Training Module

Doctors

Revised 2019

National TB Control Program

National Tuberculosis Control Program
Ministry of National Health Services, Regulation & Coordination
Government of Pakistan
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National TB Control Program

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FOREWORD

National TB Control Program, working under the Ministry of National Health Services, Regulation and Coordination, Government of Pakistan adapts and implements World Health Organization recommended 'The End TB Strategy' for effective control of TB in Pakistan. The program envisages a TB free Pakistan by year 2035. The provision of free of cost quality TB care to all who need is the prime objective of National TB Control program.

National TB Control Program Pakistan in collaboration with its Provincial TB Control Programs and partners developed these guidelines in light of WHO recommendations in 2017. With these new recommendations WHO consolidated all aspects of TB treatment and Care into one document for the ease of its readers and implementers.

To keep abreast with these new recommendations Pakistan also revised its National TB treatment guidelines and the key areas covered include TB diagnosis, TB therapy for adults, adolescents and children including special populations. We have also added testing and treatment steps in tables and algorithms for ready reference of its users which can easily be printed into posters to be available in our treatment centres all over the country.

The target audience of these guidelines are health care professionals providing care and treatment to TB Patients including doctors, clinical officers, nurses, pharmacists, service providers, laboratory technologists and program management staff.

The development of this edition of the National Guidelines has been done through extensive efforts put in by National & Provincial Technical team including WHO & partners. The process was led by National Technical team for TB treatment and conducted national consultations and getting feedback from experts and implementers and incorporating it into the document and then reviewing the final document word by word and page by page in a series of email correspondences.

We hope that this National Guideline will improve the knowledge of its readers on the new recommendations on TB diagnosis, treatment and care and will help in rapid scale up of comprehensive and quality assured TB services to its clients in Pakistan.

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SESSION 1
INTRODUCTION TO TB CONTROL IN PAKISTAN
EFFECTIVE COMMUNICATION & TB CASE MANAGEMENT DESKGUIDE

1.1 SESSION OBJECTIVES:

At the end of the session the participants will:

- Know the burden of disease and other facts on TB.
- Know the details of the END TB strategy for control of TB in Pakistan.
- WHO guidelines and standards of TB care
- Role of Health Care Facility and Provider.
- Understand the principles and importance of effective communication in health care and recognize barriers that may exist when communicating with the people.
- Understand the background, significance and use of TB desk guide.

1.2 THE BURDEN OF DISEASE IN PAKISTAN:

TB control has been given a high priority by the health authorities because:

- About 525,000 persons develop active tuberculosis every year in Pakistan.
- Three out of four patients fall in most economically productive age group.
- One untreated sputum positive patient transmits TB to 10-15 contacts in a year.
- An incompletely treated TB patient is likely to develop and spread drug resistant TB.
- According to global TB report, there were 525,000 incident TB cases in 2017 based on the incidence of 267 per 100,000 populations. There were 57,000 cases among less than 15 years and 468,000 cases in greater than 15 years.

Table-1: Estimated TB incidence by age and sex (2017)

	0-14 years	**> 14 years**	**Total**
Females	27,000	207,000	235,000
Males	30,000	261,000	291,000
Total	57,000	468,000	525,000

1.3 SDGs and GLOBAL END TB STRATEGY

The 2030 Agenda for Sustainable Development (6), adopted by all United Nations Member States in 2015, provides a shared blueprint for peace and prosperity for people and the planet, now and into the future. At its heart are the 17 Sustainable Development Goals (SDGs), which are an urgent call for action by all countries - developed and developing - in a global partnership. They recognize that ending poverty and other deprivations must go hand-in-hand with strategies that improve health and education, reduce inequality, and spur economic growth – all while tackling climate change and working to preserve our oceans and forests. {*SUSTAINABLE DEVELOPMENT GOAL 3 - Ensure healthy lives and promote well-being for all at all ages}.*

The consolidated goal for health is SDG 3. There are 13 targets set under the goal while target 3.3 specifically mentions TB. "By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases".

The End TB strategy aims to end the global TB epidemic, provides a unified response to ending TB deaths, disease, and suffering with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB (7). It sets interim milestones for 2020, 2025, and 2030.

VISION	**A world free of Tuberculosis** -zero deaths, disease and suffering due to tuberculosis			
GOAL	**End the global tuberculosis epidemic**			
INDICATORS	**MILESTONES**		**TARGETS**	
	2020	**2025**	**SDG 2030**	**END TB 2035**
Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20% (<85/100,000)	50% (<55/100,000)	20% (<85/100,000)	50% (<55/100,000)
TB-affected families facing catastrophic costs due to TB (%)	Zero	Zero	Zero	Zero

The Strategy is builds on three strategic pillars underpinned by four key principles.

Principles

1. Government stewardship and accountability, with monitoring and evaluation
2. Strong coalition with civil society organizations and communities
3. Protection and promotion of human rights, ethics and equity
4. Adaptation of the strategy and targets at country level, with global collaboration

Pillars & components

1. Integrated, patient-centered care and prevention
A. Early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
B. Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support
C. Collaborative tuberculosis/HIV activities, and management of co-morbidities
D. Preventive treatment of persons at high risk, and vaccination against tuberculosis
2. Bold policies and supportive systems
A. Political commitment with adequate resources for tuberculosis care and prevention
B. Engagement of communities, civil society organizations, and public and private care providers
C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
D. Social protection, poverty alleviation and actions on other determinants of tuberculosis
3. Intensified research and innovation
A. Discovery, development and rapid uptake of new tools, interventions and strategies
B. Research to optimize implementation and impact, and promote innovations

Globally, 10.0 million people (range, 9.0–11.1 million) developed TB disease in 2017 [global TB report 2018]. There were cases in all countries and age groups, but overall 90% were adults (aged ≥15 years), 9% were people living with HIV (72% in Africa) and two thirds were in eight countries: India (27%), China (9%), Indonesia (8%), the Philippines (6%), Pakistan (5%), Nigeria (4%), Bangladesh (4%) and South Africa (3%).

Diagnosis and successful treatment of people with TB averts millions of deaths each year, but there are still large and persistent gaps in detection and treatment. Worldwide in 2017, 6.4 million new cases of TB were officially notified. Increase in notification is seen since 2013, mainly due to increased reporting of detected cases by the private sector in India and, in 2017, an upturn in notifications in Indonesia. The 6.4 million cases reported represented 64% of the estimated 10.0 million new cases that occurred in 2017. Ten countries accounted for 80% of the 3.6 million global gap, the top three being India (26%), Indonesia (11%) and Nigeria (9%).

Gaps between the estimated number of new cases and the number actually reported are due to a mixture of under reporting of detected cases, and underdiagnoses (either because people do not access health care or because they are not diagnosed when they do). Underestimation or overestimation of the total number of new cases is also possible.

Table-2: Top Ten priority indicators

Priority indicators	End TB Strategy target 2025
1. TB treatment coverage	≥ 90%
2. TB treatment success rate	≥ 90%
3. Percentage of TB -affected households that experience catastrophic costs due to TB	0%
4. Percentage of new and relapse TB patients tested using a WHO recommended rapid tests (WRD) at the time of diagnosis	≥ 90%
5. LTBI treatment coverage	≥ 90%
6. Contact investigation coverage	≥ 90%
7. Drug susceptibility testing (DST) coverage for TB patients	100%
8. Treatment coverage, new TB drugs	≥ 90%
9. Documentation of HIV status among TB patients	100%
10. Case Fatality Ratio (CFR)	0%

NTP Pakistan's Response– National END TB Strategic Plan (2017-2020)

Pakistan adopted SDGs 2030 agenda through a unanimous resolution of parliament. The seven pillars of Vision-2025 are fully aligned with the SDGs, providing a comprehensive long-term strategy for achieving inclusive growth and sustainable development. At the federal level, a SDGs Monitoring and Coordination Unit, in coordination with UNDP, is being set up to serve as a national coordinating entity with similar units in the provinces.

Ministry of National Health Services Regulations & Coordination is committed to implementing SDG3 agenda through its localization and integration with the country health strategies and plans at National and Provincial level.

The aim of the First ***WHO Global Ministerial Conference (10)*** on Ending TB in the Sustainable Development Era: A Multisectoral Response was to accelerate the response to meet the targets agreed under the End TB Strategy and Sustainable Development Goals, through increased national and global commitments(11).

Pakistan is signatory to the Moscow declaration to End TB. Pakistan joined the member states to endorse the Political Declaration on the Fight against Tuberculosis (TB) at the UN first High-Level Meeting for TB held on 26th September; 2018(12).

National TB strategic plan to End TB (2017-2020) is aligned with WHO End TB strategy and plan proposes bold strategies to end TB in the country in line with SDGs and End TB strategy(13).

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

Goal: To end the TB epidemic by 2035.

Target: To reduce the TB incidence by 20% in 2020 (from the baseline of 270/100,000 in 2015.

1.4 WHO guidelines and standards of TB care

Ensuring optimum delivery of the cascade of care for patients with tuberculosis. This Compendium is organized to follow the pathway of persons with signs or symptoms of TB in seeking care and to include crosscutting elements essential to the patient- centred approach to care delivery that is recommended by WHO

WHO TB STANDARDS

Early detection of TB

WHO TB Standard 1

For persons with signs or symptoms consistent with TB, performing prompt clinical evaluation is essential to ensure early and rapid diagnosis.

WHO TB Standard 2

All persons who have been in close contact with patients who have pulmonary TB should be evaluated. The highest priority contacts for evaluation are those:

- with signs or symptoms suggestive of TB;
- aged < 5 years;
- with known or suspected immune- compromising conditions, particularly HIV infection;
- who have been in contact with patients with MDR-TB or extensively drug-resistant (XDR) TB.

WHO TB Standard 3

All persons living with HIV and workers who are exposed to silica should always be screened for active TB in all settings. Other high risk groups should be prioritized for screening based on the local TB epidemiology, health system capacity, resource availability and feasibility of reaching the risk groups.

WHO TB Standard 4

Chest radiography, or CXR, is an important tool for triaging and screening for pulmonary TB, and it is also useful to aid diagnosis when pulmonary TB cannot be confirmed bacteriologically. CXR can be used to select individuals for referral for bacteriological confirmation, and the role of radiology remains important when bacteriological tests cannot provide a clear answer.

Diagnosing TB disease

WHO TB Standard 5

To safely and efficiently diagnose TB and drug-resistant TB requires a functional network of quality assured laboratories with appropriate biosafety measures in place for performing different technical procedures. As such, TB programmes require a tiered network of integrated laboratories in which different levels use complementary tools to diagnose TB and HIV, and have mechanisms for referring specimens between the different levels of the network.

WHO TB Standard 6

All patients with signs and symptoms of pulmonary TB who are capable of producing sputum should have as their initial diagnostic test at least one sputum specimen submitted for Xpert MTB/RIF Ultra assay. This also includes children who are able to provide a sputum sample. A second Xpert MTB/RIF Ultra assay may be performed for all patients who initially test negative by Xpert MTB/ RIF Ultra but whose signs and symptoms of TB persist.

WHO TB Standard 7

The Xpert MTB/RIF Ultra assay should be used in preference to conventional microscopy and culture as the initial diagnostic test for cerebrospinal fluid specimens from patients being evaluated for TB meningitis. The Xpert MTB/RIF Ultra assay is recommended as a replacement test for usual practice (including conventional microscopy, culture or histopathology) for testing specific non-respiratory specimens (lymph nodes and other tissues) from patients suspected of having EPTB.

WHO TB Standard 8

For persons living with HIV, the Xpert MTB/RIF Ultra assay should be used as an initial diagnostic test. The lateral flow urine lipoarabinomannan assay (LF-LAM) can be used to assist in the diagnostic process for HIV-positive patients who are seriously ill.

WHO TB Standard 9

DST using WHO- recommended rapid tests should be performed for all TB patients prior to starting therapy, including new patients and patients who require retreatment. If rifampicin resistance is detected, rapid molecular tests for resistance to isoniazid, fluoroquinolones and second- line injectable agents should be performed promptly to inform the treatment of MDR- TB and XDR-TB

WHO TB Standard 10

Culture-based (phenotypic) drug susceptibility testing for selected medicines should be performed for patients enrolled in treatment for drug- resistant TB.

Diagnosing latent TB infection

WHO TB Standard 11

Either a tuberculin skin test (TST) or an interferon gamma release assay (IGRA) can be used to test for latent TB infection (LTBI). A TST or IGRA is not a requirement before initiating tuberculosis preventive therapy in persons living with HIV and for children less than five years who are contacts of people with active TB disease

Treating TB - *Treating drug-susceptible TB*

WHO TB Standard 12

While awaiting DST results, patients with drug-susceptible TB and TB patients who have not been treated previously with anti-TB agents and do not have other risk factors for drug resistance should receive a WHO- recommended first-line treatment regimen using quality assured anti-TB agents. The initial phase should consist of 2 months of isoniazid, rifampicin, pyrazinamide and ethambutol. The continuation phase should consist of 4 months of isoniazid and rifampicin. Daily dosing should be used throughout treatment. The doses of anti-TB agents should conform to WHO's recommendations. Fixed-dose combination (FDC) anti-TB agents may provide a more convenient form of administration.

WHO TB Standard 13

In patients who require retreatment for TB, the category II regimen should no longer be prescribed and DST should be conducted to inform the choice of treatment regimen

WHO TB Standard 14

In patients with tuberculous meningitis or tuberculous pericarditis, adjuvant corticosteroid therapy should be used in addition to an appropriate TB treatment regimen**.**

Treating TB - *Treating drug-resistant TB*

WHO TB Standard 15

In patients with rifampicin-susceptible, isoniazid-resistant TB, 6 months of combination treatment with rifampicin, ethambutol, pyrazinamide and levofloxacin, with or without isoniazid, is recommended

WHO TB Standard 16

Patients with multidrug- or rifampicin-resistant TB (MDR/ RR-TB) require second-line treatment regimens. MDR/RR-TB patients may be treated using a 9–11 month MDR- TB treatment regimen (the shorter regimen) unless they have resistance to second-line anti-TB agents or meet other exclusion criteria. In these cases, a longer (individualized) regimen with at least five effective anti-TB agents in the intensive phase and four agents in the continuation phase is recommended for 20 months or more. Partial resection surgery has a role in treating MDR-TB.

WHO TB Standard 17

A system to actively monitor and manage harms caused by anti-TB agents is required whenever drug- resistant TB patients are treated with novel or repurposed medicines and MDR-TB regimens.

Treating TB - *Treating latent TB infection*

WHO TB Standard 18

Persons living with HIV, HIV-negative children and adult household or close contacts of persons with pulmonary TB, as well as household contacts of patients with multi-drug resistant TB and who, after an appropriate clinical evaluation, are found not to have active TB but to have LTBI should be treated.

HIV infection and other co-morbid conditions

WHO TB Standard 19

HIV testing should be routinely offered to all patients with presumptive TB and those who have been diagnosed with TB.

WHO TB Standard 20

Persons living with HIV should be screened for TB by using a clinical algorithm.

WHO TB Standard 21

Antiretroviral therapy (ART) and routine co-trimoxazole preventive therapy (CPT) should be initiated among all TB patients living with HIV, regardless of their CD4 cell count.

WHO TB Standard 22

A thorough assessment should be conducted to evaluate co-morbid conditions and other factors that could affect the response to or outcome of TB treatment. Particular attention should be given to diseases or conditions known to affect treatment outcomes, such as diabetes mellitus, drug and alcohol abuse, under nutrition and tobacco smoking.

Managing TB in children

WHO TB Standard 23

The diagnosis of TB in children relies on the thorough assessment of all evidence derived from a careful history (including history of TB contacts and symptoms consistent with TB), clinical examination (including growth assessment), a TST, CXR (if available), bacteriological confirmation whenever possible, investigations for suspected pulmonary TB and suspected EPTB, and HIV testing. Whenever possible, the Xpert MTB/RIF Ultra assay should be used as the initial diagnostic test in children suspected of having any form of TB.

