Treatment After Lost to Follow Up
TB	Tuberculosis
TLCA	TB and Leprosy Control Assistant
TOR	Terms of Reference
TPT	TB Preventive Treatment
TST	Tuberculin Skin Test
UDST	Universal Drug Susceptibility Tests
UN	United Nations
UNHLM	United Nations High-level Meeting
UVGI	Ultraviolet Germicidal Irradiation
WHO	World Health Organization
WRD	WHO Recommended Rapid Diagnostics
XDR-TB	Extensively Drug Resistant Tuberculosis
Z	Pyrazinamide

Anti-Tubercular Drugs Classification

Description	Drug	Abbreviation
First-line anti-TB drugs		
Oral drugs	Isoniazid	H
	Rifampicin	R
	Ethambutol	E
	Pyrazinamide	Z
	Rifabutin	Rfb
	Rifapentine	Rpt

Second-line anti-TB drugs		
Groups	**Drugs**	**Abbreviation**
Group A: Include all three medicines	Levofloxacin *OR* Moxifloxacin	Lfx Mfx
	Bedaquiline	Bdq
	Linezolid	Lzd
Group B: Add one or both medicines	Clofazimine	Cfz
	Cycloserine *OR* Terizidone	Cs Trd
Group C: Add to complete the regimen and when medicines from Groups A and B cannot be used	Ethambutol	E
	Delamanid	Dlm
	Pyrazinamide	Z
	Imipenem–cilastatin *OR* meropenem	Ipm–Cln Mpm
	Amikacin (*OR* streptomycin)	Am (S)
	Ethionamide *OR* Prothionamide	Eto Pto
	p-aminosalicylic acid	PAS

Introduction

1.1 Background

Tuberculosis (TB) continues to be a global public health problem, particularly in the developing countries. Nearly one-third of the global population (i.e., two billion people) is infected with Mycobacterium tuberculosis (MTB) and is at risk of developing the disease. The United Nations High-Level Meeting on (UNHLM) TB on 26 September 2018, with attendance of heads of the state and other eminent people, provided a platform to reinforce the commitments and actions needed to end the global TB epidemic in line with the World Health Organization's (WHO) End TB Strategy, and by the Sustainable Development Goals (SDGs) deadline of 2030.

According to the Global TB Report 2020[1], TB causes ill health among millions of people each year and is a leading cause of death from a single infectious agent (ranking above HIV/AIDS). WHO recently released an updated report[2] on leading causes of death and disability worldwide between 2000-2019. According to that report, although TB is now the 13th leading cases of deaths worldwide with 30% reduction in global TB deaths between 2000 and 2019, it still remains among the top 10 causes of deaths in the African and South-East Asian regions, where it is the 8th and 5th leading cause respectively.

Globally, an estimated nearly 10 million (range 8.9– 11.0 million) population developed TB in 2019 and TB caused an estimated 1.2 million (range, 1.1–1.3 million) deaths among HIV-negative people in the same year (a reduction from 1.7 million in 2000). Further, it is estimated that an additional 208,000 HIV positive people died from TB (a reduction from 678,000 in 2000) in 2019. Overall, adult (aged > 15 years) men and women accounted for 56% and 32% of cases respectively while children (<15 years) made up the remaining 12% of cases globally. Among all affected, 8.2% were people living with HIV (PLHIV). South East Asia Region (SEAR) alone accounted for nearly 44 % of global TB cases in 2019.

Drug-resistant TB remains a public health crisis and a global health security threat. Globally in 2019, nearly half a million (465,000) people developed rifampicin-resistant TB (RR-TB), of which 78% had multidrug-resistant TB (MDR-TB). Furthermore, 3.3% of new TB cases and 17.7% of previously treated cases had MDR/RR-TB**.**

The Global targets and milestones for reductions in the burden of TB disease have been set as part of the SDGs, the WHO's End TB Strategy and the 2018 UNHLM with a target to end the global TB epidemic by 2030.

The SDG Target: End the epidemics of AIDS, TB, malaria and neglected tropical diseases, and combat hepatitis, water-borne diseases and other communicable diseases by 2030.

[1] WHO 2020. Global TB Report 2020. Accessed on 24 May 2020 from https://www.who.int/publications/i/item/9789240013131

[2] WHO 2020. Accessed on 30th Dec 2020 from: https://www.who.int/news/item/09-12-2020-who-reveals-leading-causes-of-death-and-disability-worldwide-2000-2019

WHO End TB Strategy[3]:

Indicators / Milestones	2020	2025	2030
Reduction in Annual Incidence Rate (new and relapse cases) compared to 2015	20%	50%	80%
Reduction in Annual TB deaths compared to 2015	35%	75%	90%
Percentage of households affected by TB facing catastrophic costs (equivalent to 20% or more of annual household income)	0%	0%	0%

UNHM 2018 Targets[4]

1. 40 million people treated for TB from 2018 to 2022, including:
    a. 3.5 million children
    b. 1.5 million people with drug-resistant TB, including 115 000 children
2. At least 30 million people provided with TB preventive treatment from 2018 to 2022, including:
    a. 6 million people living with HIV
    b. 4 million children (< 5 years)
    c. 20 million household contacts from other age groups
3. Funding of at least US$ 13 billion per year for universal access to TB prevention, diagnosis, treatment and care and at least US$ 2 billion per year for TB research from 2018 to 2022

Globally, the TB incidence rate is declining with a cumulative reduction of 9% (from 142 to 130 new cases per 100 000 population) from 2015 to 2019. However, this rate is not fast enough to reach the End TB goal of 80% reduction by 2030. However, the good news is that seven high TB burden countries, including Bangladesh, have already achieved the 2020 milestone and a total of 46 countries are well on track to reach the same.

Timely diagnosis and successful treatment of people with TB avert millions of deaths each year, but there are still persistent gaps in detection and treatment. Gaps between the estimated number of new cases and the number reported are due to a mixture of underreporting of detected cases and underdiagnoses which is still a major programmatic gap of TB program.

In 2014, the Copenhagen Consensus project[5] , with a team of 60 leading economists and experts identified 19 out of 169 targets in the SDGs that provided the highest economic returns. TB was identified as one of the highest priority public health investment options where every single dollar invested in diagnosis and treatment yielded a return of USD 43. Hence, it is crucial to encourage investment in Ending TB efforts at global, national as well as local levels.

[3] Accessed on 30th Dec 2020 from: https://www.who.int/tb/post2015_strategy/en/#:~:text=The%20strategy%20aims%20to%20end,2020%2C%202025%2C%20and%202030

[4] Accessed on 30th Dec 2020 from: https://www.who.int/tb/features_archive/UNGA_HLM_ending_TB/en/

[5] Accessed on 30th Dec 2020 from: http://www.stoptb.org/assets/documents/news/factsheet_05.pdf

1.2 Bangladesh scenario

Although Bangladesh has achieved notable progress in improving a multitude of health indicators over the last decade, including those related to TB diagnosis and treatment, TB remains a public health concern in the country. With an estimated population of 164 million, Bangladesh is listed among the 30-high burden countries for TB and 27 for MDR-TB. With 3.6% of the estimated global incident cases, it continues to be among the top 8 countries accounting for two-thirds of the Global TB burden. According to the Global TB Report 2020, 292,942 TB patients were notified to the National Tuberculosis Control Programme (NTP) in 2019. The childhood TB cases reported are nearly 4% of all cases which is still a huge challenge in Bangladesh. The incidence rate for all from of tuberculosis is 221 per 100,000 population per year. The TB mortality is 24 per 100,000 population per year with over 38,000 deaths annually. Similarly, MDR-TB was 0.7% among new and 11% among retreatment cases with a large absolute number of patients (~3,300 MDR/RR cases) that need to be treated with the second line anti-TB drugs (SLDs). Although TB treatment coverage increased from 27% in 2002 to 81% in 2019, an estimated 68,000 (19%) TB patients remain undetected every year with a static TB incidence - between 225/100,000 and 221/100,000 from 2001 to 2019.

In 1993 WHO declared TB as a global emergency and recommended a standard strategy for control of the disease known as "DOTS" or Directly Observed Treatment, Short-course. The NTP adopted the DOTS strategy in 1993. Since the introduction of DOTS, remarkable progress has been achieved in TB control in the country. The program has managed to successfully treat >85% of TB patients since 2003. This has further improved to above 90% since 2005. Further, the program achieved the initial target of detecting at least 70% of new smear positive (NSP) cases in 2006 and has been successful in consistently sustaining this.

In 2016, Bangladesh adopted WHO's End TB Strategy based on the Three Pillars, namely,(I) Integrated patient cantered care and prevention; (II) Bold policies and supportive systems and (III) Intensified research and innovation underpinned by the 4 key principles of (1) government stewardship & accountability, (2) strong coalition with civil society organizations & communities, (3) protection & promotion of human rights, ethics & equity and (4) adaptation of the strategy and targets at country level. The Government of Bangladesh, together with its many and diverse partners from the public and private sectors, is committed to further intensify the TB control activity in order to sustain the success achieved thus far and to reach the TB control targets linked to the WHO End TB Strategy well in time.

Vision of the National TB Control Programme

TB Free Bangladesh: Zero deaths, disease and suffering due to TB

Mission the National TB Control Programme

The NTP aims to strengthen TB control efforts through establishing effective partnerships, mobilizing necessary resources and ensuring quality diagnostic and treatment services under the DOTS strategy. It strives to make services equally available and accessible to all people in Bangladesh irrespective of age, sex, religion, ethnicity, social status or race.

Goal of Tuberculosis Control

The overall goal of TB control in Bangladesh is to reduce morbidity, mortality and transmission of TB until it is no longer a public health problem.

The objectives of the National Tuberculosis Control Programme

- Ninety percent (90%) reduction in the absolute number of TB deaths and 80% reduction in the TB incidence rate (compared with 2015 baseline) by 2030 (linked to the SDGs)

- Ninety five percent (95%) reduction in the absolute number of TB deaths and 90% reduction in the TB incidence rate (compared with 2015 baseline) by 2035
- Reduce transmission of TB infection though strengthening systematic contact investigation and expanding TB preventive treatment for latent TB infection (LTBI)
- Achieve zero catastrophic costs in TB affected households by 2020 and sustain that thereafter (level in 2015 unknown and needs to be assessed)

In addition to target for 2030 (linked to SDG) and for 2035, there are specific milestones for 2020 and 2025.

1.3 Strategies for control of Tuberculosis

For effective control of tuberculosis and to prevent emergence of drug resistance, it is important to have a standard treatment policy for all patients in accordance with the internationally prescribed best-practices. Close co-operation of all healthcare providers at all levels is essential for successful implementation of the control programme. Similarly, the participation of community health workers, religious groups, political leaders and voluntary organizations is also essential for successful tuberculosis control. It is important that the community is informed of the nature and extent of the problem, as well as its prevention and cure. It must be stressed that the disease is curable and preventable and there is no reason for discrimination or stigma. Another key element in controlling tuberculosis is to ensure that patients are supported to take their medicines regularly till the successful completion of treatment. Non-adherence to prescribed treatment could lead to unfavourable outcomes, continued transmission and even drug resistance. All of these could potentially result in major setbacks faced by national tuberculosis programmes.

After having successfully implemented the DOTS strategy in Bangladesh, the country embarked on the other components of the WHO recommended Stop TB Strategy[6] wherein the focus is on ensuring high quality DOTS, better outreach so that more number of patients have access to quality TB care, management of multi-drug resistant TB (MDR-TB) and TB-HIV co-infection, strengthening of health systems, involving all healthcare providers in the public sector, private sector and Non-Governmental Organizations (NGOs), strengthening the advocacy campaign, promoting Medical College involvement and research. The country has now endorsed and adapted the WHO End-TB strategy.

Pillars and Component

1. Integrated patient centred care and prevention

- Early diagnosis of tuberculosis including universal drug-susceptibility testing and systematic screening of contacts and high-risk groups
- Treatment of all people with tuberculosis including drug-resistant tuberculosis; and patient support
- Collaborative tuberculosis/HIV activities; and management of comorbidities
- Preventive treatment of persons at high risk; and vaccination against tuberculosis

2. Bold policies and supportive systems

- Political commitment with adequate resources for tuberculosis care and prevention
- Engagement of communities, civil society organizations, and public and private care providers
- Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
- Social protection, poverty alleviation and actions on other determinants of tuberculosis

[6] The End TB Strategy; Global strategy and targets for tuberculosis prevention, care and control after 2015; WHO, Geneva, 2015

3. Intensified research and innovation

- Discovery, development and rapid uptake of new tools, interventions and strategies
- Research to optimize implementation and impact, and promote innovations

Targets related to End TB Strategy and SDG along with milestones are shown below:

Indicators	Milestones		Targets	
			SDG	End TB
	2020	2025	2030	2035
Percentage reduction in the absolute number of TB deaths (compared with 2015 baseline deaths of 72,450)	35%	75%	90%	95%
Percentage reduction in the TB incidence rate (compared with 2015 baseline 225 per 100,000)	20%	50%	80%	90%
Percentage of TB affected households experiencing catastrophic costs due to TB (level in 2015 unknown)	Zero	Zero	Zero	Zero

The first UN General Assembly high-level meeting on TB was held in New York on 26 September 2018, titled United to End TB: An Urgent Global Response to a Global Epidemic. The main outcome of the meeting was a political declaration[7]. This reaffirmed the commitment of Member States to the SDGs and the End TB Strategy, and to the actions required to accelerate progress that were defined in the Moscow Declaration. The NTP Bangladesh is fully committed to reaching the global targets defined during the UN high-level meeting and country-specific targets have been defined in line with the global goals.

Indicator	Global Target	NTP Bangladesh Target
Number of people with TB disease diagnosed and treated in the five years 2018–2022	40 million Including 3.5 million children and 1.5 million with drug-resistant TB, including 115 000 children	>1.4 million Including >0.16 million children and >16,000 with drug resistant TB, including >1,800 Children
Number of people reached with treatment to prevent TB in the five years 2018–2022	At least 30 million, including 4 million children (<5 years), 20 million household contacts of people affected by TB and 6 million people living with HIV	>0.6 million, including >0.2 million children (< 5 years), >0.4 million household contacts and >9,000 people living with HIV

[7] United Nations General Assembly. Resolution 73/3: Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. United Nations; 2018

General Information about Tuberculosis

2.1 What is tuberculosis?

Tuberculosis (TB) is an airborne infectious disease caused predominantly by Mycobacterium tuberculosis species of pathogenic bacteria, first discovered in 1882 by Robert Koch. Tuberculosis typically attacks the lungs but can also affect other parts of the body. This is an airborne disease and persons become infected with TB when they inhale droplet nuclei that contain tubercle bacilli and the bacilli begin to multiply in the lungs. It can also spread to other parts of the body via the blood stream, the lymphatic system or through direct extension to other organs.

*** Tuberculosis of the lungs is the most frequent form of the disease, and over 80% of cases belong to this type. This is known as Pulmonary TB. This form of tuberculosis can be infectious.**

*** Tuberculosis affecting organs other than the lungs, most frequently the pleura, lymph nodes, spine and other bones & joints, the genitourinary tract, the nervous system and abdomen is known as Extra Pulmonary TB. Tuberculosis may affect any organ and may even become disseminated. This type of tuberculosis is usually not infectious.**

2.2 Characteristics of Mycobacterium tuberculosis bacillus

- Mycobacterium tuberculosis are fairly large, non-motile & rod-shaped bacterium that are 2-4 microns (micrometers) in length and 0.2 - 0.5 microns in width.
- It is an obligate aerobe and hence, MTB complexes are usually always found in the well-aerated upper lobes of the lungs.
- The bacterium is a facultative intracellular parasite, usually of macrophages, and has a slow generation time of 15-20 hours.
- They can be classified in to three main groups:

1. **Mycobacterium tuberculosis complex:** this group includes M. tuberculosis, M. bovis, M. africanum, M. microti, and M. Canetti. They all can cause "tuberculosis" in humans. The vast majority of tuberculosis is caused by M. tuberculosis, with the other organisms being relatively rare.

2. **Mycobacterium leprae:** causes leprosy.

3. **Non tuberculous mycobacteria (NTM):** this group includes all the other mycobacteria that can cause diseases in humans. NTM sometimes can cause clinical manifestations (in the lungs, skin, bones, or lymph nodes) similar to those of tuberculosis. Most NTM exist in the environment, are not usually spread from person to person and are often non-pathogenic in persons with intact immune system or healthy lung tissue.

- All mycobacteria are classical acid-fast organisms. These are named so because they have a waxy coating on its cell surface, primarily due to the presence of mycolic acid, and are able to retain the colour of the stain (i.e. Ziehl-Neelsen stain) after being washed by an acid
- M. tuberculosis multiplies more slowly than the majority of bacteria; this is why tuberculosis has a slower evolution (causes disease weeks or even months to years after infection) than most other bacterial infections.

2.3 Development of tuberculosis disease

Tuberculosis affects the human body in two main stages.

The first stage occurs when an individual is exposed to micro-organisms from a person with an infectious type of tuberculosis and becomes infected (tuberculous infection). Entry and establishment of bacilli in human body constitutes infection. It usually takes 6-8 weeks for the establishment and manifestation of infection. Infection is indicated by detection of release of interferon gamma by a positive reaction to a tuberculin skin test (Mantoux test) or Direct IGRA. Primary infection is an infection occurring for the first time in susceptible individuals who are exposed to tubercle bacilli. Droplet nuclei that are inhaled into the lungs, are so small (< 5µm) that they evade the muco-ciliary defenses of the bronchi and lodge in the terminal bronchiole or alveoli of the lungs. Subsequently, the bacilli multiply and invade the hilar lymph nodes through the lymphatics. The subpleural lung lesion, lymphangitis and hilar adenopathy together constitute a "primary complex". In most cases, the host's immune defenses overcome the primary infection, which generally passes unnoticed.

In the second stage, the person with tuberculous infection falls ill and manifests various symptoms and signs that indicates that s/he has developed the disease (tuberculosis disease). TB disease may occur after a latent period of many months or even years after the primary infection. Disease may occur either due to endogenous reactivation of dormant tubercle bacilli acquired from a primary infection or by exogenous re-infection. Post-primary TB disease usually affects the lungs but can involve any part of the body except nails and hair.

All those who get infected do not necessarily develop TB disease. If the body immune mechanism is not seriously compromised, approximately 90% of the infected cases will not develop tuberculosis disease; in this case the bacilli usually remain dormant within the body. The remaining 10% of infected individuals will subsequently develop disease, half of them within 1-2 years after infection, the other half later in their life.

As explained above, Tuberculosis usually affects the lungs (Pulmonary TB) but can affect other sites as well (extra-pulmonary TB). When the tubercle bacilli enter the body of an individual but remain dormant without causing disease it is called a latent TB infection (LTBI).

The life time risk of breaking down to disease among those infected with TB is 5–15%, which gets increased to 10% per year amongst those co-infected with HIV. Other determinants such as diabetes mellitus, smoking tobacco products, alcohol abuse and malnutrition also increase the risk of progression from infection to TB disease. A person is said to have tuberculous disease when s/he starts manifesting symptoms and signs. The disease is spread via air when people who are sick with pulmonary TB expel bacteria while coughing and sneezing.

2.4 Difference between TB infection and TB disease

2.4.1 TB infection:

Latent tuberculosis infection (LTBI) is the presence of Mycobacterium tuberculosis in the body without signs and symptoms, or radiographic or bacteriologic evidence of tuberculosis (TB) disease. About one quarter of the world's population has latent TB infections. This means, they are infected by the TB bacteria but are not yet ill with the disease and may not transmit the disease. The life time risk of breaking down to disease among those infected with TB is 5–15%. However, this probability increases in certain conditions which weaken the immunity of the infected patient (HIV, DM, Malnutrition etc).

2.4.2 TB disease:

This takes place when the immune system of a person is not able to prevent the bacteria present in the lungs and/or other organs from multiplying. This active multiplication is accompanied by various signs and symptoms like cough, weight loss, fever, night sweats, chest pain, haemoptysis, fatigue, and decreased appetite. This is known as TB disease.

When a person develops active TB disease, the symptoms (such as cough, fever, night sweats or weight loss) may be mild and go unnoticed for many months. This can lead to delays in seeking care, and results in continued transmission of the bacteria to others. A smear positive pulmonary TB cases can infect 10–15 other persons through close contact over the course of a year.

Characteristics of individuals with tuberculous infection and tuberculosis disease

Characteristics	Tuberculous infection	Tuberculosis disease
Symptoms	None	Most present with one or more of the following symptoms: cough, weight loss, fever, night sweats, chest pain, haemoptysis, fatigue, and decreased appetite.
Tuberculin skin test or IGRA	Usually, Positive	Usually, positive
Bacteriology	Negative	Respiratory specimens are usually smear or culture positive. However, may be negative in persons with extrapulmonary disease or minimal or early pulmonary disease.
Chest radiograph	Normal	Usually, abnormal
Infectiousness	No	Often infectious (before treatment)
Tuberculosis case	No	Yes
Preferred treatment	Preventive treatment	Tuberculosis treatment

2.5 Transmission of the tuberculosis bacilli

Patients suffering from microbiologically confirmed pulmonary TB (or in rare instances of Laryngeal TB) constitutes the most important source of infection. This is an airborne infection and occurs most commonly through droplet nuclei that is generated by a patient with untreated pulmonary TB while coughing, sneezing etc. and inhaled via the respiratory route. The chances of getting infected depend upon the duration & frequency of exposure along with the load and virulence of TB bacilli and the immune status of an individual.

During coughing, speaking, or sneezing, the patient, especially if untreated, produces tiny infectious droplets. These particles, called droplet nuclei, are about 1 to 5 microns in diameter—about 1-5/1000 of millimeter. Droplet nuclei can remain suspended in the air for several hours, depending on the environment. Transmission may occur when these infectious droplets are inhaled. Sunlight, UV light and ventilation are effective in decreasing the ability of the droplets reaching the lung.

The infectiousness of a patient is linked to the quantity of bacilli contained in his or her sputum. Patients who are positive on sputum smear microscopy are by far the most contagious. Those with smear-negative/culture-positive results are less contagious. Patients whose sputum smear microscopy and culture are both negative are usually not contagious. Patients who are infected with M.

tuberculosis but do not have active disease (LTBI), cannot transmit TB. Children are generally much less contagious than adults. This may be due to weaker cough mechanics, less sputum production and lower bacillary load.

Not everyone who is exposed to an infectious TB patient becomes infected with M. tuberculosis. The probability that TB will be transmitted depends on four factors:

- **Infectiousness of the source:** This is directly related to the number of tubercle bacilli that a diseased person expels into the air. Smear positive patients have a higher bacillary load and hence are more infectious.
- **Susceptibility:** This refers to the immune status of the exposed individual and determines whether the person will get infected post exposure. For example, PLHIV, Diabetics and malnourished persons are more likely to get infected and progress to active disease due to compromised host immunity.
- **Exposure related factors:** This refers to the proximity, frequency, and duration of exposure. For example, close household contacts of open cases are more likely to get infected.
- **Environment related factors:** These too play an important role and affect transmission. For example, inadequately ventilated settings will lead to increase transmission whereas exposure to sunlight and adequate ventilation will reduce the chances of transmission.

The most effective way to cut the chain of transmission is to promptly diagnose the patient and initiate him or her on an effective anti TB drug regimen. The exact length of time required for a TB patient to become non-infectious after starting TB therapy is not known. However, once an effective TB therapy is started, as long as the patient follows the prescribed treatment regimen, there is considerable evidence showing that the infectiousness can rapidly decline, even after a few days of treatment initiation. It is estimated that a person with smear-positive TB, undiagnosed and untreated, transmits the bacillus to 10 to 20 people per year (this varies according to lifestyle and environment)

2.6 Risk factors for developing active TB

The risk depends on a number of factors including those that lead to a weakened immune system, damaged lungs, or the intensity and duration of exposure. Examples for each of these conditions are as below:

2.6.1 Weakened host immune defences:

- HIV infection
- Diabetes mellitus
- Malnutrition
- Prolonged therapy with corticosteroids (such as prednisolone) and other immuno - suppressive therapies
- Certain types of cancer (e.g., leukaemia, Hodgkin's lymphoma, or cancer of the head and neck)
- Severe kidney disease
- Alcoholism
- Substance abuse
- Age

- Young children (children under 5 have twice the risk and higher risks are observed for those under 6 months)
  - Pregnancy

2.6.2 Conditions that damage the lung:

- Tobacco smoking
- Silicosis

2.6.3 Intensity of exposure (number of inhaled bacilli):

- Infectiousness of the source
- Environment in which the exposure took place and proximity to the source.
- Duration of exposure
- Inhabitants of high-risk congregate settings (crowded and ill ventilated residence and / or workplace)

2.7 Prognosis

TB is a severe and often deadly disease without treatment. After 5 years without treatment, the outcome of smear-positive pulmonary TB (PTB) in HIV-negative patients is as follows:

- 50-60% die (case fatality ratio for untreated TB)
- 20-25% are cured (spontaneous cure)
- 20-25% develop chronic smear-positive TB.

With adequate treatment, the case fatality ratio (CFR) in drug sensitive TB cases often falls to less than 2 to 3% under optimal conditions. Similar CFRs are seen with untreated EPTB and smear negative PTB, with an equivalent fall in CFR with adequate treatment.

Untreated TB in HIV-infected patients (not on antiretroviral) is almost always fatal. Even on antiretroviral, the CFR is higher than in non-HIV infected patients

Case Finding of Tuberculosis

Tuberculosis usually affect the lungs (pulmonary TB) but can affect other sites as well (Extra-pulmonary TB). When the tubercle bacilli enter the body of an individual but remain dormant without causing disease it is known as latent TB infection (LTBI). Approximately 10% of people infected with the bacillus, but not suffering from any other concomitant immunosuppressive condition, will develop the active disease during their lifetime. A person is said to have tuberculous disease when s/he starts manifesting symptoms and signs and the relevant Lab and / or other tests confirm or suggest active TB. However, the probability of developing TB is much higher among people infected with HIV or other co-morbid conditions that compromise one's immunity. The disease is spread from person to person through air when people who are sick with pulmonary TB expel bacteria while coughing and sneezing.

Presumptive TB refers to a patient who presents with symptoms or signs suggestive of TB.

3.1 Tuberculosis Case Definitions:

Case definition is necessary for

- Correct patient registration and reporting.
- Correct choice of appropriate standard regimen.
- Patient follow-up.
- Cohort analysis including determining trends in the proportions of different types of patients

3.1.1 Bacteriologically confirmed TB case

Bacteriologically confirmed TB case is one from whom a biological specimen is positive by smear microscopy (LED or ZN) or culture (both Liquid & solid) WHO recommended rapid diagnostic (WRD) such as Xpert MTB/RIF, Xpert ULTRA & TrueNat etc. All such cases should be notified, regardless of whether TB treatment has started or not.

3.1.2 Clinically diagnosed TB case

Clinically diagnosed TB case is one who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a registered physician based on strong clinical evidence followed by a decision to give the patient a full course of TB treatment. This definition includes cases diagnosed by clinicians on the basis of X-ray abnormalities or suggestive histology and extra-pulmonary cases without bacteriological confirmation. Clinically diagnosed cases subsequently found to be bacteriologically confirmed (before or after starting treatment) should be reclassified as bacteriologically confirmed case.

- **Only bacteriologically confirmed or clinically diagnosed patients should be initiated on TB treatment. No patient should be commenced on trial TB treatment.**
- **All pulmonary TB cases must have sputum examined for TB by a NTP and WHO recommended diagnostic tool.**

3.2 Classification of TB

TB cases (bacteriologically confirmed or clinically diagnosed) are classified according to the:

- Anatomical site of disease
- History of previous treatment
- Drug resistance
- HIV status

3.2.1 Classification based on anatomical site of the disease:

The TB Cases are categorised in to Pulmonary and Extra Pulmonary TB based on the anatomical site of the disease.

Pulmonary TB (PTB)

Pulmonary tuberculosis (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. Miliary TB is classified as PTB because there are lesions in the lungs. Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extra-pulmonary TB. A patient with both pulmonary and extra- pulmonary TB should be classified as a case of PTB.

Extra-pulmonary TB (EP TB)

Extra-pulmonary tuberculosis (EPTB) is any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs such as pleura, lymph nodes (mediastinal, hilar, cervical etc.), larynx, meninges, abdomen, genitourinary tract, spine, bones and joints, skin etc.

3.2.2 Classification based on history of previous TB treatment

New: A patient who has never taken treatment for TB or a patient who has taken anti-tuberculosis drugs for less than one month. New patients may have positive or negative bacteriology and may have disease at any anatomical site.

Previously Treated: A patient who has received anti-TB drugs for one month or more in the past. Based on the outcome of their most recent course of treatment, they are sub-classified as relapse, treatment after failure, treatment after loss to follow up and other previously treated.

Relapse	Relapse patients have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).
Treatment after failure	Patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.
Treatment after loss to follow up	Patients have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment.
Other previously treated	Other previously treated patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

3.2.3 Classification based on drug resistance

Mono-resistance	Refers to resistance to one first line anti-TB drug only.
Poly-resistance	Refers to resistance to more than one first-line anti-TB drug, other than isoniazid and rifampicin together
Multi-Drug Resistant TB (MDR-TB)	Refers to resistance to at least isoniazid and rifampicin, the two most potent anti-TB agents, with or without resistance to other first line drugs.
Extensively Drug Resistant TB (XDR-TB)	Refers to MDR TB with additional resistance to moxifloxacin or levofloxacin and to one of two other group A drugs (BDQ, LZD).
Rifampicin resistance (RR)	Refers to resistance to rifampicin detected using phenotypic or genotypic methods.

3.2.4 Classification based on HIV status

HIV- positive TB patient

Refers to any bacteriologically confirmed or clinically diagnosed case of TB who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of enrolment in HIV care, such as enrolment in the pre-ART register or in the ART register once ART has been started.

HIV-negative TB patient

Refers to any bacteriologically confirmed or clinically diagnosed case of TB who has a negative result from HIV testing conducted at the time of TB diagnosis. Any HIV-negative TB patient, subsequently found to be HIV-positive should be reclassified accordingly.

HIV status unknown TB patient

Refers to any bacteriologically confirmed or clinically diagnosed case of TB who has no result of HIV testing and no other documented evidence of enrolment in HIV care. If the patient's HIV status is subsequently determined, he or she should be reclassified accordingly.

3.2.5 Classification based on other considerations

Transfer in	A patient already registered for treatment in a DOTS centre and who is subsequently transferred to another DOTS centre
Transfer out	A patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known (this should occur only in a minority of cases) to the reporting unit
Other	Patients who cannot be included in any one of the above categories (e.g., patients who have previously been treated via an erratic or unknown TB regimen or on trial ATT).

3.3 Signs and symptoms of Tuberculosis

The highest priority for TB control is identification and successful treatment of patients who are suffering from smear-positive pulmonary TB.

Pulmonary TB should be presumed in a person who presents with persistent cough for two weeks or more, with or without production of sputum and despite the administration of a broad spectrum antibiotic (without anti TB action). Thus, Presumptive TB refers to a patient who presents with symptoms or signs suggestive of TB.

Often a patient with pulmonary TB has one or more of the following symptoms in addition to cough:

- Respiratory symptoms: shortness of breath, chest pain, coughing up of blood
- General symptoms: loss of weight, loss of appetite, fever, night sweats.

GeneXpert or Sputum microscopy should always be requested for patient who has cough for two weeks or longer even in the absence of any other symptoms. Diagnosis of Pulmonary TB should be done using the diagnosis flow chart (Chapter 4).

In addition, contacts of microbiologically confirmed TB Patients, PLHIV, diabetics, malnourished, cancer patients, patients on immune-suppressants or steroid should be regularly screened for sign and symptoms of TB

The following are also to be investigated as presumptive PTB:

- Contacts of Microbiologically confirmed TB patients having cough of any duration
- Presumptive /confirmed extra-pulmonary TB having cough of any duration
- HIV positive patient having cough of any duration

Presumptive Extra Pulmonary TB refers to the presence of organ-specific symptoms and signs like swelling of lymph node, pain and swelling in joints, neck stiffness, disorientation, etc., and/or constitutional symptoms like significant weight loss, persistent fever for 2 weeks or more, night sweats. Signs and symptoms of extra-pulmonary TB depend on the site involved. Most common examples are:

- TB lymphadenitis: swelling of lymph nodes
- Pleural effusion: fever, chest pain, shortness of breath
- TB arthritis: pain and swelling of joints
- TB of the spine: radiological findings with or without loss of function
- Meningitis: headache, fever, stiffness of neck and subsequent mental confusion

The diagnosis of extra-pulmonary TB should always be made by a graduate physician or specialist and often requires special examinations such as GeneXpert incorporated MTB/RIF or ULTRA (EP TB Sample), X-ray, MT, CT scan, MRI, biopsies, Fine Needle Aspiration Cytology (FNAC) etc.

3.4 Methods of case finding

Broadly speaking, there are 3 types of case finding activities under the NTP. They are as under:

- Passive Case Finding: When the patient voluntarily reports symptoms to the doctor.
- Intensified Case Findings: When the doctor and / or concerned hospital staff search for TB symptoms among the individual seeking care in the health facility e.g., ART Centre, Diabetic Clinics, NCD Clinics etc.
- Active Case Finding: When the Community health workers seeks for TB symptoms among the vulnerable key population in the community.

3.4.1 Target Group and strategies for ACF:

TB can affect anyone but certain groups of people are more likely to develop tuberculosis. These vulnerable groups include:

- Household contacts: Tracing & investigating household contacts of index cases
- Children (all age group, especially under 5 years) and adolescents – to be prioritised in all active case finding activities
- Elderly (65 and above) – to be prioritised in all active case finding activities
- Slum dwellers – Active case finding (household visit, outreach smearing centre, mobile van) to be carried out at least once every quarter
- Homeless/floating population – outreach mobile vans / sputum smear centres in stations / terminals etc.
- People living in congregate setting (prisons, hostels, orphanages etc.) – screening/contact tracing/ use of outreach mobile vans
- People with chronic diseases, such as Diabetes, COPD, malnutrition – to be prioritised during all active case finding activities

- Factory / garments workers - screening/ contact tracing/ mobile van
- People in hard-to-reach area – Special Campaigns / outreach sputum smear centers / contact tracing
- Migrants – Mobile van / outreach sputum smear centers

The most important method of case finding is identification of symptomatic patients attending a health facility, either on their own initiative or referred by another health facility, health worker, community volunteer, etc. Patients diagnosed with any form of TB should always be asked whether there is anybody living in the same house that has a chronic cough and be encouraged to bring or send that person to the health facility for sputum examination and/or other investigation(s).

All child household contacts of smear-positive patients should be examined for possible signs of TB. The same applies to all household contacts of identified DR TB patients. Thus these should be active approaches. In case these contacts cannot attend the health facility, the health worker or community volunteer involved in TB control should visit the house of the patient and identify persons with symptoms suggestive of TB.