WHO TB Standard 24

The principles of treating TB in children are the same as for treating TB in adults: first-line treatment of drug-sensitive TB consists of a 2 month intensive phase with isoniazid, rifampicin, pyrazinamide and, depending on the setting and type of disease, ethambutol, followed by a continuation phase with isoniazid and rifampicin for at least 4 months; however, the dose of first-line anti-TB agents differs from that administered in adults.

WHO TB Standard 25

In settings where TB is highly endemic or where there is a high risk of exposure to TB, a single dose of bacille Calmette–Guérin (BCG) vaccine should be given to all infants; however, HIV-positive children should not be given BCG vaccine. After considering local factors, BCG vaccine should be given to all infants except those who are HIV-positive for whom BCG is contraindicated

WHO TB Standard 26

All children younger than 5 years and HIV-positive children of any age should be included in contact screening and management efforts, with the aim of identifying undiagnosed TB disease and providing preventive therapy for contacts without TB disease who are susceptible to developing disease following exposure to a contact with active TB disease.

Monitoring and evaluation

WHO TB Standard 27

All providers must report both new and re-treatment TB cases and their treatment outcomes to national public health authorities in conformance with applicable legal requirements and policies; TB mortality should be monitored by using standard cause-of-death data from vital registration systems.

Supportive approaches – *Digital health*

WHO TB Standard 28

Digital technologies can be adapted to increase the effectiveness or efficiency of different components of TB programmes

Supportive approaches – *Infection control*

WHO TB Standard 29

Promptly identify persons with TB symptoms (triage); provide an adequately ventilated waiting area for them; educate them about cough etiquette and respiratory hygiene; ensure they are prioritized for TB testing; and separate infectious patients

Supportive approaches – *Patient care and support*

WHO TB Standard 30

A patient-centered approach to treatment should be developed to promote adherence, improve quality of life and relieve suffering. This approach should be based on the patient's needs and on mutual respect between the patient and the provider

WHO TB Standard 31

Prior to starting TB treatment, each patient's need for support should be assessed, and interventions to encourage adherence to treatment be offered to improve outcomes

WHO TB Standard 32

Before starting TB treatment, all patients should be assessed to determine the risk of treatment interruption, and appropriate options for treatment administration should be offered to each patient. Community- or home-based DOT is recommended over health facility- based DOT or unsupervised treatment; and DOT administered by trained lay providers or health-care workers is recommended over DOT administered by family members. Video-observed treatment may replace DOT when the technology is available and can be organized and operated by health- care providers and patients

Supportive approaches – *Palliative care*

WHO TB Standard 33

All forms of suffering associated with TB should be addressed by ensuring that patients have proper access to care and to the management of adverse reactions to treatment, management of psychological distress, means to prevent and mitigate stigma and discrimination, and by providing access to social protection mechanisms to reduce indirect costs(9)

1.5 THE ROLE OF HEALTH FACILITIES & PROVIDERS.

TB Care Services at Basic Management Unit (BMU)

- ✓ Screen people with respiratory symptoms by sputum smear examination
- ✓ Diagnose and prescribe drugs to TB patients
- ✓ Register TB patients and identify suitable treatment center for the patient
- ✓ Provide observed treatment, or refer to a treatment center for observed treatment
- ✓ Do follow up sputum smear examinations
- ✓ Prepare quarterly reports on case finding, sputum smear conversion and treatment outcome
- ✓ Maintain patient records, and stock books for drugs and materials
- ✓ Refer patient to DRTB-MU

TB Care Services at Treatment Centers

- ✓ Refer people with respiratory symptoms to the BMU
- ✓ Provide or arrange community-based observation of treatment
- ✓ Refer people with drug reactions to district level hospital
- ✓ Refer people for follow up examinations at BMU
- ✓ Trace late patients

Health Care Providers:

- The doctors at the BMU (e.g. hospital or RHC) will be responsible for diagnosing and prescribing TB treatment and declaring treatment outcome.
- The doctor at the treatment center (e.g. the nearest BHU or dispensary), where available, will be responsible for continuing care and supervising the Treatment Supporters.
- The DOTS Facilitator at BMU /TB CARE FACILITY is a paramedic male or/ and female who has the responsibility for ensuring dialogue with the patient to ensure appropriate direct observation arrangement throughout the course of treatment. In addition, they assist the BMU doctor to maintain record and analyze data and report on the number of cases registered and the outcome of treatment.
- The DOTS Facilitator at the treatment center is also a paramedic who will arrange treatment supporter to ensure direct observation throughout the course of treatment.
- The treatment supporter is the person who will carry out the direct observation of treatment. That is, they will watch patients take their tablets every day. The intensive phase of treatment is the first two months in new patients and three months in a retreatment patient. After the intensive phase, treatment supporters should continue to encourage patients to collect and take their medication till completion of treatment. Treatment supporters should be chosen in discussion with the patient, so as to identify someone who is nearby and reliable. The treatment supporter may be a community health worker (such as LHW and other village-based worker), a facility health worker or any other community member.
- Microscopist at BMU microscopy center will prepare sputum slides for AFB examination, maintain records, preserve slides in serial order for EQA, issue quarterly Lab performance reports and make arrangements for proper disposable of lab infectious material.

1.6 INTERPERSONAL COMMUNICATION& BARRIERS TO COMMUNICATION:

"The single biggest problem in communication is the illusion (false impression) that it has taken place" *George Bernard Shah*

Communication is defined as "Two-way process of reaching mutual understanding in which participants not only exchange (encode-decode) information, news, ideas and feelings but also create and share meaning.

The sender-receiver model is the simplest communication model

Interpersonal Communication is face to face verbal or non-verbal exchange of information and feelings between two or more people.

COMMUNICATION BARRIERS:

During an interview with a patient, various barriers to communication may occur that can potentially hinder the interview process if not quickly resolved. Some of these barriers may occur due to the patient's actions, while some may occur in part due to the interviewer. Barriers can be physical or nonphysical.

Examples of Communication Barriers

Physical	Non physical
· Desk or table between interviewer and patient · A person wearing sunglasses · Noise · People actively moving about the interview room · Body language suggestive of insecurity, poor listening, or disinterest · Lack of privacy · Uncomfortable room temperature	· Time pressure · Language · Interruptions · Judgmental attitude · Education level · Insecurity · Selective listening or failure to listen · Lack of cultural competency

The picture below represents few common observed barriers in communication.

Exercise 1.1

Look at the picture and list below the main communication barriers that you observe.

1. _____
2. _____
3. _____
4. _____
5. _____

EFFECTIVE COMMUNICATION

See the picture below and observe the changes that have been made to make communication more effective.

- DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD
- THEN CONTINUE READING

WHY IS GOOD COMMUNICATION IMPORTANT FOR A TB PATIENT?

Good communication is an essential part of good quality care. Many TB patients are poor, with very little money to use on health care. If the quality of care provided in our health facilities is of a low standard, patients may turn to unqualified healers or simply buy medicines and try to treat themselves. This may result in inadequate treatment (if they get any treatment at all) the patient not being cured and multi-drug resistance may become increasingly common.

- **The patients' view point**

  Interviewing someone who may have TB requires good communication skills because they are often:

  - Worried about the cause of TB, and whether they will get good treatment
  - Embarrassed by the social stigma of TB
  - Afraid about confidentiality
  - Worried about the health workers' attitude
  - Concerned about being overheard (especially so for women)

A health worker with good communication skills will be able to help the patient to overcome these barriers

- **Doctor and paramedics view point**

  From the doctor and paramedics view point:

  - Correct and complete information is vital for diagnosis
  - Two way communication with patients is vital so that we know that patients understand and complete their treatment
  - Without good communication skills the health worker may miss information that may affect:
    - Correct diagnosis
    - Determination of whether the patient is new or has had TB treatment before (re-treatment category)
    - The choice of treatment supporter
    - Compliance with treatment and cure

PRINCIPLES OF EFFECTIVE COMMUNICATION

Always remember the acronym: **WELL**

W = welcome your patient

- ensure privacy and confidentiality
- greet the patient warmly (in a friendly manner)
- offer him/ her a seat
- ask his/ her name
- show empathy ("I understand how you feel")

E = encourage your patient to talk

- asking general questions ***"what is your (presenting) health complaint"***, ***"what are you concerned about"***
- nodding , agreeing or saying ***" Tell me more about that"***

L = look at your patient

- make sure that your facial expression is warm and friendly
- maintain eye contact with your patient as they speak
- observe their feelings (as well as their general medical condition)

L = listen to your patient

- listen carefully to what your patient has to say and do not interrupt them
- show the patient that you are interested in what they are saying

OPEN QUESTIONS

Always start taking a history with open questions and only if necessary move to more closed questions later. Open questions are ones where there is no fixed answer and the patient can therefore answer the question in his/her own way. Closed questions are phrased very specifically requiring 'yes and no' answers. The problem people have with closed questions is that, some patients may answer closed questions in the way they think you want to hear.

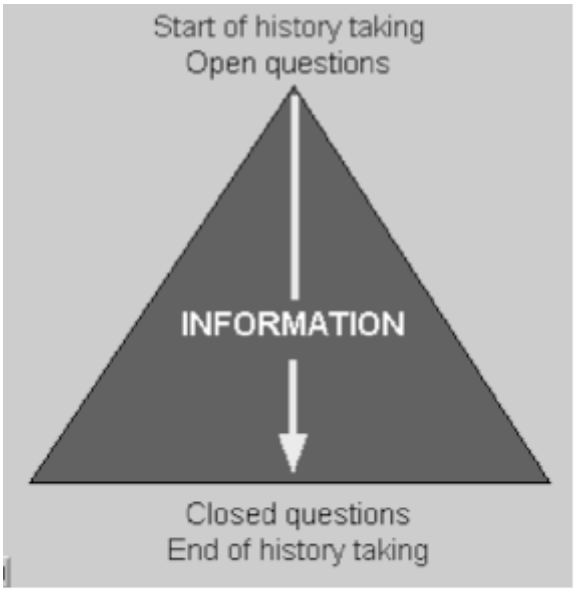
The most important symptom of TB is prolonged cough and any person who has been coughing for more than 2 weeks should be considered as possibly having TB.

Careful, non-leading, questions about the duration of cough are particularly important.

For example if a patient mentions they have a 'bad cough', you may ask an open question such as 'tell me more about your cough'. If this doesn't give you the information you want e.g. its duration, then be more specific. Make sure you ask another open question such as 'how long have you had this cough?'

If this doesn't get a clear answer, then you may need to ask a closed question but with alternatives, such as 'has this episode of cough been for a week or a month or longer?' Another way of offering alternatives would be to ask 'did your cough start before or after Ramazan? (Use an appropriate recent occasion that most patients will be able to remember.)

Avoid asking very closed questions, especially at the beginning of the consultation. If you ask a closed question, such as 'have you been coughing for more than 3 weeks? the patient may answer quickly without proper consideration and give the incorrect yes or no answer.



1.7 THE DESK GUIDE:

The desk guide is an easy to use summary of the complete process of caring for a TB patient. It has been prepared based on TB Control Program guidelines and WHO materials, but adapted to the Pakistan context through the collaborative efforts of national and international experts.

The desk guide is useful during training but more importantly, it is also useful as an easy reference in the consultation room.

- **How to use the Desk-guide bullet symbols**

  In the desk guide there is a bullet key to the symbols used, as follows:

  - **Bullet Key:**

➢ Main stepThis refers to a point/area under consideration

✓ Sub-stepThis refers to two or more points related to the main step above

☐ Condition This refers to conditionality (if), and usually followed by an action statement under that particular condition

☞ Recommended Action: This refers to an action, in the light of points considered above Condition

1.8 SUMMARY POINTS

- The desk guide deals with every stage of the management of a person with TB, page by page.
- Every health worker needs to understand the overall process of caring for a person with TB and understand in detail the role they themselves will play in this process.
- The quality of TB care can be affected by the attitude of the doctor, paramedic and community worker.
- Good communication is a two-way dialogue between doctors/ paramedics and patients.
- Always remember acronym WELL:
- TB desk guide, and should be looked at during care delivery in the consultation room.

SESSION 2
IDENTIFYING AND MANAGING A "PRESUMPTIVE TB CASE"
AND "DIAGNOSING TB"

2.1 SESSION OBJECTIVES

At the end of the session participants will be able to;

- Causative organism and mode of spread
- Understand how to identify presumptive Tuberculosis
- Why risk assessment of presumptive TB case is essential
- What is the importance of monitoring TB case finding activities at BMU/TB care facility?
- Guidelines for Collecting Sputum Specimens
- What different tests are available for diagnosis of tuberculosis?
- Know the recommendation for diagnosis of extra-pulmonary Tuberculosis.
- Understand what is systematic screening for active tuberculosis
- Use of X-Ray Chest in Supporting the Diagnosis of Tuberculosis

2.2 CAUSATIVE ORGANISM AND MODE OF SPREAD

Tuberculosis (TB) is caused by a bacterium called Mycobacterium tuberculosis. TB bacteria are spread through the air from one person to another. Tuberculosis is a highly contagious infection, transmitted to other healthy persons by infected droplets generated by coughing or sneezing of patient having active pulmonary Tuberculosis disease. These tiny droplets dry rapidly, attach themselves to fine dust particles and the smallest of them may remain suspended in the air for several hours. Only those particles that are less than 10 µm (micron) in diameter reach the pulmonary alveoli of the healthy individual through inhalation resulting in infection. While not everyone exposed to the bacterium becomes infected nor does everybody infected with it develop clinical symptoms. The chance of becoming infected depends mainly on the quantity of infectious droplets in the air, and the length of exposure to an infectious person. The closer the infectious person is, and the longer the length of exposure, the higher the risk is of being infected.

When a person breathes in TB bacteria, the bacteria can settle in the lungs and begin to grow. Tuberculosis spreads from the primary lung lesion to other parts of the body via the blood stream, lymphatic or by direct extension, and in this way may affect any organ in the body. TB is thus classified as pulmonary (Lungs parenchyma) and extra-pulmonary on the basis of anatomical site involved.

TB disease in the lungs or throat can be infectious. This means that the bacteria can be spread to other people. TB in other parts of the body, such as the kidney or spine, is usually not infectious. People with TB disease are most likely to spread it to people they spend time with every day. This includes family members, friends, and co-workers or schoolmates. TB is NOT spread by shaking someone's hand, sharing food or drink, touching bed linens or toilet seats, sharing toothbrushes or kissing.

2.3 HOW TO IDENTIFY PRESUMPTIVE CASE OF PULMONARY TUBERCULOSIS

A patient with cough (with or without other symptoms) 2 or more than 2 weeks should be investigated as "PRESUMPTIVE PULMONARY TB CASE" and must be referred to laboratory for bacteriological diagnosis of tuberculosis.

Patients with cough of less than 2 weeks, or of uncertain duration should also be investigated as presumptive TB case **IF** they present with one or more of following symptoms

- Blood stained sputum
- Fever usually at night

- Weight loss
- A history of previous TB in the patient, family or a close contact

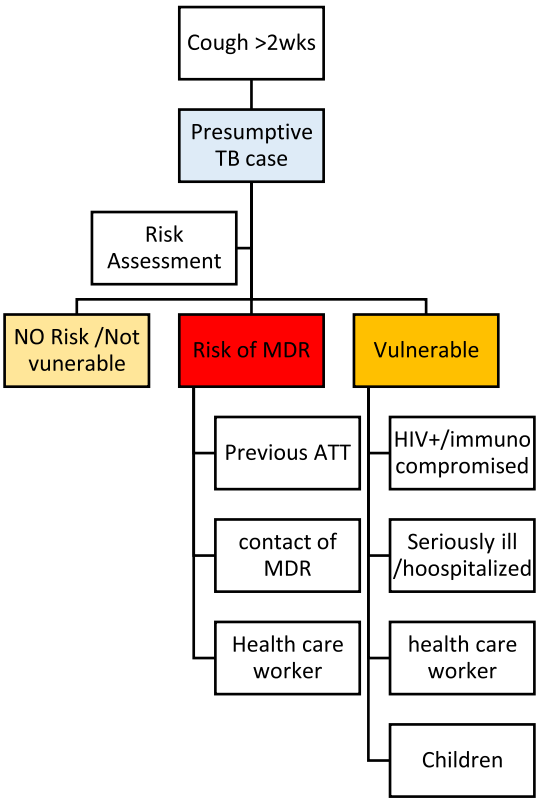
Patients often do not give a clear history, therefore careful history taking is required to find out duration of symptoms especially of cough. Tuberculosis can co-exist with other conditions e.g. diabetes and COPD. Patients with asthma or COPD may develop TB in addition to their chronic illness. It is thus very important to investigate all patients presenting with cough of more than two weeks for tuberculosis. This is to ensure that we diagnose all cases of TB with co-existing other common illnesses.

2.4 WHY RISK ASSESSMENT OF PRESUMPTIVE TB CASE IS ESSENTIAL:

Risk assessment of presumptive TB will help doctors to decide which diagnostic tool should be used for diagnosis of tuberculosis. Patient once identified as presumptive TB cases should be assessed for

- Any risk of drug resistant TB (patient with history of previous anti TB treatment and contacts of DRTB)
- The patients at high risk of developing tuberculosis such as (HIV+ive, diabetes, other immune-compromised, seriously ill and/or hospitalized and children)

Figure 1:



KEY POINTS: **Presumptive TB** refers to a patient who presents with symptoms or signs suggestive of TB (previously known as a *TB suspect*).**Risk assessment** must be conducted of all presumptive pulmonary TB cases before referring to laboratory for investigation

- DISCUSS WITH THE FACILITATOR TO CLARIFY THOSE POINTS WHICH ARE NOT UNDERSTOOD
- THEN CONTINUE READING

2.5 WHAT IS THE IMPORTANCE OF MONITORING TB CASE FINDING ACTIVITIES AT HEALTH CARE FACILITY?

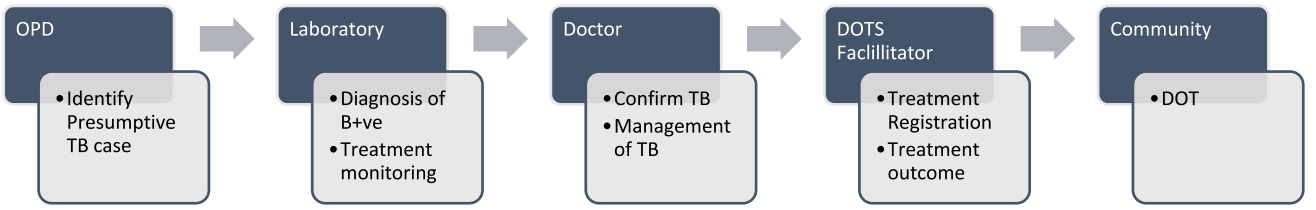
Major efforts are needed to ensure that all presumptive TB cases are investigated for tuberculosis and all diagnosed TB cases are registered for treatment and monitored for treatment compliance and treatment outcome.

In Pakistan proportion of TB cases among presumptive cases examined in laboratory is very high (>15%), this phenomenon is indicative that

- Patient either reaches health facility very late due to accessibility problem or lack of awareness.
- Failure of health care providers to identify presumptive TB case reaching health facilities
- Patient are seeking health care in private sector for TB symptoms

It is thus important to keep a check on

- All Presumptive TB cases identified are referred for diagnosis in laboratory
- All TB patient diagnosed are registered for treatment
- All TB patient registered for treatment compliance and outcome
- Contact tracing



REGISTRATION OF PRESUMPTIVE TB CASES:

It is recommended that every Presumptive TB patient identified should be registered and subject to feasibility one of following two mechanisms can be adopted.

- TB Presumptive Register
- District Health Information System (DHIS-02)

Presumptive case Register: Keep a separate presumptive case register with DOTS facilitator, every presumptive TB patient is referred to TB DOTS facilitator for registration. DOTS facilitator records the patient information in the presumptive case register from TB05 and gives orientation to patients about his illness. He then guides patient to laboratory for sputum examination. This register should ideally be cross checked with lab register on daily basis to see if all presumptive TB cases have reached laboratory and sputum has been examined. Laboratory results are entered every day to complete patient information.

This register helps to monitor that all presumptive cases are examined in laboratory by cross checking with TB lab register (TB04) and all cases diagnosed are registered for treatment by cross checking with District TB register (TB03).

District Health Management Information System-DHMIS-02 Outpatient Department (OPD) register can be also be used to record and monitor presumptive TB cases identified and TB cases diagnosed in a month at THQ and RHC.

The diagnosis is recorded in column 17. The management note is recorded in column 18 (i.e. action taken). The note mainly includes the management (i.e. drugs prescribed) and in case of TB presumptive case, AFB test advised is written in column 18.

This information could be encircled or highlighted while counting the presumptive case.

This information could also be extracted from **PHC Facility Monthly Report-** OPD Abstract Form Section IV.

Annex PTC Register

2.6 GUIDELINES FOR COLLECTING SPUTUM SPECIMENS:

It is very important to collect a good sputum specimen (not saliva). The following guidelines will guide you in helping the patient to collect sputum.

1. Sending a patient for sputum smears

Explain the importance of sputum examination to the patient. In a presumptive TB situation two specimens must be examined.

If the patient is at BMU/ TB care facility you *DO NOT* need to collect the specimen. Simply send the patient to the laboratory with the Tuberculosis sputum smear examination request form (TB05). The laboratory technician will explain the method of sputum collection and will collect the "spot" specimen. The patient should then be given an empty container (labelled) and instructions given on how to take a **"morning specimen"** (see steps below). Patients should be requested to return with the specimen to the laboratory ON the following day.

To summarize, these are the two sputum specimens that are required:

- **Spot-(A):** this is collected at the treatment or diagnostic center while the patient is still at the health facility
- **Morning-(B):** this is collected at the home and it is early morning sputum collected the day after consultation.

When possible, at least one early-morning specimen should be obtained, as sputum collected at this time has the highest yield. However, "**Same Day Diagnosis" approach** is recommended in situation where patient has travelled long distance to reach BMU or in chest camps or other special situation (active case finding), two sputum specimens may be collected (with one-hour gap) and examined on the same day (also known as front loading technique). For details Please refer to section "TB in special situations".

2. Getting good quality specimen

Good quality specimens contain sputum, not saliva! A good quality specimen is obtained by explaining and demonstrating to the patient how to take in a deep breath and cough deeply in order to bring up sputum (see step below). It is important to collect a good sputum specimen in order to make sure that any bacteria present are identified. If a poor quality sputum specimen is examined, the bacteria may not be identified, the diagnosis will be missed and ultimately, the correct treatment will not be given.

REMEMBER

Sputum specimens must be handled with care. Specimens that contain TB bacilli are potentially infectious.

Sputum collection must be done in a well-ventilated place, to reduce the chance of inhaling the bacteria (see next page). Ideally it should be collected outside within the compound of a health facility. However, if this is not possible, then a well ventilated room should be used.

Explain to the patient the importance of also being careful (as in step 4, next page), when taking the morning specimen at home. In so doing the patient will reduce the risk of infecting other people at home.

The 6 steps for specimen collection

The 6 steps for taking good sputum samples are as follows: The actions at treatment center are in italics, all other actions are at BMU/TB care facility

STEP 1: Fill in the TB laboratory form (TB05)

At BMU: The TB05 should be filled in by the doctor and the patient is sent to the laboratory for sample collection.

At *(TB CARE facility) The TB05 should be filled by the in-charge of that center, and the patient is sent to the diagnostic center along with sputum specimens.*

STEP 2: Label the sputum container

At BMU: The laboratory technician will write the laboratory serial number on the sputum containers and no of specimen (A (1^{st})B (2^{nd}) on the sputum container.

At: (TB Care facility) *The health worker will only write the name of the patient on the sputum containers & number of specimen* (A(1st) B(2nd)) *on the sputum container. He will not write anything on TB05 against the laboratory serial number. These numbers will be written when the patient is received at the diagnostic center laboratory.*

STEP 3: Instruction or collecting good quality specimen

Explain carefully and demonstrate how to breathe deeply and cough. The patient must produce sputum, not saliva.

STEP 4: Collection of specimen

- If possible the specimen should be collected outside or in a well-ventilated space, away from other people.
- Do not collect the sputum while others are watching.
- Let the person rinse his/her mouth with water.
- Do not stand in front of the patient.

STEP 5: Collect the specimen (SPOT)

- Supervise the collection of sputum.
- Give the patient the container, without the lid.
- Hold the lid yourself.
- Ask the patient to breathe deeply and cough.
- Ask the patient to spit carefully into the container, and not to contaminate the outside of the container.
- Give lid to the patient to immediately screw on tightly and ask him to check that the lid is tight.
- Ask the patient to wash his/her hands and also wash your hand

STEP 6: Explain to the patient how to transfer the specimen

Explain to him that the container with sputum contains dangerous material. It should therefore be kept hidden in a safe place, far out of reach of children.

Annex TB 05

Filling the TB05

- **Treatment unit:** It is the name of health facility where the laboratory services for sputum microscopy are present.
- **Date of request:** This is the date when first spot sputum sample is collected.
- **Patient name:** Name in full
- **Date of Birth:** Write the reported or estimated age of the patient
- **Sex:** Tick the appropriate box i.e. in case of male patient tick M □ and in the case of female tick F □
- **CNIC #:** Put in the Identity card number
- **Patient Address:** Complete address of the patient
- **Reason for examination:** this may be diagnosis, presumptive TB case, presumptive DR-TB case, and follow-up. In case of follow-up, record the month of treatment & BMU TB registration number.
- **Clinical History:** Previous treatment for TB, and if the person is infected with HIV.
- **Test requested:** Microscopy, Xpert-MTB Rif

- **Request by:** Name and signature of the person requesting sputum examination.
- **Result Section:** In addition to patients routine information (as described above), this section covers the microscopy results and also includes any of the information related to Xpert MTB/Rif assay i.e. not requested, report attached, report to follow and submit fresh specimen. Name of the person examining the smears will be recorded in the column examined by and he will put signature in relevant column. Date of completion of from will be entered.

SPECIMEN TRANSPORT MECHNISM:

The NTP Pakistan there is limited X-pert machines and is installed at strategic locations. This implies that for a person who is a potential DR-TB presumptive should either visit that site for get his/her sputum transported to that site. The NTP Pakistan recognizing the importance of this operational inconvenience for patients has recently started a new initiative in which the sputum sample which needs to be tested for possible resistance will be shifted through courier service to the Xpert site for testing. This is termed as sputum transport mechanism and is in pilot phase and will be scale-up in the country in coming months.

EXERCISE 2.1:

You are a doctor sitting at RHC Bara Kahu (a designated diagnostic center). Today is July 13, 2019. Ms. Shamim a 19-year old housewife from village Sari, DakKhana Sari, Tehsil and district Islamabad, has come to consult and you think she is a TB presumptive case. On enquiry Ms Shamim informed that she has come to this facility on her own. Now fill in the request section of TB 05 (Use the work sheet at the end of the module to complete the exercise).

- REVIEW/ REVISE ANSWERS WITH the FACILITATOR
- THEN CONTINUE READING

READING SPUTUM SMEAR RESULTS:

Sputum smear results are reported on the TB05 form (result section) by the laboratory staff. The doctor at the BMU will see the report to decide further action according to these results. Specimen 1 and 2 refers to two specimens collected for the laboratory examination of TB presumptive case. The results column refers to result of each sputum smear examined. The smear results are reported either as positive or negative. In this column, "POS" is written to record a positive result, and "NEG" is written to record a negative result.

Positive grading refers to grading according to number of acid fast bacilli (AFB) on the slide. The laboratory person will tick the appropriate positive grading column for each smear reported "POS". The positive grading is done according to WHO criteria given in the table below:

Table-3: Reporting pattern and interpretation of AFB microscopy result

	REPORT AFB smear	**INTERPRETATION**	**ACTION**
1	Positive **"3+'**	Bacteriological positive TB case (B+)	Start ATT . If patient is at risk of MDR refer sample for GeneXpert MTB/RIF assay testing.
2	Positive **"2+"**		
3	Positive **"1+"**		
4	Positive **"scanty"***		
5	NEGATIVE	AFB not seen TB NOT excluded	Clinical evaluation – If vulnerable population, refer sample for Xpet/MTB rif assay

*Exact number of AFB Pulmonary smear-positive tuberculosis is highly infectious. As mentioned earlier, one undiagnosed (and untreated) smear positive case will infect 10-15 persons per year for about two years. Patients with pulmonary smear-negative tuberculosis are ill and need treatment; however, they are much less infectious than smear-positive patients. Smear negative patients will infect only about 1 or 2 people per year.

Step-by-step instructions (See the diagnostic algorithm in the flow diagram) in the desk-guide helps the doctor to diagnose a TB case, by making appropriate use of the key and the supplement diagnostic criteria.

2.3 Considerations for recommended TB Diagnostic approaches and algorithm

All patient presumed to have TB should be carefully assessed for:

- Risk of drug resistant tuberculosis (history of previous treatment, MDR contact)
- Immune status and vulnerability to severe form of tuberculosis (Children, HIV + and other immune-suppressed, seriously ill, hospitalized)
- Difficulties in diagnosis e.g. Extra-pulmonary Tuberculosis and even PTB in adults having difficulty in expectorating sputum or where sputum/bronchial specimen are obtained using special intervention (Gastric aspirate, BAL, Bronchial biopsy).

Table-4: TB Diagnostic approaches and algorithm

Presumptive TB cases	Risk of Drug resistance	Increased risk of TB (Immune-compromised /contacts)	CXR-suggestive of TB	Xpert Testing Facility	Recommended Initial Diagnostic test	Further action
Pulmonary TB case						
ADULT	NO	NO	NOT Available/ NOT Done	On-site / Remote Linked Lab	AFB microscopy	If SSM+, Xpert MTB/RF for RR
						If SSM-ve, Clinical evaluation /CXR- Xpert MTB/RF for RR
ADULT	NO	NO	YES	On site	MTB/RIF assay	Repeat MTB/RIF if RR
				Remote linked laboratory (TAT >24hours) on site	AFB microscopy MTB/RIF assay	Refer Same specimen for Xpert MTB/RIF assay Repeat MTB/RIF if RR
ADULT	NO	YES	+/-	Remote linked laboratory (TAT >24 hours)	AFB microscopy	Same specimen for Xpert MTB/RIF assay
ADULT	YES	+/-	+/-	On site	MTB/RIF assay	If RR+, Register in TB register/ Refer & transfer out to PMDT-DRTB register
				Remote linked laboratory (TAT >24 hours)	AFB microscopy	Same specimen for Xpert MTB/RIF assay
Children <15 years	+/-	+/-	+/-			Repeat MTB/RIF if RR
				Remote linked laboratory (TAT >24 hours)	AFB microscopy if enough quantity specimen	Same specimen for Xpert MTB/RIF assay
Extra-Pulmonary TB Case						
ADULT/ Children	+/-	+/-	+/-	On site	MTB/RIF assay	Culture
				Remote linked laboratory	All specimen refer to Xpert site. AFB microscopy only If in sufficient quantity purulent material	Same specimen for Xpert MTB/RIF assay

2.10 Consideration for Diagnosis of Pulmonary TB (PTB)

All adult patients presumed to have pulmonary TB /with chest radiographic findings suggestive of TB should have sputum specimens examined in a quality-assured laboratory.

a) For AFB microscopy

AFB smear Microscopy is globally recognized as a transmission-risk indicator, as it quickly detects infectious cases of pulmonary TB, which contain sufficiently large numbers of acid-fast bacilli to be readily detected by microscopy e.g. sputum specimens from PTB patients having cavitary disease.

Principle and methods

The mycobacterial cell wall contains mycolic acids, which are fatty acids that contribute to the characteristic of "acid-fastness." The principle of the AFB smear is based on the fact that mycolic acid in the cell wall of AFB render them resistant to de-colorization with acid alcohol. Staining procedures used for the screening and/or confirmation of AFB are:

- **Ziehl-Neelson (Conventional light microscopy):** Classic procedure that allows stain to persist after heating (required for better penetration of the stain into the cell wall. Convention bright field microscopes are used to examine ZN stained smears.
- **Fluorchrome (Light-emitting diode (LED) fluorescent microscopy):** This screening procedure that is more sensitive (10%) than conventional carbol fuchsin stains (Ziehl-Neelsen or Kinyoun fluorescence microscopy is on average 10% more sensitive than ZN microscope.