All health workers and community volunteers should be encouraged to identify and refer presumptive TB patients to an appropriate health facility for sputum examination and/or other investigation(s) for early diagnosis and treatment to prevent further spread of the infection

3.4.2 Case finding by medical staff and non-medical persons

By medical staff

It is the responsibility of medical doctors (with paramedic and other field level staff) of government health facilities and staff of NGO facilities involved in the NTP to identify presumptive TB patients at the health facilities and to arrange for appropriate investigations like Chest X-Ray (CXR), smear microscopy and WRDs (Xpert MTB/RIF assay and TrueNat) at the nearest diagnostic facilities. In addition, they also need to facilitate these investigations for presumptive TB cases referred by different health providers and volunteers. Extra-pulmonary presumptive TB should be referred to the appropriate facility/specialist for diagnosis. In addition, identification of presumptive TB cases, their sputum examination and referral for diagnosis of presumptive extra-pulmonary TB are also the responsibility of medical doctors of academic institutes, prisons, defence, corporate sectors and private practitioners through direct collaboration with the NTP and / or partner NGOs.

By non-medical persons

Community awareness and participation plays an important role in identification of presumptive TB cases and motivating them to visit the nearest health facility and have their sputum examined for diagnosis and appropriate management.

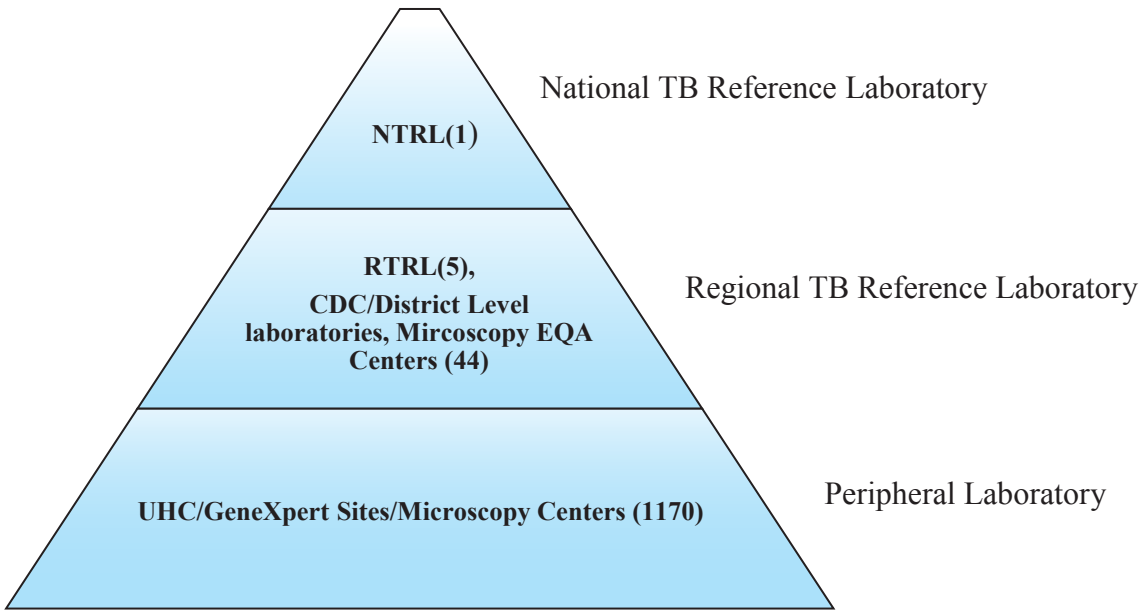
Non-medical community members include the following persons:

- Shasthya Shebikas or other health volunteers.
- Village doctors
- Cured TB patients as well as patients currently on treatment.
- Other important persons in the community such as religious leaders, opinion leaders, community leaders, political leaders, members of union councils, school teachers and persons who have a close connect with the community at the grassroots level.

Diagnosis of Tuberculosis

The World Health Organization (WHO) recommends testing all presumptive TB patients by rapid molecular diagnostic tests like the Xpert MTB/RIF Assay (GeneXpert) where available. In addition, the new WHO recommended alternative diagnostic tools including TrueNat, Line Probe Assy (LPA), Xpert MTB\XDR etc will be scaled up in a phased manner across the country.

4.1 Tuberculosis diagnosis Laboratory Network



4.2 Responsibilities of the TB laboratory network at different levels

4.2.1 National TB reference laboratory

- Acts as supervising reference laboratory for the regional laboratories.
- Performs, culture for mycobacterium, both solid & liquid (MGIT), Molecular Line Probe Assay (LPA), NGS (Next Generation Sequencing), drug susceptibility testing (1st & 2nd line) and species identification as well as microscopy and Xpert MTB/RIF assay (GeneXpert) in special situation.
- Takes the lead in reviewing and introducing new diagnostic tools in country
- Ensures proficiency of the NTP staff for carrying out good quality diagnosis by providing technical training and periodic supervision of the activities of the regional laboratories.
- Collaborates with the WHO-accredited supranational reference laboratory (SNRL) designated for Bangladesh.
- Implements quality assurance for regional and, if necessary, other tertiary Labs like chest diseases clinics and hospitals, upazilla and other special services laboratories.
- Provides guidance to the National TB Control Programme on strengthening the TB Laboratory Network
- Provides strategic oversight to ensure the effective management of laboratories in the network, the quality of the testing, and the efficient use of the network's services and TB diagnostics
- Provides input to the NSP and costing for the TB diagnostic network

- Supervises regional and intermediate level laboratories' implementation and use of bacteriological methods, as well as the laboratories' performance monitoring of peripheral laboratories
- Establishes and manages a system to oversee, monitor and supervise all labs in the network either directly or through RTRLs under the oversight of the NTRL
- Manages QA of all procedures performed at intermediate-level laboratories including microscopy, culture, and DST
- Conducts EQA for GeneXpert, DST (genotypic and phenotypic) test and work as second controller for TB Microscopy laboratories
- Conducts operational research, studies, surveys etc.
- Ensures recording and reporting as per national policy.
- Capacity building for peripheral laboratory staff by providing trainings on different diagnostic tools and procedures.
- Collects key performance indicators (KPIs) of WRD, analyze and provide feedback to NTP and RTRLs

4.2.2 Regional TB reference laboratory

- Performs GeneXpert, Culture and DST for MTB isolates to determine resistance to antiTB agents (solid and liquid)
- Performs FL/SL-LPA according to national diagnostic algorithms
- Performs digestion and decontamination of specimens, inoculates cultures
- Inoculates cultures to isolate and identify MTB from pulmonary and EP TB samples
- Refers positive cultures to appropriate reference laboratory for extended DST as required and unable to perform
- Ensures laboratory commodity management systems are in place and functional for the respective tiers under the jurisdiction of the RTRL
- Checks compliance with the diagnostic algorithm and identifying issues with the diagnostic network in the region including GX performance
- Ensures that updated recording and reporting formats are being used in the region
- Implements the biosafety and biosecurity activities at peripheral level in coordination with NTRL
- Supervises and monitors the performance of peripheral laboratories and compliance
- Provides assistance to investigate and correct problems.
- Provides training at the regional level
- Engages in PT and QI activities for peripheral laboratories
- Conducts EQA for TB Microscopy Laboratory as second controller
- Conducts regional supervision and mentorship for QMS
- Collects KPIs of WRD, analyze and provide feedback to NTP and Districts/upzilla in the region
- Train laboratory technicians on GeneXpert operation and supervises peripheral-level staff in microscopy and the use of WHO recommended rapid diagnostic tests
- Collaborates with NTRL for panel testing, provided support in implementing and validating new diagnostics, assistance with laboratory development and implementing strategies
- Ensures recording and reporting as per national policy

4.2.3 Peripheral laboratory

- Performs microscopy/GeneXpert MTB/Rif assay, TrueNat
- Participates in EQA
- Ensures recording and reporting as per national policy
- Ensure appropriate biosafety measures in place

NTRL & RTRLs are performing liquid culture (MGIT) and Line Probe Assay (LPA) of 2nd line drugs for confirmed RR TB cases to ensure early diagnosis of PreXDR and XDR TB patients. All bacteriological examinations including smear microscopy, Culture-DST, GeneXpert and LPA are provided free of cost.

4.3 Tools for diagnosis of TB

4.3.1 Sputum smear examination

Smear microscopy is simple, inexpensive and requires minimum training. It has multiple advantages like high specificity, high reliability with low inter-reader variation, can be used for diagnosis as well as follow up (for monitoring progress and defining cure), quick same day turnaround time, feasible at peripheral health institutions and also the results (grading) correlate with infectivity in pulmonary TB. NTP will replace smear microscopy with WHO recommended molecular diagnostics as the initial diagnostic test for all presumptive TB cases in a phased manner. Until the full replacement, the microscopy (preferably LED) will continue to be used for diagnosis.

4.3.2 Radiological (X-ray) examination of the lungs

Chest X-Ray, being a very sensitive tool, is ideal for the purpose of screening. However, any abnormality in chest radiograph should be further evaluated for TB including microbiological confirmation. For the diagnosis in the absence of microbiological confirmation, X-ray can be used as a tool for supportive evidence. Though (1) the inter and intra observer variability is high in X ray, (2) no X ray shadow is specific for TB and (3) 10-15% of culture positive cases may remain undiagnosed (under reading) when x-ray alone is used as a diagnostic tool, careful clinical assessment and supportive X-ray findings can be used to diagnose TB and such cases will be considered as clinically diagnosed TB. It is also useful for diagnosing extra pulmonary TB like pleural effusion, pericardial effusion, mediastinal adenopathy and miliary TB. A qualified physician should decide on the diagnosis of TB based on X-ray findings.

4.3.3 Tuberculin skin test (Mantoux Test)

This test, using standard Tuberculin at a standard dose, is used for diagnosing Latent Tuberculosis Infection (LTBI) as per the national guidelines. (Refer to TPT section). Tuberculin skin test only express the presence of infection. It does not confirm TB disease. This test will be used for certain group of people before placing them on TB preventing therapy. This is also used as an adjunct tool in the diagnosis of TB among children (unable to produce sample). It has to be kept in mind that previous exposure to non-TB Mycobacteria (NTM) may yield false-positive test result. Conversely, the tuberculin skin test result may give false negative results under certain circumstances, for e.g., when the patient is immune compromised (co infected with HIV or on immune suppressive therapy), suffering from severe malnutrition or miliary TB etc.

4.3.4 Culture of TB bacilli

Culture is still considered as the gold standard, detecting a higher proportion of patients among presumptive TB cases. A properly performed culture can detect low numbers of TB bacilli, even to

the tune of less than 100 bacilli per ml. Culture, though a highly sensitive and specific method for TB diagnosis, requires 2-8 weeks to yield results and hence does not help in early diagnosis. However, culture is widely used for follow up of patients on drug resistant TB treatment to detect early recurrence.

The Liquid culture system: Mycobacteria Growth Indicator Tube (MGIT) is an automated culture system that detects the growth of mycobacteria faster than a solid culture. The liquid culture results are usually available within a maximum of 14 days. DST results are available 14-26 days after the cultures turn positive. However, the liquid culture needs a TB Containment Lab, which is operationally challenging to create as well as maintain.

The phenotypic DST using solid media and Liquid media (MGIT) is used for first line and second line as well as newer drugs (after standardization).

4.3.5 Rapid Molecular Diagnostic Tests (RMDT)

Cartridge Based Nucleic Acid Amplification (CB-NAAT) and Line Probe Assay (LPA) are the two molecular diagnostic tools introduced in Bangladesh in 2012. Currently, the GeneXpert, which is a CB-NAAT test, is the most widely used molecular diagnostic tool to detect TB and drug resistant tuberculosis. Also NTP in planning to introduce WHO recommended new molecular tools eg TrueNat and Xpert MTB\XDR etc

Xpert MTB/RIF (GeneXpert): GeneXpert, which is a CB-NAAT test, detects DNA sequences, specific for Mycobacterium tuberculosis complex and rifampicin resistance by polymerase chain reaction. It concentrates Mycobacterium tuberculosis bacilli from sputum samples, isolates genomic material from the captured bacteria by sonication and subsequently amplifies the genomic DNA by PCR. The process identifies clinically relevant, rifampicin resistance inducing mutations in the RNA polymerase beta (rpoB) gene in the Mycobacterium tuberculosis genome in a real time format using fluorescent probes called molecular beacons. Results are obtained from unprocessed sputum samples in 105 minutes. The Xpert MTB/RIF assay is suitable for deployment at all levels of the health facilities, although certain operational requirements need to be ensured, such as uninterrupted power supply, temperature-controlled settings and well-trained laboratory staff.

Line Probe Assay (LPA): Polymerase Chain Reaction (PCR) based technologies using various modifications are used for detecting the presence of putative resistance genes (rpoB for rifampicin, katG and inhA for Isoniazid, gyrA and gyrB for Fluoroquinolones, rrs and eis for second line injectables etc.). The most widely evaluated and used assays are Line Probe Assays (LPA) which are based on in-situ hybridization on nitrocellulose strips of specific genetic targets for resistance genes. The first line LPA (FL-LPA) can detect resistance to rifampicin and isoniazid while the second line LPA (SL-LPA) can do so for Fluroquinolones and second line injectable drugs (FQs and the SLIDs) within1-2 days. However, the process needs to be conducted in moderate risk level TB laboratory with at least 3 clean rooms, which, is operationally difficult to create and maintain. Further, only smear positive samples can be subjected to LPA. Smear negative samples need to be inoculated on culture (Solid / Liquid) and the growth subjected to DST on LPA.

4.3.6 FNAC, Biopsy and Histopathology for EP TB

These are special tests for confirmation of extra-pulmonary TB and should be performed by the concerned specialists. NTP will establish at least one center at district level equipped with FNAC, histopathology, GeneXpert to diagnose EP TB .

4.4 Examination of sputum specimens

Microscopy:

Till such time that the phase wise expansion of upfront access to more sensitive tests like molecular diagnostics is completed, testing by sputum microscopy is to be continued. For this, two sputum samples are to be collected and tested as follows:

- "On-the-spot" specimen: the first specimen is collected on the spot when a patient is identified as a pulmonary presumptive TB cases (spot specimen).
- Early morning specimen: the patient is given a sputum container to collect the second specimen at home on the following morning (early morning specimen).

RMDT (GeneXpert, TrueNat etc):

- Early morning sputum is preferable for Xpert MTB/RIF (other similar testing). However, spot sample collection can be done depending on patient's convenience.

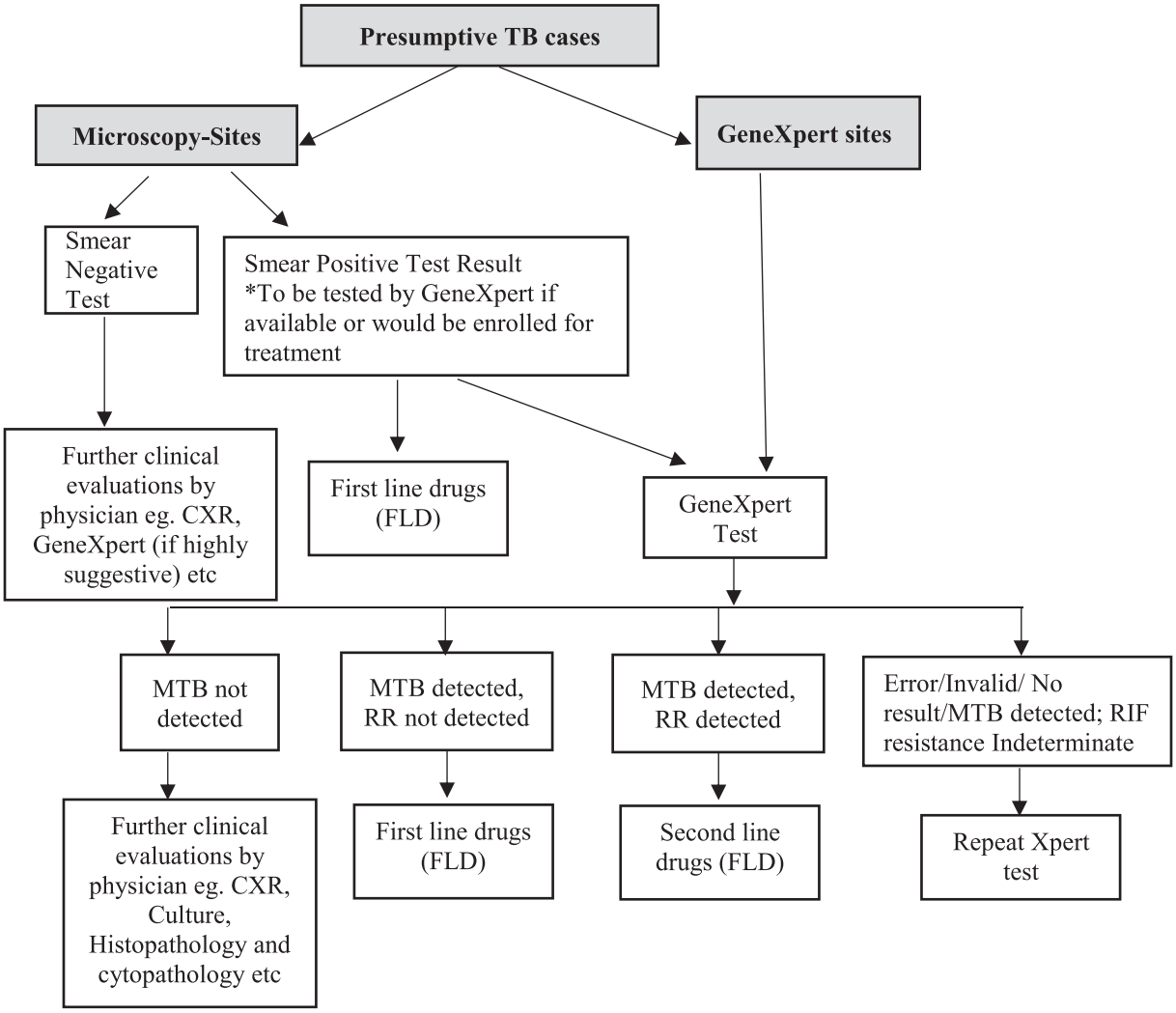
Collection and Transport of sputum specimens: The responsible paramedic/laboratory staff /health worker should provide clear instructions to the patient on how to collect quality sputum: in the open air (preferably under shade) and as far as possible away from other people. A good sputum sample consists of recently discharged material from the bronchial tree with minimum amount of oral or nasopharyngeal material, presence of mucoid or mucopurulent material and should be 2-5 ml in volume. It should be collected in a sterile container after rinsing of the oral cavity with clean water.

If the patient attends a centre where microscopy/Xpert MTB/RIF facilities are available, s/he should either be instructed to bring the specimens to the responsible staff or directly to the laboratory. If the patient attends a centre without microscopy or Xpert MTB/RIF facility, the responsible staff should ensure that the two sputum specimens are collected and transported to the laboratory as soon as possible after collection. If delay is unavoidable, the specimens should be refrigerated (for maximum up to one week) to inhibit the growth of unwanted micro-organisms.

Sputum collected in referring health facilities should be transported to the nearest Microscopy or GeneXpert site within 2 days. Once examined, the test results should be reported on the same day. The containers along with the sample MUST be disinfected with 5% phenol solution and disposed as per guidelines after the sputum smears results are recorded in the laboratory register.

To increase accessibility to diagnostic services, outreach sputum collection camps are organized by NGOs with support of government field staff at Union Health and Family Welfare Centres or other suitable places including community clinics. Patients attending these outreach camps should be provided with one sputum container and counselled beforehand to collect and bring the early morning sputum specimen with them. The spot specimen will then be collected at the outreach camps using a second pot for examination.

4.5 Diagnostic algorithm



4.6 Diagnosis of extra-pulmonary TB in adults

15%-20% of the total TB cases comprise of Extra-pulmonary TB (EP TB). Tuberculosis of organs other than the lungs such as pleura, lymph nodes, intestine, genito-urinary tract, joint and bones, meninges of the brain etc., is called as extra-pulmonary TB. Tubercular lymphadenitis and pleural effusion are most common among extra-pulmonary TB. It can occur at any age.

Demonstration of AFB in a smear from extra-pulmonary site is often difficult because of low bacillary load. The diagnosis should be supported with investigations and bacteriological examination where possible. Positive contact history of TB is an indication for suspicion of TB when a patient presents with symptoms. Patients usually present with constitutional features (fever, night sweats, weight loss) and local features related to the site of disease.

4.6.1 Diagnose the case as EPTB using the following diagnostic tools:

CB-NAAT (GeneXpert) and Liquid Culture are the preferred diagnostic technologies for microbiological confirmation of EP TB. However, there are a host of special investigations which are helpful in diagnosing extra pulmonary tuberculosis. These may be radiological, cytological/ pathological, biochemical and immunological. Details of all these tests are as under:

Confirmatory Tests:

- Molecular tests: Xpert MTB/RIF or ULTRA: Samples that can be tested are pleural fluid, pericardial fluid, ascitic fluid (laparoscopic), cerebrospinal fluid (by lumbar puncture), synovial fluid, aspirate (FNAC), tissue, lymph node aspirate, lymph node biopsy and pus. Testing of blood, urine and stool samples are not recommended except under research conditions.

(Note: Currently, these facilities are available only at NTRL & RTRLs. They will be expanded up to district level in a phased manner.)

- TrueNat will be introduced to test PTB
- Culture for AFB of bodily fluids: Samples that can be tested are pleural fluid, pericardial fluid, ascitic fluid (laparoscopic), cerebrospinal fluid (by lumbar puncture), urine, aspirate (FNAC) from any solid organ e.g. lymph node, spine, epididymis etc.

Supporting / suggestive tests:

- Histopathological or cytopathological examination- Detection of caseating granulomas on histopathological examination of the biopsy material obtained from body tissues such as lymph node, peritoneum (laparoscopic), synovium, spine, bone, liver, spleen, genital tract, etc. are strongly suggestive of tuberculosis.
- Imaging studies using X-Rays, CT Scan, Ultra Sonography, of the involved region or organ, e.g. lung/chest, spine, bone, joint, adrenal gland.
- Biochemical test, e.g. exudate.
- Cytological examination of effusions, ascites, CSF fluid, etc.
- Tuberculin skin test (Mantoux Test)
- Interferon Gamma Release Assays (IGRA)

4.7 Features and diagnostic approach of EPTB

4.7.1 Tuberculous lymphadenopathy

The lymph nodes most commonly involved are the cervical nodes. Other sites may also be involved including submandibular, supraclavicular, inguinal or axillary nodes. Involvement of lymph nodes may result from direct extension of infection or from haematogenous spread.

The usual course of lymph node disease is as follows:

- Initially they are firm and discrete.
- Later become fluctuant and matted together followed by abscess formation.
- The skin may then breakdown leading to chronic sinus formation and.
- Ultimately healing with scarring.

Diagnosis is based on FNAC (smears for AFB, Xpert MTB/RIF, or ULTRA cultures for MTB) and or biopsy (Histopathology).

4.7.2 Miliary (disseminated) TB

Miliary TB results from widespread blood-borne dissemination of TB bacilli; usually in children. Although it is often the consequence of a recent (primary) infection however, in adults, it may be due to either recent infection or reactivation of old disseminated foci.

Patients present with constitutional features rather than respiratory symptoms. They may have hepato-splenomegaly and choroidal tubercles on fundoscopy. Often the presentation is associated with fever of unknown origin and wasting may be marked. A rare presentation seen in the elderly is cryptic miliary tuberculosis which has a chronic course and remains undiagnosed unless there is a high degree of suspicion. Very rarely an acute septicaemic form, non-reactive miliary tuberculosis, occurs due to massive haematogenous spread of the tubercle bacilli.

Diagnosis is based on chest X-ray. It shows diffuse, uniformly distributed, small miliary shadows. "Miliary" means "like small millet seeds". Various haematological abnormalities may be seen including anaemia, leukopenia, neutrophilic leucocytosis and leukemoid blood reactions. Liver function tests may be abnormal. Bacteriological confirmation (smear or culture) is sometimes possible from sputum, cerebrospinal fluid, bone marrow, liver or blood. Granulomas are evident in liver or bone marrow biopsy specimen from many patients. Testing of broncho alveolar lavage is more likely to lead to bacteriological confirmation.

4.7.3 Tuberculous serous effusions (pleural, pericardial, ascites)

The presentation is usually with constitutional and local features. Microscopy/Xpert MTB/RIF of the aspirate from tuberculous serous effusions rarely shows AFB because the fluid forms as an inflammatory reaction to TB lesions in the serous membrane. TB culture, even if available, is of no immediate help. The white cell content is variable, usually with predominant lymphocytes and monocytes. The aspirate is an exudate (i.e. protein content is more than 30 g/l). Interpret the laboratory result of protein concentration in any aspirated fluid with caution. If there has been a delay in laboratory analysis, a protein clot may have formed in the sample. The laboratory result may then be falsely low.

4.7.4 Tuberculous pleural effusion:

The clinical and chest X-ray diagnosis of a pleural effusion is straightforward. Ultrasound can confirm the presence of fluid in the pleural space in case of doubt. Always perform diagnostic pleural aspiration if a patient has a pleural effusion. The fluid is usually straw-colored. The white cell count is usually high with predominant lymphocytes. Occasionally the fluid is blood-stained. The presence of pus on aspiration indicates an empyema (purulent effusion). If facilities are available, closed pleural biopsy using an Abrams needle is useful for histological diagnosis. Since the distribution of TB lesions in the pleura is patchy, the diagnostic yield of closed pleural biopsy is about 75%. Multiple biopsies increase the diagnostic yield. A small open pleural biopsy increases the yield even further.

4.7.5 Tuberculous pericardial effusion:

The diagnosis usually rests on suggestive constitutional and cardiovascular features and investigation findings (ECG, chest X-ray and echocardiography).

4.7.6 Tuberculous ascites:

Ascites results from peritoneal TB. Routes of spread of TB to the peritoneum include the following: a) from tuberculous mesenteric lymph nodes; b) from intestinal TB (pulmonary TB patients may develop intestinal ulcers and fistulae as a result of swallowing infected sputum); c) blood-borne. Patients

present with constitutional features and ascites. There may be palpable abdominal masses (mesenteric lymph nodes). Aspirated fluid is exudative with high protein content and leucocytosis with predominantly lymphocytes. The yield of direct smear microscopy/GeneXpert and culture for AFB is relatively low; culture of a large volume ascitic fluid can increase the yield. Ultrasound may show features consistent with TB, including enlarged mesenteric or retroperitoneal lymph nodes. Definitive diagnosis rests on a peritoneal biopsy. Blind percutaneous needle biopsy of the peritoneum has a low pick-up rate and a high complication rate. In experienced hands, laparoscopy under local anaesthetic has a high pick-up rate. Laparoscopy enables direct visualization and biopsy of peritoneal TB lesions. Laparotomy will confirm the diagnosis in nearly every case but is too invasive for routine use.

4.7.7 Gastro-intestinal TB

Any portion of the gastrointestinal tract may be affected by tuberculosis. The terminal ileum and caecum are the sites most commonly involved. Abdominal pain (at times similar to that of appendicitis), chronic diarrhoea, subacute obstruction, haematochezia and a right iliac fossa mass are common findings at presentation. Fever, weight loss and night sweats are also frequent. A 'doughy abdomen' due to extensive intra-abdominal inflammation may also be detected. Diagnosis rests on barium examination of the small and large intestine or on colonoscopy.

4.7.8 Spinal TB (Pott's disease)

The sites most commonly involved are the lower thoracic vertebrae (with T-10 being the most common) and upper lumbar spine but the cervical spine can also be affected. TB starts in an intervertebral disc and spreads along the anterior and longitudinal ligaments before involving the adjacent vertebral bodies. With advanced disease, collapse of vertebral bodies results in kyphosis (gibbus). A para-vertebral cold abscess may also form. This may track to sites such as the lower thoracic cage or below the inguinal ligament (Psoas abscess).

Plain X-ray of the spine is usually diagnostic. The typical appearance is erosion of the anterior edges of the superior and inferior borders of adjacent vertebral bodies. The disc space is narrowed. CT scan or MRI reveals the lesions more correctly. Aspiration of the abscess or bone biopsy confirms the tuberculous etiology by histopathology and culture. The main differential diagnoses are malignancy and pyogenic spinal infections. Malignant deposits in the spine tend to erode the pedicles and spinal bodies, leaving the disc intact. Pyogenic infection tends to be more acute than TB, with more severe pain.

4.7.9 Joint TB

Weight bearing joints are mostly affected. Tuberculosis of the hip joints causes pain and limping. TB of the knee produces pain and swelling. A history of previous trauma is often elicited. Systemic symptoms are present in about half of the patients. Pulmonary TB is detected in approximately half of these patients. Radiological abnormalities include bone erosions, joint space narrowing, and ultimately joint destruction. Diagnosis requires synovial biopsy.

4.7.10 Genito-urinary TB

Tuberculosis can involve any part of genitor-urinary tract. It is usually due to haematogenous seedling following primary infection. Local symptoms predominate. Urinary frequency, dysuria, haematuria, and loin pain are common presentations. However, patient may be asymptomatic and the disease discovered after severe destructive lesions of the kidneys have developed. Urine analysis gives abnormal result in 90% of cases, revealing pyuria and haematuria. Sterile pyuria first raises the suspicion of renal tuberculosis. An intravenous pyelography helps in the diagnosis. Calcification and

ureteric stricture are suggestive findings. AFB/Xpert MTB/RIF from centrifuge urine specimen helps in diagnosis. Culture of three consecutive morning urine specimens yields a definitive diagnosis in nearly 90% cases. Severe ureteric strictures may lead to hydronephrosis and renal damage.

Genital tuberculosis is more common in female than in male. In female patients, it affects the fallopian tubes and endometrium and may cause infertility, pelvic pain and menstrual irregularities. Diagnosis requires biopsy and/or culture of specimens obtained by dilatation and curettage (D and C). In male patients, tuberculosis preferentially affects the epididymis (producing a slight tender mass), orchitis and prostatitis may also develop. In almost half of cases of genitourinary tuberculosis, urinary tract disease is also present.

4.7.11 Hepatic and Splenic TB

Disseminated TB may involve the liver or spleen and can cause diagnostic confusion. Solitary or multiple abscesses may develop. Ultrasound or CT scan and guided FNAC give diagnosis in most of the cases.

Less common extra-pulmonary forms

Tuberculosis may cause chorioretinitis, uveitis, panopthalmitis, phlyctenular conjunctivitis. In the nasopharynx, tuberculosis may simulate Wegner's granulomatosis. Cutaneous manifestations of tuberculosis include primary infection due to direct inoculation, abscess and chronic ulcers, scrofuloderma, lupus vulgaris, miliary lesions, and erythema nodosum. Adrenal tuberculosis is a manifestation of advanced disease presenting as sign of adrenal insufficiency.

4.7.12 CNS tuberculosis

This is described under the childhood tuberculosis (but it can also occur in adults).

Treatment of Tuberculosis

Rapid identification of presumptive cases, prompt diagnosis, early initiation of an appropriate regimen and successful completion of treatment, especially for infectious cases of tuberculosis, helps to cut the chain of transmission of TB infection in the community and are the most effective ways of preventing TB.

Treatment of tuberculosis should be started immediately after confirmation of TB diagnosis. Treatment regimens define the specific drug combinations used and the intended length of treatment. Anti-Tuberculous drugs are the most important component of tuberculosis treatment. Adequate treatment is one of the most efficient means of preventing the spread of tuberculosis bacilli. The current requirements for adequate treatment are an appropriate combination of at least three effective anti-tuberculous drugs, to not only kill the bacilli but also protect against the development of resistance. These should be prescribed in the correct regimen and dosage and taken regularly by the person with tuberculosis for a sufficient period of time to prevent relapse of the disease after completion of treatment.

5.1 Aims of treatment

Short Course Chemotherapy (SCC) is the recommended treatment for tuberculosis. The aims of treating TB are:

- To render the patient non-infectious, break the chain of transmission and decrease pool of infection.
- To cure the TB patient
- To prevent death from active TB or its late effects (disability)
- To prevent relapse of TB
- To prevent the development of acquired drug resistance

5.2 Basic Principles of TB treatment

The goal of treatment is to achieve a relapse free cure by effectively killing all TB bacilli in the infected patient. To achieve this, the basic principles of effective TB treatment are:

- Prescribing an appropriate combination of drugs
- Administering the drugs for the required duration (several months).
- Ensuring correct dosage to achieve the optimum therapeutic effect.

Treatment approaches

5.2.1 Standardized treatment or regimen:

All patients in a defined group should receive the same regimen. Different groups might receive a different regimen. For example:

- All patients with a strain susceptible to first-line drugs should receive the same standard treatment regimen for 6 months, (may be extended up to 12 months, depending on the site of involvement).
- Patients who fail to respond to the first-line anti-TB drugs, will be tested with Gene Xpert and when ever possible both 1st line and 2nd line DST (LPA, Liquid culture & DST) will be done and patient will be managed as per DR TB guidelines.

5.3 When should the treatment of tuberculosis be started

Treatment should be initiated as early as possible after confirmation of the disiease. The responsible medical officer/graduate physician should categorize the patient. Designated staff will fill-up the treatment card and register the patient in the TB register and maintain other documents related to the diagnosis and treatment of the patient.

The first dose of drugs should be administered at the respective health facility and subsequently, the patient is then referred to the designated DOT provider for the remaining treatment. At the time of starting treatment itself, all the drugs for the entire course of treatment (both intensive and continuation phase) for each patient should be made available at the designated DOT centre/s.

The medical officer or TB manager/supervisor should conduct a weekly review and cross check the TB register with the laboratory register to ensure that all patients diagnosed in the laboratory are registered and enrolled for treatment.

Patients who are Bacteriological positive according to the laboratory register but are yet to be registered and initiated on treatment should be traced within two weeks after the laboratory result is available and started on the appropriate treatment regimen.

5.4 Standardized Regimens

Bangladesh has adopted the use of standardized regimens of anti-tubercular drugs for new and relapsed/re-treatment cases. Standardized regimens have the following advantages over individualized prescription of drugs:

- Programmatic condition, ease of implementation
- Less risk for drug resistance development due to reduction in prescription errors.
- Better estimates of drug needs for procurement, distribution and monitoring.
- Facilitate staff training.
- Reduced costs.
- Facilitates regular drug supply when patients move from one facility to another.

5.5 Treatment category for all TB patients

New TB patients:

- All Drug Sensitive TB (DS TB) patients, whether bacteriologically confirmed or clinically diagnosed, will receive the standard Treatment Regimen comprising of 4 drugs – HRZE - for the initial 2 months (Intensive Phase) and 2 drugs – HR - for the remaining 4 months (Continuation Phase).
- The Treatment may be extended in certain forms of EP-TB like CNS TB, Skeletal TB, Disseminated TB etc. based on clinical decision of the treating physician on a case-to-case basis.