AFB microscopy services

Microscopy services are well established in the country with an average of one microscopy laboratory for 120K population. All health facilities were initially equipped with bright field microscopes for examination of ZN stained smears. After the endorsement of WHO, Programme has successfully introduced LED fluorescent microscopes in more than 50% of the microscopy centres.

Limitation of AFB microscopy

Direct smear microscopy is relatively insensitive and more than 5,000 bacilli per milliliter of sputum are required to detect AFB. Smear microscopy is thus less sensitive to diagnose paucibacillary form of TB diseases e.g. in children, patients with HIV-co-infection and extra-pulmonary TB. Furthermore, AFB microscopy cannot distinguish Mycobacterium tuberculosis from NTM, viable from non-viable organisms, or drug-susceptible from drug-resistant strains.

Recommendation on Use of AFB microscopy

Keeping in view the advantages (low cost, better coverage, early detection of infectious cases) and disadvantages (low sensitivity) of AFB microscopy , cost implication and availability of Xpert testing facilities, challenges in specimen transport systems and turnaround time, AFB microscopy is recommended as:

- Front line tool for diagnosis of all type patients presumed to have TB, seeking health care from facilities where Xpert MTB/RIF testing is not available on site. However, after making smear for microscopy same specimen may be referred for Xpert testing as per national guideline (see below)
- Front line test for diagnosis of PTB in Adult patients presumed to have TB not at risk of Drug resistant TB and not immunocompromised
- Test for monitoring treatment response of;
    - PTB patients on first line drugs
    - Drug resistant PTB patients on second line drugs along with culture.

Two sputum specimen should be examined as follows:

- **Spot Specimen:** Sputum sample is collected on first day a
- **Early morning Specimen:** Sputum sample is collected early morning next day at home. Morning specimen has the highest yield and should be tested whenever feasible.

When possible, at least one early-morning specimen should be obtained, as sputum collected at this time has the highest yield. However, "**Same Day Diagnosis" approach** is recommended in situation where patient has travelled long distance to reach BMU or in chest camps or other special situation (active case finding), two sputum specimens may be collected (with one-hour gap) and examined on the same day (also known as front loading technique). For details Please refer to section "TB in special situations".

b) For Xpert MTB/Rif assay

One specimen is recommended for testing. This recommendation applies also to the use of X-pert MTB/RIF

- in processed and unprocessed sputum specimens.
- to gastric lavage and aspirates
- EPTB specimen

Note:

- For all patients group where X-pert /MTB rif assay is recommended as preferred tool, it is recommended that for facilities where X-pert testing is not available on site and specimen requires transportation to higher level laboratory, smear microscopy should be performed in local laboratory and same specimen transported to X-pert site. While X-pert results are awaited, patient should be managed based on microscopy results /clinical diagnosis.
- In situation where xpert MTB/Rif assay is performed as follow on to microscopy, Xpert MTB/RIF assay can be performed on one of the specimen used for microscopy.
- Diagnosis in Children: X-pert MTB/RIF is recommended as initial test in all children suspected of having tuberculosis but those with a single X-pert MTB/RIF negative result should undergo further diagnostic testing, and a child with high clinical suspicion for TB should be treated even if an X-pert MTB/RIF result is negative or if the test is not available

The X-pert MTB/RIF is the only WHO-recommended Rapid Molecular Diagnostic Test that simultaneously detects TB and resistance to rifampicin in less than two hours. GeneXpert is currently the only fully automated cartridge based real-time DNA based test. It is more sensitive than microscopy and with detection limit of 136 (MTB/Ml of sputum) and thus has a high sensitivity in smear-negative tuberculosis. The sensitivity of the Xpert MTB/RIF assay (Cepheid, Sunnyvale, CA, United States) for detecting TB is similar to that of solid culture (88% when compared with liquid culture as a reference standard). The specificity is also high (99%) Sensitivity of a single X-pert MTB/RIF test in smear-negative/ culture-positive patients is reported to be 72.5% and increased to 90.2% when three samples are tested.

The Xpert MTB/RIF Ultra assay has a higher sensitivity than the Xpert MTB/RIF assay, particularly in smear-negative, culture-positive specimens and in specimens from HIV-positive patients. It has at least as good accuracy for detecting rifampicin resistance. However, as a result of the increased sensitivity, the Xpert MTB/ RIF Ultra assay also detects non-replicating and non-viable bacilli, particularly in patients with a recent history of TB, which reduces the overall specificity of the Xpert MTB/RIF Ultra assay in high-burden settings. Nonetheless, in low burden settings and when testing specimens to diagnose EPTB and paediatric TB, false positive results were not a major concern.

Recommendation on use of X-pert MTB/RIF

WHO endorsed the use of X-pert MTB/RIF assay in 2010. WHO Policy recommendations on the X-pert MTB/RIF assay (X-pert MTB/RIF) were issued in early 2011 and were updated in 2013.

WHO recommends use of X-pert MTB/RIF as an initial diagnostic test in individuals (adults and children) presumed to have TB or DR-TB or HIV-associated TB. However, subject to resource implication use of X-pert MTB/RIF is recommended as a follow-on test to microscopy in adults presumed to have TB but not at risk of DR-TB or HIV associated TB.

Based on WHO recommendation and keeping in view coverage and resource implication following is recommended:

Use of Xpert as initial diagnostic test

- Individual presumed to have Drug resistant PTB (Adults and children) including those with previous history of TB treatment, Contact of RR/MDR TB patient, Health care workers
- Children (less than 15 years) presumed to have TB
- Immunocompromised individual presumed to have TB
- Individual(adults and children) presumed to have Extra pulmonary TB cases
- Individual Presumed to have PTB with CXR showing changes suggestive of TB

Use of Xpert as follow on to microscopy

- AFB smear positive TB cases
- AFB smear Negative cases with CXR showing changes suggestive of TB

Table-5: Reporting and interpretation of X-pert MTB Rif results

DR-TB risk assessment	Interpretation	Treatment decision
Report-1: MTB Detected - Rif resistance NOT detected		
No previous history of ATT	Definite TB case NO Rifampicin resistance	Start treatment for new case
Past History of TB episode, > 2 year interval between current and past episode.	Definite TB case NO Rifampicin resistance	Start treatment for new case
Past History of TB, <2yrs interval between current and past episode.	Definite TB case NO Rifampicin resistance	Start treatment for a retreatment case Fresh sample for comprehensive DST, adjust treatment based on DST results.
Past history of TB with unfavorable treatment outcome (TAF, TAD, Others)	Definite TB case NO Rifampicin resistance	Start treatment for a retreatment case Refer fresh sample for comprehensive DST – Adjust treatment based on DST results
Report-2: MTB Detected - Rifampicin Resistance Detected		
No previous history of ATT	Definite TB case with Rifampicin resistance	*Repeat X-pert MTB/Rif assay on fresh sample in same laboratory– If -RR Not detected - start on FLD on treatment for new case. -RR detected – Register patient in HF TB-register, then –"Transfer out" to PMDT site for DRTB treatment.
History of previous ATT	Definite TB case with Rifampicin resistance	Register patient in HF TB-register, then –"Transfer out" to PMDT site for DRTB treatment
MTB Detected - Rifampicin Resistance (indeterminate)		
	Definite TB case but Rifampicin status not reported	Register patient on TB treatment, based on history of previous treatment history (as above) Repeat Xpert on fresh sample –if same results- and patient is at risk of MDR send sample for phenotypic DST.
MTB Detected –TRACE (Rifampicin Resistance (indeterminate)		
No past history of TB	Definite TB case	Repeat on Fresh morning sample – If same results Register on treatment for new case.
Past history of TB Treatment		Repeat on Fresh morning sample – If same results exclude possibility of dead bacilli in case of recent history of TB by careful history and clinical evaluation. Register on treatment for new case. send sample for phenotypic DST.
Report-3: MTB not detected		
Irrespective of previous history of TB treatment	MTB not detected, TB not excluded but unlikely	Consider repeat Xpert testing if TB is highly suspected OR call for follow up after 2 weeks if symptoms persist and repeat clinical assessment.
Report-4: MTB not detected in AFB smear positive specimen		
Irrespective of Previous history of TB treatment	Possibility of Mycobacteria other than TB	Repeat AFB smear microscopy and Xpert/MTB Rif-assay – If same result- refer patient for management of MOTT

*Rifampicin resistance detected in patients not at risk of drug resistance should be repeated on fresh sample in same laboratory/ Xpert sites. This practice will help to exclude any possibility of administrative error in identification of sample or reporting before referring patients for treatment of RR-TB. Confirmation of RR report before referral will help avoid unnecessary inconvenience to patients of going to DRTB treatment site and delay in first line TB treatment in case of any error.

c) **Culture and Species Identification**

Mycobacterial culture and identification of M. tuberculosis provide a definitive diagnosis of TB and is currently considered reference gold standard for diagnosis. Solid (Lowenstein Jensen and Agar) and Liquid media are used for culture. Detection limit of Liquid Culture is 10 bacilli/ml. Liquid culture increases the case yield by 10% over solid media, and automated systems reduce the diagnostic delay to days rather than weeks. Liquid systems are, however,

more prone to contamination and the manipulation of large volumes of infectious material mandates appropriate and adequate biosafety measures. The main limitation of culture as diagnostic tool in routine practice is slow growth of bacilli with long reporting time (1-2 weeks on liquid and 4-8 weeks on solid culture media). Furthermore, culture services demands technically complex infrastructure, expertise and resources, therefore use of culture as initial diagnostic test for diagnosis in routine programme condition is not recommended not feasible therefore not recommended .

However, culture services are essential for programmatic management of drug resistant TB as culture provides the necessary isolates for identification and drug susceptibility testing and is also used for monitoring treatment response of drug resistant TB patient.

Coverage of culture services

National TB Control Programme has established 22 culture laboratories across country and 7 of these laboratories have DST capacity. The DST laboratories are located in national/ provincial reference laboratories and have both liquid and solid culture facilities, whereas other 15 laboratories are equipped with solid culture facilities only.

Culture-based (phenotypic) drug susceptibility testing

DST uses critical concentrations of anti-TB medicines to determine the susceptibility or resistance of a M. tuberculosis culture isolates. The critical concentration is defined as the lowest concentration of anti-TB medicines in vitro that will inhibit the growth of 99% of phenotypically wild type strains of M. tuberculosis complex.

Critical concentration are defined for first line drugs(FLD) including Rifampicin, Isonaiazid , ethambutol , streptomycin and Pyrazinamide and second line drugs (SLD) including Ofloxacin , Levofloxacin, Moxifloxacin, Amikacin, Capreomycin, Kenamycin , Clofozamine, lenozolid , Bedaquilline and Delamanid

Molecular (genotypic) drug susceptibility testing

- **Xpert MTB/RIF assay:** As mentioned above Xpert simultaneously detect MTB and Rifampicin resistance in MTB positive specimen. Rifampicin is a good proxy indicator for MDR, and second line treatment is recommended for both RR and MDR patients. All bacteriologically confirmed TB cases should be tested at time of registration for Rifampicin resistance. For patient tested upfront with Xpert, Rifampicin results will be available but those diagnosed on microscopy should be screen for Rifampicin resistance using Xpert MTB/Rif assay.
- **Line Probe Assay:** Commercially available molecular Line Probe Assay (LPAs) have good accuracy when used for either from Clinical specimen (direct) or culture isolates of M. tuberculosis complex (indirect testing) for resistance to anti TB agents. WHO recommends using commercially available molecular line probe assays (LPAs) as the initial test, instead of phenotypic culture-based DST to detect resistance to First (rifampicin and isoniazid) and second line anti-TB agents (fluoroquinolones and second-line injectable agents). Second-line LPA can be used to identify persons eligible for enrolment on the shorter MDR-TB regimen.

d)Other laboratory Test for diagnosis of Tuberculosis

Histopathology

Histological examination can play a role in diagnosis of tuberculosis (caseating granulomas) in the absence of bacteriology examination or negative result. However, histology is non-specific and patient's risk of tuberculosis should be considered to avoid misclassifying non-caseating granulomatous processes due to tuberculosis as sarcoidosis, Crohn's disease, or other granulomatous disease or other way round.

With availability of more sensitive molecular tools, probability of diagnosing paucibacllary TB disease has improved, It is strongly recommended that in all presumptive TB patient with extra pulmonary disease , aspirated /biopsied specimen(collected in normal saline) should be referred for Xpert MTB/Rif assay for definite diagnosis of TB .

Test having no role in the diagnosis of Tuberculosis

- **Serological Test:** Dozens of commercial serological tests for tuberculosis are being marketed in many parts of the world. An updated systematic review was commissioned by WHO to synthesize the evidence on the

diagnostic accuracy of commercial serological tests for pulmonary and extra-pulmonary tuberculosis. Commercial serological tests provide inconsistent and imprecise findings resulting in highly variable values for sensitivity and specificity. It is strongly recommended that these tests should not be used for the diagnosis of pulmonary and extra-pulmonary TB.

- **Other Lab tests:** Blood examination e.g. Hemoglobin, white blood counts and ESR are nonspecific tests. Anemia is more likely to be due to other causes than TB, WBC is usually normal or lower than normal in TB and ESR is usually raised in TB but high ESR is also seen in many other condition and normal result.

e) DIAGNOSIS OF PULMONARY TB (PTB) IN VULNERABLE POPULATION PATIENT LIVING WITH HIV:

Use of Xpert MTB/RIF is recommended as preferred initial diagnostic test rather than conventional microscopy and culture in HIV +ve patients presumptive of having TB.

Xpert MTB/Rif is also recommended as preferred test in other presumptive TB patient with compromised immunity, in seriously ill and hospitalized patients.

f) WHAT ARE THE RECOMMENDATIONS FOR DIAGNOSIS OF PULMONARY TB (PTB) IN PATIENT AT RISK OF DRTB

Xpert MTB/RIF should be used rather than conventional microscopy and culture as the initial diagnostic test in all patients presumed of having DR TB. Following group of patient are considered at risk of drug resistant tuberculosis

- Presumptive /PTB case with history of previous anti TB treatment. All Previously treated cases should be screened for Rifampicin resistant using expert MTB/Rif assay at start of treatment.
- All DR-TB contact should be screened for TB and Rifampicin resistant simultaneously.**KEY MESSAGE ;** Xpert /MTB Rif assay is recommended as preferred tool in Diagnosis of TB in patients at risk of DR TB , HIV+ve , seriously ill and/ or hospitalized and children under 15 yrs . Less then 5 Years

Drug-susceptibility testing (DST) serves three main purposes: first, it can be used to guide the choice of chemotherapy for a patient. Second, it is valuable in confirming that resistance has emerged when a patient has failed to have a satisfactory response to treatment. Third, it can be used for the surveillance of resistance to anti-TB medicines. Two main methods for detection of anti-microbial drug resistance are Conventional culture based methods and new molecular based rapid method.

g) Laboratory test for diagnosis of TB infection

No tool allows direct measurement of M. tuberculosis infection in humans, and the diagnosis of LTBI is based on a positive result by either tuberculin skin test (TST) or interferon gamma release assay (IGRA), indicating an immune response to M. tuberculosis. However, these tests cannot accurately predict the risk of developing active TB disease.

h) Tuberculin Skin Test

TST is based on the detection of delayed-type hypersensitivity to PPD, a mixture of antigens shared by several mycobacteria that gives rise to a skin reaction. TST is not expensive, requires an injection into the skin and adequately trained staff. However, it requires two visits of patient one for injection and second after 48-72 hours for reading of results.

- Interpretation of TST (Annex Montoux Wall Chart):
    - ≥ 5 mm (MOTT)
    - ≥10 mm (mycobacterial infection in non BCG vaccinated persons) &
    - ≥15 (mycobacterial infection in BCG vaccinated) have been recommended

BCG vaccination may cause false-positive results in younger persons.