Previously Treated TB patients:

- All cases will be subjected to drug susceptibility testing (DST) and the regimen decided based on the DST results.
- If the DST results show that the patient is susceptible to both rifampicin and isoniazid, all bacteriologically confirmed previously treated pulmonary as well as extra-pulmonary TB patients will be given Cat.1 regimen i.e., 2EHRZ/4HR. The treatment may be extended in certain forms of EP-TB like CNS TB, Skeletal TB, Disseminated TB etc. based on clinical decision of the treating physician on a case-to-case basis.

- All clinically diagnosed pulmonary TB cases with a history of previous treatment (PT Cases) will be given a 4-drug regimen for 6 months (6HRZE).
- Patients in whom DST shows Rifampicin-susceptible but Isoniazid-resistant TB (Hr-TB) or INH DST result not available/not done, are given a 5-drug regimen for 6 months [6 (H)REZ- Lfx].
- Patients with additional resistance patterns need to be managed accordingly.

5.6.1 Treatment phases

Treatment of drug-susceptible tuberculosis comprises of two phases:

- The intensive phase (IP): This is administered daily for the initial two months (4FDC) of treatment. The objective of combining four drugs in the intensive phase (IP) is to achieve rapid killing of actively multiplying bacillary population. This phase will eliminate naturally occurring drug resistant mutants and prevent the further emergence of drug resistant mutants. The infectious patients quickly become non-infectious (within approximately two weeks of treatment initiation).
- The continuation phase (CP): This is administered for four months (2FDC) and is essential to eliminate the remaining bacterial population (mainly persisters) which are largely responsible for relapses. In some special cases, the CP can be extended beyond 4 months (described above). The drugs are administered daily for the rest of the treatment duration according to the category.

Previously treated (PT) patients, eligible for retreatment, should be referred for a rapid molecular test or drug susceptibility testing to determine the resistance status to at least rifampicin, and also preferably isoniazid.

If R is sensitive but resistance to H is detected (Hr-TB)/ H DST unknown, then the patient is initiated on a 6-month regimen of 5 drugs [6 (H) REZ- Lfx].

If rifampicin resistance is detected, an MDR-TB regimen should be prescribed according to recent drug resistant TB treatment guidelines.

Standardized treatment regimen for each diagnostic category (adults)

<table>
<tr><th rowspan="2">TB diagnostic category</th><th rowspan="2">Type of Patient</th><th colspan="2">Treatment regimen</th></tr>
<tr><th>Intensive phase (Daily)</th><th>Continuation Phase (Daily)</th></tr>
<tr><td rowspan="4">New Cases (never been treated for TB or have taken ATT for < 1 month)</td><td>Bacteriologically positive PTB patients</td><td rowspan="4">2 (HRZE)</td><td rowspan="4">4 (HR)</td></tr>
<tr><td>Bacteriologically negative PTB patients</td></tr>
<tr><td>Extra-pulmonary TB*</td></tr>
<tr><td>TB/HIV co-infected</td></tr>
<tr><td rowspan="4">Previously Treated Cases (received ≥ 1 month of ATT in the past) **</td><td>If no resistance to TB drugs (both H and R sensitive P and EP TB Cases)</td><td colspan="2">6 HRZE</td></tr>
<tr><td>Clinically diagnosed PTB</td><td colspan="2">6 HRZE</td></tr>
<tr><td>Complicated EP cases (TB meningitis, Neurological TB, Bone TB, non-resolving lymph node)</td><td colspan="2">12 HRZE-Lfx</td></tr>
<tr><td>If Rif susceptible and INH resistant or unknown in bacteriologically confirmed PTB & EP-TB</td><td colspan="2">6 (H)REZ- Lfx</td></tr>
</table>

** Treatment for certain EP TB may be prolonged till 12 months if non-resolving lymph nodes at 6 months; 12 months in case of CNS, TB meningitis, bone TB etc.*

5.6.2 Fixed-dose combinations (FDCs)

In the management of TB patients with first line drugs, fixed-dose combination (FDCs) of anti-TB drugs are recommended over individual drugs. Fixed Dose Combinations refer to products containing two or more active ingredients in fixed doses, used for a particular indication(s).

Tablets of fixed-dose drug combinations have several advantages compared to individual drugs:

Advantages

- Prescription errors are likely to be less frequent because dosage recommendations are more straightforward and adjustment of dosage according to patient weight is easier
- With less number of tablets to ingest, FDCs are more patient friendly and helps improve treatment adherence.
- It prevents concealed irregularity as, in the absence of DOT, the patient cannot be selective in the choice of drugs to ingest
- Drug resistance is less likely to occur because mono therapy is avoided
- It helps simplify drug management

Disadvantages

- Risk of over dosage or under dosage (sub therapeutic blood levels) of all drugs occurring if number of tablets prescribed or taken is more or less than the treatment guidelines.
- Health care workers may be tempted to evade Directly Observed Therapy, erroneously believing that adherence is automatically guaranteed
- Poor rifampicin bioavailability is a problem with low quality FDCs. Quality assurance is therefore essential
- Using FDCs does not obviate the need for individual drugs for a minority of patients who develop drug toxicity

FDC tablets are composed as follows

- 4 FDC: isoniazid 75 mg + rifampicin 150 mg + pyrazinamide 400 mg + ethambutol 275 mg
- 2 FDC: isoniazid 75 mg + rifampicin 150 mg

The use of fixed-dose combination tablets is recommended over separate drug formulations in treatment of patients with drug-susceptible TB

5.6.3 Drug dosages and frequency

- Treatment dosages are based on weight bands.
- Dosage should be appropriately modified if the patient changes to a new weight band during the course of treatment.
- Drugs should be given daily. Intensive phase is for 2 months (60 doses).
- Intensive phase is stopped after the patient completes 60 doses. Intensive phase should not be extended beyond 60 doses for any reason.
- Continuation phase is daily for 4 months (120 dose).
- Continuation phase is stopped after the patient completes 120 doses. Continuation phase should not be extended except for certain severe forms of EPTB (explained earlier).

weight (kg)	Intensive Phase	Continuation Phase	INH Resistant	
	4FDC daily (first 2 months)	2FDC daily (next 4 months)	4FDC (6 month)	Levofloxacin (Lfx) 250 mg (6 month)
30-37	2 Tablets	2 Tablets	2 Tablets	2 Tablets
38-54	3 Tablets	3 Tablets	3 Tablets	3 Tablets
55-70	4 Tablets	4 Tablets	4 Tablets	4 Tablets
> 70	5 Tablets	5 Tablets	5 Tablets	5 Tablets

5.7 Monitoring of Treatment

Monitoring of tuberculosis patients on treatment include:

- Bacteriological monitoring of pulmonary TB cases by examination of sputum smears at regular intervals during the course of treatment.

Sputum must be examined at periodic intervals to monitor the progress of treatment for all pulmonary TB patients. The sputum smear examinations are carried out at the end of **2nd month** (end of IP), the end of the **5th month** and at the end of treatment (**6th month**). Sputum must also be examined for patients who were smear-negative to start with at the end of the **2nd** month of treatment.

If an EP case on treatment develops chest symptoms, then his or her sputum should be collected and examined by smear microscopy/gene Xpert.

In case sputum is positive on smear microscopy in any of the follow up examination, additional samples needs to be collected and sent for Xpert MTB/RIF testing.

Patients on treatment, who remain smear positive at the end of IP (2nd month) but whose Xpert MTB/RIF results are sensitive for rifampicin, should be initiated on the continuation phase of treatment.

- Clinical monitoring is carried out at periodic intervals by checking for symptomatic improvement and weight gain, especially in the case of extra-pulmonary and clinically diagnosed pulmonary TB cases.

The patient's weight should be monitored on a monthly basis and the drug dosages should be modified if it crosses the initial weight band. Details of all medications given, bacteriological response and adverse reactions should be documented on the patient's records, including the TB Treatment Card.

- Adherence to treatment needs to be monitored by reviewing the treatment cards for drug intake during intensive phase and drug collection during the continuation phase and whenever possible by interviewing the patients.

*** If a patient is found to harbor a drug-resistant strain of TB at any time during therapy, treatment is declared as failed and the patient should be referred for DR-TB management.**

*** For new pulmonary TB patients being treated with a Rifampicin containing regimen, extension of IP is not needed.**

5.7.1 Schedule for follow-up sputum examination in pulmonary bacteriologically confirmed TB patients

Phase of Treatment	Sputum Smear Examination at	If Smear Negative	If Smear Positive
Intensive Phase (IP)	End of Month 2	Start Pt on CP	Test on Xpert MTB/RIF. • If Rif Sensitive, start Pt. on CP • If Rif Resistant, declare Treatment Failure and start DR TB management protocol
Continuation Phase (CP)	End of Month 5	Continue CP	Declare Treatment Failure and evaluate for drug resistance. Manage accordingly
	End of Month 6	Declare Cure	

5.8 Treatment for extra-pulmonary TB patients

All EP TB patients will receive the same treatment as pulmonary TB patients and the total duration of treatment too will remain the same, i.e., initial 2 months of intensive phase followed by 4 months of continuation phase (**2HRZE/4 HR**). For certain complicated/severe forms of EP TB a total of 12 months of treatment may be considered by the treating physicians, i.e., **2 months of IP (HRZE)** followed by **up to 10 months of CP (HR)** to be decided at the end of 6 months of treatment. EP TB patients who do not improve at the end of 6 months must be investigated for drug resistant TB and should be referred to specialist physicians or tertiary care centres (CDC, CDH, Medical colleges and NIDCH) for further management.

5.8.1 TB Lymph node

If there is no noticeable improvement in the TB lymphadenitis even after 6 months of treatment, then, based on clinical judgement of the treating physician, the continuation phase may be extended upto10 months. These cases should also be investigated for DR-TB at the end of 6 months of treatment.

5.8.2 TB Meningitis

The duration of treatment for TB meningitis is 12 months because of the uncertain penetration of the blood brain barrier by some anti-TB drugs. It is also recommended that all patients with TB meningitis and TB pericarditis, an initial adjuvant corticosteroid therapy with dexamethasone or prednisolone, tapered over 6-8 weeks, should be used. The drug most frequently used is prednisolone, in a dosage of 0.5 – 1 mg/kg daily, increased up to 2 mg/kg daily in the case of severely ill patients, for 4 weeks. The dose should then be gradually tapered down @ 2.5 - 5 mg every week over 4 to 8 weeks (1-2 months in total duration).

Alternatively, dexamethasone can be used as an adjuvant therapy for CNS disease. The recommended dosage is 0.1 - 0.2 mg/kg/day (depending on severity of the disease) for 2-4 weeks followed by gradual tapering of the dose @ 0.1mg/kg/week until it reaches a dosage of 0.1mg/kg/day (0.3 mg/kg per day in 1st week of tapering, 0.2 mg/kg per day in the 2nd week and 0.1 mg/kg per day in the 3rd week). This is followed by weekly tapering of oral dexamethasone @ 1 mg/week (4 mg/day, 3 mg/day, 2 mg/day and 1 mg/day, each for a period of 1 week). The total duration of this therapy is usually of 12 weeks.

5.8.3 Osteoarticular TB and spinal TB (Pott's disease)

Treatment of osteoarticular TB and spinal TB for treatment is 12 months with 2 (HRZE)/10 (HR). Pott's disease is a severe form of TB that should be treated on a priority basis because of the risk of

neurological sequelae due to the chronic compression of the spinal nerves. In the absence of significant deformity and neurological deficit, most cases of spinal TB can be successfully treated with rest, back support bracing and anti-TB drugs. Surgery should be considered for patients with neurological deficit, an unstable spine lesion, and/or when they are not responding to therapy.

Monitoring response to extra pulmonary treatment:

For patients with extra pulmonary TB, clinical monitoring is the usual way of assessing the response to treatment

5.9 Newer regimen for drug-susceptible TB: Various new regimens are on trial.

5.10 Management of new smear-positive cases after interrupting treatment

Length of Treatment	Length of Interruption	GeneXpert	Record Rx Outcome	Re-register	Treatment
Less than 1 month	Less than 1 month	Not required	No	No	Continue treatment (CAT I) and compensate for missed doses. Ensure that the total number of doses planned for the initial phase and continuation phase is given.
	More than 1 month	MTB not detected	No	No	Continue CAT I and compensate for missed doses
		MTB detected and RR not detected	No	No	Restart CAT I and complete full course under DOT
		If RR detected	Yes	Yes (under DR TB unit)	Refer the patients to start DR TB treatment
More than 1 months	Less than 2 months	MTB not detected	No	No	Continue CAT I and compensate for missed doses. Ensure that the total number of doses planned for the initial phase and continuation phase is given.
		MTB Detected	No (if Rx <5 months)	No	
			Yes (if Rx >5 months). Record outcome as "Failure"	Yes, register as "Treatment after failure" if Rif Sens.	Depends on Xpert MTB/RIF result. If both R and H susceptible then start Cat. 1, if RS but H resistant (or H DST unknown, not done) then start Retreatment regimen with Lfx; and if RR, manage as a DR TB Case
	More than 2 months	MTB detected	Yes, record outcome as lost to follow-up	Yes, register as *TALF	Depends on Xpert MTB/RIF result (as above)
		If RR detected		Yes (under DR TB unit)	Refer the patients to start DR TB treatment
		MTB not detected		Yes, register as *TALF	Based on clinical evaluation (consider treatment as above)

*TALF= Treatment after loss to follow-up

5.11 Treatment outcome of TB patients

All TB patients need to be provided with an outcome at the end of the treatment and this needs to be duly recorded for each TB patient. The following table shows the possible outcomes for TB patients.

Treatment Outcomes	Description
Cured	A bacteriologically confirmed pulmonary TB patient who completed full course of treatment as recommended by the national policy, with evidence of bacteriological response[8] and no evidence of failure. (*Completion of treatment course, no evidence of failure, smear result negative at the end of treatment and at 5 month*)
Treatment Completed	A patient who completed treatment as recommended by the national policy, whose outcome does not meet the definition for cure or treatment failure. *(Full course treatment, no evidence of failure and no bacteriological evidence/documentation of cure)*
Treatment failure	A patient whose treatment regimen needed to be terminated or permanently changed[9] to a new regimen or treatment strategy. *(Bacteriological reversion (in two smears at least 7 days apart) after conversion)*
Died	A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow up	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.
Transferred out	A patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known (this should occur only in a minority of cases) to the reporting unit
Not evaluated	A patient whose treatment outcome is not known (other than transfer out).
Treatment success	The sum of cured and treatment completed.

5.12 Referral and transfer of patients

A patient during treatment may require referral or transfer to another designated DOTS centre for continuation of treatment. In these cases, the medical officer of the referring/transferring centre should fill the Tuberculosis Referral/Transfer Form (TB 07) in triplicate. One copy should be sent to the referral/transfer centre, one copy is given to the patient and one copy remains in the file of the treatment initiation centre.

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[8] "Bacteriological response" refers to bacteriological conversion with no reversion. • "bacteriological conversion" describes a situation in a patient with bacteriologically confirmed TB where at least two consecutive cultures (for DR-TB and DS-TB) or smears (for DS-TB only), taken on different occasions at least 7 days apart, are negative. • "bacteriological reversion" describes a situation where at least two consecutive cultures (for DR-TB and DS-TB) or smears (for DS-TB only), taken on different occasions at least 7 days apart, are positive either after the bacteriological conversion or in patients without bacteriological confirmation of TB.

[9] Reasons for the change include: • no clinical response and/or no bacteriological response (see note '8'); • adverse drug reactions; or • evidence of additional drug resistance to medicines in the regimen

When treatment is continued in the receiving DOTS centre, the patient should be registered there as a "transfer in" case. The lower portion of the form (TB 07) should be returned to the centre from where the patient was referred.

If a patient was treated without being registered (e.g., in a hospital or by a private practitioner) and will continue treatment in the designated DOTS centre, this constitutes a referral and not a transfer. In this case, the receiving centre will register the patient as per treatment category (new, relapse, treatment after loss to follow up, failure) and not as transfer in.

Every effort should be taken to collect the treatment outcome of the transferred-out patients from the referred centre and final outcome be reported by the referring centre in order to minimize the number of transfer outs in treatment outcome. Referred centres should also try their best to inform the referring centres on the outcome of treatment of transfer in cases.

TB in Special Situations

6.1 Pregnancy

Anti-TB treatment should be started as soon as the diagnosis is made, and the full course of treatment should be given. The basic principles of treatment of TB in pregnancy are the same. Most anti-TB drugs are safe to use during pregnancy.

- All pregnant women should also receive preventive treatment for isoniazid-related peripheral neuropathy. For this, they should be given oral Vit B6 (Pyridoxine) at a dosage of 10 mg/day along with their anti-TB drugs for the entire duration of treatment.
- Rifampicin can increase the metabolism of vitamin K, resulting in clotting disorders. Prophylactic administration of vitamin K to the mother and the neonate is recommended to prevent the risk of post-natal haemorrhage when the mother has received rifampicin during pregnancy:

For the Mother:
Vitamin K; PO: 10 mg/day for the 15 days prior to expected date of delivery
For the new-born infant:
Prophylactic IM vitamin K to prevent haemorrhagic disease of the new-born.
Vitamin K; IM: 1 mg as a single dose, the day of birth

- In Previously Treated pregnant cases, fluoroquinolones like Lfx should be avoided and instead, 4FDC (RHEZ) for 6 months should be prescribed.

6.2 Breast-feeding women

Breast feeding mothers with TB should receive the full course of anti-TB treatment. Proper treatment is the best way of preventing transmission of TB to the baby. All anti-TB drugs are compatible with breast-feeding. Breast feeding should be continued in the normal manner while the mother is taking anti-TB treatments. Breastfeeding should be avoided only in cases where the mother has TB/HIV co-infection.

Breast-feeding women on ATT should routinely receive preventive treatment for isoniazid-related peripheral neuropathy. For this, they should be given oral Vit B6 (Pyridoxine) at a dosage of 10 mg/day along with their anti-TB drugs for the entire duration of treatment. In addition, the breast-fed infant should receive INH preventive therapy after ruling out active TB.

The mother should be advised about cough hygiene measures such as covering the nose and mouth while coughing, sneezing or any act which can produce sputum droplets. Constant use of a face mask by the mother should be encouraged. She should breast feed the infant in an adequately ventilated place and minimise sharing common breathing space with the infant.

6.2.1 Management of a new-born child of a mother with active TB

- Do not separate the child from the mother unless she is acutely ill.
- If the mother is sputum smear negative, and if the infant has no evidence of congenital TB, BCG is given to the infant.
- If the mother is sputum smear-positive at the time of delivery, infant should be carefully examined for evidence of active disease.

- If the infant is ill at birth and congenital TB is suspected, a full course of anti-TB treatment should be given.
- If the child is well, give prophylactic treatment of daily INH and Rifampicin for 3 months (3RH regimen) at recommended dosages. BCG is withheld till completion of prophylactic treatment.
  - The Mantoux skin test is done after three months of prophylactic treatment.

- If the Mantoux test is negative and the child is well, prophylactic treatment with 3RH is stopped and child is given BCG.
- If the Mantoux test is positive, careful examination of the child for active TB is carried out using Chest X-ray, GeneXpert (sputum/ BAL/ gastric lavage/ stool) etc.
  - ➢ If active disease is diagnosed, a full course of anti-TB treatment should be initiated.

6.3 Use of Contraceptives in TB patients

Rifamycins (Rifampicin, Rifabutin etc.) are potent inducer of hepatic enzymes, and hence, the protective efficacy of oral contraceptive pills may be decreased. Hence, female TB patients of reproductive age group on ATT may choose alternate methods of contraception like use of IM medroxyprogesterone, barrier methods like diaphragm, condom, IUD etc. or, as a last option, an OCP containing a higher dose of oestrogen (50 µg /tab), throughout the course of treatment.

6.4 Liver disorder

Patients with past history of acute hepatitis and excessive alcohol consumption, provided there is no clinical evidence of chronic liver disease i.e., a normal liver function; can receive the usual regimen but they should be closely monitored. However, hepatotoxic reactions to anti-TB drugs may be more common among these patients and should therefore, be anticipated and regularly evaluated.

6.4.1 Drug-induced hepatitis:

Anti-TB drugs can cause liver damage. Pyrazinamide is the most hepatotoxic, followed by isoniazid and rifampicin . When a patient develops hepatitis during TB treatment, it may be due to the effect of anti-TB drugs but may also be due to other causes/s. It is important to rule out other possible causes before concluding that the hepatitis is drug-induced.

If the diagnosis of drug-induced hepatitis is made, the anti-TB drugs should be stopped and withheld until the jaundice or hepatic symptoms have resolved and liver function tests have returned to normal. In most cases, the patient can be restarted on the same anti-TB drugs without the recurrence of hepatitis. This can be done either gradually (drugs reintroduced one after the other; less hepatotoxic to more hepatotoxic) or all at once (if the hepatitis was mild). However, if the hepatitis produced severe jaundice, it is advisable to avoid rifampicin and pyrazinamide altogether.

The alternative regimen depends on the suspected drug causing the toxic hepatitis, suggested regimens in such patients are as follows, if

- **Pyrazinamide is involved: 2 HRE 7 HR or 9HRE**
- **Isoniazid is involved: 9 RZE**
- **Rifampicin is involved: 9 Lfx-HZE**
- **Pyrazinamide and rifampicin are involved: 10 Lfx-HE**

6.4.2 Acute viral hepatitis

TB treatment should be deferred until the acute hepatitis has resolved. Once the hepatitis resolves, patients can receive the usual anti-TB regimens provided there is no clinical and bio-chemical evidence of liver function impairment. However, hepatotoxicity to anti-tuberculosis drugs may be more common among these patients and should therefore be closely monitored with routine LFTs. In patients with unstable and persistent hepatitis, treat with 8 months of isoniazid, rifampicin plus ethambutol and avoid pyrazinamide.

6.4.3 Chronic liver disease

Patients with chronic liver disease should not receive pyrazinamide. Isoniazid plus rifampicin plus ethambutol can be used for a total treatment duration of 9 months (2HRE/7HR).

6.5 Tuberculosis and renal insufficiency

The recommended initial TB treatment regimen for patients with renal failure or severe renal insufficiency is two months of isoniazid, rifampicin, pyrazinamide and ethambutol, followed by 4 months of isoniazid and rifampicin.

Isoniazid and rifampicin are eliminated by biliary excretion, so no change in dosing is necessary. Ethambutol and metabolites of pyrazinamide have significant renal excretion and thus, dosing adjustments are required. Three times per week administration of these two drugs at the following doses is recommended: pyrazinamide (25mg/kg), and ethambutol (15 mg/kg) specifically in late stages of renal disease (Stage 4 and Stage 5).

While receiving isoniazid, patients with severe renal insufficiency or failure should receive pyridoxine 10 mg daily in order to prevent peripheral neuropathy.

6.6 Tuberculosis and diabetes

Patients with diabetes are more vulnerable to develop TB. Comorbidity with TB and Diabetes tends to worsen the outcomes of both the diseases. Studies have shown that there is increased morbidity and mortality in patients who have TB & diabetes co-morbidity. Therefore, early diagnosis and management of TB in diabetics as well as diagnosis and proper glycaemic control of diabetes in patients with TB is important to improve outcome of TB treatment.

Treatment of TB is the same as for non-diabetics. It is important to assess renal function and patients with renal function impairment should be managed as described above. During the course of anti-TB treatment, blood sugar levels due to diabetes should be strictly controlled, preferably with insulin.

6.7 Important drug interactions

Many TB patients have concomitant illnesses. At the start of TB treatment, all patients should be asked about medicines they are currently taking. The most important interactions with anti-TB drugs are due to rifampicin. Rifampicin induces pathways that metabolize other drugs, thereby decreasing the concentration and effect of the other drugs. To maintain a therapeutic effect, dosages of the other drug may need to be increased. When rifampicin is discontinued, its metabolism-inducing effect resolves within about two weeks, and dosages of the other drug will then need to be decreased again.

Rifampicin substantially decreases the concentrations of certain drugs. The most important ones are as under:

- Antimicrobials
  - o Antibacterial – Clarithromycin, Doxycycline, Chloramphenicol, Linezolid.
  - o Antifungals – Fluconazole, Itracanazole, Ketoconazole
  - o Antiretrovirals
- Hormones – Oestrogen, Progestogen, Levothyroxine
- Corticosteroids
- Tamoxifen
- Methadone
- Anticoagulants – Warfarin, Apixaban, Rivaroxaban
- Immuno suppressives – Cyclosporin, Mycophenolate, Tacrolimus
- Anticonvulsants – Carbamazepine, Phenytoin
- Cardiovascular agents - Digoxin, Calcium channel blockers (Verapamil, Nifedipine, Diltiazem), Beta blockers (Propranolol, Metoporol)
- Theophylline
- Hypoglycaemics – Sulfonylureas
- Lipid lowering drugs – Atorvastatin, Simvastatin
- Antipsychotics – Haloperidol
- Anxiolytics – Benzodiazepines
- Cytotoxics – Gefitinib, Imantinib

Adverse Effect Management

Most TB patients complete their treatment without any significant adverse effects of drugs. However, a few patients do experience adverse effects. Patients sometimes discontinue the treatment due to major or even minor adverse effects. It is therefore important that patients are clinically monitored during treatment so that adverse effects can be detected promptly and managed properly. Routine laboratory monitoring is not necessary. Managing drug reactions rapidly and aggressively is an important means to increase tolerance. Generally, with minor adverse effects, drugs need not be stopped. In most cases, counselling the patient and use of ancillary medicines is all that is necessary. With major adverse effects, the offending drugs often have to be stopped and the regimen modified suitably. Health workers/ DOT providers can monitor side effects of drugs by teaching patients to recognize symptoms of common side effects and to self-report promptly if such symptoms develop. They should also enquire about occurrence of any side effects during their routine patient visits and when the patient comes to collect drug refills.

Minor Adverse Effect		
Side Effects	**Drugs Responsible**	**Suggested Management**
Anorexia, Nausea/vomiting, Abdominal pain	Pyrazinamide Rifampicin	• Nausea and vomiting are frequent, especially during the first few weeks of therapy. • Reassurance and give drugs with or after meals. • Anti-emetics are commonly used either as needed or on a daily standing basis (typically 30 minutes before the drugs intake). Proton pump inhibitors (omeprazole) can also provide relief. • For patients with significant vomiting (especially if diarrhoea is associated), hydration status should be assessed and dehydration corrected as necessary.
Arthralgia/ Joint pain	Pyrazinamide Fluoroquinolones	• Arthralgias generally diminish over time. Serum uric acid levels may be elevated, anti-hyperuricemic therapy may be administered. • Begin therapy with an anti-inflammatory agent, e.g. ibuprofen PO: 400 to 800 mg 3 times daily. Paracetamol PO: 500 to 1000 mg 2 to 3 times daily may also help bring relief when given together with an anti-inflammatory drug
Burning/ tingling sensation or numbness in limbs	Isoniazid	• Give pyridoxine 100 mg daily • Aside from prophylaxis, correction of vitamin deficiencies in patients with nutritional compromise is needed.
Photosensitivity	Fluroquinolines	• Recommend the patient to avoid direct exposure to the sun, to wear protecting clothes (long sleeves) and to use sunscreens.

Minor Adverse Effect		
Side Effects	**Drugs Responsible**	**Suggested Management**
Itching with minor skin rash	All drugs	• Rule out other possible causes not related to drugs (i.e., scabies, contact dermatitis due to an environmental allergen). • Give an oral antihistamine
Itching with skin Rash (moderate to severe)	All drugs	• Stop all anti-TB drugs • In the event of severe generalized rash, along with oral or parenteral antihistamine, a parenteral corticosteroid (i.e., dexamethasone IM or IV: 5mg 3times daily) may be needed. • Once the reaction has resolved, try to determine which drug caused the reaction. Rechallenge the patient with a sequential introduction of anti-TB drugs. A typical sequence is the following order: H-R-Z-FQ-E • Any drug resulting in Stevens-Johnson syndrome or anaphylaxis should never be reintroduced.
Jaundice (other causes excluded) hepatitis	Most anti-TB drugs (especially isoniazid, pyrazinamide and rifampicin)	• Symptoms include nausea, vomiting, jaundice, scleral icterus, pale stool, and diminished appetite. If the patient has symptoms of hepatitis, check liver function: • If patient is asymptomatic but liver enzymes are elevated to less than 5 times the normal values, continue anti-TB therapy but conduct weekly follow liver function tests. • If liver enzymes are elevated to more than 5 times the normal limits, stop all anti-TB medications and monitor liver function weekly. If liver enzymes continue to increase, then progressive drug induced hepatitis or an unrelated cause must be suspected. • If liver enzymes plateau or revert to normal and symptoms resolve, restart anti-TB drugs, beginning with the agents least likely to be hepatotoxic (E-FQ) followed by sequential introduction of one drug per week in the following order R-H-Z . The liver enzymes should be checked at the end of each week. • The offending agent can generally be identified in this manner and discontinued or replaced.
Visual impairment	Ethambutol	• This rare adverse effect is typically due to E and usually reversible after discontinuation of the drug.

Minor Adverse Effect		
Side Effects	**Drugs Responsible**	**Suggested Management**
(other causes excluded)		• Loss of red-green colour distinction is usually the first sign. In this case, stop the causative agent permanently.
Shock syndrome, purpura, acute renal failure, acute hemolytic anaemia	Rifampicin	• Shock syndrome, purpura, acute renal failure and acute hemolytic anaemia can occur in rare cases. • Thrombocytopenic purpura is more common with intermittent use of Rifampicin • Stop Rifampicin immediately and treat shock, renal failure and thrombocytopenia aggressively. • Stop rifampicin and never use again
QT prolongation	Fluroquinolones	• Mfx causes the greatest QT prolongation. Lfx has a lower risk of QT prolongation. • Monitor combination of FQs with other drugs that prolong QT interval • In addition, care should be to check electrolytes • The patient's renal function should be monitored and the dose of FQ adjusted if needed.

Tuberculosis in Children

This chapter gives an overview of the important aspects of TB in children. Details on diagnosis of childhood TB, including drug-resistant TB, TB-HIV co-infection, treatment, prevention and operational aspects of control of childhood TB are elaborately described in the NTP "National Guidelines for the Management of Tuberculosis in Children", 3rd Edition, 2021.

8.1 Background

Globally, children less than 15 years old comprise 10% of all TB cases. However, the source of TB infection in a young child is usually an adult, generally a family member living in the same household, with bacteriologically positive PTB. About 10.0 million people fell ill with TB in 2019. Of these, 56% (5.6 million) were men, 32% (3.2 million) were the woman and 12% (1.2 million) were children (aged <15); overall, 8.2% of people with TB were living with HIV. During 2019 in Bangladesh, an estimated 361,000 people developed TB; among them 33,000 were children. However, of these, only 291,600 TB patients were notified of which, only 4% were children. An estimated 69,400 people with TB were missed (not notified) of which, 20,670 were children. This indicates that there is substantial under-diagnosis of TB in children in Bangladesh. Adults with smear-positive PTB usually infect children, but not all children develop the disease after infection. The likelihood of developing disease is the highest shortly after infection. Infants and children under 5 years are at particular risk of developing TB disease. Immunosuppressive illnesses including measles, malnutrition, whooping cough, and HIV infection facilitate progression of TB infection to disease.

8.2 Key Risk factors

Children infected with M. tuberculosis are not usually ill and do not exhibit symptoms of TB unless the disease is active. Only a small percentage of children who inhale the TB organism develop active disease. Certain groups are at far greater risk than others.

Key risk factors for TB in children

1. Household or close contacts of a smear positive or culture positive pulmonary TB (parents, siblings, close relatives, caregivers, neighbors and teachers)
2. Age <5 years: The risk of developing TB disease is highest in very young children, who are immune immature
3. Severe malnutrition or other Immunosuppressive conditions
   - Measles in the previous 3 months
   - Whooping cough
   - HIV infection
   - Being on steroids or other immunosuppressive drugs
4. The time since exposure or infection: the vast majority of children who develop TB disease do so within the first year of exposure to and infection with M. tuberculosis.

Other high risk factors are HIV/AIDS, diabetes, end-stage renal failure, cancer, connective tissue disease, silicosis, gastrectomy, solid organ transplantation and patients on prolonged steroid. Both type 1 and type 2 diabetes patient have the increased risk of having TB

Age-specific risk of progression to disease after primary infection with M. tuberculosis in immunocompetent children

Age at primary infection (yr)	Risk of Progression to Disease (%)		
	Pulmonary Disease	Disseminated Disease or Tubercular Meningitis	No Disease
< 1 year	30-40%	10-20%	50%
1–2 years	10-20%	2-5%	75-80%
2–5 years	5%	0. 5%	95%
5–10 years	2%	< 0.5%	98%
> 10 years	10-20%	< 0.5%	80-90%

8.3 Clinical spectrum of childhood TB

8.3.1 Symptom criteria for PTB

- Persistent, non-remitting cough for >2 weeks not responding to conventional antibiotics (amoxicillin, co-trimoxazole or cephalosporins) and/or bronchodilators

and/or

- Persistent documented fever (>38°C/100.4°F) for >2 weeks where common causes such as typhoid, malaria or pneumonia have been ruled out

and/or

- Documented weight loss or no weight gain during the past 3 months (especially if not responding to de-worming together with food and/or micronutrient supplementation) OR severe malnutrition

and/or

- Fatigue, reduced playfulness, decreased activity, irritability, refusal to feed etc.

Any one of the above symptom criteria in a child (<15 years) in close contact with a known bacteriologically confirmed TB or clinically confirmed TB should be regarded as presumptive TB case and referred to a physician for evaluation.

8.3.2 Extra-pulmonary TB: Signs and symptoms

Common EPTB in children-

- Tubercular lymphadenopathy
- TB pleural/pericardial effusion
- Tubercular meningitis
- Spinal TB (Pott's disease)
- Abdominal TB
- Tubercular arthritis

8.3.3 Symptoms and signs suggestive of EPTB

Extra-pulmonary TB	Symptoms and Sign
TB lymphadenitis (commonly cervical)	A painless enlarged mass of matted lymph nodes (>2x2 cm), usually in the neck, not fixed to the underlying tissues, initially firm and fluctuant later, that may present with sinus, and is not responding to a course of antibiotics
Pleural TB, Pericardial TB	Cough and shortness of breath
TB meningitis, Tuberculoma	Reduced playfulness, irritability, weight loss, headache, vomiting without diarrhea, drowsiness, lethargy, unconsciousness, convulsions; and not responding to antibiotic
	Abdominal pain, altered bowel habit, unexplained mass or abdominal ascites
Spinal TB	Gibbus (acute angulation of vertebrae)
TB arthritis	Chronic pain and swelling of joint(s), usually single

If any of the above symptoms are associated with a history of contact, possibility of TB is high

8.4 Diagnosis of tuberculosis in children

Diagnosis of TB in children is difficult as symptoms are often non-specific, most children cannot produce sputum for microscopy/geneXpert examination, X-rays are often non-specific and the Mantoux test is often negative in children with severe malnutrition. Establishing the diagnosis in children requires careful and thorough assessment of all the information derived from careful history taking, clinical signs and symptoms and relevant investigations like Mantoux test (TST), chest X-ray (CXR), smear microscopy, geneXpert and other investigations.

PTB is a common form of TB in children although bacteriological confirmation may not always be possible for young children. In this group, sputum induction and gastric aspiration have been documented to be an effective method for collection of specimens. Every attempt to collect sputum should be made whenever possible. Sputum sample collection is strongly encouraged for the children who are able to produce a sputum sample.

8.4.1 Diagnosis of TB in children is often difficult for several reasons

- Symptoms are often non-specific, particularly in young children and often mimics common childhood illness.
- Childhood TB is paucibacillary & a microbiological diagnosis is often not possible.
- It is difficult to obtain sputum or other respiratory specimen for bacteriological confirmation.
- The Tuberculin Skin Test (TST or Mantoux Test) is often negative in malnourished children or in children with overwhelming TB. Moreover, a positive MT cannot differentiate active TB disease from infection.
- CXRs are often non-specific and prone to variable interpretation.

8.4.2 Recommended approach to diagnose TB in children

1. Careful history taking (including history of contact with TB and symptoms suggestive of TB)
2. Clinical assessment (including serial weight monitoring/growth assessment)

3. Investigations

- Mantoux test
- Chest X-ray and other radiological evaluation
- Bacteriological confirmation whenever possible: Smear microscopy, Xpert-MTB RIF, Culture of respiratory sample / gastric lavage
- Other supportive investigations relevant to suspected PTB/EPTB
- HIV testing

8.5 Anti-Tuberculosis drug doses for children

Dosages are calculated according to body weight and not according to age. Weight is important for monitoring treatment response and should be recorded during the initial as well as all follow up visits. TB drugs are well tolerated in the majority of children.

The risk of developing optic neuritis (eye damage) from Ethambutol in children is minimal, and hence, four drugs are now used in all new cases of paediatric TB. It is important to be aware that eye problems are possible and to check all children for visual problems during their treatment course. The parents / guardians of the child on treatment too must be counseled to promptly report any vision related symptoms.

The pharmacokinetics of anti-tuberculosis drugs is such that children generally need higher doses (per kg body weight) than adults to achieve effective serum concentration

8.5.1 Recommended daily dose of First-Line Anti-TB

Drugs	Daily Dose
Rifampicin	15 mg/kg (10-20 mg/day) with a max of 600 mg per day
Isoniazid	10 mg/kg (7-15 mg/kg) with a max of 300 mg per day
Pyrazinamide	35 mg/kg (30-40 mg/kg) with a max of 2000 mg per day
Ethambutol	20 mg/kg (15-25 mg/kg) with a max of 1500 mg per day
Levofloxacin for H resistant cases	15-20 g/kg

8.6 Treatment of TB in children

Once a diagnosis of TB has been made, most children may be treated on an outpatient basis; however, children with severe disease will require hospitalization. Children with any of the following conditions must be admitted to the hospital:

- respiratory distress
- severe forms of EPTB such as TB meningitis, miliary TB, spinal TB and pericardial TB
- severe adverse reactions such as hepatotoxicity

All children with TB will receive a standard treatment regimen. All seriously ill children who have been previously treated for TB, such as, relapse, treatment after failure, treatment after lost to follow up or not improving on new treatment regimen should be investigated for drug resistant TB. Ensure strict DOT in all cases of TB in children.

8.6.1 Recommended treatment regimen

Anti-TB treatment is divided into two phases: an intensive phase and a continuation phase. The purpose of the intensive phase is to rapidly eliminate the majority of organisms and to prevent the

emergence of drug resistance. The purpose of the continuation phase is to eradicate the dormant organisms.

TB drugs for the treatment of TB in children come in Fixed Dose Combinations (FDC) and dosed according to standardized weight bands. Depending on their weight, children can be treated using the pediatric FDCs or the adult FDCs. Older children falling into higher weight ranges will receive adult FDCs.

All children must be treated using child-friendly (dispersible and flavoured) FDC. The new fixed-dose combination of HRZ (50 mg / 75 mg / 150 mg) and HR (50 mg / 75 mg).

Ethambutol is included for the treatment of TB in children and comes as a separate tablet (to monitor ophthalmic ADRs) with the paediatric formulation (100 mg).

Weight bands	Number of Tablets		
	Intensive Phase		Continuation Phase
	HRZ (50/75/150)	E (100mg)	HR (50/75)
4-7 kg	1	1	1
8-11 kg	2	2	2
12-15 kg	3	3	3
16-24 kg	4	4	4
25+ kg	Use adult dosages and preparations		

Weight band for INH mono resistant TB (Hr-TB)

Weight bands	Number of Tablets		
	6(H) RZ + E + Lfx		
	RHZ (75/50/150)	E (100)	Lfx (100)
4-7 kg	1	1	1
8-11 kg	2	2	2
12-15 kg	3	3	3
16-24 kg	4	4	4
25+ kg	Use adult dosages and preparations (up to 1.5g / day)		

If levofloxacin 100mg dispersible tablet is not available, the 250mg tablet can be used with 6(H) RZ+E in children aged 0-14 years, based on a slightly different weight band from the one above:

Weight bands	Levofloxacin 250 mg
5-6 kg	½ tablet/day
7-9 kg	¾ tablet/day
10-15 kg	1 - 1½ tablet/day
16-23 kg	1½ - 2 tablets/day
24-30 kg	2 - 2½ tablets/day
31+ kg	Follow adult schedule (up to 1.5g / day)

8.6.2 Treatment duration

Pulmonary TB and EP TB are treated for 6 months (2 months of HRZE + 4 months HR). All severe forms of EP TB are treated for 9-12 months by extending the CP by 3-6 months. These include TB meningitis, TB osteomyelitis, military TB, TB pericarditis/effusion and other severe forms of TB (2 months HRZE + 7-10 months HR - a total treatment duration of 9 to 12 months).

Pyridoxine

Pyridoxine should be given along with isoniazid in HIV infected children to prevent isoniazid associated neuropathy. A dose of 12.5 mg/day is recommended for children 5 to 11 years of age, and 25 mg/day for children ≥12 years.

Corticosteroid

Corticosteroids should generally be used sparingly in children, but are of benefit in cases of TB meningitis, some cases of TB pericarditis and in managing complications of airway obstruction caused by TB lymphadenitis.
In such cases, prednisolone should be given at a dose of 2mg/kg/day for 4 weeks. The dose should then be gradually reduced over 1-2 weeks before stopping. The dosage can be increased to 4mg/kg/day (maximum: 60mg/day) in the case of seriously ill children to account for increased steroid metabolism induced by rifampicin.

8.7 Preventive therapy for children

Children are more susceptible to TB infection, more likely to develop active TB disease soon after infection and are more likely to develop severe forms of disseminated TB. Children aged less than 5 years of age, who are close contacts of a bacteriologically confirmed (smear or Xpert +ve) TB patient, should be evaluated for active TB by a medical officer / paediatrician. After excluding active TB, the child should be given INH preventive therapy irrespective of their BCG or nutritional status. The dose of INH for preventive therapy is 10 mg/kg body weight, administered daily, for a period of six months.

The child should be followed up at least once a month till the completion of chemoprophylaxis. An infant born to a mother with infectious pulmonary TB can be safely breastfed if isoniazid prophylaxis is given. If a child receiving isoniazid develops symptoms, he or she should be assessed for TB. If the child has not been vaccinated with BCG, it should be given after completion of isoniazid prophylaxis.

Serious limitations of the quality of evidence prevent drawing any recommendations on MDR-TB preventive therapy as a public health measure. Strict clinical observation and close monitoring for the development of active TB disease for at least two years is preferred over the provision of preventive treatment for contacts with MDR-TB cases.

Drug-Resistant Tuberculosis

The confirmation of drug resistance depends on a laboratory diagnosis. The conventional method is to show that strains of Mycobacterium tuberculosis grow on culture media in the presence of one or more anti-TB drugs (phenotypic testing). Newer genotypic (molecular) techniques are now available to detect mutations, which are associated with resistance to certain drugs. Different patterns of drug resistance carry different implications for treatment and management.

Drug resistant (DR) TB	Refers to active tuberculosis disease caused by Mycobacterium tuberculosis bacilli that are resistant to one or more anti-TB medicines.
Mono-resistance	Refers to resistance to one first line anti-TB drug only.
Poly resistance	Refers to resistance to more than one first-line anti-TB drug, other than isoniazid and rifampicin together.
Rifampicin-resistant TB (RR-TB):	Refers to resistance to rifampicin detected using phenotypic or genotypic methods.
Isoniazid-resistant TB (Hr-TB)	Refers to *Mycobacterium tuberculosis* strains in which resistance to isoniazid and susceptibility to rifampicin has been confirmed in vitro
Multidrug resistance (MDR)	Refers to resistance to at least isoniazid and rifampicin, the two most potent anti-TB agents, with or without resistance to other first line drugs.
MDR TB with Quinolone resistance	Refers to MDR TB with additional resistance to moxifloxacin or levofloxacin.
Extensive drug-resistance (XDR)	Refers to MDR TB with additional resistance to moxifloxacin or levofloxacin and to one of two other group A drugs (BDQ, LZD).

9.1 Causes of Inadequate Anti-TB Treatment

Health Care Providers: Inappropriate Treatment	Drugs: Inadequate Supply/Quality	Patients: Inadequate Drug Intake or Treatment Response
• Inappropriate guidelines • Non-compliance with guidelines • Absence of guidelines • Poor training • Financial disincentives • Poor patient education • No monitoring of treatment • Poor management of adverse drug reactions • Poor treatment support • Poorly organized or funded TB control programmes	• Poor quality medicines • Unavailability of certain medicines (stock-outs or delivery disruptions) • Poor storage conditions • Wrong dose or combination • Poor regulation of medicines	• Lack of information • Lack of means to adhere to treatment (transportation, food, etc.) • Adverse effects • Social barriers • HIV • Diabetes mellitus • Under nutrition • Malabsorption • Substance abuse/dependency • Psychiatric condition

9.2 Target Groups for DR TB and First-line DST

If available, rapid DST will be offered to all presumptive TB cases before starting TB treatment. In case not available, then the following groups will be prioritised for DST (Presumptive DR TB):

- All Previously Treated (Retreatment) cases at diagnosis
  - ➢ Failure of Cat-1 and retreatment regimen
  - ➢ Relapse
  - ➢ Treatment after loss to follow-up
- Non-Converter (remain positive at month 2 of treatment follow-up)
- Close contacts of DR TB patients with symptoms
- HIV Infected person, with /without TB S/S
- Bacteriologically negative Pulmonary TB turning smear positive at 2 months or extra pulmonary TB patients showing clinical deterioration or no signs of clinical improvement, despite treatment as per NTP guidelines.

Ensure proper history taking and quality lab performance including follow up sputum examination for identification of presumptive DR TB as per above groups

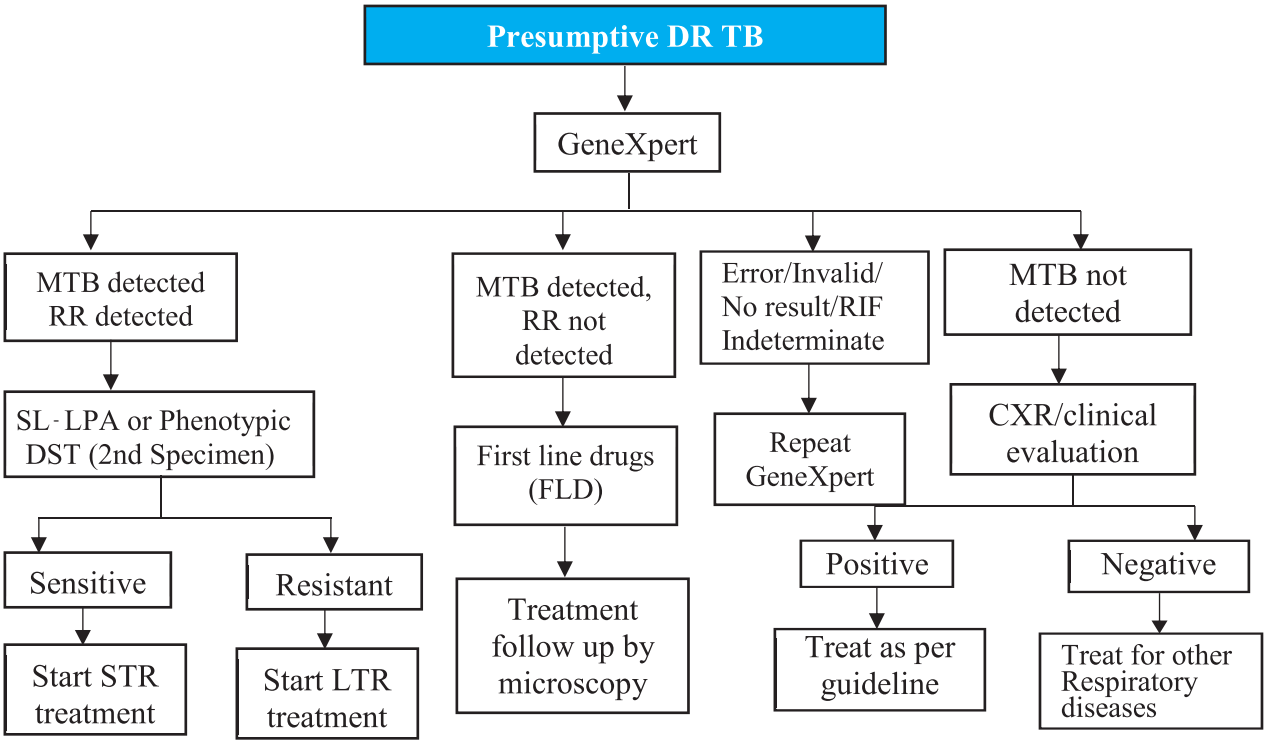
9.3 Targeting Risk Groups for DST for Second-line Drugs

Drug susceptibility testing for second-line anti TB drugs enables case-finding for XDR TB and guides proper treatment.

- All the patient diagnosed as RR TB by GeneXpert will be subjected to second line DST on LPA.
- Those with resistance to Fluoroquinolones would be subjected to phenotypic culture and DST (preferably liquid C-DST).
- Extended DST for high dose Mfx (1µg/ml), BDQ, Lzd and Cfz will be performed for guiding DST based treatment.

DST for Z, BDQ and DLM (by MGIT) will be started at NTRL and RTRLs in a phased manner.

9.4 Diagnostic algorithm (DR TB)



9.5 The Standard DR TB Regimen

One of the most important principles of the treatment of DR TB is to diagnose the patient early (before there is extensive lung damage), to stop transmission, and promptly start the appropriate treatment. All DR TB regimens perform better (with higher successful treatment outcomes) when there is less extensive lung damage at the start of treatment.

9.5.1 Regimen for rifampicin-susceptible and isoniazid-resistant TB (Hr-TB)

In patients with confirmed rifampicin-susceptible and isoniazid-resistant tuberculosis, the recommended treatment regimen is a combination of **rifampicin, ethambutol, pyrazinamide and levofloxacin** for a duration of 6 months

Regimen: 6 (H) R- E- Z- Lfx

- In cases where a diagnosis of Hr-TB is strongly presumed (e.g. close contacts of known Hr-TB cases with active TB but without laboratory confirmation of Hr-TB), **(H) REZ–levofloxacin** regimen may be initiated and then suitably modified based on subsequent DST results.
- DST results eventually indicate susceptibility to isoniazid
  - ➢ For new TB cases, levofloxacin is stopped and the patient completes a **2HREZ/4HR** regimen.
  - ➢ For Previously Treated (retreatment) cases, levofloxacin is continued along with **6HREZ** regimen.
- For other patients, in whom **Hr-TB** is detected provide 6 months 6LfxHREZ regimen.

9.5.2 Shorter regimen (STR)

MDR/RR-TB patients who have not been previously treated for more than 1 month with second-line anti TB medicines used in the shorter MDR-TB regimen or in whom resistance to fluoroquinolones has been excluded by SL-DST/LPA, the recommended shorter MDR-TB regimen is largely standardized. This is a daily regimen of 9–11 months with an intensive phase of 4 to 6 months, followed by a continuation phase of a fixed duration of 5 months.

Eligibility for STR:

The following MDR/RR-TB patients, with confirmed resistance to at least rifampicin, are eligible:

- No documented or suspected resistance to any of the medicines in the shorter regimen (except isoniazid resistance)
- No prior exposure to any of the medicines in the shorter regimen for more than 1 month. However, patients with an exposure of more than a month can be considered if there is documented evidence showing effectiveness of the drugs on a DST.
- The patient should not be suffering from extensive TB or severe extra-pulmonary TB
- The patient should not be pregnant.
- Only children aged 6 years and above are eligible.

Regimen and duration of treatment:

The shorter all-oral Bedaquiline containing MDR/RR-TB regimen is given in 2 phases as under:

- Intensive Phase (4 – 6 months): The IP contains 7 drugs, namely, bedaquiline, levofloxacin, clofazimine, ethionamide, ethambutol, high dose isoniazid and pyrazinamide given for 4 months. The IP can be extended up to 6 months if the patient remains sputum smear positive or culture positive at the end of the fourth/fifth month.

- Continuation Phase (5 months): The IP is followed by a CP containing 4 drugs, namely, levofloxacin, clofazimine, ethambutol and pyrazinamide given for a fixed period of 5 months.

Important:

- Bedaquiline is used for a fixed duration of 6 months (24 Weeks). It is taken daily for the first 2 weeks of treatment, followed by three times a week for the remaining 22 weeks (total 24 weeks).
- All other medicines are taken once a day for the entire course of the treatment.

Regimen: (4 - 6) Bdq(6m)-Lfx-Eto-Cfz-Z- $H^{high\ dose}$-E / 5 Lfx-Cfz-Z-E

Initial phase: **(4 - 6) Bdq(6 m)-Lfx-Cfz-Z-E- $H^{high\ dose}$-E**

Continuation phase: **5 Lfx-Cfz-Z-E**

Considerations for the all oral STR

Any changes to the regimen composition or the duration of the initial or continuation phase (including prolonging these phases in case of lack of response) is not advisable while using the shorter all-oral bedaquiline-containing MDR/RR-TB regimen under programmatic conditions. The only modifications that are allowed are as under:

- If the sputum smear or culture does not become negative by the fourth month, the initial phase is prolonged until the sputum smear or culture converts. However, the initial phase cannot be prolonged beyond 6 months (i.e., the IP can be extended only for a maximum of 2 months). The duration of the Continuation Phase remains fixed at 5 months regardless.
- Bedaquiline is used for 6 months.
- Prothionamide may be used instead of ethionamide.
- Moxifloxacin may be used instead of levofloxacin.
- Any other changes to the regimen (e.g. removing ethionamide or replacing ethionamide or clofazimine by linezolid etc.) are not recommended in programmatic use.

9.5.3 Longer MDR TB Regimens (LTR)

All MDR/RR-TB patients may be treated with longer regimens; however, the longer regimen is preferably given to those MDR/RR-TB patients who are not eligible for shorter all-oral regimens, including those with quinolone resistance.

Eligibility for LTR:

- MDR/RR-TB patients with extensive TB disease and severe EP TB, additional resistance to fluoroquinolones or exposure to treatment with second-line medicines for more than 1 month (without DST results).
- Any patient – child or adult – with MDR/RR-TB is eligible for the longer MDR-TB regimen
- All MDR/RR-TB patients for whom the shorter all-oral bedaquiline-containing MDR-TB regimen cannot be used or continued.
- If required, a patient initiated on the shorter all-oral bedaquiline-containing MDR-TB regimen can later be transferred to the longer MDR-TB regimen. The recommended regimen are:

For Quinolone susceptible: 6(Bdq-Lzd-Lfx-Cfz-Z)/14(Lzd-Lfx-Cfz-Z)

For Quinolone resistant: 6(Bdq-Dlm-Lzd-Cfz-Z-Cs)/14(Lzd-Cfz-Z-Cs)

Grouping of medicines recommended for use in longer MDR-TB regimens:

Group	Drugs
Group A (include all 3 medicines)	1. Levofloxacin OR Moxifloxacin 2. Bedaquiline 3. Linezolid
Group B (include one or both medicines)	1. Clofazimine 2. Cycloserine OR Terizidone
Group C (add to complete the regimen when drugs from group A and B cannot be used)	1. Ethambutol 2. Delamanid 3. Pyrazinamide 4. Imipenem–Cilastatin OR Meropenem 5. Amikacin (OR Streptomycin) 6. Ethionamide OR Prothionamide 7. P-Aminosalicylic Acid

Principles of Individualized Longer MDR-TB regimen formulation:

In MDR/RR-TB patients on longer regimens, all three Group A agents and at least one Group B agent should be included to ensure that treatment starts with at least four TB agents likely to be effective, and that at least three agents are included for the rest of the treatment after bedaquiline is stopped. If only one or two Group A agents are used, both Group B agents are to be included. If the regimen cannot be composed with agents from Groups A and B alone, Group C agents are added to complete it. Kanamycin and Capreomycin are no longer recommended for use in longer regimens.

9.5.4 BPaL Regimen

Data from the single arm, open-label Nix-TB study assessed the efficacy of a 6-9-month novel treatment regimen consisting of 3 drugs - Bedaquiline, Pretomanid and Linezolid - and demonstrated that this regimen safely improves treatment outcomes in patients with XDR-TB when compared with other regimens conforming to WHO guidelines. This regimen is being considered for treatment of multidrug-resistant tuberculosis (MDR-TB) patients with additional resistance to fluoroquinolones (pre-XDR), XDR-TB, intolerant and non-responsive MDR-TB, who have either had less than 2 weeks previous exposure to Bedaquiline and Linezolid under operational research conditions to acquire adequate evidence on safety and efficacy for use under programmatic conditions.

BPaL regimen should be used under operational research conditions with proper ethical approval, patient-centered care and support, pre-defined eligibility criteria, informed consent from patients and implemented according to the principles of good clinical practice, with active drug safety monitoring and management, treatment monitoring, outcome evaluation, and comprehensive, standardized data collection.

BPaL regimen: 6–9 Bdq- Pa-Lzd

Treatment delivery and Adherence

10.1 Adherence to treatment

Good treatment adherence is that when the patient follows the treatment as prescribed. Adherence to regular and complete treatment is the key to relapse free cure from TB. Failure to take anti-TB drugs regularly as advised or stopping the treatment too soon, can lead to treatment failure or relapse. Additionally, it may contribute to the development of drug resistance, which may complicate subsequent treatment, thereby may decrease the chance of successful outcomes. There are several factors that can influence adherence such as barriers related to the patient, the treatment or the therapeutic environment. All the factors; especially the patient factors are not always possible to control but the treatment and therapeutic environment-related factors may be controlled by proper monitoring of TB programme.

10.2 Factors that influence adherence

10.2.1 Patient-related factors

- Socioeconomic factors such as having a job, a home, education, family or other support, being stigmatized or marginalized;
- Psychological factors such as depression and feelings of discouragement.
- Understanding and perception of the disease and treatment: a patient might continue or abandon treatment because s/he sees, or does not see, improvement. S/he might also have trouble taking an active part in treatment if s/he attributes the illness to supernatural causes, etc.

Personal difficulties should be discussed at patient visits. Solutions will depend on the context and the patient's problem, and need to be found on a case-by-case basis

10.2.2 Treatment-related factors

- Simplicity of treatment improves adherence. The use of fixed-dose combinations (FDCs) and introduction of shorter treatment courses simplifies the treatment by reducing the pill burden (number of tablets) as well as duration of treatment. In addition, FDCs also prevents the patient from selectively taking TB medication (by removing one or more medications from the blister packs).
- Adverse effects are often the reason why patients interrupt their treatment and hence, they must be quickly detected and adequately managed.

10.2.3 Factors related to the therapeutic environment

- Patient's comfort and welfare is essential. Waiting times at clinics should be reasonable. For hospitalized patients, accommodations (comfort, food etc.) should be adequate.
- The relationship between the health care worker and the patient influences the adherence. If a patient trusts or has confidence in his/her health care worker, s/he is more likely to follow instructions and advice and to collaborate with the health care worker. Patients may also be more likely to bring questions and concerns to the health care worker's attention.
- Free care (visits, laboratory tests and treatment, including those related to management of adverse effects) limits the number of patients who abandon treatment for financial reasons.
- The co-management of HIV infection and TB requires coordination between the TB and HIV/AIDS programmes at all levels. Systems that set up a "one-stop service", where patients receive both TB and HIV care, reduce the number of visits and decrease waiting times resulting in higher patient satisfaction and better results.

- Linkages for diagnosis and management of other comorbidities, like diabetes and hypertension, too can take place in the same clinic to decrease the burden on the patient and improve treatment outcomes.
- Drug supply management must be meticulous. It is essential to avoid shortages, which can lead to treatment interruption and negative impact adherence (patients waste time in pointless travel, loss of confidence in the clinic, etc.).

10.3 Patient care and support

Patient compliance is a key factor to treatment success. Health education and counselling on the disease and treatment adherence should be provided to all TB patients as well as family members. Some patients may stop the treatment midway for various reasons. Hence, strict adherence to treatment should be ensured to stop the transmission of TB, cure the patients and prevent the emergence of drug-resistance. Patient support is the shared responsibility of the entire health care team (clinicians, nurses, treatment supporters, social workers, etc.) and is a continuous process till the end of treatment.

10.3.1 Patient education

- Helping the patient to understand his/her disease and treatment
- Enabling the patient to acquire and maintain skills that allow him/her to optimally manage his/her disease in daily life
- Answering the patient's questions throughout the treatment

10.3.2 Psychological support

Listen to the patient, provide encouragement, and gain his/her trust, so that s/he does not hesitate to share all treatment related issues or disclose possible lapses in treatment. These things happen fairly often, and it is important to know about them in order to help find solutions.

10.3.3 Social support

Implement social support measures for patients with limited resources. Depending on the specific needs of patients:

- Social workers can help to obtain disability allowances, housing assistance, shelter for the homeless, etc.

- **Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment (Strong recommendation, moderate certainty in the evidence)**
- **A package of treatment adherence interventions may be offered to patients on TB treatment in conjunction with the selection of a suitable treatment administration option (Conditional recommendation, low certainty in the evidence)**
- **Psychological support to patient**

10.4 Ambulatory versus hospital treatment

Over 95% of the TB patients can be treated on an ambulatory basis. Hospitalization itself has little or no effect on the outcome of the treatment except in severe form of tuberculosis. Hospitalization may be necessary if the patient cannot receive ambulatory treatment under direct observation. In-patient treatment may also be necessary (often only for a short period) for severely ill patients, e.g. tuberculosis with complications viz. severe haemoptysis (blood-stained sputum), spontaneous pneumothorax (air in the inter-pleural space resulting in collapse of the lung), TB meningitis, cardiac temponade etc. or for those with other associated serious diseases.

10.5 Directly Observed Treatment

Directly Observed Treatment (DOT) is a very important component in the internationally recommended policy package for TB control (DOTS strategy). Community or home-based directly observed treatment (DOT) is recommended over health facility-based DOT or unsupervised treatment. DOT administered by trained health-care workers is recommended over DOT administered by family members or unsupervised treatment. DOT means that an observer watches the patient swallowing their drugs, which is essential to ensure correct and complete treatment and recovery from TB. This ensures that the patient takes the right anti-TB drugs, in the right doses, at the right intervals and for the right period. This also gives an opportunity for patient counselling as well as early detection of adverse drug reactions if any. All patients, irrespective of the treatment category, should receive all doses of the anti-TB drugs under DOT.

10.6 DOT providers

To ensure adherence to treatment, DOTS should be provided with the objective of maximising the patient's convenience. This often means making necessary arrangement for DOTS as close to the patient's home or workplace as possible. If the patient wishes to attend any of the NTP recognized DOTS centres to take their medication, then this should be arranged in consultation with the patient.

The DOTS provider may be a facility or community-based health worker or a trained community member. These DOTS providers include TB & Leprosy Control Assistant (TLCA), assistant health inspectors (AHIs), health assistants (HAs), community health care providers (CHCP), community health workers (CHWs), Shasthya shebikas, village doctors, community leaders, cured patients, etc. All non-medical DOTS providers should be supervised at least once a month.

Medical officers and paramedics in consultation with patients, should identify the DOTS provider, the name and address of whom should be recorded on the patient's treatment card. The medical officer or paramedic has to ensure that the DOTS provider receives the filled-up copy of Treatment Card (TB 01), Identity Card (TB 02) and drugs at the specified intervals.

10.6.1 Drug supplies to DOT providers

If DOT is provided at the centre where the patient is registered, the drugs for that patient for the whole course of the treatment should be arranged and kept at a secured and suitable place in that centre. The paramedic responsible for DOT should be given the drugs for two weeks at a time.

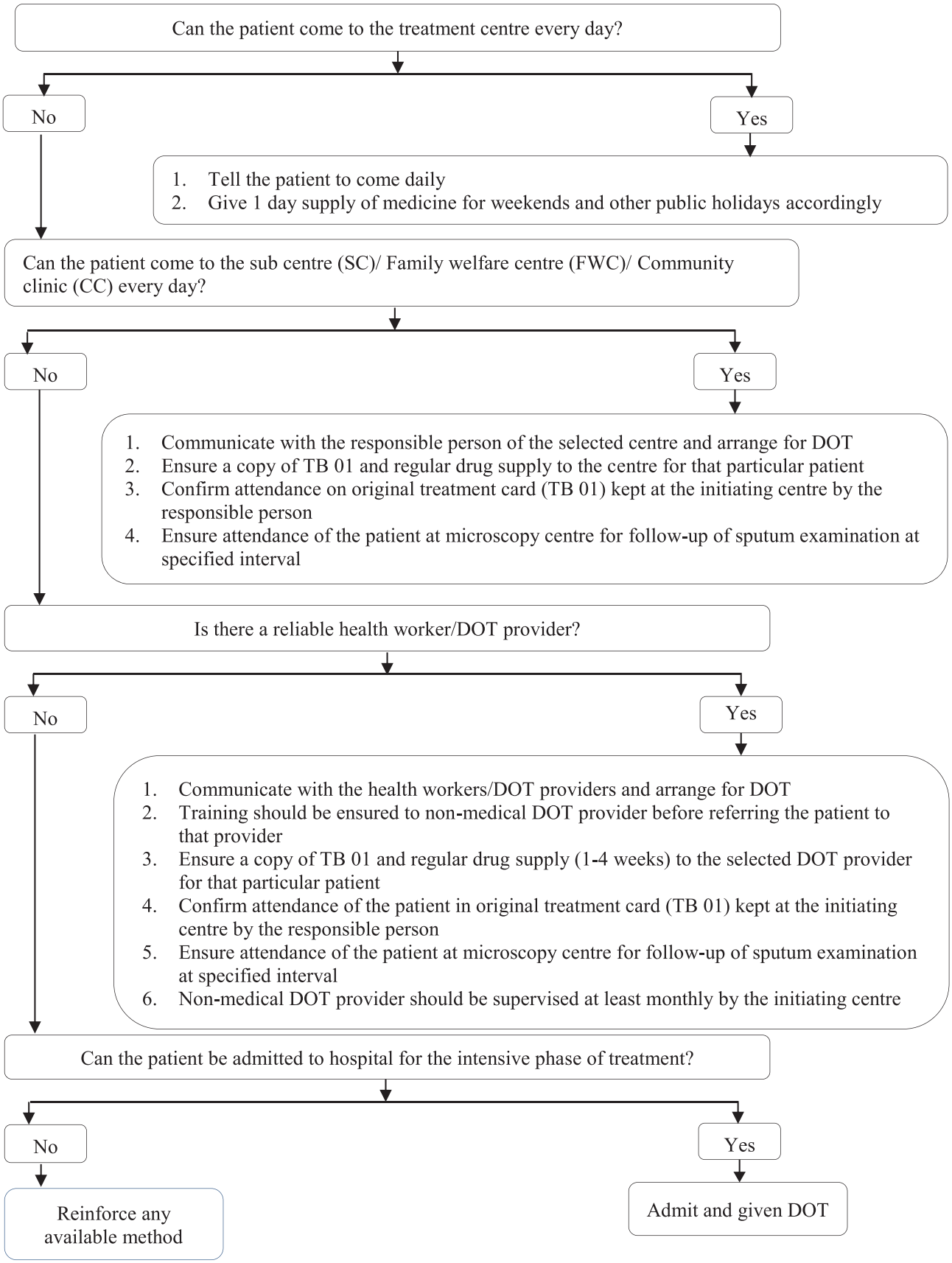
If DOT is provided from a sub-centre, where the patient is not registered for the treatment or at community level by a health worker/village doctor/shasthya shebika drugs needed for two to four weeks should be given at a time to the DOT provider until the end of the treatment.

10.6.2 Regularity of treatment

DOTS providers should ensure that the patients swallow the drugs according to prescription. They should take up prompt action for tracing and retrieval of patients who miss their doses and prevent patients from becoming lost to follow up. Priority must be given to smear-positive pulmonary TB patients. If a patient misses three consecutive doses of the treatment, he/she must be traced immediately to resume DOTS without delay.

To ensure easy tracing of patients the detailed address should be filled up on the Tuberculosis Treatment Card and TB Register (valid Mobile number should be included if available with the patient). The patients should be encouraged by the DOTS providers to visit the treatment initiation centre fortnightly during the intensive phase so that the patient can be evaluated for any adverse events as well as to assess prognosis by evaluating the remission of symptoms, weight gain etc.

10.6.3 Methods of DOT



Contact Investigation

Contact investigation is a procedure for identifying people who were exposed to someone with infectious TB disease, evaluating these people for active TB disease or latent TB infection (LTBI) and providing appropriate treatment for those with TB disease as well as LTBI. The purpose of contact investigation is to find persons who have active TB disease and at the same time identify eligible contacts for TB Preventive Treatment (TPT) among children and adults.

The contact investigation procedure will be used for early case finding of TB including Drug Resistant TB (DR TB), as a way of preventing on going transmission of TB, both in the household and in the community.

In addition, it is important to closely follow up contacts of patients with multidrug-resistant tuberculosis (MDR-TB) or extensively drug-resistant tuberculosis (XDR-TB) in order to prevent further spread of drug-resistant TB.

Standard Definitions of commonly used terms:

Index patient (index case) of TB: is the initially identified person of any age with new or recurrent TB in a specific household or other comparable setting in which others may have been exposed. An index patient is the person on whom a contact investigation is centered but is not necessarily the source.