Tuberculosis Interferon Gamma Release Assays

Research over the past decade has resulted in the development of two commercial interferon gamma release assays (IGRAs), based on the principle that the T-cells of individuals who have acquired TB infection respond to re-stimulation with Mycobacterium tuberculosis-specific antigens by secreting interferon gamma (IFN-γ).

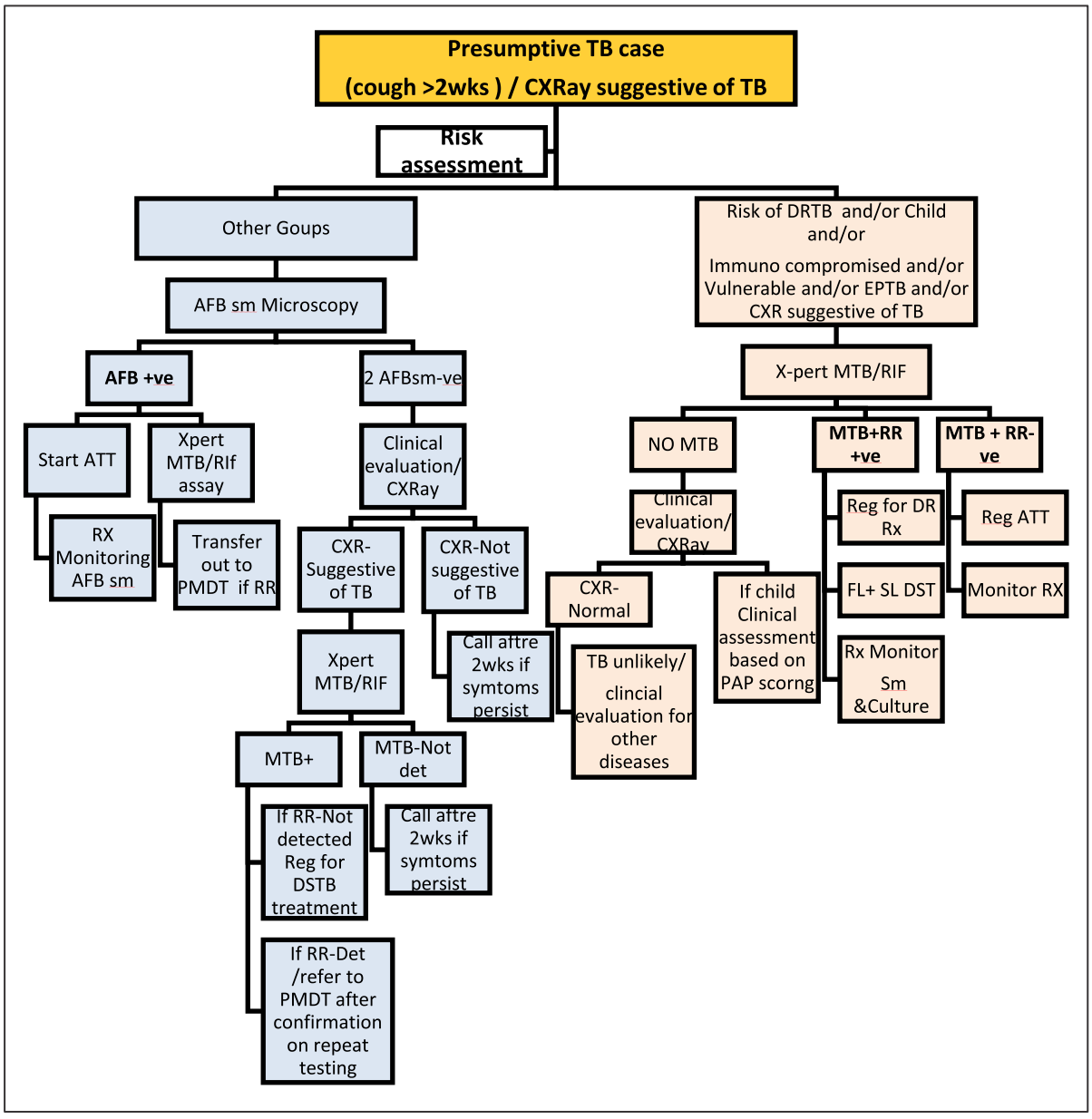
WHO recommends that either a TST or IGRA be used to test for LTBI in both high- and low- TB-burden countries and that active TB disease be ruled out prior to prescribing preventive treatment. There is no strong evidence that one LTBI test should be preferred over the other. The choice will depend on the availability, cost and the health infrastructure.

- **Testing for TB in BCG-Vaccinated People:** Vaccination with BCG may cause a positive reaction to a TB skin test. A positive reaction to a TB skin test may be due to the BCG vaccine itself or due to infection with TB bacteria.

  TB blood tests (IGRAs), unlike the TB skin test, are not affected by prior BCG vaccination and are not expected to give a false-positive result in people who have received BCG. For children under the age of five, the TB skin test is preferred over TB blood tests.

  A positive TB skin test or TB blood test only tells that a person has been infected with TB bacteria. It does not tell whether the person has latent TB infection or has progressed to TB disease. Other tests, such as a chest x-ray and a sample of sputum, are needed to see whether the person has TB disease.

Figure-2: Flow diagram for diagnosis of pulmonary tuberculosis



2.8 Consideration for Diagnosis of Extra-Pulmonary Tuberculosis

a) Diagnosis of tuberculosis meningitis

Depending on the organ involved, diagnosis of extra-pulmonary tuberculosis can only be made based on positive X-pert/MTB. AFB smear or mycobacterium (MTB) culture or cytological/histological finding consistent with tuberculosis (caseating granulomas) and/or clinical/radiological evidence of active extra-pulmonary tuberculosis.

It is recommended that X-pert MTB/RIF should be used in preference to conventional microscopy and culture as the initial diagnostic test in testing cerebrospinal fluid specimens from children (and adults) suspected of having TB meningitis

For CSF specimens, if the sample volume is low, X-pert MTB/RIF should be preferentially used over culture, in order to reach quick diagnosis. If sufficient volume of material is available, concentration methods should be used to increase yield

b) Extra-pulmonary TB at other sites

X-pert MTB/RIF may be used as a replacement test for usual practice (including conventional microscopy, culture, and/or histopathology) for testing of specific non-respiratory specimens (lymph nodes and other tissues) from patient (adults +children) suspected of having extra-pulmonary TB.

- Patient (adults and Children) suspected of having extra-pulmonary TB but with a single X-pert MTB/ RIF-negative result should undergo further diagnostic testing, and those with high clinical suspicion for TB should be treated even if an X-pert MTB/RIF result is negative or if the test is not available.
- Pleural fluid is a suboptimal sample for the bacterial confirmation of pleural TB, using any method. A pleural biopsy is the preferred sample. The sensitivity of X-pert MTB/RIF in pleural fluid is very low. Nevertheless, any positive X-pert MTB/ RIF result based on pleural fluid should be treated for pleural TB, while those with a negative X-pert MTB/RIF result should be followed by other tests.
- These recommendations do not apply to stool, urine or blood, given the lack of data on the utility of X-pert MTB/RIF on theses specimens

c) Other test for diagnosis of Extra-pulmonary specimen

Number of bacilli in EPTB specimen (tissue, biopsy, pus, urine) is much lower compared to sputum, as a result diagnostic yield of AFB smear is also low in extra-pulmonary specimen. However, AFB microscopy should be attempted for diagnosis of TB in clinical specimen in situation where access to more sensitive diagnostic tools is not available.

2.9 Consideration for systematic screening for active Tuberculosis

The primary objective of screening for active TB is to ensure that active TB is detected early and treatment is initiated promptly, with the ultimate aim of reducing the risk of poor treatment outcomes, health sequelae and the adverse social and economic consequences of TB, as well as helping to reduce TB transmission.

However, while the systematic reviews show that there is some evidence that screening can improve the early detection of TB, the direct evidence remains weak for the impact of screening on health outcomes and TB transmission when compared with passive case-finding alone. Furthermore, data are lacking on the cost effectiveness of screening compared with other interventions to improve early detection, and it is clear that indiscriminate screening can requires a lot of resources and is therefore NOT recommended . Decisions on when and how to screen for active TB, which risk groups to prioritize and which algorithm to be use for screening and diagnosis would depend on the epidemiological situation, the capacity of the health system, and the availability of resources.

Key principles for systematic screening for active TB

The following key principles should be considered when planning a TB screening initiative:

1. Before screening is initiated, high-quality TB diagnosis, treatment, care, management and support for patients should be in place, and there should be the capacity to scale these up further to match the anticipated rise in case detection that may occur as a result of screening.

2. Indiscriminate mass screening should be avoided. The prioritization of risk groups for screening should be based on assessments made for each risk group.
3. The choice of algorithm for screening and diagnosis should be based on an assessment of the accuracy of the algorithm for each risk group considered, as well as the availability, feasibility and cost of the tests.
4. TB screening should follow established ethical principles for screening for infectious diseases, observe human rights, and be designed to minimize the risk of discomfort, pain, stigma and discrimination.
5. The TB screening approach should be developed and implemented in a way that optimizes synergies with the delivery of other health services and social services.
6. A screening strategy should be monitored and reassessed continually to inform re-prioritization of risk groups, re-adaptation of screening approaches when necessary and discontinuation of screening at an appropriate time.

Recommendations on risk groups to screen

Seven recommendations on prioritizing risk groups for screening have been developed including three strong and four conditional recommendation.

Three strong recommendation is one for which the desirable effects of adhering to the recommendation are judged to clearly outweigh the undesirable effects and for which screening is judged feasible, acceptable and affordable in all setting and include:

1. Household and other close contacts of TB patients
2. people living with HIV at each visit to health facility
3. Current and former workers in workplaces with silica exposure.

A conditional recommendation is one for which the desirable effects of adhering to the recommendation probably outweigh the undesirable effects and includes

4. prisons and other penitentiary institutions
5. people with an untreated fibrotic chest X-ray lesion
6. People who are seeking health care or who are in health care and who belong to selected risk groups (underweight, old age, diabetics, COPD)
7. subpopulations that have very poor access to health care, such as people living in urban slums, homeless people, people living in remote areas with poor access to health care, and other vulnerable or marginalized groups including some indigenous populations, migrants and refugees.

Algorithms for screening and diagnosis

The algorithms have different costs, and requirements in terms of human resources and health systems. The choice of algorithm for screening and diagnosis depends on the risk group, the prevalence of TB, the availability of resources and feasibility.

Subject to availability of resources, different screening options can be used:

a) Symptoms screening (cough >2 weeks, or cough of any duration with haemoptysis, weight loss, fever or night sweats).
b) Chest X-Ray screening.

If symptom screening is used initially, then chest radiography can be used as a second option to improve the pretest probability of the subsequent diagnostic test, and to reduce the number of people who need to undergo further diagnostic evaluation.

Symptomatic screening for active tuberculosis in contact of TB patients

Contacts of tuberculosis patients are at high risk of infection and of developing tuberculosis, justifying active case detection in these individuals. It is recommended that contact investigation be conducted for house hold and close contacts when

Index case is

- Sputum smear-positive pulmonary TB, (better to screen contacts of all TB cases to increase contact group)
- Multi-drug-resistant TB (MDR-TB or extremely-resistant TB (XDR-TB)
- PLHIV or
- Child < 5 years of age

Contact has/is

- Symptoms suggestive of TB (all ages)
- Child < 5 years of age,
- Known or suspected immune-compromising conditions (especially PLHIV)
- Contacts of MDR-TB or XDR-TB

2.10 USE OF X-RAY CHEST IN SUPPORTING THE DIAGNOSIS OF TUBERCULOSIS:

Chest radiography, or chest X-ray (CXR), is an important tool for;

i. For the clinical management of a person seeking healthcare for one or several unexplained complaints or concerns

ii. For mass screening in the community /special setting for active TB case finding.

iii. For Clinical diagnosis of TB in bacteriologically negative TB cases as well as diagnosis non-TB chest diseases

CXR, is a good screening tool for pulmonary TB because of its high sensitivity (87% to 98%) meaning that up to 98% of those with culture-positive TB have an abnormal CXR. However, CXR has low specificity in an active case-finding situation (46% to 89%, depending on how it is read), meaning that a significant proportion of individuals without TB will have an abnormal test result. This is due, in part, to the fact that CXR identifies many types of lung abnormalities, whether due to TB or to other lung conditions. However CXR screening will filter out patients having high probability of suffering from TB and thus will reduce the cost on number tests required to detect a bacteriologically confirmed TB case.

All patient having abnormal CXR suggestive of TB should be investigated with a bacteriological confirmatory test that has high sensitivity and specificity for TB. Diagnosis of PTB based on CXR and clinical criteria alone in patient who screen positive by CXR but are negative by bacteriological tests need to be carefully evaluated and these should not constitute more than a very small fraction of all notified PTB cases.

From the perspective of the person being screened, CXR is a valuable tool because it provides rapid screening results for a range of medical conditions and not a TB-specific tool. It can be used to improve care for patients with respiratory diseases.

Technology

Two types of technology are used for CXR: analogue (that is, a system using film) or digital. It is important to highlight that both of these technologies employ the same principle of X-ray production; the difference is the method of recording the result. In conventional systems, the result is recorded and displayed on an X-ray film but in digital systems, the result is recorded on a detector and displayed in a digital format on a computer screen (and it can also be printed on X-ray film or paper or sent to a digital device).

Digital systems have several advantages over conventional systems. They reduce procedure time, have very low running costs (particularly when a hard copy image is not needed), save on staff requirements because the system is more user-friendly, produce superior image quality, give a lower radiation dose, allow for easier archiving and are more environmentally friendly. Moreover, they allow for telemedicine solutions and can be used for computer-aided reading.

Computer-aided detection of TB (CAD4TB)

New technologies for analysing the results of CXR evaluations are being developed, including computer aided detection (CAD) software that can analyse digital CXR images for abnormalities and the likelihood of TB being present. An abnormality score ranging from 0 to 100, with higher scores indicating greater likelihood of TB (>70). A threshold score is the abnormality score below which TB is considered ruled out. Currently, a score below 70 is not considered as TB presumptive. Such technology could help reduce inter reader variability and delays in reading radiographs when skilled personnel are scarce.

X-rays in Childhood TB:

Chest X-ray has an important diagnostic value in childhood TB. In the majority of cases, children with pulmonary TB have chest X-ray changes suggestive of TB. Good quality X-ray is essential for proper evaluation. Chest radiographs with typical changes suggestive of tuberculosis should always be considered in conjunction with the proof of infection and symptoms of tuberculosis to make the diagnosis. This is because no radiographic pattern is absolutely diagnostic of tuberculosis. The ability to identify these findings on chest X-ray is highly dependent on the experience of the medical officer reading them. The most frequent abnormal finding is enlarged unilateral mediastinal lymph nodes often accompanied by shadowing in the lung field. A normal chest X-ray can occur even in the presence of a positive sputum smear or culture. This is because endobronchial disease either from an ulcerated area in a bronchus, or a gland eroding into a major bronchus may discharge caseous materials into an airway.

Pulmonary tuberculosis is a disease that may run a long and uneven course, and relapses and remissions may interrupt the process of healing. The variations in the clinical course may be reflected in the X-ray appearances. During a relapse, an established lesion may break down and cavitate, leading to a spread of the disease, or fresh areas of infiltration may appear in previously clear lung. Healing is frequently accompanied by fibrosis.

Course of major X-ray signs developed during TB:

The changes in the lung and in the lymph nodes are together known as the “primary complex”. From that time the result depends upon the power of the child to resist the multiplication of the bacilli and limit the amount of caseation. When resistance is poor as in young or malnourished children the primary focus may increase in size. It may leak in the pleural space and it may open into a small bronchus and the caseous material is discharged by coughing. During this process there may be a stage when air can enter the small cavity when the patient is breathing in but cannot escape when he is breathing out. The result is the formation of a small thin-walled cavity. This process can spread infection to other parts of the lungs. Spread may also occur by the erosion of the tuberculous nodes through the bronchial wall. Caseous material and TB from the nodes may then spread through the bronchi to other parts of the lung.

Bacilli from the primary focus reach the lymph nodes by direct drainage. These nodes lie near to the air passages (bronchi). Both the nodes and the air passages get larger towards the centre (root) of the lung. The bacilli in the nodes cause a change which is the same as that in the focus in the lung and the node becomes larger and may soften. In very young child the nodes can press upon and narrow the soft air passages and cause collapse of that part of the lung. In the older child a node can break through the wall of the bronchus. When that happens the soft contents of the node can leak into the air passage and as the child breathes in the material containing bacilli can be drawn further into the lung. So the disease is spread.

X-ray suggestive of TB:

There are different signs observed in X-rays of children that could help making a diagnosis. However so far there is no single sign on X-ray that could provide a confirmatory diagnosis.

Signs that could be suggestive of TB includes;

- Miliary mottling: Mainly seen in cases who have disseminated TB
- Enlargement of lymph nodes: Usually the enlargement include enlargement of hilar, mediastinal, or subcarinal lymphnodes and lung parenchymal changes (atelactasis, consolidation, effusion).
- Pleural effusion
- Cavitation
- Parenchymalinfiltrates
- Calcification

The non-specific signs includes;

- Ill-defined opacity/infiltrate
- Marked broncho-vascular marking

Identifying radiological signs of TB:

Full size chest radiograph must be taken. If possible, a lateral chest radiograph should also be taken, as this increases the diagnostic yield in childhood TB. It is important to appreciate what does a normal chest X-ray looks like and what steps are involved in examining a chest X-ray.

Checklist to Examine a Chest X-ray in relation with Tuberculosis:

1. Review bone , soft tissue and the heart shadow structure in the X-ray
2. Review mediastinum:
   - A. overall size and shape
   - B. trachea: position
   - C. margins
3. Review lungs and pleura:
   - A. Compare lung sizes
   - B. Evaluate pulmonary vascular pattern: compare upper to lower lobe, right to left, normal tapering to periphery
   - C. Review hila:
   - i. normal relationships
   - ii. size
   - iii. shape

D. Pulmonary parenchyma

E. Pleural surfaces

- a. fissures - major and minor - if seen
- b. follow pleura around rib cage

1. Location:

In majority of cases, pulmonary tuberculosis manifests itself by presenting radiological signs limited to the upper zones. Chest X- ray can be divided into three radiological zones.

a) Upper zone i.e up to lower margin of 2nd rib

b) Mid zone i.e from lower margin of 2nd rib to lower margin of 4th rib

c) Lower zone i.e from 4th rib to diaphragm

2. Infiltrates:

Infiltrates found in tuberculosis can be divided into three types.

a) Mottling is the commonest type with the individual shadows being from 1-5 mm in diameter. The outline of the shadows is initially rather hazy and indistinct, later becoming harder. These shadows tend to remain single and distinct even when the disease is spreading.

b) Less commonly, consolidation may present as isolated larger opacities, roughly circular in shape and 0.5- 2 cm in diameter. The outline is also dim and soft. They may be more than one, but they are never as numerous as the smaller infiltration.

c) Occasionally the lesion may appear as larger area of homogeneous consolidation. They may involve a smaller segment to an entire lobe. This can be confused with the other chest conditions, and the only clue to the diagnosis, apart from its location, may be the presence of a little infiltration in the adjacent lung, or in the opposite mid zone.

3. Lung damage and fibrosis:

The pulmonary tuberculosis often causes destruction of lung tissues, this heals by fibrosis, and in most cases the shadows of infiltration are combined with the evidence of fibrosis. The actual strands of fibrous tissue cannot usually be distinguished from the normal vascular markings and the diagnosis 'fibrosis' can only be made when the shrinking caused by the fibrous tissue produces an alternation in the position of the normal landmarks. In many cases of pulmonary tuberculosis a part or the whole, of a lung may become partially or completely collapsed

4. Cavitation:

Cavitation is very common in pulmonary tuberculosis and is one of the hallmarks of the disease. It usually indicates active disease, and a cavity is frequently the source of tuberculous bacilli. There are two types of cavities.

a) A cavity may appear as a translucent area within the consolidation. These cavities usually occur in the active phase of the disease. The inner margins of the cavity may be rough and irregular, sometimes showing projections into the lumen from the wall. There may be a fluid level.

b) The wall of the cavity is usually of fairly even thickness. The lung around tuberculous cavities almost invariably shows evidence of some infiltration and fibrosis. An isolated cavity in an otherwise normal lung should never be considered tuberculous without strong supportive evidence.

5. Calcification:

Tuberculous lesions often caseate, and as they heal, many of them calcify. The calcium is usually laid down in the center of the healing lesion. The calcified foci are irregular in size and shape, and are often grouped together in clusters. Calcification of a tuberculous focus always implies some degree of healing, though it is seldom safe to assume that the disease is healed beyond the possibility of reactivation.

6. Pleural Effusion:

The diagnosis of TB pleural effusion is made by combining the clinical and radiological pictures. The diagnosis can be further substantiated by doing a diagnostic tap of the effusion. TB pleural effusion is characterized by the predominance of lymphocytes in the fluid. In younger children, the effusion is usually part of complicated lung disease. In nearly all cases the TB effusion clears up rapidly on treatment. After three to four weeks of treatment, the pleural effusion will have cleared, with only slight pleural thickening still present.

Tuberculosis can also present with many other radiological features. However distinguishing them from patients with other pulmonary conditions showing similar X-ray changes will require an expert opinion.

2.11 SUMMARY POINTS

- Any patient with a cough for more than 2 weeks is a presumptive TB case (PTC) and must submit a sputum specimen for examination
- Risk assessment of PTC is an important step
- Page 1 of the desk guide deals with the management of a patient who presents with a cough
- Many people who are identified as PTCs may not actually have TB.
- Sputum examination is the most specific, cost effective and reliable test for diagnosis of pulmonary TB.
- Two sputum specimens must always be collected for sputum examination (spot, morning sputum).
- Good quality sputum specimen (not saliva!) is required in order to increase the likelihood of TB bacilli being identified.
- Many patients with TB will be diagnosed on the basis of sputum examination.

SESSION 3

CLASSIFYING, PRESCRIBING AND REGISTERING A CASE OF TUBERCULOSIS

3.1 SESSION OBJECTIVES

At the end of the session, the participants will be able to:

- Classify the disease into pulmonary and extra-pulmonary tuberculosis
- TB Case Definitions and Types
- How to prescribe TB treatment correctly acc. to the type of patient.
- Fill in the TB01 Card.
- Fill in the patient card (TB02)
- Know the content and purposes of the TB register (TB03).
- Fill in the first part of the TB register (TB03)
- Identify & record the source of referral on TB01 card

Basics about TB disease

Causative organism and mode of spread

Tuberculosis (TB) is caused by a bacterium called Mycobacterium tuberculosis. TB bacteria are spread through the air from one person to another. Tuberculosis is a highly contagious infection, transmitted to other healthy persons by infected droplets generated by coughing or sneezing of patient having active pulmonary Tuberculosis disease. These tiny droplets dry rapidly, attach themselves to fine dust particles and the smallest of them may remain suspended in the air for several hours. Only those particles that are less than 10 µm (micron) in diameter reach the pulmonary alveoli of the healthy individual through inhalation resulting in infection. While not everyone exposed to the bacterium becomes infected nor does everybody infected with it develop clinical symptoms. The chance of becoming infected depends mainly on the quantity of infectious droplets in the air, and the length of exposure to an infectious person. The closer the infectious person is, and the longer the length of exposure, the higher the risk is of being infected.

When a person breathes in TB bacteria, the bacteria can settle in the lungs and begin to grow. Tuberculosis spreads from the primary lung lesion to other parts of the body via the blood stream, lymphatic or by direct extension, and in this way may affect any organ in the body. TB is thus classified as pulmonary (Lungs parenchyma) and extra-pulmonary on the basis of anatomical site involved.

TB disease in the lungs or throat can be infectious. This means that the bacteria can be spread to other people. TB in other parts of the body, such as the kidney or spine, is usually not infectious. People with TB disease are most likely to spread it to people they spend time with every day. This includes family members, friends, and co-workers or schoolmates. TB is NOT spread by shaking someone's hand, sharing food or drink, touching bed linens or toilet seats, sharing toothbrushes or kissing.

3.2 Latent TB Infection and TB disease

LTBI is a state of persistent immune response to stimulation by M. tuberculosis antigens with no evidence of active TB. The majority of infected people have no signs and symptoms of TB but are at risk of developing active TB and may become infectious. On average, 5 to 10% of those who are TB-infected will have active TB over the course of their lives, usually within the first five years after infection. The risk of occurrence of active TB depends on several factors, the most important being the immunological status of individuals.

TB Disease: TB bacteria become active if the immune system cannot stop them from growing. When TB bacteria are actively multiplying in the body, this is called TB disease. People with TB disease are sick. They may also be able to spread the bacteria to people they spend time with every day.

Many people who have latent TB infection never develop TB disease. Some people develop TB disease soon after becoming infected (within weeks) before their immune system can fight the TB bacteria. Other people may get sick years later when their immune system becomes weak for another reason.

For people whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is much higher than for people with normal immune systems.

3.3 Signs and Symptoms

The symptoms of TB vary depending on which part of the body is affected. TB disease usually develops slowly; symptoms might not begin until months or even years after the initial infection.

Pulmonary Tuberculosis

TB bacteria usually grow in the lungs (pulmonary TB). TB disease in the lungs may cause symptoms such as:

- cough more than two or more weeks, or of any duration with following symptoms
- pain in the chest
- coughing up blood or sputum (phlegm from deep inside the lungs) Other symptoms of TB disease are:
- weakness or fatigue
- weight loss
- reduced appetite
- chills
- fever
- sweating at night

Extra Pulmonary Tuberculosis

Symptoms of TB disease in other parts of the body depend on the area affected. Following are the main forms of extra- pulmonary TB are listed below with symptoms:

Table-6: Extra Pulmonary Tuberculosis

	EPTB Disease SITE	Specific symptoms
1	Lymph nodes-Extra-thoracic	Swelling, matted occasionally with pus drainage
2	Lymph node –Intra thoracic	Broadening of mediastinum, hilar shadows
3	Central Nervous system	In case of TB meningitis- headache, fever, neck stiffness and mental confusion
4	Osteo articular – Spine	Loss of function in lower limbs when there is gibbous and spinal involvement
5	Osteo articular – Other than Spine	Pain and swelling when joints are involved
6	Peritoneal/Intra-abdominal	Intestinal TB include abdominal pain, anemia. Patients may present with symptoms of obstruction, right iliac fossa pain, or mass in the right iliac fossa
7	Pleural	Pleural effusion (dry cough, shortness of breath, heaviness on the effected side)
8	Other	Infertility in case of reproductive tract. Symptoms of urinary tract infection in case of genito-urinary involvement
9	Miliary /Multiple	Miliary tuberculosis (TB) is the widespread dissemination of Mycobacterium tuberculosis via haematogenous spread, seeding of TB bacilli in the lung, as evidenced on chest radiography.

Asymptomatic TB Cases

The TB patients may present with atypical symptoms, which makes diagnosis difficult. It has also been reported in disease prevalence survey in which all patients undergo both symptom and X-ray screening that significant number of bacteriological confirmed TB cases had not complaint of any symptoms and were investigated based on abnormalities on X-ray. In view of the evidences from prevalence surveys (4), mass X-Ray screening is now being used in high risk target population for identification of presumptive TB cases among asymptomatic (4,15). It is important to mention that indiscriminate X-Ray screening is not recommended.

TB Risk factors

Some people develop TB disease soon after becoming infected (within weeks) before their immune system can fight the TB bacteria. Other people may get sick years later, when their immune system becomes weak for another reason.

For persons whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is much higher than for persons with normal immune systems. Generally, persons at high risk for developing TB disease fall into two categories:

(1) Persons who have been recently infected with TB bacteria includes:

- Close contacts of a person with infectious TB disease
- Children less than 5 years of age who have a positive tuberculin test
- Groups with high rates of TB transmission, such as homeless persons, injection drug users, and persons with HIV infection
- Persons who work or reside with people who are at high risk for TB in facilities or institutions such as hospitals, homeless shelters, correctional facilities, nursing homes, and residential homes for those with HIV.

(2) Persons with medical conditions that weaken the Immune System: Babies and young children often have weak immune systems. Other people can have weak immune systems, too, especially people with any of these conditions:

- HIV infection (the virus that causes AIDS)
- Substance abuse
- Silicosis
- Diabetes mellitus
- Severe kidney disease
- Low body weight
- Organ transplants
- Head and neck cancer
- Medical treatments such as corticosteroids or organ transplant
- Specialized treatment for rheumatoid arthritis or Crohn's disease

3.2 TB case definitions

Presumptive TB refers to a patient who presents with symptoms or signs suggestive of TB and/ or abnormal chest x-rays suggestive of TB.

Note: *The asymptomatic people with high risk of developing TB on the basis of their living conditions & other comorbidities should be included & tested for TB Case definitions*

Bacteriologically confirmed TB case (B+) is one from whom a biological specimen (sputum, pleural fluid, peritoneal fluid, pus, cerebrospinal fluid etc.) is positive at smear microscopy, culture or WHO approved rapid diagnostic (WRD) such as X-pert MTB/RIF.

Table-7: TB Case definition based on AFB smear and Xpert results

AFB smear results	Xpert MTB/RIF results	**Case definition**	**Remarks**
Positive	Not done	B+TB Rifampicin status not known	**Fresh sample for Xpert**
Positive	MTB+/ RR-Not Detected	B+TB Rifampicin resistance not detected	**Drug susceptible TB**
Negative	MTB+/ RR-Not Detected		
NOT done	MTB+/ RR-Not Detected		
Positive	MTB+/ RR- Detected	B+ TB Rifampicin resistant (RR) detected	**RR-TB cases Register in local health facility TB register and then transfer out to PMDT**
Negative	MTB+/ RR-Not Detected		
NOT done	MTB+/ RR-Not Detected		
Positive	MTB+/ RR- Indeterminate	B+ TB Rifampicin status not know	**Repeat Xpert test if same results consider ref sample for DST**
Negative	MTB+/ RR- Indeterminate		
NOT done	MTB+/ RR- Indeterminate		

Note: *All such cases should be notified, regardless of whether TB treatment has started.*

Clinically diagnosed TB case is one who does not have bacteriological confirmation but has been diagnosed with active TB by a clinician. This definition includes TB cases diagnosed on the basis of radiological (X-ray, CT-Scan, MRI. Ultra-sound scan) abnormalities or suggestive histology without laboratory confirmation. Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified and notified as bacteriologically confirmed TB case.

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.

Extra-pulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs.

New TB case: The patients who have never been treated for TB or have taken anti-TB drugs for less than 1 month.

Previously treated TB case: TB patients who have received 1 month or more of anti-TB drugs in the past. Previously treated cases are further classified by the outcome of their most recent course of treatment as follows:

- **Relapse -**TB patients who were previously treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment. Relapse may either be due to reinfection or reactivation of dormant bacilli.
- **Treatment after failure**- TB patients who were previously treated for TB and treatment failed at the end of their most recent course of treatment.
- **Treatment after loss to follow-up** - TB patients who were previously treated for TB and but interrupted treatment and were declared lost to follow-up at the end of their most recent course of treatment. (These were previously known as treatment after default patients.)
- **Other previously treated** - TB patients who were previously treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.
- **Patients with unknown previous TB treatment history** do not fit into any of the categories listed above (these patients will be treated as New cases).

Incident TB cases: New, Relapse & patients with Unknown previously treatment history are counted as incident TB cases.

Index case (index patient): The initially identified case of new or previously treated TB of any age in a specific household or other comparable setting in which others may have been exposed

Contact: Any person who has been exposed to an index case (as defined above)

Household contact: A person who shares the same living space for one or more nights or for frequent or extended periods during the day with the index case during the past 3 months before commencement of the current treatment episode (once effective treatment is started; index case is less likely to transmit infection to contacts)

Close contact: A person who is not in the household but shared a space, such as a social gathering place, workplace or facility, for extended periods during the day with the index case during the past 3 months before commencement of the current treatment episode.