1. **Source case or patient:** The case or person who was the original source of infection for secondary cases or contacts - can be, but is not necessarily, the index case
2. **Contact:** is any individual who was exposed to a person with TB disease.
3. **Close contact:** is a person who is not in the household but shared an enclosed space, such as at a social gathering, workplace or facility, for extended periods during the day with the index patient.
4. **Household contact:** is a person who shared the same enclosed living space with the index patient for one or more nights or for frequent or extended periods.
5. **Contact investigation:** is a systematic process for identifying previously undiagnosed people with TB disease and TB infection among the contacts of an index TB patient and/or other comparable settings where transmission occurs. Contact investigation consists of identification, clinical evaluation and/or testing and provision of appropriate anti-TB therapy (for people with confirmed TB) or TB preventive treatment (for those without TB disease).
6. **TB preventive treatment (TPT):** Treatment is offered to individuals who are considered to be at risk of developing TB disease, in order to reduce that risk. It is also referred to as treatment of TB infection or LTBI treatment.
7. **Active case finding (ACF):** Health workers, NGO staff, and/or community volunteers screen individuals for TB by asking a series of standard questionnaire related to signs, symptoms and contact history of TB. When the verbal symptom screening is positive, the presumptive TB cases are evaluated by investigation. If the laboratory test confirms a diagnosis of TB, the patient is put on appropriate treatment and their contacts are in turn screened and tested for TB.

11.1 Transmission of TB and contact investigation

Mycobacterium tuberculosis is an airborne pathogen that is transmitted from someone with infectious TB.

The risk of acquiring TB infection is related to the intensity and duration of exposure to a person with infectious TB. Therefore, household and close contacts of people with infectious TB, particularly contacts who live in the same house, are at the highest risk of acquiring TB infection.

11.2 Procedure of contact Investigation

The contact investigator should visit the home of the index patient to conduct interviews and ensure referral of all symptomatic household and close contacts for evaluation. In addition, all asymptomatic contacts will be evaluated for the eligibility of TPT as per NTP guidelines. Eligible contacts need to be counselled for proper referral by the Health care providers.

11.2.1 Who should be Included in a Contact Investigation?

All household and close contacts (ref, definitions above) of all bacteriological positive cases will be included. Contact investigation for less infectious cases (i.e. clinically diagnosed pulmonary TB) should also be carried out when possible.

The focus should be on household and close contacts, but people in the workplace and other settings in which there is exposure should not be ignored.

11.2.2 When to Conduct Contact Investigation:

- If a Presumptive TB case is confirmed as a bacteriologically Positive Pulmonary TB case, an evaluation for all household and close contacts should be started
- HCWs usually conduct contact tracing.
- If contact investigation is to be initiated, the index case should be interviewed as soon as possible after diagnosis (generally within 1 week) to elicit the names of household and close contacts.

11.2.3 Who will be under investigation?

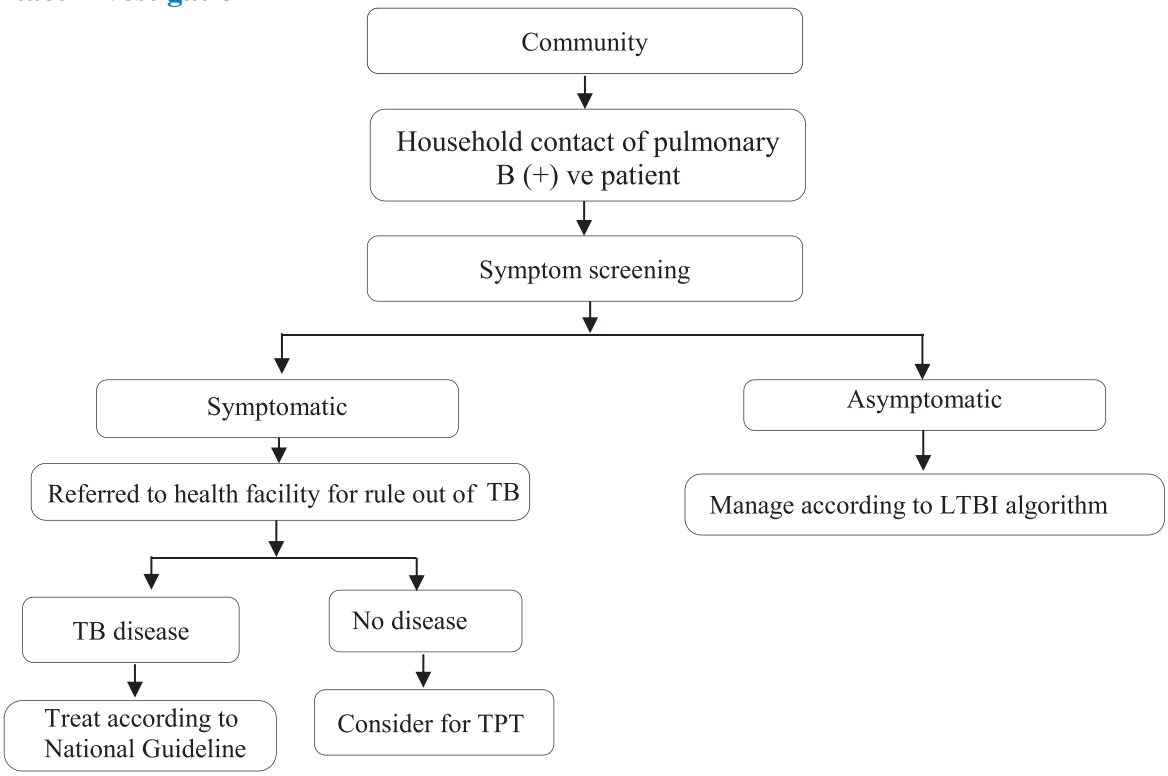
- Household contacts: Any person who lives in the home of the TB patient (sleeps and eats at least one meal per day there)
- Other close contacts: Any person who spends prolonged time closely with patient with TB regularly (i.e., coworkers or friends).

11.2.4 Steps of contact Investigation:

- For each Bacteriologically Confirmed patient a CI form will be initiated by the TLCA/ /responsible person for the DOT centres. One CI form will be generated for each Index case. For two or multiple patients in one family each form should be used for individual patient. DR TB contact Investigation form will be yellow, and the DS TB will be white colour.
- TLCA/ DOT corner will fill in the upper portion of the CI form (Block A). TLCA will hand over all the CI form of the index cases to the HI/ HI (In-charge) to distribute this form to Govt field staff (HA, FWA, MPV)/NGO field staff. HI In-charge will hand over the CI forms to the relevant HAs during monthly/ weekly meeting and HAs will then conduct household visit to the index cases to collect further information of CI form (Block-B).

- For urban settings, the respective field staff will fill in the upper portion of the CI form (Block A) and then distribute to the CHW (community Health care workers)/ DOT provider during the monthly/weekly staff meeting.
- The responsible HA or the CHW (community Health care workers)/ DOT provider will visit the home of the Index Case for collecting further information and fill up Block-B of CI form of close contact of index case. S/he will interview the Index Case and family members to identify contacts. S/he will also do primary screening of symptoms of household and close contacts and refer all symptomatic (adult and children) to the respective Government Facilities/ NGO clinics for further evaluation.
- All asymptomatic contacts of index DS TB cases should be referred for further evaluation and initiation of TPT to the respective Government Facilities / NGO clinics .
- Only symptomatic contacts (all ages) of index DR TB cases should be referred for further evaluation to diagnose possible TB / DR TB.
- HA/HCW will refer the contact by issuing a referral slip to each of those contacts.
- After issuing a referral slip, HA will communicate with respective DOT Providers of index cases to ensure timely referrals.
- The HA will return his/her filled in CI form to the HI during weekly/ monthly meeting and HI will hand over the form to the TLCA. The TLCA will fill up the CI registration book based on the information of CI form.
- Returned CI form will be preserved at the treatment unit (upazilla Health Complex/ other government facilities/NGO clinics) where the contacts will be evaluated by a physician.
- Referred contacts with the referral slips will be evaluated at the health facilities and the outcome of the evaluation will be documented in CI registration book.
- Contact Investigation of hospitalised DR TB patients will be carried out by the concerned HA/ HCWs as soon as possible post admission. This will be done under the supervision of UH&FPO through TLCA.
- Contact investigation Register should be maintained by the TLCA and the recorded data should be checked and countersigned by the UH&FPO monthly. Quarterly Contact Investigation report will be generated by the TLCA and sent to the NTP under the signature of UH&FPO.
- Relevant NGO Workers and managers will ensure proper implementation of contact investigation and recording & reporting of CI.

11.3 Contact Investigation



11.4 Monitoring and Evaluating of Contact Investigation process:

- Data from the contact investigation will be collected in standardized form and register. (Annex).
- National TB control programme will routinely evaluate the effectiveness of contact investigations and design interventions to improve performance.
- Data collection during contact investigations has multiple purposes. First, good information is important for the management and follow-up of index cases and their contacts. Secondly, systematic collection and analysis of data will provide useful insights on the overall yield of contact investigations as well as for specific groups and epidemiological settings. Thirdly, data on indicators of care are useful for evaluating programme performance objectives.
- At field level, overall the UHFPO will be responsible for ensuring proper implementation, recording and reporting of Contact Investigation. S/he will review regular implementation updates, analyze reports and use this data for program updates & improvement.
- HA, HI, AHI, DOTS providers and TLCA will coordinate with each other and ensure prompt visits to the index case household, referral of all symptomatic (adult and children) and asymptomatic contacts for evaluation.
- At least, the following information will be collected:
    - number of contact investigations carried out;
    - number, age, sex of contacts identified;
    - number who completed medical evaluation and relevant investigations;
    - the number with TB cases identified from contact investigation;
    - and the numbers of contacts put on preventive treatment.

Latent TB Infection

Latent tuberculosis infection (LTBI) is defined as a state of persistent immune response to stimulation by Mycobacterium tuberculosis antigens without evidence of clinically manifested active TB. One third of the world's population is estimated to be infected with M. tuberculosis. The vast majority of infected persons have no signs or symptoms of TB disease and are not infectious, but they are at risk to develop active TB disease. It is estimated that the lifetime risk of an individual with LTBI for progression to active TB is 5–10%. Among them the majority develop TB disease within the first five years after initial infection. However, the risk of developing TB disease following infection depends on several factors and the most important one is the immunological status of the host.

Prevention of active TB disease by treatment of LTBI is a critical component of the WHO End TB Strategy. Management of LTBI involves a comprehensive package of interventions that includes (1) identification and testing of pre-defined at-risk population (household and close contacts, esp. children below 5 years and ≥60 years, PLHIV and other immune-compromised patients etc.), (2) ruling out active TB disease, (3) delivering an effective and safe treatment with no or minimal loss to follow up and adverse events and (4) systematic monitoring and evaluation of the process.

12.1 Identification of populations for testing for LTBI

Not all individuals infected with M. tuberculosis develop active TB. For the programmatic management of LTBI, systematic testing and treatment of LTBI should be carried out in the at-risk populations. People who have risk of acquiring TB infection and subsequently developing TB disease are defined as priority or target groups to receive TPT. These groups include:

- People living with HIV
- Contacts of TB patients with following conditions
  - <5 or ≥ 60 years old
  - Diabetics
  - Other clinical vulnerabilities
    - CKD with or without on dialysis
    - Anti-TNF treatment
    - Transplantation (including candidate)
    - Silicosis
    - Smoking
    - Substance abuse

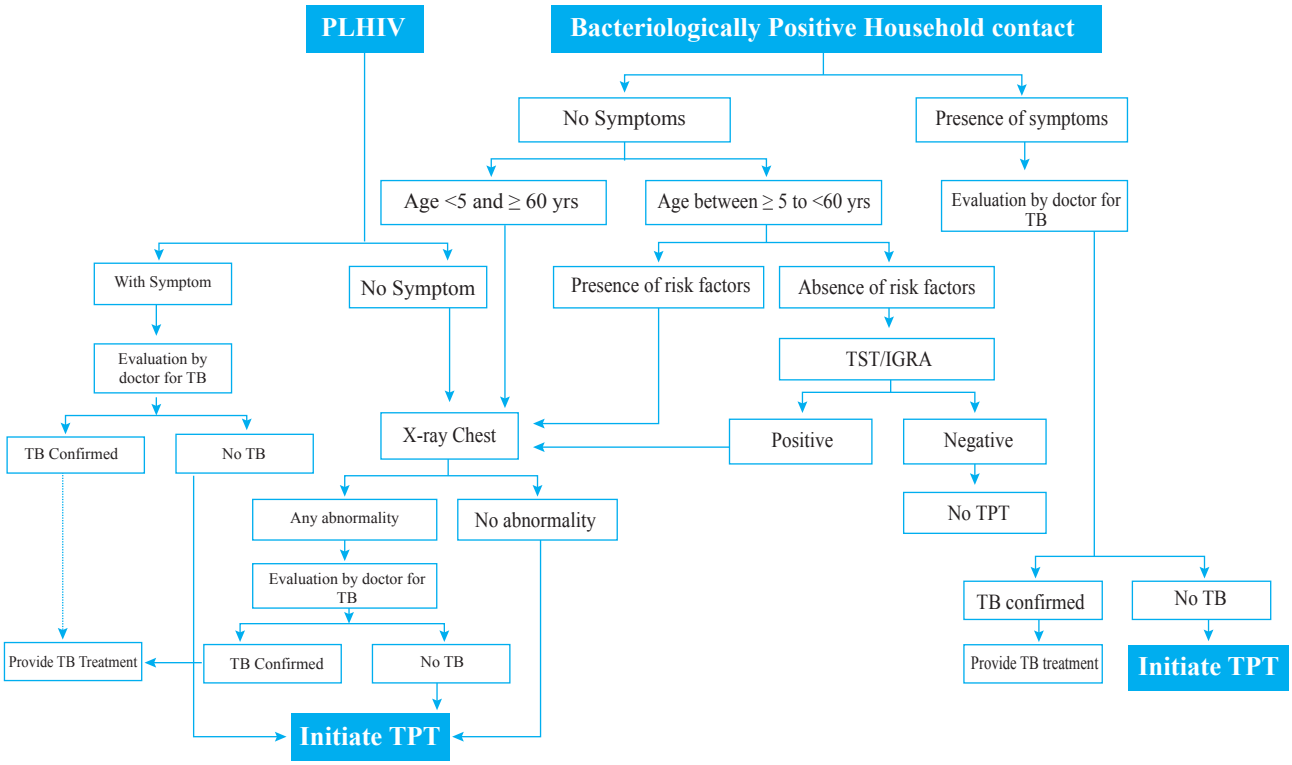
Note: Emphasis should be given in special conditions ie; prisoners, co-workers etc for testing and treatment for LTBI.

12.2 Testing for latent tuberculosis infection

Either a tuberculin skin test (TST) using standardised PPD of recommended strength or IGRA can be used to test for LTBI. However, IGRA should not replace TST. Neither TST nor IGRA can differentiate between active and latent TB. Individuals should be asked about symptoms of TB before

being tested for LTBI. Chest radiography can be done if efforts are intended also for active TB case finding. Individuals with TB symptoms or any radiological abnormality should be investigated further for active TB and other conditions. TPT should never be prescribed without ruling out active TB disease by symptom screening, and if required, by Chest X Rays and sputum examination.

12.3 Algorithms for diagnosis of LTBI



Risk Factors

- Diabetics
- Other clinical vulnerabilities
- CKD with or without on dialysis
- Anti-TNF treatment
- Transplantation (including candidate)
- Silicosis
- Smoking
- Substance abuse

12.4 Treatment options for LTBI [10]

Regimen	Age group	Drugs	Administration
3HP	>15 years (All adult)	FDC of Isoniazid 300 mg + Rifapentine 300 mg	FDC Tablets once weekly dose for 12 weeks (3 months)
3RH	<10 years	Rifampicin 75 mg /Isoniazid 50 mg as per weight band below*	Daily dose for 90 days (3 months)
3RH	>10 to <15 years child	Rifampicin 10 mg / kg / day and Isoniazid 10 mg / kg / day or as per weight band below*	Daily dose for 90 days (3 months)
6H	All adult with PLHIV	Isoniazid 300mg	Daily dose for 180 days/6 months

*

Weight Band	4 – 7 Kgs	8 – 11 Kgs	12 – 15 Kgs	16 – 24 Kgs	>25 Kgs
RH (75 / 50 mg)	1 Tab	2 Tabs	3 Tabs	4 Tabs	Adult Dose

12.5 Preventive treatment for contacts of MDR-TB cases

Limitations of the quality of evidence prevent drawing any recommendations on DR-TB preventive therapy as a public health measure. So TPT for contacts of DR-TB patient is not recommended in NTP Bangladesh yet.

12.6 Adverse events monitoring

Individuals who receive treatment for LTBI do not have active disease, and therefore, it is mandatory to minimize risks during treatment. Drug-specific adverse reactions can occur with isoniazid (asymptomatic elevation of serum liver enzyme concentrations, peripheral neuropathy and hepatotoxicity); rifampicin and rifapentine (cutaneous reactions, hypersensitivity reactions, gastrointestinal intolerance and hepatotoxicity). While most adverse drug reactions are minor and occur rarely, special attention should given to prevention of drug induced hepatotoxicity.

Baseline laboratory testing should be undertaken for individuals with the following risk cofactors: history of liver disease, regular use of alcohol, chronic liver disease, HIV infection and pregnancy or the immediate postpartum period (i.e., within three months of delivery). For individuals with abnormal baseline test results, routine periodic laboratory testing should be carried out.

12.7 Adherence and completion of preventive treatment

Adherence to the full course and completion of treatment are important determinants of clinical benefit to the individual as well as to the success of the programme.

[10] WHO operational handbook on tuberculosis preventive treatment accessed on 30th Dec 2020 from: https://www.who.int/publications/i/item/9789240002906

TB/HIV Co-Infection

The HIV/AIDS pandemic presents a significant challenge to the global efforts to control tuberculosis (TB). There is a positive co-relation between the TB incidence and mortality and HIV prevalence. HIV is the most potent risk factor for progression of Mycobacterium Tuberculosis (MTB) infection to TB disease. In fact, the risk of developing tuberculosis (TB) as per the Global TB Report 2020 (Page 34) is estimated to be 18 times (range, 15 – 21) greater in people living with HIV than among those without HIV infection. On the other hand, Tuberculosis is the most common opportunistic infection amongst HIV-infected individuals. It is a major cause of mortality among patients with HIV and poses a risk throughout the course of HIV disease. TB infection is also known to accelerate progression of HIV infection to Acquired Immunodeficiency Syndrome (AIDS) and reduce survival of the infected person. TB is therefore the leading preventable cause of death among PLHIV.

13.1 TB/HIV policy in Bangladesh:

Bangladesh has adopted the WHO policy recommendations for collaborative TB-HIV activities published in 2014.

The recommended activities for TB/HIV collaboration focus on establishing mechanisms of collaboration between TB and HIV programs at all levels, decreasing the burden of TB in people living with HIV (PLWHIV) through intensified case finding, Isoniazid preventive therapy & infection control (the 3 I's) and decreasing the burden of HIV in TB patients through Provider Initiated Testing and Counseling (PITC), adopting recommended prevention methods, Cotrimoxazole preventive therapy (CPT), HIV treatment and care and support for TB/HIV co-infected patients.

13.1.1 Goal

The goal of collaborative TB/HIV activities is to reduce HIV associated TB mortality and morbidity through close coordination between National AIDS/STD Program and National Tuberculosis Control Program.

13.1.2 Objectives

- To establish mechanisms for coordination between the National Tuberculosis Control Program and National AIDS/STD Program
- To decrease the burden of tuberculosis among people living with HIV
- To decrease the burden of HIV among TB patients

13.1.3 Strategy

Implementation of collaborative TB/HIV activities in Bangladesh is based on three pillars

- Establishing functional collaboration between the NTP, NASP and all implementing partners with clear and mutually agreed roles and responsibilities
- Integrating the TB/HIV services into existing program implementation structures considering feasibility and sustainability
- Generating national evidence on the burden of disease, appropriate interventions and feasible model for implementation

13.2 Criteria for TB/HIV Referral

13.2.1 PLHIV and high risk group for TB screening

- All HIV-positive patients
- Suspected TB cases among the high-risk groups
- Immediate family, partners and contacts of HIV positive patients.

13.2.2 TB patients for HIV screening:

- In 23 high priority districts
  - All TB cases should be screened for HIV
  - All DR TB cases should be screened for HIV
- In other districts, the following should be screened for HIV:
  - TB with history of high-risk behavior (IDU, unsafe blood transfusion, sex workers, migrant workers, H/o STI, MSM, transgender/ Hijra)
  - Complicated extra-pulmonary TB, Relapse and treatment failure cases
  - Clinical suspects of HIV infection
  - Children of mothers known to be HIV-positive
  - DR TB Patients

13.3 Mechanism for TB/HIV Referral:

13.3.1 PLHIV and high-risk group for TB screening:

All PLHIV are screened for TB using rapid diagnostic tool (Xpert MTB/RIF) at least once a year. Similarly, all MDR patients are screened for HIV during initiation of treatment. Once a PLHIV is diagnosed as having TB, anti TB treatment is initiated immediately and this patient is closely monitored by both the HIV and TB programme by regular documented follow ups. DOT is usually provided by care giver/peer educator.

Currently, in Bangladesh, verbal screening for TB is carried out for all identified key population (KP) visiting any of the service delivery points (i.e. CDIC, DIC, sub-DIC, outlets, etc.) and at community level. Anyone with signs/symptoms of TB (i.e., cough for more than 2 weeks, fever, gradual weight loss etc.) are promptly referred to the government designated TB centres for further management. Diagnosis and treatment are ensured by both the NTP as well as ASP.

13.3.2 TB patients for HIV screening:

All DR TB patients are screened for HIV during initiation of treatment. All TB patients in the 23 priority districts too are screened for HIV at diagnosis. In all the remaining districts, HIV screening is also carried out for complicated TB cases and TB among patients with high-risk behaviour. HIV screening facilities will be available at DOTS centre. Anyone screening positive for HIV will be referred to the nearest ART centre (Annex-) for confirmation and registration followed by initiation of ART. These activities are implemented and followed up by both NTP and ASP.

13.4 Diagnosis and Management of TB/HIV co-infection

This is described in the "National Guidelines on TB/HIV Management Program Collaboration & Implementation Manual"

13.5 TB Preventive Treatment (TPT)

TPT is very effective in preventing active TB in individuals who have LTBI. All HIV-positive persons in whom active TB has been excluded should be started on TPT. Although Isoniazid TPT is the most widely used form of TPT, other regimens are also effective. The safety of isoniazid TPT has been well established, including in pregnant women and children. When administered correctly after ruling out active TB, isoniazid TPT has not been associated with development of isoniazid resist¬ance. Risks of isoniazid TPT include isoniazid-induced hepatitis, peripheral neuropathy and inad¬equate treatment of persons with active TB with the potential development of isoniazid resistance. Strict adherence to laid down criteria for TPT eligibility, along with proper monitoring and follow-up, will minimise these risks.

13.5.1 Eligibility criteria for TPT in PLHIV

The individual, to be eligible for TPT, must:

- Have no symptoms or signs of TB – current cough, fever, weight loss, night sweats, enlarged lymph nodes, or fatigue, blood in sputum, chest pain, diarrhoea, shortness of breath and loss of appetite,
- Have no history of alcoholism,
- Have no history of active liver disease, liver insufficiency, or jaundice,
- Patients who are unwell; particularly in case of unexplained illness.
- Have no history of hypersensitivity to isoniazid (if isoniazid TPT is being considered),
- Have no history of exfoliative dermatitis, and
- Be convinced and motivated enough to complete the full course of TPT after being counselled about the benefits, possible side-effects and risks.

13.5.2 When to initiate TPT

Same day ART and TPT initiation is recommended for newly diagnosed PLHIV who are eligible. All PLHIV on ART and not yet on TPT should be screened for TB at every visit and initiated on TPT as soon as eligible. PLHIV, who have successfully completed TB treatment, should be assessed for TPT with the aim of initiating a TPT course immediately after completing the full course of TB treatment. All details of the person receiving TPT must be recorded as required in the TPT/IPT register and the TPT/IPT identity card or other patient-held records. TPT status should also be recorded in the HIV pa¬tient care booklet (if HIV positive). An outcome should be given to all patients registered for TPT.

13.5.3 Contraindications of TPT

Individuals with one or more of the following conditions should not receive TPT:

- Active tuberculosis.
- Symptoms compatible with tuberculosis, even if the diagnosis of TB cannot be confirmed.
- Abnormal chest X-ray.
- Diagnosis and treatment of TB in the past 3 years.
- Poor prognosis (terminally ill AIDS patients).
- History of poor compliance with treatment.
- Active hepatitis (chronic or acute).

- Known or reported high daily alcohol consumption.
- Prior allergy or intolerance to isoniazid.
- History of close contact with MDR-TB patient.

13.6 Viral load monitoring with GeneXpert

Viral load monitoring using gene Xpert is considered as an integral part of HIV care, support, and treatment. Under the national ART guideline (2019) the recommended viral load monitoring for PLHIV should be carried out on Day 0 (as baseline) and 6 months after initiation of ART. Where facilities are available, the follow up viral load monitoring should be carried out once every 12 months to monitor treatment adherence and early detection of treatment failure. PN/POW/CPC will ensure that the viral load testing is conducted for all PLHIV at recommended intervals through the accompanied referral system. ASP will follow up with the patient for other necessary procedures in coordination with NTP.

13.7 Supervision, Monitoring and Reporting

Routine supervision and monitoring of TB and HIV activities will be carried out by the individual programmes through a joint M&E plan prepared by NTP and NASP.

TB and Nutrition

Nutritional deficiencies are generally associated with an increased risk for contracting TB and has an effect on the severity of the disease. Undernutrition and tuberculosis (TB) are closely linked and both are public health problems. In TB, as in many other infectious diseases, there is a bidirectional interaction between nutritional status and active disease, undernutrition is associated with an increased frequency, severity and fatality of infections, including TB; while infections in turn lead to undernutrition. The association between TB and undernutrition has long been known. TB makes undernutrition worse and undernutrition weakens immunity, thereby increasing the likelihood that latent TB will develop into active disease. Most individuals with active TB are in a catabolic state and experience weight loss and some show signs of vitamin and mineral deficiencies at diagnosis. Weight loss among those with TB can be caused by several factors, including reduced food intake due to loss of appetite, nausea and abdominal pain; nutrient losses from vomiting and diarrhoea and metabolic alterations caused by the disease. Low body mass index (BMI) (lower than 18.5 kg/m2) and lack of adequate weight gain with TB treatment are associated with an increased risk of death and TB relapse and can be an indication of severity of TB, poor treatment response and/or the presence of other comorbid conditions. A weakened immune system - caused by malnutrition - can be quickly and easily corrected by just giving the body the nutrients it needs. Thus, nutritional intervention in combination with appropriate pharmaceutical therapy could improve the outcome in malnourished TB patients.

14.1 Nutritional response to infection

Once infected with TB, the body starts using more and more energy trying to fight the infection, and in addition, the infection often causes a loss of appetite in the patient, resulting in the patient losing weight. An increase in protein breakdown leads to muscle wasting in these patients. The breakdown of protein and other reserves due to fever may also worsen under nutrition and further impair resistance against the infection. The increased energy expenditure and tissue breakdown associated with infection are thought to increase the requirements of micronutrients such as vitamin A, E, B6, C, D and folate. It is also known that a decrease in trace elements such as iron, zinc and selenium occur during the infection.

14.2 Nutritional assessment

Nutritional assessment is a prerequisite for provision of appropriate nutritional support in patients with TB, and on follow-up of the patient. Nutritional assessment may vary according to the population groups, e.g., adult patients (above 18 years), children and adolescents (6–18 years), children under 5 years of age, and pregnant mothers.

Nutritional assessment will include the following:

A. Clinical assessment: This includes a nutrition-oriented history and a nutrition-oriented examination

B. Anthropometric assessment

C. Dietary assessment and laboratory assessment wherever feasible and appropriate.

Assessment at diagnosis

It is important to identify undernutrition at the onset of diagnosis and establish the baseline of nutritional indicators to monitor the response to treatment in patients with TB. It is also important to identify children and adults who may be severely undernourished, with or without other complications and who may require initial treatment in a hospital.

Assessment at follow up

In patients who continue to be moderate- severely undernourished during follow-up, further risk factor and dietary assessment will be necessary, as follows:

- Poor TB treatment adherence and/or response, resistance to TB drugs
- Clinical assessment for other non-dietary causes of malnutrition, including identification of important co-morbidities such as diabetes, HIV, alcohol abuse.
- Biochemical assessment whenever possible
- Dietary assessment, including assessment of food security.

Weight loss or failure to regain or maintain a healthy weight, at any stage of disease should trigger further assessment and appropriate interventions. Nutritional status of patients with MDR-TB is particularly important as treatment outcomes in this group of patients are sub-optimal and poor nutritional status has been associated with greater frequency of side-effects, delayed time to sputum conversion and mortality

A. Clinical assessment

Nutrition-oriented examination in patients with active TB

Macronutrient malnutrition	
Loss of body fat	Seen in Orbital region (sunken eyes), over ribs, over triceps
Loss of muscle mass	Wasting over temples, clavicles, scapula, thigh, calf
Protein deficiency	Bilateral oedema: It may be classified as- +/Grade 1: over both feet (below ankles); ++/Grade 2: over both feet and legs (below knees); +++/Grade 3: over feet, legs, arms, face Easily pluckable sparse, depigmented hair, flag sign
Body mass index	Calculate as weight in kg/ (height in meter
Mid-upper arm circumference	Measure in centimeters at the mid-point between the acromion and the olecranon process. Measure in patients with severe undernutrition (BMI < 16 kg/m2), where the patient cannot stand, has pedal oedema or in a pregnant woman with TB.
Micronutrient deficiencies	
Iron	Pallor, spooning of nails, angular stomatitis
Iodine	Goitre
Vitamin	Conjunctival xerosis, Bitot spots, follicular hyperkeratosis
Folic acid	Pallor
B12	Pallor, loss of joint position and vibration sense
Vitamin C	Swollen, bleeding gums

B. Anthropometric assessment

Height and weight: This is a measure of weight adjusted for height, which is calculated by dividing the weight in kg by the square of height in metres.

$$\text{BMI} = Weight\ in\ kg / (Height\ in\ m)2$$

BMI is useful as a measure of the fat and muscle mass of the body. It is also useful as an indicator of risk of morbidity and mortality, which increase linearly in subjects with both BMI higher and lower than normal. At higher BMI, the risk of CVD deaths increases, while at lower BMI subjects are at greater risk of dying due to respiratory causes including TB

Classification of nutritional status and associated risk using BMI as criteria

BMI (Kg/m2)	Weight category	Risk
< 14.00	Extremely underweight	Extremely high
<16.00	Grade III underweight	Increased
16.00 – 16.9	Grade II underweight	Increased
17.00 – 18.4	Grade I underweight	Increased
18.50 – 24.9(*)	Normal weight	Normal
25-29.9(*)	Overweight	Increased
30.0 – 34.9(#)	Grade 1 obesity (Overweight)	High
35.0 – 39.9(#)	Grade 2 obesity (Obesity)	Very High
> 40.00(#)	Grade 3obesity (Morbid	

*A WHO expert consultation in 2004 proposed different cut-offs for overweight and obesity in Asians on the basis of available data which suggests that Asians have a higher percentage of body fat than White people of same age, sex and BMI. The consultation identified potential action points: Underweight BMI less than 18.5; Normal- BMI 18.5-22.9; Overweight- BMI 23.0-26.9; Obesity-BMI> 27.0 (64).

Situation not likely to be common in case of TB patients.

Mid upper arm circumference (MUAC)

MUAC is the circumference of the left upper arm -measured midway between the tip of the shoulder (acromion) and elbow (olecranon). It is an indicator of nutritional status (including fat and protein stores), and like the BMI is also independent of height. It can be measured in pregnant women and those who are unable to stand.

MUAC <23 cm in Men and < 22 cm in women correlates with a BMI of < 18.5 kg/m2 and is suggestive of undernutrition. MUAC reflects of the effect of acute undernutrition more than BMI, and has been seen to an independent predictor of mortality in both HIV positive and HIV negative individuals. Patients with a MUAC less than 19 cm had 5 times the mortality rate of those with a MUAC > 24 cm. There are no standard MUAC cut-offs for different grades of adult undernutrition. In WHO Integrated management of Adolescent and Adult illness, a cut-off of MUAC < 16 cm was used to define severe undernutrition. However, a cut off of less than 16 cm would correspond to a situation of virtually no peripheral energy stores, and excess mortality has been seen at levels of MUAC which are higher than this cut-off in patients with active TB.

Propose criteria for initiation of nutritional support in an inpatient setting for adults (>18 years):

Suggested cut-offs for MUAC for moderate – severe undernutrition in adults

MUAC < 19 cm: Severe undernutrition

MUAC 19–22 cm: Moderate acute malnutrition

C. Biochemical and laboratory evaluation

Hemoglobin:

Anemia due to deficiency of micronutrients like iron and folates is very common in patients with TB and can contribute to poor performance status in patients with TB.

Criteria to classify anemia in males and females (WHO)

	Normal Hb	Mild anemia	Moderate anemia	Severe anemia
Men	≥13 g/dl	10 – 12.9 g/dl	7 – 9.9 g/dl	< 7 g/dl
Non-pregnant women	≥12 g/dl	10 – 11.9 g/dl	7 – 9.9 g/dl	< 7 g/dl
Pregnant women	≥11 g/dl	10 – 10.9 g/dl	7 – 9.9 g/dl	< 7 g/dl

Serum albumin

Is affected by malnutrition but is also affected by inflammation. The normal range is 3.5 to 5.5 g/dL. In patients with TB, hypoalbuminemia (e.g., serum albumin less than 2.7 g/dl) has been associated with increased risk of death, while a higher albumin was inversely related to treatment failure in patients with extensively drug resistant TB

Serum electrolytes

Measurement of serum potassium and magnesium is desirable, if patient has severe undernutrition and has been admitted for inpatient management. This is because patients with severe undernutrition are deficient in these, and low levels of potassium and magnesium are risk factors for re-feeding syndrome

14.3 Nutritional assessment of children and adolescents

In children between 6 and 18 years the classification of malnutrition can be based on the BMI-for-age percentile charts for girls and boys

Anthropometric measurements and classification in children 6–18 years of age

Nutritional indicator	Age group	Severe acute Malnutrition (SAM)	Moderate acute malnutrition (MAM)
BMI for age	6 years to less than 18 years	Less than -3 z Score (< -3 z score)	>-3 z score to < - 2 z score
MUAC	6 years to less than 10 years	Less than 11.5 cm (<11.5 cm)	>13.5-14.5 cm
	10 years to less than 18 years	Less than 16.0 cm (<16.0 cm)	≥16.0 &< 19.0 cm
Edema	6 years -18 years	Present	Absent

Cut offs for diagnosis and classification of anemia in children 5–18 years of age

Age group	Normal Hb	Mild anemia	Moderate anemia	Severe anemia
Children 5-11 years	≥11.5	11 – 11.4	8 – 10.9	< 8
Children 12-14 years	≥12	11 – 11.9	8 – 10.9	< 8
Boys >15 years	≥13	10 – 12.9	7 – 9.9	< 7
Girls >15 years	≥12	10 – 11.9	7 – 9.9	< 7

Hb= hemoglobin in gm/dL

14.4 Nutritional assessment of under-5 patients

- Clinical assessment: History and examination
- Documentation of social assistance schemes patient is already entitled to/
- Anthropometric assessment
  - Weight for length (0-1 year of age)
  - 1-5 years: WHO growth charts, weight for age for boys and girls
- Biochemical assessment
- Basic dietary assessment as informed by mother.

14.5 Nutritional assessment of pregnant women

The clinical assessment remains same with added information about

- last menstrual date and trimester
- pre-pregnancy weight if available
- clinical assessment to rule out high risk pregnancy or pregnancy with complication
- routine antenatal care and advise

For first trimester BMI can be used for nutritional assessment. Throughout pregnancy, weight gain should be recorded during each visit and mother should be asked to come with her Mother and Child Protection card to the DOTS center. During second and third trimester, MUAC can be used for classifying nutritional status. During pregnancy the suggested MUAC cutoff for

14.6 Nutritional treatment of TB

The risk and morbidity of infections are influenced by the nutritional status of the individual. Likewise, the nutritional status and the intake and utilization of foodstuffs are profoundly altered during the body's response to infection. Factors that affect food intake, such as food availability, appetite, eating patterns, medication side effects, traditional food taboos, lifestyles (smoking, alcohol, physical activity, caffeine intake, use of social drugs), psychological factors (stress and depression), stigma, and economic factors are also very important to consider. All individuals with active tuberculosis (TB) should receive (i) an assessment of their nutritional status and (ii) appropriate counselling based on their nutritional status at diagnosis and throughout treatment.

14.7 Management of severe acute malnutrition

School-age children and adolescents (5–19 years of age), and adults, including pregnant and lactating women, with active TB and severe acute malnutrition should be treated in accordance with the WHO recommendations for management of severe acute malnutrition.

Children who are less than 5 years of age with active TB and severe acute malnutrition should be treated in accordance with the WHO recommendations for the management of severe acute malnutrition in children who are less than 5 years of age.

14.8 Management of moderate undernutrition

- School-age children and adolescents (5–19 years of age), and adults, including lactating women, with active TB and moderate undernutrition, who fail to regain normal body mass index after 2 months' TB treatment, as well as those who are losing weight during TB

treatment, should be evaluated for adherence and comorbid conditions. They should also receive nutrition assessment and counselling and, if indicated, be provided with locally available nutrient-rich or fortified supplementary foods, as necessary to restore normal nutritional status.

- Children who are less than 5 years of age with active TB and moderate undernutrition should be managed as any other children with moderate undernutrition. This includes provision of locally available nutrient-rich or fortified supplementary foods, in order to restore appropriate weight-for-height.
- Pregnant women with active TB and moderate undernutrition, or with inadequate weight gain, should be provided with locally available nutrient-rich or fortified supplementary foods, as necessary to achieve an average weekly minimum weight gain of approximately 300 g in the second and third trimesters.
- Patients with active multidrug-resistant TB and moderate undernutrition should be provided with locally available nutrient-rich or fortified supplementary foods, as necessary to restore normal nutritional status.

14.9 Micronutrient supplementation

- A daily multiple micronutrient supplement at 1× recommended nutrient intake should be provided in situations where fortified or supplementary foods should have been provided in accordance with standard management of moderate undernutrition, but are unavailable.
- All pregnant women with active TB should receive multiple micronutrient supplements that contain iron and folic acid and other vitamins and minerals, according to the United Nations Multiple Micronutrient Preparation, to complement their maternal micronutrient needs.
- For pregnant women with active TB in settings where calcium intake is low, calcium supplementation as part of antenatal care is recommended for the prevention of pre-eclampsia, particularly among those pregnant women at higher risk of developing hypertension, in accordance with WHO recommendations
- All lactating women with active TB should be provided with iron and folic acid and other vitamins and minerals, according to the United Nations Multiple Micronutrient Preparation, to complement their maternal micronutrient needs.

14.10 Contact investigation

In settings where contact tracing is implemented, household contacts of people with active TB should have a nutrition screening and assessment as part of contact investigation. If malnutrition is identified, it should be managed according to WHO recommendations

14.11 Nutritional rehabilitation is important for people with TB

- TB causes weight-loss and macro- and micro-nutritional deficiencies.
- The bi-directional association between undernutrition and TB leads to a high prevalence of undernutrition among people with TB.
- Proper TB treatment helps restore normal weight and nutrition. However, the time to full nutritional recovery can be long and many TB patients are still undernourished after TB treatment is completed.

- Proper nutritional care improves nutritional recovery for people who are undernourished, and therefore helps reduce future health risks.

14.12 Food support may help improve access to care and mitigate catastrophic costs of TB

- Food-insecurity can be an important barrier for accessing and adhering to TB treatment.
- Catastrophic costs of TB illness and TB care can increase food-insecurity. There is often a vicious circle of underlying vulnerability leading to TB, and TB leading to aggravated vulnerability.
- The evidence on food support as an enabler for accessing and adhering to TB treatment is inconclusive. However, experiences suggest that food support is a critical component of enablers and social protection packages, especially in food-insecure populations.

TB Infection Prevention and Control (IPC)

Transmission of TB is a recognized risk in health care facilities and communities, especially in resource-limited settings, where transmission is further facilitated by inadequate TB infection prevention and control measures. TB Infection Prevention and Control (TB-IPC) is a combination of evidence-based measures intended to prevent exposure and reduce the risk of TB transmission. These consist of administrative measures, environmental controls and respiratory protection. However, the early detection of TB and the prompt initiation of appropriate treatment is key to reducing transmission.

15.1 Goal and Objective of TB Infection Prevention Control

The goal of TB-IPC measures, in conformity with the definition of TB-IPC, is to reduce transmission of TB (particularly MDR-TB) in health facilities, congregate settings and households.

The objectives that have to be achieved are the following:

- To strengthen coordination between all concerned stakeholders for implementing appropriate TB-IPC measures.
- To minimise the generation of aerosols and thereby the exposure to droplet nuclei.
- To reduce concentrations of infectious particles in the environment
- To reduce inhalation of infectious particles.

Airborne infection control comprises of measures aimed at minimising the risk of transmitting micro-organisms through the air. Prevention of transmission in health facilities and other high-risk congregate settings is based on a series of priorities. The set of interventions that will lead to achieving the objectives are categorized according to the objectives as under:

- Administrative controls
- Environmental controls
- Personal protective measures

There is no doubt that the proper implementation of a combination of prevention and control measures, specified for each service delivery level and setting, will lead to achievement of the above objectives and goal. Moreover, implementation of the recommended control measures along with a risk assessment at each location together can further optimise the development of location-specific TB-IPC plans.

15.1.1 Administrative controls

The administrative controls include decisions, policies and procedures aimed at reducing generation & transmission of and exposure to infectious droplet nuclei. These include measures for prompt identification and treatment of infectious cases and are hence regarded as the first line of defence in terms of TB infection prevention and control.

TB IPC requires action at national and sub-national level to provide managerial direction, and at health facility level to implement TB IPC measures. The set of IPC related recommendations and policies at the national and sub-national level are necessary to facilitate implementation of TB IPC in health-care facilities, congregate settings and households. The range of activities includes:

- Identifying (or creating) and strengthening a national coordinating body to spearhead this
- Preparing and adopting a national Strategy and Guidelines (including recommendations on HR strengthening)

- Carrying out risk assessments using standardised tools to assess the TB IPC related baseline situation at all levels of health care and congregate settings
- Comprehensive planning and budgeting
- Systematic surveillance of TB disease among health workers
- Appropriate designing, construction, renovation, use and maintenance of TB IPC equipment at health care facilities
- Targeted ACSM (SBCC)
- Routine and systematic monitoring and evaluation of the TB IPC measures.

Patients triage

All patients, upon entry into the health facility, should be promptly screened for cough by a member of the medical staff. Where possible, patients with cough over two weeks should be sent to a separate and well ventilated waiting room. All patients with current cough of any duration should receive tissues or face masks, and they should be counselled to keep their nose and mouth covered at all times. The clinical as well as laboratory investigations of all such patients should be prioritized and fast tracked to minimize their time inside the health facility.

Patient, visitors and attendants' flow

- Encourage patients and attendants to spend as much time as possible outdoors (if the weather permits) or in areas that are well ventilated (open on three or four sides).
- Restrict access to TB wards by using prominent signages on entry doors.
- Limit visitation duration, particularly for contagious patients.
- Encourage visits outside the building and in the open, especially for contagious patients.
- Have visiting areas clearly demarcated with signage. The signage should also include information on respiratory hygiene and encourage everyone visiting the high risk settings to follow those.
- Before any visit, the nurse/ health workers should provide counselling on risk of transmission, the usage of respirators if caregivers need to enter the high risk areas such as Labs or clinics were diagnosis of TB is being undertaken and indoor units housing smear-positive, drug-resistant TB (DR-TB) and smear positive previously treated patients
- The patient flow in the health facilities should be designed in such a manner that presumptive or confirmed TB patients do not come in to contact with other patients visiting the hospital to avoid unnecessary exposure and cross infections.

Segregation of hospitalized patients

Hospitalisation should be avoided unless absolutely necessary. Presumptive or confirmed TB and DR TB patients should be physically separated from other patients.

Immediate initiation of treatment for diagnosed patients

All diagnosed TB patients should be immediately initiated on the appropriate treatment to reduce the bacteria load and minimise chances of transmission.

TB IPC training

All healthcare personnel should receive initial training on TB transmission, information on high-risk areas in the facility and on protective measures. Continuing education should be offered annually. The training should also include counselling of patients, visitors and attendants about the risk of TB transmission and infection prevention measures (cough etiquette, use of masks and respirators etc.)

15.1.2 Environmental control

Environmental controls is regarded as the second line of defence. These set of measures aim at reducing the concentration of infectious particles (droplet nuclei) in the air.

Ventilation:

Ventilation (replacement of inside air with outside air) is the most effective means for reducing the concentration of M. tuberculosis in the air, and as a result, the risk of transmission. The WHO recommends that in areas where TB transmission might occur, a minimum ventilation rate of 12 air changes per hour (ACH) should be achieved.

Effective ventilation can be obtained by natural (assisted or not) or mechanical means

- Natural ventilation: Natural ventilation, especially cross-ventilation (windows/doors in opposite sides of the room), has the best cost-effective ratio. It should be done with the windows and outside doors open (as much as weather conditions permit). Inside doors should be closed so that the flow of air is directed outside and not toward the corridors. Create shady spaces so that patients, attendants and visitors can stay outside during the day.
- Mechanical ventilation: When natural ventilation cannot reach adequate rates, centralised mechanical ventilation should be considered in some settings, such as in colder climates. Centralised mechanical ventilation relies on the use of mechanical equipment to maintain an air pressure difference between two areas in order to draw air into a room and vent it to the outside. It requires uninterrupted electricity and continuous & meticulous maintenance, which renders it costly and difficult to implement and operate

Architectural considerations

Airborne infection control should be always considered during the planning/construction stages of new health facilities and those being modified. It is important to achieve the following:

- Building layout and design with maximised natural ventilation (assisted or not) and sunlight. Waiting areas should be open on three sides. Design of TB wards should avoid internal hallways with doors from the rooms and wards opening into them. Instead, doors should open to outer hallways that are open to outside air (this may not be feasible in cold climates).
- Specific areas (open air, sputum collection booth, etc.) should be reserved for procedures with a high risk of M. tuberculosis transmission (e.g. sputum collection, sputum induction, etc.).
- Allow patient flow that reduces exposure of patients at risk to patients that are infectious (e.g. separate waiting rooms for different cohorts, one patient per room in a hospital). If designing a new TB ward, incorporate plenty of single rooms or at least small rooms with 2 to 4 beds placed at least 3 feet apart for easier separation of the different cohorts of patients. General hospitals should also have isolation rooms available for TB suspects and contagious patients.

Ultra-violet germicidal irradiation

Ultra-violet germicidal irradiation (UVGI) lamps may be used when adequate ventilation cannot be achieved in high-risk areas. When properly installed, designed, maintained and operated, an UVGI system, in addition to 6-12 ACH ventilation, could be the equivalent of 10-25 ACH.

- Main requirements and constraints in UV lamps usage include:
  - Expertise in installation and testing
  - Rigorous monitoring and maintenance
  - Electricity, relative humidity less than 70%, good air mixing.
- Potential hazards include: Transient eye and skin injuries from overexposure and mercury poisoning (broken or mishandled lamp).

Areas requiring specific measures

- Sputum collection areas: Wherever feasible, these areas must be located outside in the open or in well ventilated rooms so that any bacilli containing aerosol can be quickly dispersed. Sputum collection should not be done in closed areas such as toilets and in ill-ventilated rooms to avoid build up of infectious particles in the air.
- Laboratory: All laboratories should undergo a risk assessment, and IC measures should be adapted accordingly. In any case, only authorized persons should be allowed access to the Lab. The use of ventilated workstation is strongly recommended for sample processing and smear preparation (microscopy and GeneXpert). In laboratories where culture is carried out, Class II (preferably Type A2) Biological Safety Cabinets (BSC), must be used.
- Laboratories must have easy to clean working surfaces (avoid wood) to allow proper disinfection. In the absence of mechanical ventilation, the Labs should have large windows to let in sunlight and allow natural ventilation. Water-filters should be used to avoid contamination by saprophyte mycobacteria that are sometimes present in the water.

15.1.3 Personal protective measure

Personal respiratory protection is the third line of defence especially aimed at protecting heath care workers (HCWs). This refers to items specifically used to protect the health care providers, the patients and the community from exposure to droplet or airborne infection.

Respirators

A respirator is a personal protective equipment that, when worn correctly, has the capacity to filter particles and prevent the inhalation of infectious droplet nuclei by the person who wears it correctly.

Exposed staff: Staff must wear a respirator, regardless if they are the caregiver or not. Respirators should be worn:

- When in contact with contagious patients (suspect or confirmed TB case)
- When collecting sputum samples
- When collecting and disposing of sputum containers
- In areas where droplet nuclei could be present (i.e. a room that has been occupied by a TB case, prior to the time required for air cleaning).

Visitors/attendants: Visitors and attendants must wear a respirator when entering a contagious TB patient's room.

Face or surgical masks

Face masks are medical devices that prevent patients from spreading infectious droplets when talking, coughing or sneezing. They should be worn by contagious patients (suspect or confirmed) when they leave their rooms to go to another department or any other enclosed area. They should not be worn when the patient is alone in his/her room and outdoors.

Advocacy Communication and Social Mobilization (ACSM)

Tuberculosis is a communicable disease with significant medical and social aspects. The sixth element of the WHO Stop TB Strategy 2010-2015 emphasised the empowerment of people with TB and affected communities through advocacy, communication and social mobilization (ACSM) and the use of a patient charter developed to guide the patient and health workers on rights and responsibilities regarding TB care. ACSM is a package of strategies with the purpose of obtaining people-centric responses to the TB epidemic in a country. Bangladesh is one of the 30 high TB & MDR TB burden countries in the world. ACSM activities are essentially required for effective TB control in Bangladesh and to achieve target 3.3 of SDG goal 3.

16.1 End TB strategy 2016-2035

Communities and patient-centric care are important elements in the End TB strategy and ACSM is reflected in the vision, principles, the pillars and components of the strategy. The vision is to achieve a world free of tuberculosis with zero deaths, disease and suffering due to TB. The principles include building strong coalitions with civil society, organizations as well as communities for protection and promotion of human rights, ethics and equity. The first of the three pillars of the strategy is integrated, patient-centric care and prevention while the second entails bold policies and supportive systems. It also emphasises the engagement of community, civil society and various organizations to ensure social protection, poverty alleviation and actions on other determinants of TB.

16.2 Advocacy

Advocacy mainly comprises of policy advocacy, programme advocacy and media advocacy. Policy advocacy engages senior politicians and administrators on improving laws and policies. Programme advocacy is achieved by engaging with and involving community leaders. Media advocacy helps in the process of validating TB related issues in order to raise awareness of possible problems and solutions.

16.3 Communication

In healthcare and service, communication is a two-way process of exchanging information, views and opinions between service providers and recipients. Through communication, we can spread awareness on issues like symptoms of TB, how it spreads, testing, treatment and free of cost availability of these and other relevant services. NTP carries out a lot of communication related efforts on its own and/or with the help of NGO partners and other stakeholders.

16.4 Social Mobilization

Social mobilization involves and motivates relevant stakeholders such as general population, health workers, policy makers, etc. Organizing and taking action for a common purpose to assist delivery of resources and services to strengthen community participation for sustainability, self-reliance and resilience is the goal of social mobilization. The aims of social mobilization are to bring about a social change within the country and to build up partnerships. To achieve its goal, NTP has been working with more than thirty NGOs in the different TB control activities.

ACSM helps in the TB control process by improving case detection and treatment adherence, combating stigma and discrimination, empowering people affected with TB and mobilizing political commitment and resource for TB.

16.5 Intended outcomes are:

- Patient-centered quality services provided by public and private health facilities as well as through civil society organizations (NGOs, CBOs).
- Engagement of communities to find local and innovative solutions to the challenges faced by the NTP to strengthen early case finding, TB diagnosis, contract tracing, IPT intervention, increased adherence to treatment and reduce social stigma.

Effective communication strategies, address social factors including poor quality of life, poor housing, overcrowding, under-nutrition, smoking and abuse of substances, lack of education, large families, early marriage, lack of awareness regarding cause and transmission of TB and improve the quality of services.

Beside improving early case detection and treatment adherence, ACSM is now addressing components like TB/HIV co-infection, MDR-TB, childhood TB, contact tracing, IPT intervention, infection control and vulnerable groups such as prisoners, migrants, FDMN and others.

16.6 ACSM organizational framework

NTP is the lead implementing authority to coordinate and develop policies and oversee the management. The implementation arm (NGO) of the NTP is the ACSM Technical Working Group (TWG) in line with other working groups already established for DR-TB, Childhood TB, PPM, Lab, IC, M&E and Research. The ACSM Committee is policy oriented and has the responsibility of developing policy guidelines, finalize and endorse the ACSM Strategic Plan and monitor its overall implementation.

Public Private Mix (PPM) For TB Control

This chapter highlights the important aspects of PPM. Details are included in the "Guidelines for Public Private Mix for Tuberculosis Control – 2006 edition", the 'National Strategic Plan for Public-Private Mix (2016-2020) and the National Operational Plan on PPM in Tuberculosis 2017-2020. Public-Private Mix is a strategy that links the resources of public and private health care providers, NGOs and the corporate sector to achieve national TB Control targets. It also aims to promote partnerships among stakeholders and create a shared vision and course of action among NTP and its key PPM partners.

17.1 The importance of PPM in the context of Bangladesh

In Bangladesh private practitioners constitute a large proportion of the service delivery infrastructure. Almost half of the patients with chest related problems are estimated to seek care from the private sector. Thus, it is important that the private sector is incorporated as an integral component in the delivery of TB services under the umbrella of the NTP. It is widely recognized and experienced that the quality of and access to health care provision can be greatly enhanced by involvement of all health care providers through PPM. The combined efforts of the public and private sector are critical for Bangladesh in order to help halt and reverse the TB burden.

Although many private providers in Bangladesh are already providing services to TB patients, TB management practices in the private sector are not standardized and the exact number of TB cases detected and treated in the private sector is not known. This is due to the lack of sufficient interaction and formal linkages between NTP, private, NGO and public sector providers. Their greater involvement in the delivery of services for TB will enable provision of high quality and effective TB services by all care providers.

17.2 The PPM approaches for TB Control in Bangladesh

NTP and its partners implement several PPM approaches:

1. Public with Private (example: NTP collaborating with NGOs and private sector)
2. Public with Public, (example: NTP collaborating with Medical College Hospitals, Defence, Police Health Services etc.)
3. Private with Private health care providers (example: NGOs working with Private Practitioners, Hospitals and Clinics etc.)

17.3 Current and Potential Providers of PPM

The current and potential providers of PPM are:

Institutional Providers:

- National TB Control Programme
- City Corporation Health Services
- NGO partners
- Academic Medical Institutions e.g.: Medical Colleges, Specialized Institutions and Universities
- Government Hospitals e.g.: District Hospitals, Upazilla Health Complexes, Chest Disease Clinics and Hospitals
- Corporate and social sectors e.g.: Export Processing Zone (EPZ), Port, Railway, Tea gardens, RMGs (Readymade Garment Industries) and other companies etc.

- Prison Health Services
- Defence/ Police Medical Services
- Private Hospitals, Clinics and Laboratories
- Professional associations and bodies, e.g., Medical professional associations, National anti TB association (NATAB) etc.

Individual Providers:

- Specialist Physicians
- Graduate Private Medical Practitioners (GPP's)
- Non-graduate PPs (NGPPs) e.g.: Sub-assistant Community Medical Officer (SACMO), Medical Assistant, Practitioners with LMF (Licentiate Medical Faculty) and MFPC (Member of the Faculty of Polio and Chickenpox etc.
- Non-qualified Informal Health Care Providers e.g., village doctors, pharmacists, drug sellers, pharmacy staff and owners etc. Refugee camp authorities Community Health Volunteers e.g.: Shastho Shebika, Cured TB Patient, etc.

17.4 Roles of Diverse PPM Partners

The leadership and coordination of all partners and PPM activities is the responsibility of the NTP. For this purpose, NTP has established the PPM committee and working group whose responsibilities are to lead, advocate for resource mobilization, coordinate and provide guidance to all PPM activities.

The responsibilities of NTP include the following:

- Advocacy and policies to prioritise and place TB Control high on the agenda of the Government of Bangladesh (GOB) and MOHFW.
- Create, enhance and expand partnerships at all levels, including capacity building as per felt need.
- Ensure engagement of NTP staff at divisional, district and upazila levels in PPM planning, supervision, monitoring and reporting.
- Policy development and adaptation of related policies, tools, guidelines and strategies.
- Appropriate and timely dissemination of related TB documents and annual reports.
- Appropriate management of GOB resources and grants for ensuring uninterrupted supplies of anti-TB drugs, supplies, commodities and necessary financial support for activities.
- Training and supervision of providers.
- Program supervision, monitoring and evaluation.

The responsibilities of PPM Implementing Partners include the following:

- Local level planning for implementation of PPM related activities
- Appropriate and timely implementation of PPM activities outlined in annual operational plan which include providing free sputum smear microscopy, anti-TB drugs and organizing delivery of DOT. Appropriate recording and timely sharing of reports, tools, best practices and lessons learned with NTP and among other PPM partners.
- Utilization of national NTP guidelines and training materials while engaging the individual providers and ensure proper referral from the private sector partners and individual providers
- Training the individual providers
- Establishing successful linkages among NTP, providers and partners
- Proper supervision and monitoring using the standard tools approved by the NTP.

The responsibilities of individual providers include the following:

- Management of TB patients following the approved national guidelines.
- Ensuring proper referral of presumptive TB cases for testing as well as notification and referral of diagnosed TB cases to the NTP and the local implementing partners

To formalize partnership between Institutional providers and NTP, contractual tools such as Memorandum of Understanding (MoU) is to be used, whereas, to establish effective linkages with individual providers, NTP recommends the use of Letter of Agreement (LoA) as a tool for contract. These tools need to be drafted after discussion and with mutual consensus and it should clearly describe the exact roles, responsibilities and deliverable of the collaborating partners. While this approach is recommended, it should also be noted it may not always be feasible to enter into formal contracts with all the individual providers. In such cases, engagements through regular orientations and workshops should be prioritized to encourage their engagement with the national program.

Supply of Drugs, Laboratory Consumables and Documentation Materials

Uninterrupted supply of adequate amounts of quality assured anti TB drugs and other consumables is mandatory for the smooth functioning of tuberculosis control activities across the country. Diagnosis of TB and the entire course of treatment for all registered TB patients are provided free of charge. The central level of NTP is responsible for planning, procurement and supply of anti-TB drugs, laboratory consumables and documentation materials (R&R formats and registers) to its implementing partners.

Estimates of the drugs and other items should be prepared taking the current and future requirements into account as well as the available stocks. Adequate buffer stocks are maintained at all levels to prevent stock outs due to unforeseen delays/disruption in supply as well unanticipated increase in number of patients. The entire process of drugs and logistics management has several interconnected components. The components of this management cycle are given below.

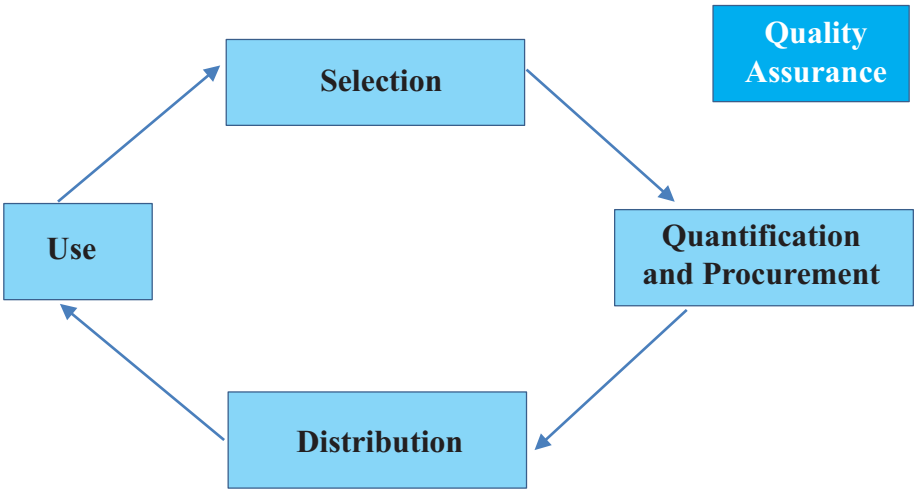


Fig: Drug Management Cycle

18.1 Selection and requirement of drugs

Selection of the drugs for procurement depends on regimens as well as categorization of patients. NTP follows global recommendation while selecting the optimum regimens or categorization of TB patients.

Quantification is based on the quantity of drugs required for treatment of different categories of patients (annex 4). Quantification of anti-TB drugs is usually carried out annually or as per requirement at the central level by the NTP managers with the technical assistance from partners. NTP uses GDF (Global Drug Facility) recommended tool, QuanTB, for quantification of TB drugs. This estimation of amounts of drugs required is based on the number of TB cases (category-wise) enrolled recently as well as estimated patients for the procurement period, treatment regimens to follow, amount of buffer stocks, stock-in-hand and stock on order (pipeline) at the time of the drug order.

Quantification of anti-TB drugs at the upazila, CDC or city level is usually done quarterly through drug requisition form or TB 08. This form has defined formula based on the number of patients (in different categories and regimens) diagnosed during the previous quarter, current stock and buffer. The local health authorities, in collaboration with NGOs, will calculate the quantity of drugs required and fill in the requisition form for drugs (TB 08) at the end of every quarter. The form will be signed by the Upazila Health and Family Planning Officer (UH&FPO) or unit chief, countersigned by the Civil Surgeon (or supervisor for the unit) and forwarded to the central level, preferably within the first week of the following month. The concerned NGOs will collect the drugs from central level and deliver them to the respective indenting authority. Alternatively, the NTP may arrange for central supply of the drugs to the indenting authority. A tool for electronic indenting is in use in the program. The electronic indenting is connected to the Warehouse Inventory Management System (WIMS) used in Shyamoli Central TB Warehouse (CWH) for inventory as well as supply management. The electronic system follows the same calculation as the paper based TB08.

The NGOs will collect the required drugs from the designated UHC through an indent to the UH&FPO and will report consumption and balance of drugs and other delivered logistics/laboratory consumables to the respective UH&FPO (or unit chief).

The information about drug consumption and stock at the upazila level will be communicated quarterly to the central level along with the case finding and treatment outcome reports. It is the responsibility of the UH&FPO (or unit chief) to ensure that this information is sent on time to avoid delays of supplies and possible stock outs. The buffer stock of drugs and laboratory consumables for the peripheral stores will be for one quarter.

18.2 Requirement of Laboratory Consumables

All health facilities require an adequate supply of sputum containers to collect and transport sputum specimens to diagnostic sites e.g., microscopy centres, Xpert sites and C-DST Labs. In addition, the TB laboratories need to be provided with good quality binocular / LED microscopes and GeneXpert machines, regular supply of slides and Xpert cartridges and other Lab reagents. The "Laboratory Request Form" (Annex 5 and 6) explains the process of calculating the required quantities of the various consumables necessary for preparation of the stains and other supplies. Further details are given in the "Laboratory Manual on Smear Microscopy for Tuberculosis and its Quality Control in the NTP of Bangladesh" and “Operational Manual for GeneXpert testing”.

18.3 Requirement of Documentation Materials

Each registration unit needs a TB Register (one register will usually be sufficient for one year), TB treatment cards and patient identity cards based on the estimated number of patients. In addition, sputum request forms should be available in the TB diagnostic facilities. One sputum request form will be used for requesting (1) diagnostic examination of two sputum specimens from a Presumptive TB cases (2) diagnostic examination on GeneXpert and (3) for each follow-up examination during treatment. Depending on the number of suspects and follow-up cases examined, each laboratory will need one or more TB laboratory registers per year. On an annual basis, all registration units (UHC, CDC, urban clinic, medical college hospital, etc.) need 25 copies of the quarterly report forms on case finding, smear conversion, laboratory reporting form, IPT form and treatment outcome forms. All districts need 15 copies of the "Requisition Form for Drugs" and the" Laboratory Request Form". NTP will ensure procurement and indent-based supply of all necessary recording and reporting formats.

18.4 Inspection and Storage of Drugs and Supplies

Upon receipt, all drugs and supplies should be inspected by a 'Survey Committee' constituted for the store. The committee will tally the supplies with the 'Invoice' and will report discrepancies or damages, if any.

Drugs and supplies should be stored under optimum conditions in a secured room and follow the good warehouse practices. The drugs and laboratory reagents should be monitored regularly for expiry date. The drugs with shorter expiry dates should be placed in front and those with longer expiry dates behind (FEFO or first expiry-first out). A stock ledger must be maintained and updated whenever drugs and other materials are received or dispensed. In addition, a stock card (bin card) should be maintained for each drug. The bin card must be updated whenever drugs are received or dispensed, so that the actual physical balance and the balance as per stock ledger always match.

The officer in charge of the store will ensure inspection of supplies, its optimum storage and proper recording as detailed in the "Standard Operating Procedures for Managing Drugs and Supplies".

18.5 Issuance of Drugs and Supplies

Drugs and other supplies will be issued quarterly based on completely and correctly filled form TB 8 "Requisition Form for Drugs form" and "Laboratory Request Form", according to the distribution schedule.

18.6 Monitoring and Supervision of Stores

Monitoring and supervision of drugs/supplies management must be done at all levels. Reports of case finding and drug stock status from the upazila received through indent form as well as quarterly stock status from the Central Store should be the basis for conducting systematic monitoring. Drug and other supply management (especially GDF drugs) should be included in the agenda of monitoring meetings at all levels.

Supervisory visits, including drug/other supply management, should be conducted using the checklist included in the general supervisory checklist. Reports of the supervisory visits should be analysed for monitoring and feedback.

Supervision, Monitoring and Evaluation

19.1 Supervision

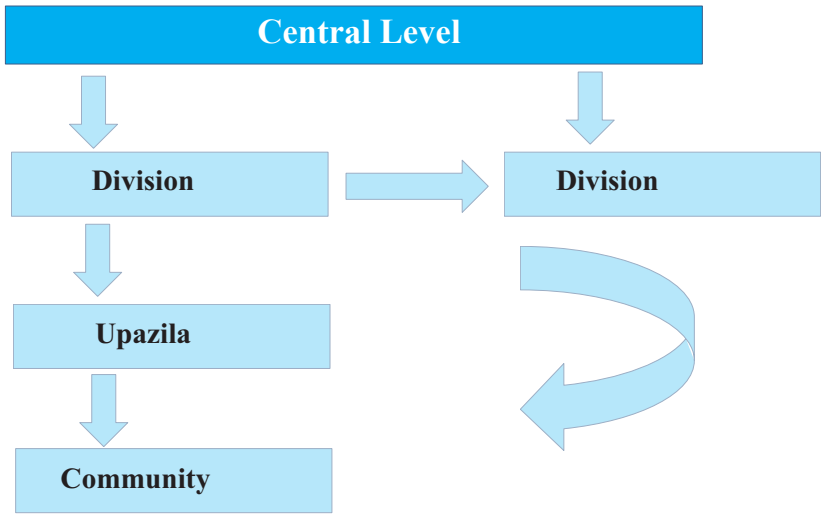
Supervision is the key element of TB control and is considered a cornerstone for sustainability of different NTP activities. Supportive supervision is the process of helping people to improve their performance in order to meet the desired target and objectives. Supervision is the part of monitoring that looks at the job performance of the people in the programme.

All health workers need support to solve problems and overcome difficulties. They need constructive feedback on their performance and encouragement for their work. Supervision will encourage, motivate, train, support, monitor, guide and boost staff morale. It is a set of activities to improve staff competence, effectiveness and efficiency of work through observation, discussion, technical support, demonstration and record reviews. The focus of supervisory visits is on-the-job training, coaching, mentoring, coordination, motivation, facilitation and guidance in implementation of the activities as per NTP guidelines with the overall objective to achieve national targets and goals.

Supervisory visits are planned with the following aims:

- To ensure effective implementation.
- To provide technical guidance and administrative support.
- To cross-check and validate reported data.
- To review the bottlenecks in implementation and take corrective measures wherever required.
- To ensure patient and staff satisfaction
- To strengthen the relationship between the central, intermediate and peripheral levels and the implementing staff

19.2 TP supervision policy



19.3 Process of supervision

To be effective, supervisory visits must be planned meticulously. The schedule for each supervisory visit should be prepared in advance. Before each visit, it is important to review the findings and recommendations of previous supervisory visits and any additional information about the health facility.

19.4 Tools for supervision

19.4.1 Supervisory checklist

Supervisory checklists are to be used to review and identify the administrative and technical issues methodically (Annex 3). Checklist should be systematically filled in, calculating all indicators and answering all questions along with the relevant health worker. The checklist should be completed by the end of the supervisory visit. The checklist provides a broad guideline, but the supervisory visit should not be confined only to the checklist and there is ample scope to look at other issues that are locally relevant.

19.4.2 Points to be focused during supervision

General

- Availability of the National Guidelines and Operational Manual for TB; other NTP guidelines and SOPs including laboratory manual
- Availability of all updated recording and reporting formats
- Availability of all standard ACSM/IEC/BCC materials for TB
- Human resources: staff status (post sanctioned and vacant), availability of job description; availability of the individual work plan, training status of staff; knowledge, skills and attitude of relevant staff; job satisfaction.