TB case finding approaches

In Pakistan, based on population estimates of 197 Million and TB incidence rate of 267/100K population, 525,000 new TB cases were developed in 2017 and 369,897 (68%)TB cases were notified. This accounts for more than 157,000 TB cases missed to notification during year 2017 in Pakistan.

In 2017, 6th population and housing census was conducted in Pakistan, and based on the census results estimated country's population was revised upwards to 207 M. Increase in Population estimates means increase in estimated TB disease burden and further widening of gap between estimated and notified cases. Concerted efforts are needed to improve TB case finding and diagnosis to meet milestone of treatment coverage of 90% by 2025.

Top priority actions include;

1. Notification of all TB cases treated including those treated outside national surveillance systems through mandatory notification of TB cases.
2. Enhance case finding efforts for diagnosis of TB cases accessing health care in public or private sector but are missed in health system.
3. Active case finding for TB cases in the community.

To achieve the 1st milestone of END TB Strategy by 2020 (reduction in number of TB deaths by 35% compared to 2015, reduction in TB incidence by 20% compared to 2015 & Zero % of TB patients and their households experiencing catastrophic costs due to TB), optimum use of existing interventions, achievement of universal Health coverage (UHC) for essential prevention, treatment and care interventions as well as efforts to address social determinants and consequences of TB will be required. A wider multi-sectoral collaboration is essential through including ministries, civil society, communities and the private sector to reach milestones set in the END TB strategies (12).

To improve tuberculosis control, patient with active TB disease must be diagnosed quickly and treated immediately. TB case finding effort were mostly limited to passive case finding approaches and stagnant TB case notification is seen in the public sector for past several years. It is evident there are undiagnosed cases in the community and there is need to reach community to find missed TB cases in marginalized/high risk population (16). Main difference between passive and active case finding approaches are described below.

Passive Tuberculosis case finding

Relies on sick people seeking health care, examination is recommended for:

- Presumptive TB cases (cough > two weeks or any duration with relevant symptoms) who present themselves at health facilities
- Patient with abnormal shadows on chest X-Ray consistent with Tuberculosis.

Passive approaches, for TB case finding depends on patients to seek care and depends on awareness about TB symptoms, health seeking behavior, access to the TB care facilities, in addition the passive case finding also depends at the knowledge and practices of the health care providers, it is known that many patients with symptoms of TB presenting at health facilities are missed to identification as presumptive and thus not evaluated for TB. Some patients who present with atypical symptoms are also missed to diagnosis of TB. It is important to understand that unidentified TB patient poses greater risk of transmission of disease, higher the duration higher the risk.

Active Tuberculosis case finding

Active case finding is predominantly provider initiated with goal to reduce TB diagnostic delay and reduce TB transmission in the community. Active TB case finding aims to reduce barriers to access TB care due either to lack of awareness or difficulties to access health care.

The Program recommends active case findings among pre-determined target groups

- Household contacts of all bacteriologically confirmed pulmonary TB patients. (In case of CHTB case reverse contact screening to find source TB case)
- Marginalized population e.g. Urban slums

- High vulnerable population prisons and institutes
- Internally displaced population

Different interventions are used for TB case finding in the community e.g. Community workers/ volunteers/LHWs/ are mobilized for TB contact tracing and special chest camps are organized to find TB cases in urban slums, workplaces, hot spots identified by Epi data, and congregate settings. Indiscriminate active case finding in general population is not recommended.

REFER " DECIDE THE TYPE OF PULMONARY TB" IN DESK GUIDE & DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD

Objective of treatment

Treatment of tuberculosis is focused on both curing the individual patient and minimizing the transmission of Mycobacterium tuberculosis to other persons, thus, successful treatment of tuberculosis has benefits both for the individual patient and the community in which the patient resides.

The objectives of tuberculosis therapy are

1. to rapidly reduce the number of actively growing bacilli in the patient, thereby decreasing severity of the disease, halting transmission of M. tuberculosis & preventing death;
2. to eradicate populations of persisting bacilli in order to achieve durable cure (prevent relapse) after completion of therapy; and
3. to prevent acquisition of drug resistance during therapy.

It is very important that people who have TB disease are treated, finish the medicine, and take the drugs exactly as prescribed. If they stop taking the drugs too soon, they can become sick again; if they do not take the drugs correctly, the TB bacteria that are still alive may become resistant to those drugs. TB that is resistant to drugs is harder and more expensive to treat.

Following is the responsibility of provincial /district health management:

- **Universal DST:** All bacteriologically confirmed should be universally tested for rifampicin susceptibility before /at start of treatment. Bacteriologically confirmed TB patient diagnosed on Xpert will simultaneously have Rifampicin results. If patients are diagnosed on AFB microscopy the specimen should be referred for Xpert testing for Rifampicin susceptibility. Rifampicin testing at start of treatment ensure that patients is prescribed effective treatment.
- **Uninterrupted availability of TB drugs:** It is the responsibility of the health facilities registering TB case to ensure uninterrupted availability of free of cost quality assured ATT drugs for complete course of TB treatment for every TB patient.
- **Quality assurance of anti TB drugs:** The quality of anti-Tuberculosis drugs should be ensured through regular and random testing of batches of drugs after procurement during entire shelf life of drugs when drugs are stored in province, district and local health facility stores.
- **Use of First line TB drugs for other disease:** The use of Rifampicin, for diseases other than mycobacterial diseases, should be restricted or limited to very carefully considered indications.

First Line TB Drugs and treatment regimens

The four essential first line anti-TB drugs (FLD) used in the treatment of Tuberculosis are; Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E). First line drugs are prescribed for treatment of drug susceptible TB (DSTB) case. Standard First line treatment regimen is not effective for treatment of RR and MDR cases and results in unfavorable treatment outcomes. It is therefore important that DST using WHO-recommended rapid tests should be performed for all TB patients prior to starting therapy, including new patients and patients who require treatment.

Prescribing standardized drug regimen for drug susceptible TB is the responsibility of the clinician at the TB care facility. All patients with RR should be registered in TB register and referred/ transferred out to DRTB treatment site for second line treatment.

General guidance for TB treatment

- **Combination antimicrobial therapy:** Large bacterial populations contain a small proportion of naturally resistant mutant (10-6 to 10-8) that are resistant to any particular anti-TB drug. When bacterial population is exposed to 1 or 2 drugs, the sensitive bacteria are killed; but resistant mutant bacteria survive, which subsequently multiply and replace the susceptible bacterial population leading to drug resistance. However, when bacterial population is exposed to combination four anti TB drugs the majority of bacterial population including mutant bacilli is killed.

Thus, TB patients are given combination of four drug during initial phase for initial two months and subsequently, are treated with 2-3 drugs phase, during the continuation phase.

- **Fixed dose combination (FDC) drugs:** Evidence has shown that FDCs are non-inferior and as effective as separate formulations of anti-TB agents in terms of treatment failure, death, and treatment adherence and adverse. The standardized fixed dose combination (FDC) treatment of TB is recommended to avoid under treatment, acquired drug resistance, side effect of over-treatment and to maximize cost-effective use of resources. The Fixed dose combination also have other advantages over individualized prescription of drugs e.g. it reduces errors in prescription thereby reducing the risk of development of drug resistance, facilitates estimation & supply of drug requirements. Separate drugs can be prescribed in special conditions. (Refer Chapter-12)
- **Weight based drug dosages:** The tubercle bacilli are killed only when anti TB drugs are given in correct dosages according to body weight to attain appropriate level of bioavailability. Under-dosage leads to drug resistance.
- **Dosing and preferred time for Anti TB drugs intake:** Anti TB medication should be taken in single daily dose in the morning. The absorption of anti-TB drugs is best if taken empty stomach and should be preferred.
- **TB treatment Regimen and duration:** The bacteria grow at different rates and intervals in bacterial population. However, studies have proven that 6months treatment is adequate and there are minimal chances of relapse. TB treatment regimen consists of two phases – the initial and continuation phases.
- **TB treatment prescription coding:** The standard code for anti-TB treatment regimens uses an abbreviation for each anti-TB drug: isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E). The number at the front of each phase represents the duration of that phase in months. Example, 2HRZE: Duration of this phase is 2 months and drug treatment is daily (no subscript numbers after the abbreviations) with isoniazid, rifampicin and pyrazinamide.
- **Patient support and care:** Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment
- **Directly Observed Treatment:** Directly Observed treatment (DOT) is required for entire duration of treatment in both New and Previously treated cases to avoid the risk of drug resistance. DOT should be used for ALL patients with TB disease, including children and adolescents. There is no way to accurately predict whether a patient will adhere to treatment without this assistance.

Treatment regimen for New TB cases

The standard 6-month regimen for drug susceptible TB (2 months of isoniazid, rifampicin, pyrazinamide and ethambutol followed by 4 months of isoniazid and rifampicin, denoted as 2HRZE/4HR) is the recommended regimen 1 for new patients and it showed better outcomes than other regimens using first-line anti-TB agents for treating drug-susceptible TB.

- **Initial Phase:** During the initial phase a combination of four drugs (Isoniazid, Rifampicin, Pyrazinamide and Ethambutol "HRZE") are administered for a period of two months (sixty doses).
- **Continuation phase:** During continuation phase isoniazid and rifampicin (HR) are administered daily for four months.

All New bacteriologically confirmed TB patients should be tested for rifampicin resistance (RR) before/at start of TB treatment. All New TB patients including B+ve/ Rif Sensitive (RS) and clinical diagnosed are enrolled on first line TB treatment (treatment for new case). The treatment is given in two phases, the initial & continuation phase

Treatment regimen for previously treated TB cases

WHO has recently revised and/or updated its guideline with regard to empiric Cat-II treatment (2017), which recommends that the category II regimen should no longer be prescribed and DST should be conducted to inform the choice of treatment regimen.

In TB symptomatic patients with history of previous TB treatment, every effort should be made for the bacteriological confirmation of Tuberculosis especially in those with pulmonary lesions. As all TB patients with history of previous TB treatment are at increased risk of drug resistance, rifampicin testing should be ensured for all previously treated TB cases before start of treatment and first line treatment should be prescribed only if RR is excluded after testing.

TB diagnosis without bacteriological confirmation should be limited to those PTB and EPTB cases in whom collection of specimen is not possible and there is a strong clinical evidence of active TB.

Preferably clinically diagnosed previously treated PTB cases should not be more than 5% of all notified previously treated PTB cases.

Previously treated TB

- All previously treated TB cases B+/Rifampicin susceptible: This group of patient are at higher risk of drug resistance, Fresh specimen from all these patients should be referred for comprehensive DST.
- Regimen: Patient should be started on empiric treatment for previously treated case and treatment adjusted based on DST results (if Poly or mono drug resistance).
- **Initial Phase:** During the initial phase Isoniazid, Rifampicin, Pyrazinamide and Ethambutol, (HRZE) are given for the first two months.
- **Continuation phase:** During the continuation phase, Isoniazid, Rifampicin, and Ethambutol (HR) are administered daily for four months under observation.

Table-8: Patient Category

Sr.	Patient Category	Initial	Continuation
1	New TB case B + & B - (Regimen 1)	2HRZE	4HR
2	Clinically diagnosed previously treated cases	2HRZE	4HR
3	Bacteriologically confirmed previously treated cases with INH resistance (laboratory confirmed) and FQ resistance (laboratory confirmed) or FQ status unknown (Regimen 3)	6HRZE	6HRZE
4	Bacteriologically confirmed previously treated cases with INH resistance and FQ sensitive (laboratory confirmed) (Regimen 3) Enrolled as new patient	6HRZE+ LFx	6HRZE+ LFx

Clinically diagnosed previously treated EPTB patients

Patient should be treated based on disease site and clinical evidence of the disease.

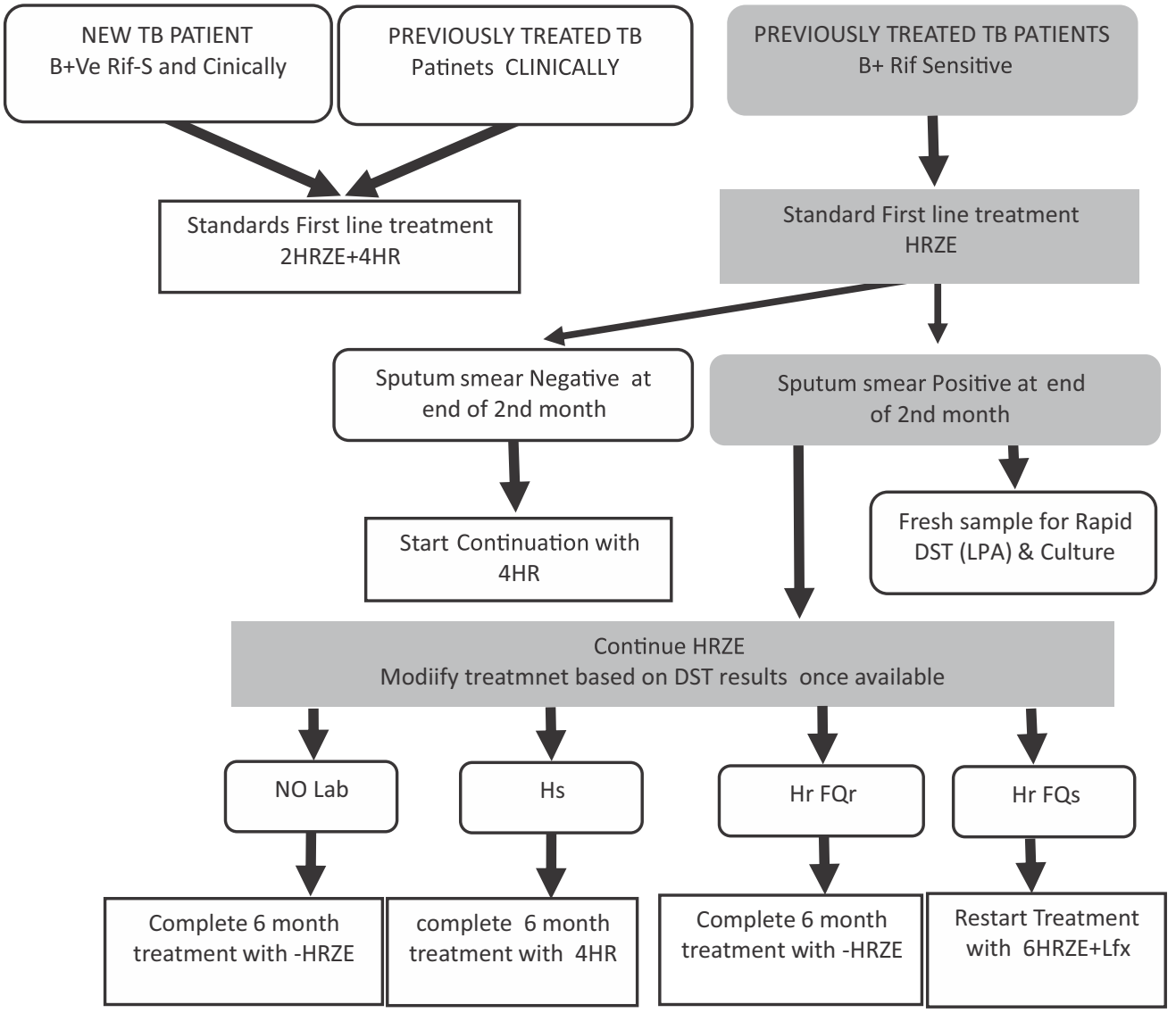
Rifampicin sensitive - Isoniazid resistant TB case:

Patients with Rifampicin sensitive and only INH resistant will be treated with HRZE for six months if resistance to FQ or FQ status unknown

Patients with Rifampicin sensitive and only INH resistant will be treated with HRZE + Levofloxacin for six months if sensitive to FQ

Note: All previously treated TB patients who are clinically diagnosed will be treated as" NEW TB CASE" All TB patients on Rifampicin need administration of drugs under direct supervision

Flow Chart for Treatment Regimen Decision Making RIF. Sensitive TB



Note:

All B+ve should be tested for Rif at start of treatment.