Identification of presumptive TB cases and laboratory diagnosis

- Trends of presumptive cases: number of Presumptive TB cases per month; presumptive TB notification rate (Presumptive TB cases detected during a defined period in a defined geographic area /total population of that area x 100,000)
- Review data outliers and unusual scenarios and provide feedback; e.g., number of sputum samples examined per presumptive TB case (if there are multiple instances of single sample examination, this usually indicates poor patient counselling and / or incorrect identification of presumptive TB.
- Review the source of referral of presumptive cases
- Triangulation: check that all patients who are diagnosed as per the TB Laboratory Register (TB 04) have been started on treatment [treatment card (TB 01) available] and are registered in the TB register (TB 04). Cross check the consistency of data recorded in these 3 records.
- Check that clinically diagnosed presumptive TB cases (smear negative) are referred to a qualified physician for further investigations according to TB diagnostic algorithm
- Calculate sputum positivity rates among both, presumptive TB cases as well as during follow up examinations. Conduct in depth review to find out possible causes for very low or very high sputum positivity rates and suggest remedial measures.
- Quality of sputum samples; quality and quantity
- Check the quality of smears (size, shape, thickness, evenness, staining)
- Review reporting turnaround times and discuss issues identified if any.
- Check the upkeep and maintenance status of microscope, Xpert, functional module/s of Xpert, and other equipment and logistics
- Check whether there is adequate supply of laboratory consumables for at least one month
- Check for Infection control measures (patients waiting area, sputum collected outside, availability and use of mask, etc.).

19.5 Verification of TB records

19.5.1 Trends in case notification:

Number of TB cases per quarter (bacteriologically confirmed cases, retreatment cases, all cases); case notification rate (cases detected during a defined period in a defined geographic area / total population of that area x 100,000) – review any unusual or inconsistent events and suggest remedial measures..

19.5.2 Sputum conversion rate:

a) For new bacteriologically confirmed cases: Total number of new bacteriologically confirmed cases becoming smear-negative after two months of treatment/total new bacteriologically confirmed cases registered during the same quarter x 100

b) for Previously Treated bacteriologically confirmed cases: total number of Previously Treated bacteriologically confirmed cases becoming smear-negative after two months of treatment/total Previously Treated bacteriologically confirmed cases registered during the same quarter x 100

These rates are expected to be around 85-90%. Investigate further in cases of low or very high conversion rates and provide feedback.

19.5.3 Treatment success rate:

Total number of new bacteriologically confirmed cases who were declared "cured" or "Treatment Completed"/total number of new bacteriologically confirmed cases registered in the same period x 100. This rate can be calculated in the same way for Xpert MTB/RIF positive cases, Previously Treated cases, clinically diagnosed cases and extra-pulmonary cases. Review unusually high or low treatment success rates and provide feedback. The treatment completion rate (where patient has completed the full course of treatment but cannot be declared as Cured as 2 negative follow up results - including the last follow up - are not available) for bacteriologically confirmed cases should not exceed 5%.

Unsuccessful outcomes: Lost to follow up rate, failure rate, death rate and transferred-out rate. Total number of new- bacteriologically confirmed cases who were "lost to follow up", "failed", “died” or were "transferred out" / total number of new bacteriologically confirmed cases registered during the same period x 100. These rates can be calculated in the same way for Previously Treated, clinically diagnosed and extra-pulmonary cases. Analyse reasons for poor treatment outcomes and provide feedback.

Health education and counselling

- Check availability and use of updated BCC materials
- Review counselling procedures
- Interview some patients randomly
- Relate your findings with the information available on the patient cards,
- Check knowledge about the diseases, duration of treatment and consequences of interruption of treatment

19.5.4 Supervision Report

Feedback is one of the most important parts of the supervision. It is encouraged to fill the checklist on the spot together with the related health personnel. This will facilitate capacity as well as relationship. Supervision report helps identify and improve areas of concern in the facility visited and also enables the subsequent supervisor visiting that facility to follow up on the recommendations made. Supervision reports should be submitted to relevant authorities and feedback must be provided to the concerned field staff and officials.

19.6 Monitoring

Monitoring is defined as the systematic ongoing collection, collation, analysis and interpretation of data with a view to detect any deviations from the expected norms and is followed by dissemination of feedback for corrective actions. It is an ongoing process of observing whether an activity or service is occurring as planned. Monitoring of a program or intervention involves the collection of routine data that measure progress toward achieving program objectives. It is used to track changes in program performance over time. Its purpose is to permit stakeholders to make informed decisions regarding the effectiveness of programs and the efficient use of resources. It also facilitates early identification of any diversions from a planned course of action thereby allowing timely solutions to problems.

In our case it relates to maintaining and improving the health care for Presumptive as well as Active TB patients so that it meets our aspirations, and to take appropriate action to improve performance. It is an ongoing process carried out by the programme implementers. Monitoring is the activity that ensures that measurable information of a programme is implemented, recorded and reported.

19.6.1 Methods of Monitoring

- Routine report review
  - o The core of a monitoring system
  - o Focuses on data management, supply, finance, training, quality assurance, and drug use
- Supervisory visits
  - o Reinforce routine reporting requirements
  - o Provide on-the-spot training, informal and direct monitoring
- Sentinel reporting
  - o Supplements routine reporting
  - o Most useful when a system is undergoing rapid or substantial change; can detect unexpected or unintended outcome

Both monitoring and supervision are ongoing processes. There should be a plan for regular supervision and monitoring at all levels.

19.7 Evaluation

Evaluation refers to the periodic assessment of the programs / projects activities. It involves systematic recording and review of information regarding the interventions and outcomes of programs to improve program effectiveness and support informed decisions on future strategies. Evaluation measures how well the program activities have met expected objectives and/or the extent to which changes in outcomes can be attributed to the program or intervention. It indicates whether the programme has achieved its targets and takes necessary steps for developing strategies and interventions for further improvement as per requirements of the programme.

The NTP advocates continuous periodical internal monitoring of the programme. External joint evaluations are conducted by both the NTP and external national and international experts at an interval of two to three years.

Monitoring and evaluation log framework

Input	Process	Output	Outcome	Impact
• Policy environment • Strategies Guidelines • Human Resources • Infrastructure • Funding for TB and lcprosy • Medicines, basic needs and commodities	• Coordination and management • Training • Procurement and supply chain management • Communication • Advocacy • Distribution • Dissemination	• Incrased diagnostic and treatment services delivered • Increased numbers reached • Improved knowledge, attitudes, and practices • Reduced stigma • Well equipped laboratories	• Improved coverage • Changed behaviour • Improved Case detection • Improved case management	• Reduced prevalence of TB infection • Reduced prevalence of TB disease • Reduced TB morbidity • Reduced TB mortality • Reduced leprosy Prevalence

19.8 Data Quality Assurance (DQA)

Data Quality Assurance (DQA) is defined as efforts or activities aimed at ensuring that reported data and results accurately reflect the actual health system outputs. This is a pre-reporting tool. The DQA team intends to look the reliability, validity, accuracy, completeness and timeliness of the data.

For example, the number of all form TB Case reported accurately reflects the actual number of TB cases detected in specific period of time in specific facility. Examples of data quality assurance activities are accuracy checks, capacity building of persons responsible for data recording and indicator compilation, and data quality performance indicator monitoring (e.g. accuracy, timeliness and completeness of reporting).

The purpose of a DQA is to ensure that the National Tuberculosis Program (NTP) is aware of the strengths and weaknesses of the data they obtain about project and program performance, as determined by reviewing actual data on indicators against validity, integrity, precision, reliability and timeliness.

Recording and Reporting

A standardized recording and reporting system is an important component of the National TB Programme and allows for rigorous monitoring and evaluation of the outcome of every patient diagnosed put under treatment. It allows for assessment of case detection and treatment outcomes against the targets. It also allows facilitates surveillance and monitoring along with regular communication among central, intermediate (e.g., divisions and districts) and peripheral levels. Collection of tuberculosis (TB) data forms part of the general health information system, which aims to:

- Ensure a continuum of care, information-sharing with patients and transfer of information between health facilities,
- Enable managers at different levels in the NTP to monitor programme performance in a systematic, standardized and internationally accepted manner, and
- Provide the basis for programmatic and policy development.

Establishment of a reliable recording and reporting system is an essential part of the End TB strategy. The programmatic progress and achievements of NTP should be assessed at different levels of implementation e.g. community, upazila, district, division, city and central levels. These guidelines are accompanied by standardised forms, registers and reporting templates that are designed for paper-based and electronic recording and reporting systems.

20.1 Tuberculosis Treatment Card (TB 01)

This card is issued and completed for every patient after being diagnosed with TB. The medical officer or relevant staff e.g., PO, TLCA fill-up the Tuberculosis Treatment Card as soon as a patient is diagnosed with TB. It contains information about the TB patient's details (name, age, sex, address, and contact details), the patient's diagnostic classifications, results of initial and follow-up sputum-smear examinations, treatment regimen, medicine doses, initial and follow-up body weight, HIV status, and medicine collection data. There is a special box for paediatric TB cases and the drug doses of child TB should be filled up in the box accordingly. If during the course of treatment, the dosages (number of FDC tablets) change due to changes in the weight band (due to weight gain or loss), the revised number of tablets should be documented underneath the boxes preceded by the date of change.

The original card should be kept at the health facility where the patient is registered and duplicate is sent to the treatment centre from where the patient received DOTS. This card needs to be updated on a daily basis and in real time to correctly reflect the medicine intake of the patient. The DOT provider should mark each and every dose in the designated spaces in the Tuberculosis Treatment Card. Once every fortnight, the original treatment card needs to be updated with the information recorded on the duplicate card. This card updating takes place during supervisory visits and while the provider visits the registering health facility for collection of medicines.

20.2 Tuberculosis Identity Card (TB 02)

The medical officer or relevant staff e.g., PO, TLCA, prepare this card for each and every TB patient at diagnosis. This card has to be safely retained by the patient. The most important information recorded on this card are the date of treatment initiation and the categorization of the patient. The patient should be instructed to carry this card each time s/he attends the health facility to avail any TB related services (follow up visits, visits to address possible ADRs etc.). The patient should be advised to safely retain this card after completing treatment for future reference.

20.3 Tuberculosis Register (TB 03)

This register is kept at the TB treatment facility. The Tuberculosis Register contains all the important general information of the patient, classification of the disease, and type of patient, date of start of treatment, X-ray results, smear microscopy results, Xpert MTB/RIF results, histopathology results and the treatment outcome. This register should be updated regularly according to the Tuberculosis Treatment Card of the patient.

The date of registration is the date the patient is registered in the Tuberculosis Register. This date may be different from the date the patient was diagnosed in the laboratory or started treatment. Space should be kept blank at the end of each quarter to highlight the end of the quarterly cohort. This will facilitate preparation of the quarterly reports and cohort analysis of treatment outcome. At the end of the quarter, a tally can be made by age, sex (males and female patients), disease classification, type of patient or treatment outcome. Each quarter should be started on a new page. From this register the quarterly reports on case notification, case detection and treatment outcome will be compiled. The information in the TB Register also entered in the electronic TB register. At every opportunity the electronic register should be updated and regular reports generated from it for programmatic use. On the regular basis, the paper-based registers and the electronic register should be compared to ensure concordance. It is the responsibility of the staff that maintains the register to keep it up-to-date.

20.4 Tuberculosis Laboratory Register (TB 04)

The purpose of the register is to record all relevant details of each and every test performed in a TB Laboratory. This helps in ensuring that all presumptive TB cases have the correct diagnostic test requested and performed, and the test results recorded. The Tuberculosis Laboratory register is kept at all laboratories performing sputum examination for AFB and Xpert MTB/RIF. The microscopist or medical technologist lab who examines the smears, enters all information into the register.

The register gives information on the number of presumptive TB cases examined, the number of bacteriologically confirmed TB cases detected and the number and results of follow up smear examinations. It also gives information on the number of Xpert MTB/RIF positive cases detected (if available).

A Laboratory Serial number is assigned to each patient who has been referred for sputum examination and it starts with 1 at the beginning of each calendar year. Some blank space should be left at the end of each quarter in the register. At the end of each quarter, the following information should be recorded (1) number of presumptive TB cases (2) number of total smears examined (3) number of smear-positive patients diagnosed (4) number of follow up smears examined and (5) number of positives among the follow up smears examined. Source of referral (referred by) also needs to be documented. Each quarter will start on a new page but the serial number will continue throughout the year.

20.5 Request form for AFB Microscopy/Xpert MTB/RIF examination (TB 05)

The medical officer or relevant staff e.g., PO, TLCA, paramedic who requests the smear/Xpert MTB/RIF examinations should fill up this form. If the smears are examined at the facility where the patient attends, the form should be brought to the laboratory with the first "on-the-spot" specimen. The patient should be given a sputum cup for the early morning specimen. If smears are examined at another facility, the two smears/samples with the filled-in request form should be brought to the examining laboratory.

It is essential to indicate whether the sputum is sent for diagnosis or follow-up. A detailed address (including mobile phone number) of the patient should be recorded if sputum is sent for diagnosis. This is important to trace the patient if sputum is found positive and the patient does not return to the health facility.

Early morning sample is preferable for testing on Xpert MTB/RIF (if available). If facility to perform Xpert MTB/RIF is not available, sputum sample should be transported to the nearest facility with Xpert MTB/RIF. This form will be used for sample other than sputum too, and hence, the nature of sample collected / referred for testing needs to be clearly mentioned.

20.6 Form DR TB 06 - Request form for Diagnosis/Follow up of Drug Resistant TB

This form should be kept at all DOTS Centres. This form will be used for requesting Lab tests for presumptive DR TB cases (for diagnosis) and DR TB cases on treatment (for follow up). It is mandatory to completely fill all the four parts (A-D) of the form and send it to the designated NTRL / RTRLs or Xpert MTB/ RIF sites along with the samples or the patient f(or diagnosis or follow up) from the DOTS centres. It should be ensured that the reason for requesting culture & DST and Xpert MTB/RIF test is clearly mentioned, indicating the risk group.

After examining samples for diagnosis (in case of presumptive DR TB cases) or follow up (in DR TB cases on treatment) the lower part (E) of the form should be filled up completely by NTRL/RTRLs or Xpert MTB/RIF sites and sent back to requesting sites (DOTS Centers) immediately.

20.7 Tuberculosis referral/transfer form (TB 07)

This form is used for referring or transferring patients from one health facility to another. It should be filled in triplicate: one copy goes to the receiving centre, one is given to the patient and one remains in the file. The receiving facility should fill the bottom part of the form and return it to the referring institution as soon as the patient reports.

20.8 Requisition form for Drugs (TB 08)

This form should be prepared quarterly with a copy to the concerned District authority. The requirement for each item is calculated by multiplying the number of cases in the last quarter (by category), the number of treatment doses and average units per dose to arrive at the working stock or running requirement. This figure is then multiplied by 2 to estimate the required and buffer stock for one quarter. The stock in hand stock, at the time of the indent, is then subtracted from the estimated requirement (calculated above) to arrive at the requirement for each drug item for one quarter. At a minimum, adequate stock for at least one patient from each category should be ensured at all times - even when there were no patients during the previous quarter/s (especially for Previously Treated and Paediatric TB cases). Over stocking should be avoided by redistribution of excess medicines to the nearest low stock facilities before preparing the indent for the next quarter. In the unlikely event of a drug stock out, the actual duration, in days, should be mentioned in the remarks column.

20.9 Absentee tracing form (TB 09)

This form should be used for retrieval of patients who do not turn up for their scheduled drug intake

20.10 Quarterly report on case finding (TB 10)

Prepare this report as follows:

- Identify all patients registered in the Tuberculosis Register during the quarter under reporting
- Looking at the columns "Category" and "Pre-treatment smear examination", count the number of new male smear-positive cases, using tally marks with a pencil or every patient counted
- Continue in the same way with the new female smear-positive cases
- All new smear-positive cases have now been identified and they should be entered in the Block 1 (Column 1)
- In the same way Xpert MTB/RIF positive cases should be identified and entered in Block 1
- Divide the new smear-positive male and female patients according to the age groups and record the numbers in Block 2. Verify that the total number of males and females for all age groups matches with the number reported in Block 1. In the same way, numbers of Xpert MTB/RIF positive cases should be counted, recorded and verified according to sex and age category in Block 3.
- Count (and mark) (1) the smear-positive previously treated patients, divided into relapses, treatment after failure and treatment after LTFU, (2) the Xpert MTB/RIF new & previously treated, (3) the smear-negative cases, (4) the extra-pulmonary cases and (5) the other previously treated, divided into males and females, and enter these numbers in the respective columns of Block 1
- Add the totals of column 1-8/9 and enter these in column 6
- Verify that all patients registered during the quarter concerned have been accounted for and included in the report
- Do the same for smear-negative and extra-pulmonary patients and enter the numbers in Blocks 4 and 5.
- The information for Block 6 will be collected from TPT/IPT register. This register will be maintained according to the TPT guidelines. The age group below 15 years will get 3HR, the 15 years and above age group will get 3HP and PLHIV will get IPT and have to be reported accordingly (0 to less than 10 years and 10 to less than 15 years).
- In Block 8 and 8B, data of presumptive TB cases among PLWHA should be reported.

The report should be filled in triplicate. One copy should be sent to the District Medical Officer, one to the NTP HQ in Dhaka and one should be kept in the records. The report should be prepared and submitted promptly at the end of the quarter (latest by the 15th of the next month).

20.11 Quarterly Report on Treatment Results (TB 11)

This report is for cohort analysis of the treatment results. The different types of patients are evaluated separately. The evaluation is done quarterly for the cohort that started the treatment 12 - 15 months earlier. The information should be collected from the updated Tuberculosis Register.

Description of the treatment outcomes is presented in section 5.11. The report should be prepared in the same way as the case finding report.

20.12 Quarterly Report on Sputum conversion at 2/3 Months of Smear-positive Pulmonary TB Cases (TB 12)

This report provides information about the smear result at the end of the first two months (new bacteriologically confirmed TB patients) or three months (retreatment patients) of treatment. Unusually low conversion rates indicate wrong categorization or poor treatment adherence while excessively high conversion rates may indicate poor quality microscopy (scanty or low grade positive smears are missed). The report should be prepared in the same way as the case finding report.

20.13 Laboratory Performance Report (TB - 13)

This report replaces the TB 13 report:" Quarterly Report on Laboratory Findings of Tuberculosis". This report is prepared quarterly and provides information on diagnostic and follow-up smears examined, for positive, scanty and negative results and the type of Microscopy used (ZN or FM microscopy). The results of Xpert MTB/RIF too can be interpreted. This report is part of the smear rechecking system and included in the EQA SOP.

20.14 Presumptive TB cases Referral Form (TB - 14)

This form should be used for referral of patients with a cough of 2 weeks or more, with or without other signs and symptoms of TB, to the nearest DOTS centre for further examination. This may also be used for referring presumptive TB among household contacts (defined earlier), patients with unexplained cough, fever, weight loss or night sweats for one week or more.

20.15 Preparation of reports

The table below is provided as a handy reference on reporting timelines. The reports should be sent within two weeks after the quarter is finished. A cohort is a group of patients diagnosed and registered for treatment during a quarter.

A year is divided into four quarters and each quarter contains three months. 1st quarter (January, February, March), 2nd quarter (April, May, June), 3rd quarter (July, August, September), 4th quarter (October, November, December).

Reporting quarter for case finding, smear conversion and treatment result.

Case finding (form TB 10)	Smear conversion (form TB 12)	Treatment result (form TB 11)
4th Quarter 19	3rd Quarter 19	4th Quarter 18
1st Quarter 20	4th Quarter 19	1st Quarter 19
2nd Quarter 20	1st Quarter 20	2nd Quarter 19
3rd Quarter 20	2nd Quarter 20	3rd Quarter 19

COVID-19 and its impact on TB

Coronavirus disease, or COVID-19, typically affects the lungs and people affected by it may show symptoms similar to TB, such as cough and fever. The lung damage and compromised immunity caused by TB may render these patients more vulnerable to getting severely ill with COVID-19. The COVID-19 outbreak has placed unprecedented demands on our health system. Our health workforce is stretched by a plethora of activities related to managing the pandemic, and in doing so, there is substantial risk of compromising on the essential health services which communities expect from the health system. Continuing to provide essential health services, while managing the COVID-19 related activities, is important to maintain the trust of the community in the health system to deliver essential health services and to minimize any potential increase in morbidity and mortality from other health conditions.

Pandemics like the ongoing COVID-19 could, potentially, derail all progress made by the NTP on ending TB through disruptions to diagnosis, treatment and other interventions like supply chains of medicines and medical supplies. A recent modelling exercise[11] to understand the potential impact of short-term lockdowns on TB incidence and mortality over the next 5 years estimates that, due to the COVID-19 pandemic, an additional up to 12% excess cases and up to 19% additional deaths may take place between 2020 2025 in high-burden countries. It is clear now that the pandemic may result in severe disruptions in NTP service delivery and patient care (and care seeking behaviour), with profound consequences on the ongoing efforts to reach the END TB targets.

Hence, the focus should be on building and sustaining strong health systems. Resilient health systems are critical to help respond to unprecedent emergencies like the COVID-19. When these situations arise, the health systems should be in readiness to take immediate steps to ensure health worker protection, communication to affected communities, maintenance of essential services, supply chain coordination, early replenishment of stocks, disinfection of assets, and safe & efficient waste management. Additional activities include pandemic preparedness assessment, laboratory testing, sample transportation, use of surveillance infrastructure, infection control in health facilities, and information and advocacy campaigns.

[11]http://www.stoptb.org/assets/documents/news/Modeling%20Report_1%20May%202020_FINAL.pdf?fbclid=IwAR1I4py4vDnzh-DTxErv4abXNF1NC4Dv-6iRbByE0GJSIsOe1_Lzycg2Svg

Annex: 1

National Tuberculosis Control Programme-Bangladesh
Directorate. General of Health Services
Mohakhali, Dhaka
Supervision Check List

Date of Visit:

Name of Centre:

Address: _____

Catchments Population:

Estimated Number of TB patients (All Forms):

Name of Supervisor:

Follow up of previous visit:

Date of last Visit: ……../……/

Problems identified and recommendations of Last visit:

_____
_____
_____
_____
_____

Status of implementation according to recommendations:

_____
_____
_____

Training status of health worker(s), including laboratory technologists, at the time of the visit:

1. Number of health worker(s) directly involved in TB Control Programme

i) Health Center :

II) Peripheral Health Workers :

2. Number of Health Worker (s) present on the day of visit :

3. Interview with health workers/DOTS providers (if available during visit):

- Knowledge of the disease — Satisfactory ❑ — Unsatisfactory ❑
- Do they refer suspects — Yes ❑ — No ❑
- Do they supervise treatment — Yes ❑ — No ❑
- Do they follow-up reaction cases — Yes ❑ — No ❑

4. Interview some patients to check their knowledge and satisfaction of services available (Answered satisfactorily)

- Name of the disease he/she is suffering from? Yes ❑ No ❑
- How can we suspect whether a person has TB or not? Yes ❑ No ❑
- Duration of treatment Yes ❑ No ❑
- Understanding of irregular treatment Yes ❑ No ❑
- Danger of irregular treatment Yes ❑ No ❑
- Availability of free treatment (who and where) Yes ❑ No ❑

5. Availability of NTP manual/Laboratory Manual (Available) Yes ❑ No ❑

6. Documentation:

6.1 Treatment Cards Complete ❑ Incomplete ❑

6.2 Laboratory register (check last quarter)

a. Number of suspect with negative smear ❑
b. Number of suspect with positive smear ❑
c. No. of follow up examination ❑
d. No. suspects with 1 smear examination ❑
e. Number of cases registered in TB register ❑
f. No. of +ve smear among follow-up exam ❑
g. Case/Smear of positivity rate ❑
h. % of suspects with 1 smear examination ❑

6.3 TB register Yes ❑ No ❑

6.4 Patient Statistics (Available)

i. Case registered Yes ❑ No ❑
ii. Sputum conversion Yes ❑ No ❑
iii. Treatment outcome Yes ❑ No ❑

7. Laboratory services:

7.1 Microscope functioning

i. Presence of fungus Yes ❑ No ❑
ii. Preservation of microscope Yes ❑ No ❑
iii. Stock of slides Sufficient ❑ Insufficient ❑
iv. Stock of contains Sufficient ❑ Insufficient ❑
v. Lab regents Sufficient ❑ Insufficient ❑

7.2 Reagents (Carbol fuchsine, methyl blue, HCL etc.) Sufficient ❑ Insufficient ❑ Absent ❑

7.3 Date of last supply:

7.4 Examining slides:

7.4.1 Size of the smear appropriate ❑ inappropriate ❑
7.4.2 Thickness of the smear appropriate ❑ inappropriate ❑
7.4.3 Evenness appropriate ❑ inappropriate ❑
7.4.4 Staining of slides appropriate ❑ inappropriate ❑

7.5 Quality Assurance in place Yes ❑ No ❑

7.6 Regular Collection of slides for EQA Yes ❑ No ❑

7.7 Feedback of EQA available Yes ❑ No ❑

7.8 Action taken Yes ❑ No ❑

7.9 Disposal of lab. Wastage (properly done) Yes ❑ No ❑

8 TB register

8.1 Information of patients Complete ❑ incomplete ❑

8.2 Cross check whether all +ve from lab register are registered Yes ❑ No ❑

9 Patients statistics:

9.1 No. of all cases registered

9.1.1 Case notification rate (all cases)

9.1.2 Case detection rate (all cases): (No. of all cases in last 4 quarter x 100)/No. of expected cases for a year

9.2 No. of new smear +ve cases registered:

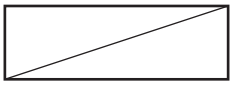
9.2.1 Case notification rate NSP: (No. of NSP cases in last 4 quarter x 100000)/Population:

9.3 No. of patients referred by private practitioner: +ve -ve EP

9.4 Check for the correctness of the last quarter report

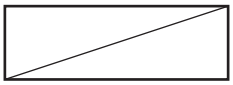
9.4.1 Sputum conversion Correct ❑ Incorrect ❑

(No. of new smear +ve cases that became negative at the end of the intensive phase/No. of new smear positive cases registered previous quarter)



9.4.2 Treatment success rate: …… Correct ❑ Incorrect ❑

(No. of new smear positive cured/No. of new smear positive cases registered of 6-9 months ago)



10 Drug Management and other logistics

10.1 Drugs stock

10.1.1 Drugs available for full quarter with reserve stock Sufficient ❑ Insufficient ❑

10.1.2 Anti-TB drugs are stored in cool and dry space and labeled appropriately Yes ❑ No ❑

(a) Cool and dry space Yes ❑ No ❑

(b) Labeled appropriately Yes ❑ No ❑

(c) Temperature chart maintained Yes ❑ No ❑

10.1.3 Bin Card (Available) Yes ❑ No ❑

10.1.4 FEFO principle (Applying) Yes ❑ No ❑

10.1.5 Expiratory statement (Available) Yes ❑ No ❑

10.1.6 Are stock ledger updated with information of all receipt, deliveries and signed by responsible officer? Yes ❑ No ❑ Please specify, if no

…… .

10.1.7 Are store maintained with exhaust fan/well ventilated? Yes ❑ No ❑ Please specify, if no ……..

10.2 Other logistics

i. Form/cards/register Sufficient ❑ Insufficient ❑

11. ACSM Activities:

i. Presence of Posters/Sticker Yes ❑ No ❑

ii. Display of poster/sticker Yes ❑ No ❑

iii. Presence, distribution and use of educational materials (Leaflet, flip, char, flash, brochure) Yes ❑ No ❑

iv. Signboard with DOTS facilities in front of health center Yes ❑ No ❑

v. Health education on TB by health facility Yes ❑ No ❑

vi. DOTS committee meeting held regularly Yes ❑ No ❑

vii. DOTS committee meeting minutes available Yes ❑ No ❑

12. Infection Control:

12.1 Any designated person/coordinating body to supervise TB infection control in the facility Yes ❑ No ❑ Comment ❑

12.2 How many health care workers have been trained in TB infection control Yes ❑ No ❑ Comment ❑

12.3 Have any ACSM/IEC materials (for example leaflets, stickers, posters on cough etiquette) are in place Yes ❑ No ❑ Comment ❑

12.4 Appropriate ventilation present in facility Yes ❑ No ❑ Comment ❑

12.5 Provision for separation and fast track in place Yes ❑ No ❑ Comment ❑

12.6 Sputum collection, slide processing and disposal are being ensured following guideline Yes ❑ No ❑ Comment ❑

13. TB/HIV

13.1 No. of TB patients screened for HIV in last quarter:

13.2 No. of TB patient found HIV positive in last quarter:

13.3 No. of PLWHIV in last quarter screened for TB in last quarter:

13.4 No. of TB cases diagnosed among total PLWHIV examined in last quarter:

14. DR TB:

14.1 No. of DR TB suspects referred for diagnosis in last quarter

14.2 No. of DR TB patients confirmed among them

14.3 No. of DR TB patients under treatment

14.4 Have health care workers been trained in MDR TB Yes ❑ No ❑

14.5 Documents updated (Register, Treatment card) Yes ❑ No ❑ Not available ❑

14.6 Interview with health workers/DOT providers/Patient (if available during visit): ❑

14.6.1 DOT provider's knowledge of the disease and treatment Satisfactory ❑ Not satisfactory ❑

14.6.2 Patient's knowledge of the disease and treatment Satisfactory ❑ Not satisfactory ❑

16. ETB manager activities in place Yes ❑ No ❑

17. Childhood TB:

17.1 Number of under-5 children eligible for IPT in last quarter Yes ❑ No ❑

17.2 Number of under-5 children registered for IPT in last quarter Yes ❑ No ❑

18. Name and designation of key personnel's present during supervision:

1. ……
2. ……
3. ……

19. Summary of major findings

_____

_____

_____

_____

_____

_____

_____

20. Recommendation/Comments of supervisor

_____

_____

_____

_____

_____

_____

21. Name of Supervisor/s with signature:

1.

2.

3.

4.

How to calculate:

Case notification rate (CNR): Number of cases registered and reported to NTP per one thousand population per year.

CNR= (Number of cases registered in last 4 quarter/Total population) x100,000

Case detection rate (CDR): Number of cases detected expressed as a percentage of cases estimated to occur during a period of one year.

CDR: Number of cases registered in last 4 quarter/No. of estimated cases in last 4 quarter) x100

Treatment success rate: Total number of new smear-positive cases who were declared "cured" or "Treatment Completed" x 100/total number of new smear-positive cases registered in the same period.

Annex: 2

List of 'Priority Districts' for HIV

Sl. No.	Division	District
1	**Barisal**	Barisal
2	**Chattogram**	Chattogram
3		Cox's Bazar
4		Noakhali
5		Comilla
6		Chandpur
7	**Dhaka**	Dhaka
8		Gazipur
9		Kishoreganj
10		Mymensingh
11		Narayanganj
12		Tangail
13	**Khulna**	Khulna
14		Bagerhat
15		Jessore
16		Sathkhira
17	**Rajshahi**	Rajshahi
18		Bogra
19		Chapai
20		Nawabganj
21	**Rangpur**	Dinajpur (Hili)
22	**Sylhet**	Sylhet
23		Moulvibazar
24		Sunamganj

Annex: 3

TB-01

National Tuberculosis Control Program
Directorate General of Health Services, Bangladesh
Treatment Card (Front Page)

TB Registration No: Date:
e-TB manager Registration No:
Name & Address of Health Institution/ DOTS Centre:

Name:
Father's/Husband's name:

Sex M ☐ F ☐ Age: BCG ☐ No scar ☐ Scar seen ☐

Occupation: Phone No:
Address (in full):
Name & Address of Contact Person:
Phone No:
Name & Address of person providing DOT:

Pulmonary		Extra Pulmonary	
Bacteriological confirmed	**Clinical Diagnosed**	**Bacteriological confirmed**	**Clinical Diagnosed**
Smear Positive ☐ Xpert Positive ☐ Culture Positive ☐	Diagnosed By ☐ X-Ray ☐ Others ☐	Smear Positive ☐ Xpert Positive ☐ Culture Positive ☐	Diagnosed By X-Ray ☐ Others ☐

*Referred by	Graduate PP	GFS	VD	Gov. Hospital	TB Patient	CHCP
	Non Graduate PP	NGFS/SS	Private Hospital	Self	Others Specify:	

New ☐ Previously Treated ☐
Treatment History Unknown ☐ Relapse ☐
Transfer In ☐ Failure ☐
Treatment After loss to follow up ☐
Others ☐

History of previous Anti TB Treatment: Yes ☐ No ☐ If yes duration: ☐

H/O Contact:	Yes	☐	No	☐	If Yes specify	TB	☐	DR TB ☐

I. Intensive Phase- Prescribing regimen and dosages
Frequency: Daily
Tick category and indicate number of tablets per dose
New Case ☐ Retreatment Case ☐ **Child ☐**

4FDC ☐ 4FDC ☐ Lfx ☐ **3FDC** ☐

H	R	E	Z	H	R	E	Z	Lfx	H	R	Z	E	Lfx
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Month	Date	Result of Sputum Examination				Weight (Kg)
		Smear-1	Smear-2	Lab. No	****Xpert Result	

TB/HIV		
	Date	**Result**
HIV Test		
**CP Start Date		
***ART Start Date		

**CP=Co-tromoxazole preventive Therapy'; ART=Anti-retro Viral Therapy

Enter √ in the appropriate box to indicate the date when the drugs have been swallowed under direct observation. Enter - swallowed but not supervised. Enter 0 when not taken

Month/Year	Day																													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

*PP= Private Practitioner, GFS= Government Field staffs, NGFS= Non Gov. Field staffs, SS=Shastha Shebika, VD=Village Doctor, CV= Community Volunteer, CHCP=Community Health Care Provider
**** X-Pert result
T= MTB detected Rif resistant not detected; RR= MTB detected Rif resistant detected; TI= MTB detected Rif resistant indeterminate; N= MTB not detected' I=Invalid/No result/Error

Signature of Medical Officer

TB-01

Tuberculosis Treatment Card (Back Page)

II. Continuation Phase- Prescribed Regimen and Drug Dosage
Put √ Mark on Appropriate Box

New Case ☐
2FDC ☐

R	H

Retreatment CAT-I ☐
4FDC ☐

R	H	E	Z	Lfx

Child ☐
2FDC ☐

☐	☐
R	H

Enter √ in the appropriate box to indicate the date when the drugs have been swallowed under direct observation. Enter **-** swallowed but not supervised. Enter **0** when not taken

Month/Year	**Day**																													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Treatment Outcome

Date of Decision ……

- ☐ **Cured**
- ☐ **Treatment Completed**
- ☐ **Died**
- ☐ **Treatment Failure**
- ☐ **Lost to follow-up**
- ☐ **Transferred out**
- ☐ **Not Evaluated**

_____
Signature of Medical Officer

Types of Drugs reaction (if any):

Remarks (if any)

টিবি ০২

জাতীয় যক্ষা নিয়ন্ত্রণ কর্মসূচি

স্বাস্থ্য অধিদপ্তর ঢাকা, বাংলাদেশ

পরিচয়পত্র

রোগীর নাম : _____

পূর্ণ ঠিকানা : _____

(ক) বর্তমান : _____

(খ) স্থায়ী : _____

বয়স: _____

লিঙ্গ: পুরুষ ☐ মহিলা ☐

যক্ষা রেজিষ্ট্রেশন নং : _____

চিকিৎসা শুরুর তারিখ : _____

New ☐ Retreatment ☐ Child ☐

স্বাস্থ্য প্রতিষ্ঠানের নাম : _____

রেফারকৃত ব্যক্তি/ প্রতিষ্ঠানের নাম : _____

প্রতিষ্ঠানের ফোন নং : _____

ডট (DOT) প্রদানকারীর নাম : _____

ফোন নং : _____

ঠিকানা (প্রতিষ্ঠান) : _____

রোগীর শ্রেণি

ফুসফুস ☐ ফুসফুস বর্হিভূত ☐

জীবাণুযুক্ত ☐ স্থান : _____

জীবানুমুক্ত ☐ _____

রোগীর শ্রেণি

নতুন (New) ☐ **পুণঃ আক্রান্ত** (Retreatment) ☐

অন্য স্থান হতে প্রেরিত (Transfer in) ☐

খেলাপী রোগী (Loss to Follow up) ☐

অন্যান্য (Others) ☐

স্বাস্থ্য কেন্দ্রে উপস্থিতির তারিখ :

টিবি ০২

_____
_____
_____
_____
_____
_____

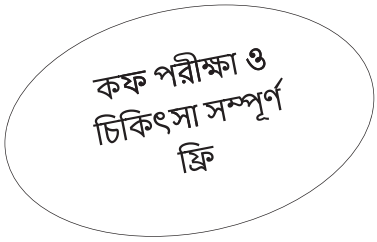
(১) আপনার কার্ডের যত্ন নিন।
(২) নির্দেশিত সময় পর্যন্ত সঠিক মাত্রার ঔষধ নিয়মিত সেবন করুন।
(৩) অসম্পূর্ণ চিকিৎসা মারাত্মক যক্ষা রোগের সৃষ্টি করে যা সহজে আরোগ্য হয় না।
(৪) যেখানে সেখানে কফ ও থুথু ফেলবেন না।
(৫) হাঁচি বা কাশির সময় নাক-মুখ ঢেকে রাখুন।
(৬) চিকিৎসা সম্পূর্ণ শেষে কার্ডটি যত্ন সহকারে রাখুন।

বিঃ দ্রঃ ঔষধ সংগ্রহের সময় এই কার্ডটি অবশ্যই সঙ্গে আনতে হবে।

চিকিৎসা শেষের ফলাফল : _____

চিকিৎসা শেষের তারিখ : _____

একনাগাড়ে ২ সপ্তাহ বা তার বেশি কাশি যক্ষা রোগের প্রদান লক্ষণ



NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Directorate General of Health Services, Bangladesh

Tuberculosis Register

Date of Registration	TB Registration No	e-TBM No.	Name in Full	Sex M/F	Age	Occupation	Name of Treatment Unit	Date of Start of Treatment and Category	Disease Classification P/EP	*Type of patient							Refd By	Remarks
										New (N)	Treatment history Unknown (U)	Transfer Inn (T)	Relapse (R)	Treatment Failure (F)	Treatment After Loss to follow-up (L)	Other (O)		

***Enter the Appropriate Code**
U = Treatment History Unknown: Patient with unknown previous TB treatment history
N = New case: a patient, who has never taken Anti Tuberculosis drugs or has taken drugs for less than a month
R = Relapse: a previously treated patients, who was declared cured or treatment completed but is now diagnosed as TB again
T = Transfer In: a patient, who has been transferred from one reporting unit to another. For transfer in patient name of the center from where patient was transferred out should be written in remarks column
L = Treatment after loss to follow-up: a patient who returns to treatment after having interrupted for 2 consecutive months or more
F = Treatment failure: A TB patient whose sputum smear or culture is positive at month 5 or later during treatment or a new or retreatment smear-positive patient who was diagnosed with DR TB during the course of treatment or A patient who was initially smear-negative and was found smear positive at the end of the second month of treatment
O = Other: A patient whose outcome history of previous treatment is unknown

TB-03

NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Directorate General of Health Services, Bangladesh

Tuberculosis Register

Chest X-ray	Histopathology (FNAC/Biopsy)	Sputum Examination: Upper Space Result; Lower Space: lab Serial Number & Date						Treatment Outcome & date						TB/HIV Activities			Remarks
		Pre Treatment			Follow-up Smear			**Outcome						HIV Result	***ART	****CPT	
Result (Suggestive for TB Yes/No)	Result (Yes/No)	Smear 1	Smear 2	*(Xpert MTB/Rif result) if done	2nd Month	5th Month	6th Month	Cured	Treatment Completed	Died	Treatment Failure	Lost to Follow-up	Transferred out/Not Evaluated	Positive/ Negative (P/N) (date)	Y/N (Start Date)	Y/N (Start Date)	

***Xpert MTB/Rif test result reported as follows:**

*****ART= Anti-retroviral Therapy**

******CPT= Cotrimoxazole Preventive Therapy**

T = MTB detected, Rif resistant not detected; RR= MTB detected, Rif resistant detected; TI= MTB detected, Rif resistant indeterminate
N = MTB not detected; I= Invalid/no result/Error

****Enter date in the appropriate code**

1. Cured: Treatment completed and negative smear results on 2 or more consecutive occasion at 5 months and at the end of treatment
2. Treatment completed: Full course of treatment completed but smear result not available
3. Died: Patient known to have died from any cause during treatment
4. Treatment failure: A patient whose sputum smear or culture is positive at month 5 or later during treatment. Or A new or retreatment smear-positive patient who was diagnosed with DR TB during the course of treatment or A patient who was initially smear-negative and was found smear-positive at the end of second month of treatment
5. Lost to follow-up: A TB patient whose treatment was interrupted 2 consecutive months or more
6. Transferred out/ not evaluated: A patient who has been transferred to another DOTS centre and whose treatment outcome is unknown to the reporting unit. Name of the centre where the patient was transferred out should be written in the remarks column.

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Directorate General Health Services, Bangladesh

Tuberculosis Laboratory Register

Lab Serial No.	Date of specimen received	Name in full	Address in full	Occupation	Age	Sex		Name of treatment/ referring facility	Reason for examination		Result of Smear Examination		*** Result of Xpert MTB/ RIF Examination	TB Registration No./e-TBM No.	Referred by**	Signature	Remarks
						M	F		Diagnosis (Tick)	*Follow up	1	2					

*Enter Month of follow-up

**Enter the appropriate code:

GPP = Graduate Private Practitioner, NGPP = Non-graduate Private Practitioner, GFS = Government Field Staff, SS = Shastha Shebika, NGFS = Nongovernment Field Staff, VD = Village Doctor,

CV = Community Volunteer, GH = Government Hospital, PH = Private Hospital, CHCP = Community Health Care Provider, TBP = TB Patient, Self = Self, Other (specify) =

***Xpert MTB/Rif test result reported as follows:

T = MTB detected, Rif resistance not detected; RR = MTB detected, Rif resistance detected; TI = MTB detected, Rif resistance indeterminate; N = MTB not detected; I = invalid/no result/error.

TB-05

NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Directorate General of Health Services, Bangladesh
Request Form for AFB Microscopy

(The completed form with results should be sent promptly by the laboratory to the referring facility)

Name and address of Referring facility[1]: _____ Date: _____

Name of patient: _____ Age: Sex: M ☐ F ☐

Occupation: _____ Father's/ Husband's name: _____

Full address of patient: _____

Telephone no of patient/ Contact person: _____

OPD Reg. No. (if any); (for presumptive TB case only) _____

Reason for Examination: Diagnosis ☐ Follow-up ☐ if Follow-up, No of Month of Treatment: _____

Disease Classification: Pulmonary ☐ Extra – Pulmonary☐ If EP, Site: _____

Nature of Specimen: Sputum ☐ Urine ☐ Pus ☐ Other ☐ Specify: _____

Specimen identification No. _____ Patient TB registration No. _____

e-TB Manager No.

(for Follow-up patients) _____

Request for Test: Microscopy ☐ GeneXpert ☐

Signature of person requesting Examination: _____

Name and Designation of person requesting examination: _____

[1]***Including all public and private health facilities/providers***

RESULTS (to be completed in the laboratory)

Lab registration No. _____

Visual appearance of the specimen (if it is sputum): Muco-purulent ☐ Blood-stained ☐ Saliva ☐

Microscopy result: ZN ☐ LED ☐

Date of collection*	Specimen	Result					
		Negative	Scanty1**		1+	2+	3+
			ZN (1-9)	LED (5-29)			

Sputum collected by: _____ Examined by: _____

Signature: _____ Name: _____

Name: _____ Date: _____

Name and address of Laboratory _____

*To be completed by the person collecting the sputum

**Please Mention the number as per type of Microscopy

Organization: _____

DR TB 06

Government of the People's Republic of Bangladesh
National TB Control Programme
Programmatic Management of Drug Resistant Tuberculosis (PMDT)
Request and Reporting form for Diagnosis/Follow up of Drug Resistant TB

A. Patient identification (ID):

Previous TB registration No (If any):

TB registration No (Current): _____ _____ DR TB registration No: _____

e-TB registration No: Name of patient:

_____ _____ Age (yrs): __ Sex: ___ *HIV-status: Pos / Neg / Unknown

Address of patient:

_____

Cell Phone #: _____

B. TB Disease Type and Treatment History

Type : A) Pulmonary B) Extra Pulmonary (Specify Site) ……

History:

1) Failures of Category I (remain positive at month 5 or later and smear negative patients who become smear positive at month 2)

2) Non converters of Category I (remain positive at month 2)

3) Failures of Retreatment (remain positive at month 5 or later)

4) Non converters of Retreatment (remain positive at month 2)

5) Relapses- a) Category I b) Retreatment

6) Treatment after loss to follow up- a) Category I b) Retreatment

7) Close contacts of DR TB patient with symptoms, a) Unknown history ☐ b) New ☐ c) Prev.treated ☐

8) HIV infected person, with TB S/S a) Unknown history ☐b) New ☐c) Prev.treated ☐

9) Others (Specify) i. Pulmonary, clinically diagnosed, a) Unknown history ☐b) New ☐ c) Prev.treated☐

ii) Extra Pulmonary, a) Unknown history ☐ b) New ☐ c) Prev.treated☐

iiii) Pulmonary, Bacteriologically Confirmed a) Unknown history ☐ b) New ☐

10) Presumptive Pulmonary Smear Negative TB Cases a) Unknown history ☐b) New ☐ c) Prev.treated

11) Presumptive TB- a) Unknown history ☐ b) New ☐

C. Origin of request

Division name & ID: _____ District name & ID: _____ Local laboratory name & ID: _____

Local laboratory registration/serial number: ____ Date of test: …../…../….. Smear result: 1st __ 2nd __ specimen

Microscopy technique used: Ziehl-Neelsen (ZN) ☐LED Fluorescence microscopy (FM) ☐

D. Request for test at the reference laboratory: NTRL /RTRL ____ /X-Pert MTB/RIF Site: _____

1) Diagnosis 2) Follow Up: Month of ……

Date specimen(s) collected: ____ / ____ /20 Specimen Identification number (s): _____

Specimen: Sputum ☐ Sputum in preservative, type ☐ specify _____ Other (specify): _____

Requested tests: ☐ microscopy (type: ZN/LED ☐ culture (L-J / MGIT) ☐ Xpert MTB/RIF ☐ DST Conventional ☐ Line Probe Assay (LPA)

Others (Specify) _____

Person requesting examination: Name: _____ Position: _____ Cell Number: _____

Organization: Government/Non-Government (specify): _____ Signature (with official seal) and Date: _____

* Information that can be disclosed optionally

E. Reference laboratory results:

Date of specimen received/Collected in the reference laboratory: NTRL / RTRL ____ / X-Pert MTB/RIF Site: _____

Reference laboratory specimen ID: _____

1. Microscopic examination: Date reported _____

Previous Report and Date (If any) _____

Ziehl-Neelsen ☐ LED fluorescence ☐ Others (specify)

Direct smear ☐Concentrated smear ☐

ID#	Neg	Scanty	1+	2+	3+

2.Gene Xpert (MTB/RIF) result: Date reported _____

Previous Report and Date (If any) _____

ID#	T= MTB detected, Rif resistance not detected	RR=MTB detected, Rif resistance detected	TI=MTB detected, Rif resistance indeterminate	N=MTB not detected	I=invalid/no result/ error

3. Culture result: Method used: Solid (LJ) ☐ Liquid (MGIT) ☐ Date reported _____ previous report and Date (If any) _____

ID#	Contaminated	Neg	Positive	A typical Mycobacteria (species)	Mycobacterium tuberculosis complex			
					<20 =1-19 colonies Actual count	1+=20 — 100 colonies	2+=>100 - 200 colonies	3+=>200 colonies

4. Results of M. tuberculosis drug susceptibility testing: Date reported: _____

Method used: ☐ Proportion method (L-J) ☐ Liquid (MGIT) Line Probe Assay (LPA) ☐ X-Pert MTB/ Rif

ID#	Legend: S = susceptible; R = resistant; C = contaminated; ND = not done								
	INH (H)	Rifampicin (R)	Ethambutol (E)	Streptomycin (S)	Pyrazinamide (Z)	FQ: Ofloxacin/ Levofloxacin	Kanamycin (Km)	Others	
								(specify)	(specify)
Result									

Date: ____ / ____ /20 ____ Name:

Designation:
Cell Number:
Signature with official Seal _____

TB 07

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Directorate General of Health Services, Bangladesh

Tuberculosis Referral/ Transfer Form

(Fill out in triplicate with carbon paper between sheets)

Name of Referring/ Transferring Unit _____

Name of Institution to where patient is referred (If known): _____

Name of Patient: _____Age _____Sex_____

Address (in full): _____

_____ Phone No.: _____

TB Registration No.: _____ e -TB Registration No.: _____

Type of Patient:

Bacteriologically Confirmed				Clinically Diagnosed	
Pulmonary		EP Site ……			
Smear positive	☐	Smear positive	☐	Pulmonary Negative	☐
Xpert positive	☐	Xpert positive	☐	EP	☐
Culture positive	☐	Culture positive	☐	Site	

Type of Treatment:
☐ CAT 1
☐ Retreatment
☐ DR TB
☐ Child

Date of treatment started: _____

No. of days for which patient received drugs at last attendance _____

Reasons for referral: _____

Remarks: _____Signature_____

Name & Designation _____

Organization _____

Date Referred/transferred _____

For use by the institution where the patient is referred to send the outcome report to the institution where patient was initially registered

Name of patient: _____Age _____Sex: M ☐ F ☐

TB Registration No.: _____ e -TB Registration No.: _____

TB Registration no (of the organization from where the patient was referred):

Treatment result:

Cured ☐ Date: _____ Treatment completed ☐ Date: _____Failure ☐ Date: _____

Lost to follow up/ Defaulted ☐ Date: _____Died ☐ Date: _____

Signature_____

Name & Designation _____

Organization _____

Date Referred/transferred _____

Send this part back to the referring unit as soon as the treatment outcome report is available.

For use by institution where patient has been referred

Name of patient: _____ Age _____Sex: M ☐ F ☐

TB Registration No.: _____ e -TB Registration No.: _____

Date Referred/ Transferred: _____

Date of Received at this institution on: _____

Signature: _____

Name & Designation: _____

Organization: _____

Name of institution from where patient was referred: _____

District: _____ Date: _____

Send this part back to the Referred Unit as soon as patient has reported and been registered and also send the treatment outcome to the center from where the patient was referred after completion of treatment.

NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Directorate General of Health Services, Bangladesh
Requisition form for First Line TB Drugs

Year: Quarter:
Name of Health facility:
City/District/Upazila:
Name and Designation of the person filling the form: Contact No. :
Name of the UH&FPO/Centre chief: Contact No. :

Number of the registered case during the previous quarter						
Adults (>15 Years)					Children (<15 Years)	
					Child category-I (Adult formulation) = (c)	Child category-I (Dispersible formulation) = (d)
New /Category-I= (a)	**Retreatment = (b)**					
All New/Cat-I Cases together (P+, P-, EP, Meningitis, Bone & Neurological TB)	P+ve (b1)	P-ve (b2)	EP (b3)	Meningitis, Bone & Neurological TB (b4)		
					<5 Years Child registered for IPT (e)	

Drug requisition estimation:

Drug	[1]Quantity required for one Quarter			[2]Total required Quarterly (+Buffer) (i) = 2X(h)	[3]Existing Balance (j)	Expiry Date	Amount to be Supplied = (i) - (j)	Actual Quantity Requested	Remarks
	Cat-I (f)	Retreatment (g)	Total (h) = (f+g)						
4FDC (R150/H75/Z400/E275)	=(a+c) x 180	= (b1+b2+b3) X540+b4X1080							
3FDC (R150/H75/E275)									
2FDC (R150/H75)	=(a+c) x 360								
3FDC (R75/H50/Z150) (Dispersible)	= d x 180								
2FDC (R75/H50) (Dispersible)	= d x 360								
Pyrazinamide 400 mg									
Pyrazinamide 500 mg									
Isoniazid 100 mg (Dispersible)- for IPT	= e x 360								
Isoniazid 300 mg									
Rifampicin 150 mg									
Rifampicin 450 mg									
Rifampicin 300 mg									
Ethambutol 400 mg									
Ethambutol 100 mg	= (d x 180)/2								
Levofloxacin 250 mg		=(D20+F20)* 270+G20*540							
Levofloxacin 500 mg		= (b1+b3) X540+b4X1080							

[1] Multiply the number of patients (a/b/c/d/e) in each treatment category with the number needed for treatment of one patient
[2] The quantity include buffer stock (100%) for a quarter
[3] Indicate the remaining balance from the drug ledger at the end of the previous quarter

Note:
1) Stock of minimum one patient's medicine for each category should be ensured at all-time even there was no patient during previous quarter
2) Over stock should be avoided by redistribution of medicines to the nearest low stock facilities before preparing request for next quarter, if there is any

Prepared by: _____ Sign by UH&FPO/Centre chief: _____

Checked by: _____ Counter sign by CS/ Controlling Authority: _____

টিবি ০৯

জাতীয় যক্ষ্মা নিয়ন্ত্রণ কর্মসূচি
স্বাস্থ্য অধিদপ্তর ঢাকা, বাংলাদেশ

গর-হাজিরা যক্ষ্মা রোগীর বাড়ি পরিদর্শন ফরম

স্বাস্থ্য কেন্দ্র_____

প্রতি,

.....

স্বাস্থ্য সহকারী/স্বাস্থ্য কর্মী

ওয়ার্ড নং .....

ইউনিয়ন/মহল্লা .....

জনাব/জনাবা .....পিতা/স্বামী .....

বয়স .....টিবি রেজিঃ নং .....ঠিকানা .....

.....

একজন যক্ষ্মা রোগী । তিনি গত .....তারিখ হতে ঔষধ গ্রহণে বিরত থাকায় অতি সত্বর তাহার বাড়ি পরিদর্শন করে সংশ্লিষ্ট মেডিকেল অফিসার -এর নিকট রিপোর্ট প্রদানের জন্য আপনাকে নির্দেশ দেয়া হলো ।

আদেশক্রমে

_____

স্বাস্থ্য কর্মকর্তা

বাড়ি পরিদর্শনের রিপোর্ট

_____

স্বাস্থ্য সহকারী/স্বাস্থ্য কর্মী

NATIONAL TUBERCULOSIS CONTROL PROGRAM

TB 10

Directorate General of Health Services, Bangladesh

Quarterly report on case finding of tuberculosis

Name of District:	**Patients registered during**	**Date of Completion of this Form:**
Name of Upazila/ Centre/ Address:	quarter ____ Year ____	**Name, Designation, Signature & Contact no. of Person completed the Form:**
Name & Signature of UH&FPO/ In-charge of DOTS/ Health Unit:	**Population of the area:**	Write here the Name & Desig. of Person com. the Form
Write here the Name of CS/ In-charge	**Bact. Confirm New Cases:**	Write here Contact no.
	Bact. Confirm CNR:	

Block 1: All TB cases registered (excluding "Transfer in")

Pulmonary																								Extra-Pulmonary										Total (19)		
Bacteriologically Confirmed TB cases												Clinically Diagnosed												Bacteriologically Confirmed / Clinically Diagnosed TB cases												
Treatment History Unknown (1)		New (2)		Previously treated								Treatment History Unknown (7)		New (8)		Previously treated								Treatment History Unknown (13)		New (14)		Previously treated								
				Relapses (3)		Treatment after failure (4)		Treatment after loss to follow up (5)		Others (Treatment Outcome Unknown) (6)						Relapses (9)		Treatment after failure (10)		Treatment after loss to follow up (11)		Others (Treatment Outcome Unknown) (12)						Relapses (15)		Treatment after failure (16)		Treatment after loss to follow up (17)		Others (Treatment Outcome Unknown) (18)				
M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Total
Age-groups																																				
0-4																																				
5-14																																				
15-24																																				
25-34																																				
35-44																																				
45-54																																				
55-64																																				
>=65																																				
Total																																				

Comment (if any):

District:

Upazila/ Address & Ward No:

TB 10

Block 2: No. of Patients Referred by*:

PP (graduate)	Non-graduate PP	GFS	SS/ NGFS	VD	CV	Govt. Hospital	Private Hospital	CHCP	TB Patient	Self	Others (specify)	**Total**

Note: Like as treatment card

Block 3: Laboratory Activity - Sputum smear microscopy**

No. of Presumptive TB cases examined for diagnosis by sputum smear microscopy			No. of Presumptive TB cases with positive sputum smear microscopy result		
Male	Female	**Total**	Male	Female	**Total**

Block 4: Laboratory Activity – GeneXpert test**

No. of Presumptive TB cases examined by GeneXpert			No. of Presumptive TB cases with MTB positive and RIF susceptible result		
Male	Female	**Total**	Male	Female	**Total**

** This information to be included in the Lab report form

Block 5: TB/ HIV activities

5 (A) Diagnosed TB cases (with high risk for HIV)	No. of TB patients tested for HIV before or during TB treatment			No. of patients found HIV positive before or during TB treatment		
	Male	Female	**Total**	Male	Female	**Total**
Bacteriologically Confirmed New/ treatment History Unknown Pulmonary TB cases						
Clinically diagnosed New/ treatment History Unknown Pulmonary TB cases						
New/ treatment History Unknown Extra Pulmonary TB cases						
All re-treatment cases						

5 (B) ***PLWHA suspect for TB	No. of PLWHA tested for AFB			No. of AFB positive result among tested PLWHA		
	Male	Female	**Total**	Male	Female	**Total**

Block 6: IPT activities

No. of eligible child			No. of child registered for IPT		
Male	Female	**Total**	Male	Female	**Total**

Age-groups (Registered child)						
<1 year		**1 to <5 years**		**Total**		
Male	Female	Male	Female	Male	Female	**Total**

Block 7: Laboratory Activity- X-Ray test

No. of X-Ray conducted			No. of X-Ray suggestive for TB			No. of X-Ray suggestive presumptive sent for Gene Xpert		
Male	Female	**Total**	Male	Female	**Total**	Male	Female	**Total**

No. of X-Ray suggestive presumptive sent for Gene Xpert found MTB Detected RR not detected			No. of X-Ray suggestive presumptive sent for Gene Xpert found MTB Detected RR detected		
Male	Female	**Total**	Male	Female	**Total**

Comment (if any):

* PP-Private Practitioner, GFS-Govt. Field staff, SS-Shastha Shebika, NGFS-Nongovernment Field Staff, VD-Village Doctor, CV- Community Volunteer, CHCP- Community Health Care Provider

***PLWHA-People living with HIV/AIDS

NATIONAL TUBERCULOSIS CONTROL PROGRAM
Directorate General of Health Services, Bangladesh
Quarterly Report on Treatment Outcome of TB Patients Registered 9-12 months earlier

Name of District:	**Patients registered during** quarter Year	**Date of Completion of this Form:**
Name of Upazila/ Centre/ Address:		**Name, Designation, Signature & Contact no. of Person completed the Form:**
Name & Signature of UH&FPO/ In-charge of DOTS/ Health Unit:	**Treatment Success Rate of new bacteriologically positive cases during above quarter :**	

Block 1: Treatment outcome of all types of TB patients

Total No. of Patients reported during the above quarter			Type of Patients	(1) Successfully Treated (Cured+Treatment Completed) Age Group 0-14		15+		(2) Died		(3) Failure		(4) Lost to follow up		(5) Transferred out		(6) Not Evaluated		(1 to 6) Grand Total		
M	F	T	**1. Pulmonary Bacteriologically Confirmed**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			1.1 New/ Treatment History Unknown																	
			1.2 Relapses																	
			1.3 Treatment after failure																	
			1.4 Treatment after loss to follow up																	
			1.5 Others Previously Treated																	
			1.6 Total																	
M	F	T	**2. Pulmonary Clinically Diagnosed**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			2.1 New/ Treatment History Unknown																	
			2.2 Relapses																	
			2.3 Treatment after failure																	
			2.4 Treatment after loss to follow up																	
			2.5 Others Previously Treated																	
			2.6 Total																	
M	F	T	**3. Extra-Pulmonary Bacteriologically Confirmed/ Clinically Diagnosed**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			3.1 New/ Treatment History Unknown																	
			3.2 Relapses																	
			3.3 Treatment after failure																	
			3.4 Treatment after loss to follow up																	
			3.5 Others Previously Treated																	
			3.6 Total																	

Block 2: Treatment completed status

Total No. of Treatment completed among Pulmonary Bacteriologically Confirmed cases registered during the above quarter	
New	Retreatment

Block 3: TPT outcome

TPT Started during the above quarter		TPT Completed among registered during the above quarter	
M	F	M	F

Comment (if any):

District:

Upazila/ Address & Ward No:

TB 11

Block 3: Treatment outcome of TB patients with known HIV status

Total No. of TB Patients with known HIV status reported during the above quarter			Type of Patients	(1) Successfully Treated (Cured+Treatment Completed)				(2) Died		(3) Failure		(4) Lost to follow up (Defaulted)		(5) Transferred out		(6) Not Evaluated		**(1 to 6) Grand Total**		
				Age Group																
				0-14		**15+**														
M	F	T	**1. TB patients tested for HIV**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			1.1 Bacteriologically Confirmed New/ treatment History Unknown Pulmonary TB cases																	
			1.2 Clinically diagnosed New/ treatment History Unknown Pulmonary TB cases																	
			1.3 New/ treatment History Unknown Extra Pulmonary TB cases																	
			1.4 All re-treatment cases																	
			1.5 Total																	

M	F	T	**2. TB patients found HIV positive**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			2.1 Bacteriologically Confirmed New/ treatment History Unknown Pulmonary TB cases																	
			2.2 Clinically diagnosed New/ treatment History Unknown Pulmonary TB cases																	
			2.3 New/ treatment History Unknown Extra Pulmonary TB cases																	
			2.4 All re-treatment cases																	
			2.5 Total																	

TB/HIV activities*

TB/HIV Patient (Total)		No. of patients on CPT		No. of patients on ART	
M	F	M	F	M	F

Comment (if any):

* Includes TB Patients continuing on CPT started before TB diagnosis and those started during TB treatment (till last day of TB treatment)
* Includes TB Patients continuing on ART started before TB diagnosis and those started during TB treatment (till last day of TB treatment)

NATIONAL TUBERCULOSIS CONTROL PROGRAM
Directorate General of Health Services, Bangladesh
Quarterly Report on Sputum Conversion at 2 Months of Pulmonary TB patients registered 3-6 months earlier

Name of District:	**Patients registered during**	**Date of Completion of this Form:**
Name of Upazila/ Centre/ Address:	**quarter** **Year**	**Name, Designation, Signature & Contact no. of Person completed the Form:**
Name & Signature of UH&FPO/ In-charge of DOTS/ Health Unit:		

Total No. of Pulmonary Patients reported during the above quarter			Type of Patients	(1) Smear Negative		(2) Smear Positive		(3) Died		(4) Failure		(5) Lost to follow up		(6) Transferred out		(7) Not Evaluated		**(1 to 7) Grand Total**		
M	F	T	**1. Pulmonary Bacteriologically Confirmed**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			1.1 New/ Treatment History Unknown																	
			1.2 Relapses																	
			1.3 Treatment after failure																	
			1.4 Treatment after loss to follow up																	
			1.5 Others Previously Treated																	
			1.6 Total																	
M	F	T	**2. Pulmonary Clinically Diagnosed**	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**Total**
			2.1 New/ Treatment History Unknown																	
			2.2 Relapses																	
			2.3 Treatment after failure																	
			2.4 Treatment after loss to follow up																	
			2.5 Others Previously Treated																	
			2.6 Total																	

Sputum Conversion Rate

New		**Retreatment**	

Comment (if any):

TB 13

NATIONAL TUBERCULOSIS CONTROL PROGRAM
Directorate General of Health Services, Bangladesh
Laboratory Performance Report

Center: ……. Upazila: ……. District: ……. Division: …….
Name of Lab Technologist: ……. Date of report preparation: …….

Technologist trained by NTP: Yes ☐ (Year) No ☐ No. of Microscope available: No. of Microscope in running condition:

Chest X-ray	
No. of X-ray performed	No. of X-ray suggestive for TB

Quarter/ Year	Diagnosis Examination (Case Finding)					
	Presumptive TB cases Tested (No. of people tested) (a)	AFB positive cases (No. of positive person) (b)	Smears tested (No. of smear tested) (c)	Positive Smears		Only One sample tested (f)
				(1+, 2+, 3+) (d)	Scanty (e)	

Follow-up Examination		
Smears tested (No. of smear tested) (g)	Positive Smears	
	(1+, 2+, 3+) (h)	Scanty (i)

Diagnosis by Xpert MTB/RIF					
Result					
Presumptive TB cases Tested (No. of people tested) (j)	RR=MTB detected, Rif resistant detected (k)	T=MTB detected, Rif resistant not detected (l)	Rif indeterminate (m)	N= MTB not detected (n)	I= Invalid/Error/ NO result (o)

Total number of smears tested (c+g)*	(W)
Total no. of (1+, 2+, 3+) smears (d+h)**	(X)
Total number of scanty smears (e+i)**	(Y)
Total number of negative smears (W-X-Y)**	(Z)
Positive rate among presumptive TB case (%)***	(b)/(a)x100 %
Positivity rate among follow-up (%)***	(h+i)/(g)x100 %

Problem identified and supports required by the Center form NTP/EQA centre:

* This data will used for planning of supplies

** This data will be used for quarterly report re-checking in EQA centre

*** This could be used to monitor program performance

Copy to:
Respective EQA centre

Prepared by:
Lab Technologist

Approved by:
NTRL/RTRL Coordinator/UH&FPO/Jr. Consultant/NGO Clinic Manager

জাতীয় যক্ষ্মা নিয়ন্ত্রণ কর্মসূচি
সম্ভাব্য যক্ষ্মা রোগী প্রেরণের ফরম

সম্ভাব্য রোগীর নামঃ
_____

বয়সঃ
_____

ঠিকানাঃ
_____
_____

প্রেরনকারীর নামঃ
_____

পদবীঃ
_____

ঠিকানাঃ
_____
_____

স্বাক্ষরঃ
_____

(একনাগাড়ে ২ সপ্তাহ বা তার বেশি কাশি যক্ষ্মা রোগের প্রধান লক্ষন।)

জাতীয় যক্ষ্মা নিয়ন্ত্রণ কর্মসূচি
সম্ভাব্য যক্ষ্মা রোগী প্রেরণের ফরম

সম্ভাব্য রোগীর নামঃ
_____

বয়সঃ
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ঠিকানাঃ
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প্রেরনকারীর নামঃ
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পদবীঃ
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ঠিকানাঃ
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স্বাক্ষরঃ
_____

(একনাগাড়ে ২ সপ্তাহ বা তার বেশি কাশি যক্ষ্মা রোগের প্রধান লক্ষন।)

National Tuberculosis Control Program
Directorate General of Health Services, Bangladesh
Previous TB Treatment History Form

Preserve this record attached with TB patient treatment card

A. Particulars of the patient

Name …….. Lab Serial. No…….....

B. Diagnosis: ☐ Pulmonary ☐ Extra-pulmonary ☐

C. History (related to TB treatment)

Did you take Anti-TB treatment before Yes ☐ No ☐

If Yes,

☐ Private ☐ Government

Do you have ☐ TB prescription ☐ TB Treatment card ☐ TB patient ID card

How many occasion you received TB treatment? ……

Category of TB treatment received

☐ New

☐ Retreatment

☐ DR TB

☐ Others

Did you complete the treatment?

☐ Yes

☐ No

Duration (If No)

< 1 month ☐

>1 month ☐

Do not know ☐

D. Contact history with ☐ TB patient ☐ DR TB patient ☐ No

Signature & date: ……

Name: ……

Designation: ……..

Organization: ……

National Tuberculosis Control Program
Directorate General of Health Services, Bangladesh

TB Preventive Therapy (TPT) Register

	<5 years			5-10 years			10-15 years			15 years and above		
Total number of index TB patients registered in the DOT centers	M	F	T	M	F	T	M	F	T	M	F	T
Total number of household contacts registered under index TB cases												
Total number of index TB cases for whom household contact investigation was conducted												
Total number of household contacts registered under index TB cases												
Total number of households screened for TB from household contacts registered under index TB cases												
Total number of household contacts identified as possible TB among those who symptom screened												
Total number of household contacts tested positive for TB from symptom positive household contacts (adults and children)												
Total number of household contacts of index evaluated to ascertain TPT eligibility (Adults and Children)												
Total number of household contacts enrolled for TPT												
Total number of household contacts enrolled and completed TPT												

Date	Name of Eligible Person	Age		Sex	Address	Co-morbidity	TB Registration no. of source cases	Relation with source cases	**TPT Registration no.	TPT Registration date	TPT Regimen			TPT Starting Date	TPT Completion Date	Outcomes	Remarks
		Year	Month								H	3HR	3HP				

***Eligible for TPT:**
1. Household/Close contact with pulmonary bacteriologically confirmed TB patient who has no active TB disease

****TPT Registration number:** This number will be for eligible person for TPT

*****Outcomes:**
1. Preventive treatment completed: Full course of TPT completed (3/6 months)
2. Monitor any adverse effects during the course of TPT

National Tuberculosis Control Program
Directorate General of Health Services, Bangladesh
TB Preventive Therapy (TPT) Register

	<5 years			5-10 years			10-15 years			15 years and above			Total	
	M	F	T	M	F	T	M	F	T	M	F	T	M	F
Number of eligible for TPT														
Number of register for TPT														
Regimen Started														
H														
3HP														
3HR														
No. of eligible for IPT (PLHIV)														
No. registered for IPT (PLHIV)														
Chest X-ray														
No. of X-ray performed														
No. of X-ray suggestive for TB														

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Tuberculosis Control Programme (NTP), Directorate General of Health Services
Ministry of Health and Family Welfare, Dhaka, Bangladesh.