All TB patients B+ Rif -sensitive and clinically diagnosed shall be started on standard First line treatment (Streptomycin will no longer be used).

*Where feasible and easily accesible, refer / send sample for H -DST at start of treatment for patients at higher rislk of H resistance eg. retreatment TB cases aftre failure and lost to follow up and modify treatment once DST results are available.

Send samples for H- DST for all previously treated TB patients who remain/are AFB smear positive at end of 2nd month of treatment.

For all retreatment TB patinets who are /remaon AFB smear positive at the end of two month treatmnet continue treatment with RHZE.

Specmens from all TB patinets who are reported H-resistant should first be tested for FQ resistance.

Patient reported having HrFQs -TB shall be given a full course of treatment with 6HRZE+Lfx.

Tuberculosis Treatment in Adults

Dosage and duration of Treatment:

The dosages & duration of fixed dose combination and individual drugs for each category of treatment are given in the tables below:

Table-9: New cases and previously treated cases regimen and fixed-dose combinations dosages in adults

		Duration	Weight band (kg)/ based FDC drug dose (Tablets)		
			30-39	40-54	55 & >
NEW	**New TB and B+and CD Previously treated TB cases**				
Initial Phase	HRZE (H 75mg + R 150mg + Z 400mg + E 275mg)	2month	2	3	4
Continuation Phase daily	HR (H 75mg + R 150mg)	4month	2	3	4
Clinically diagnosed previously treated cases	HR* (H 150mg + R 300mg)	4month	1	1.5	2
Previously treated TB Cases	**All B+/Rif sensitive Previously treated TB cases**				
Bacteriologically confirmed previously treated cases with INH resistan ce (laboratory confirmed) and FQ resistance (laboratory confirmed) or FQ status unknown					
Initial Phase	HRZE (H 75mg + R 150 mg + Z 400mg + E 275mg)	2 month	2	3	4
Continuation Phase daily	HRZE (H 75mg + R 150mg + Z 400mg + E 275mg)	4month	2	3	4
Bacteriologically confirmed previously treated cases with INH resistance and FQ sensitive (laboratory confirmed)					
		6HRZE+ LFx	2	2	3

*(H = Isoniazid, R = Rifampicin, Z = Pyrazinamide, E= Ethambutol, If HR (H 75mg + R 150mg) is not available, then use HR (H 150mg + R 300mg) + E (E400 mg+ Levofloxacin 250 mgs)

Note: Anti-TB drugs may need to be temporarily suspended or stopped in case of severe drug intolerance or toxicity prolonging treatment beyond the recommended period of 6 months has minimal benefits provided the patient has taken the medication without interruption. Except for situation mentioned below.

Table-10: Duration of treatment in EP TB

Site of EP	Regimen	Total duration
Cervical lymph node & pleural effusion	2 HRZE / 4 HR	6 months
TB meningitis	2 HRZE / 10 HR	12 months
Other forms of EP	2 HRZE / 10 HR	12 months

The use of adjuvant steroids: Is recommended in the treatment of Extra pulmonary TB disease

- In patients with tuberculous meningitis, an initial adjuvant corticosteroid therapy with dexamethasone or prednisolone tapered over 6-8 weeks should be used (Strong recommendation, moderate certainty in the evidence).
- In patients with tuberculous pericarditis, an initial adjuvant corticosteroid therapy may be used (Conditional recommendation, very low certainty in the evidence).

Managing patients who interrupt treatment and Treatment Outcomes

Review the Record of Previous Treatment: Management of patients after treatment interruption is based on review of information about treatment before interruption and current smear results and Xpert results of the patient. Record of the previous treatment (before interruption) is important to know:

- The patient's previous type
- Length of treatment before interruption
- Length of interruption

Table-11: Management of New TB patients with Interrupted Treatment

Length of interruption	Do a smear?	Result of smear	Do Xpert?	Result Xpert	Register again as	Treatment
Length of treatment			<1 month			
<2 weeks	No	-	No	-	-	Continue on same treatment for new case
2-8 weeks	No	-	No	-	-	Start again on treatment for new case
>8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	*Treatment after lost to follow-up	Start on treatment for new case If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR MTB+RR+ MTB ND	*Treatment after lost to follow-up	Start on treatment for new case If RR+ Transfer to PMDT Send for culture & wait for result
Length of treatment			>1 month			
<2 weeks	No	-	No	-	-	Continue on same treatment for new case
2-8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+		Start again on same treatment for new case If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR- MTB+RR+ MTB ND		Start again on same treatment for new case, If RR+ Transfer to PMDT Send for Culture, Send for culture,& wait for result
>8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	*Treatment after lost to follow-up	Start on Previously treated regimen case & send sample for DST If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+ MTB ND	*Treatment after lost to follow-up	Start on Re-treatment regimen & send sample for DST If RR+ Transfer to PMDT Send for culture,& wait for result

Table-12: Management of Previously Treated TB Patients with Interrupted Treatment

Length of interruption	Do a smear?	Result of smear	Do Xpert?	Result Xpert	Treatment
Any length of treatment					
<2 weeks	No	-	No	-	Continue on “Previously treated regimen”
2-8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	Start again treatment at “Previously treated regimen” If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+	Start again treatment for “Previously treated regimen” If RR+ Transfer to PMDT
>8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	Register as Treatment after lost to follow up and start treatment for “Previously treated regimen” and send sample for DST If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+ MTB ND	Register as Treatment after lost to follow up and start treatment for “Previously treated regimen” and send sample for DST If RR+ Transfer to PMDT Send for culture,& wait for result

Chapter-3 B Tuberculosis Treatment in Children

Principles of treatment of TB in children are same as for adults. Children with TB usually respond well with symptomatic improvement during initial phase and good outcome.

Dosages are calculated according to weight (not age) TB drugs are very well tolerated in almost all children and the most important adverse event is hepatotoxicity.

Register all children receiving anti-TB treatment. Weight is important for monitoring treatment response. Treatment outcomes should be reported

Dosage and duration of treatment

The section below has been adapted from the recent WHO childhood TB guidelines 2014. For children above 25Kgs weight adult dosages and preparations can be used

Table-13: Recommended daily dose for 1st line anti-TB drugs for children up to 25 kg

First Anti TB drugs	Dose and range (mg/kg body weight)	Maximum dose (mg)	Remarks
Isoniazid(H)	10 (7-15)*	300	The higher end of the range of isoniazid dose applies to young children; as the children grow older the lower end of the dosing range becomes more appropriate
Rifampicin(R)	15 (10-20)	600	
Pyrazinamide (Z)	35 (30-40)	-	
Ethambutol(E)	20 (15-25)	-	Ethambutol can be safely used at recommended dosages in all ages.

The higher end of the range of isoniazid dose applies to young children; as the children grow older, the lower end of the dosing range becomes more appropriate.

Table-14: Recommended treatment regimens for TB in children

	TB diagnostic type	Anti-TB drug regimens [a]	
		Initial phase	Continuation phase
	Low HIV prevalence (and HIV-negative children) and low isoniazid resistance settings [b]		
PTB	Smear negative pulmonary TB Intrathoracic lymph node TB	2HRZ	4HR
EPTB	Tuberculosis peripheral lymphadenitis		
PTB	Extensive pulmonary disease (define extensive) Smear-positive pulmonary TB	2HRZE**	4HR (months to reconfirm)
EPTB	Severe forms of extra-pulmonary TB (other than tuberculous meningitis/ osteoarticular TB)		
EPTB	Tuberculous meningitis* and osteoarticular TB	2HRZE**	10HR

*The decision on the regimen for a child with tuberculous meningitis should be made by an experienced clinician. It is suggested that the patient be treated in a hospital.

**For children under 5 Kg, Ethambutol usage should be limited to recommendation by the pediatrician under special circumstances. For children over 5 Kg, regular visual acuity and red-green discrimination checks should be arranging and drug should be stopped in case of any change.

Table-15: Weight band table using widely available dispersible FDC

		Duration	Weight Band / Number of Tablets						
			Less than 2 kg	**2-2.9 kg**	**3-3.9 kg**	**4-7.9 kg**	**8-11.9 kg**	**12 - 15.9 kg**	**16 - 24.9 kg**
Initial Phase	HRZ (50/ 75/ 150)	2 month	1/4	1/2	3/4	1 Tab	2 Tab	3	4
	E 100	2 Month	1/4	1/2	3/4	1	2	3	4
Continuation Phase daily	HR (50/ 75)	4 month	1/4	1/2	3/4	1	2	3	4

The use of childhood TB medicines is critical, as there is greater understanding that crushing adult tablets for children may result in incorrect dosages.

See “Definitions and distinctions” section for discussion of WHO definitions of high and low prevalence of HIV and isoniazid resistance.

New Paediatric Fixed Dose Combination Drugs

The need for childhood TB medicines has been critical in recent years as there is greater understanding that crushing adult tablets for children may result in incorrect dosages. This raises question of efficacy of treatment and the subsequent threat of drug resistance. The previously used drug formulation in dispersible FDCs were also not in line with the dosages recommended for childhood cases, with calculations required to estimate the correct dosage.

Accordingly, the new FDC's have been developed to ensure proper dosing of childhood cases. It is important to note that the dosage parameters (by weight) as given in WHO 2014 guidance document remains the same; the formulation of the associated FDCs have been changed. Some information about the new FDCs is given below in Table .

Table-16: New Pediatric Fixed Dose Combination Drugs Profile

Product	· Isoniazid 50 mg, Rifampicin 75mg, Pyrazinamide 150mg (2 months’ initial phase) · Isoniazid 50 mg, Rifampicin 75mg, (4 months continuation phase)
Formulation	· Tablets come in palatable fruit flavors · Tablets are dispersible in 10 seconds, to be mixed in 50 ml of water · Once reconstituted the dispersible should be drunk in 10 minutes
Training needs	· Designed to be easy to use and allow the WHO recommended dose without crushing and chopping · Minimum training needs for providers including parents to administer
Administration	· FDC to be dissolve in 50 ml of water and child should consume the complete fluid within 10 second of dissolving to be taken on an empty stomach.

Pakistan Paediatric Association Scoring Chart

Table-17: Pakistan Paediatric Association Scoring Chart (REVISED 2016)

	1	2	3	4	5
Age	< 5 years				
Close Contact*	TB suggestive	B-ve (Clinically diagnosed TB)	B+ve (Bacteriological positive)		
PEM/SAM**	Yes	Not responding to Nutritional rehabilitation for 02 months			
H/O Measles, Whooping Cough	3-6 months	< 3 months			
HIV		Yes			
Immuno-compromised ***	Yes				
Clinical Manifestation ******		Suggestive		Strongly Suggestive	
Radio Diagnostic imaging *******	Non-specific	Suggestive of TB	Strongly suggestive		
Tuberculin Skin /PPD testing	5-10 mm		> 10mm		
Xpert test					Positive for TB
Granuloma	Non specific				Positive for TB

Table-18: Interpretation

Score	Interpretation	Suggested Actions
0-2	Unlikely TB	- Investigate other reasons of illness
3-4	Possible TB	- Do not treat for TB - Manage the presenting symptom(s) - Monitor monthly the condition(s) for 3 months using scoring chart
5-6	Possible TB	- Investigate and exclude other causes of illness - Investigation may justify therapy - Start ATT if positive on GeneXpert or Granuloma seen
7 or more	Probable TB	- confirm (if possible)

Table-19: Description of Condition to be assessed for diagnosing Childhood TB (Revised PPA Scoring chart 2016)

*** Close contact**	**History of cough** for more than 2 weeks among the house hold of child (score 1), contact tracing is required **B-ve TB patients** among the house holds (score 2), may or may not be receiving/completed anti tuberculous treatment **B+ve TB patient** among the house holds (score 3). May or may not be receiving/completed anti tuberculous treatment
****PEM/SAM**	**(Protein Energy Malnutrition/Severe acute malnutrition)** Use WHO Recommended Z. scoring chart (1) **Not responding** to Nutritional rehabilitation for 02 months (2)
***** Immunocompromised status**	**Malignancies** like leukemia or lymphomas etc. **Immunodeficiency** diseases like agammaglobunemia etc. **Chemotherapy /Immuno- suppressive** therapy such as steroids for more than 2 weeks.
****** Clinical Manifestation**	**Suggestive of TB:** Pulmonary Findings (unilateral wheeze, dullness), weight loss, Hepato- splenomegaly, Lymphadenopathy, ascites etc. **Strongly suggestive of TB:** Matted lymph nodes, abdominal mass or doughy abdomen, sinus formation, gibbous formation, chronic mono arthritis, meningeal findings (bulging fontanel, irritability, choroid tubercle, papilledema)
*******Radio-Diagnostic/ imaging studies includes Chest X-ray, CT Chest/MRI etc.**	Non-specific Ill-defined opacity or patchy infiltrates on chest X-Ray, marked broncho-vacular marking. **Suggestive of TB:** Consolidation not responding to antibiotic therapy, Para -tracheal, or mediastinal lymphadenopathy, **Strongly suggestive:** Miliary Mottling, cavitation, Tuberculoma on CAT scan/MRI brain, collapse vertebrae etc.

· READ "PRESCRIBE DRUG S TO TB PATIENT" IN THE DESKGUIDE

3.5 INTRODUCTION TO TB PATIENT (TB01) CARD:

TB 01 card is filled for every newly diagnosed TB patient. This card contains important administrative and technical details about the patient and his/her treatment and should be kept at BMU. Data from Tb01 card is transferred to the TB register, which forms the basis of program monitoring and quarterly reporting.

The first side of the front side of TB 01 card, which contains mainly the administrative data on the patient and the backside of the TB 01 card are briefly described below. The rest of the TB01 card, which covers a lot of technical details, will be explained in the subsequent sessions.

TB 01: FRONT SIDE

- **Name of BMU:** It is the facility where patient is diagnosed and registration for treatment.
- **TB Care Facility:** It is the facility where treatment is provided to the patient.
- **CNIC #:** Write patient CNIC number with age 18 and above and family CNIC of patient is less than 18.
- **Patient Name:** write the patient's name in full .
- Contact No. Mention phone number of patient or family member in case of female or children case of female or child.
- **TB Registration No.:** Assign TB registration number as per guidelines.
- **Father's/Husband's name:** Write the father's name if patient is either a male or unmarried female. Write the father's/Husband's name if patient is a married female.
- **Sex:** Tick the appropriate box I.e. In case of male patient tick M and in case of female tick F.
- **DoB:** Mention date of birth of patient. (as per CNIC if available)
- **Age:** Write the reported or estimated age of patient. (as per CNIC if available)
- **Date of registration:** Write the date on which the patient is registered and Tb01 card is prepared and treatment is

started e. g 20-05-2017 (Note if patient is "transferred in" , then record the date when he has started the treatment at first facility.

- **Patient Address:** Complete address where the patient is living/residing.
- **Occupation:** Mention occupation of the patient.
- **Name/type of treatment supporter:** Write full name of treatment supporter who will ensure the intake of drug by the patient and tick on type of treatment supporter.
- **Referred by:** Tick the appropriate box. (Self, CW, LHW, etc).
- **Disease Site:** Disease site and type of patient: Put a Tick "√" in the appropriate box to record the disease site (Pulmonary or extra pulmonary). In case of extra pulmonary TB, mention the site of the disease, and evidence of disease and evidence of disease confirmation. Tick the appropriate box for type of patients. (History, X-ray, ultrasound, MRI or other). In case of both, tick both.
- **Recording Smear Results/Xpert results on TB 01 Card:** According to the NTP protocol sputum examination should be held at months: pretreatment 0, and at the end of 2 and 6 months. If sputum is not done due to any reason write ND in these month sputum smear examination result column.
- **Risk Factor:** Tick risk factor from which patient body.
- **TB Treatment-Initial Phase:** Tick on the appropriate treatment regimen as per national guidelines.

The **date** of first Sputum smear examination and **laboratory serial number** is transferred from the TB05 and/or TB04 to TB01 card. The **weight** of the patient and results of **other investigations,** if advised, including X-rays are also recorded in the appropriate columns (e.g. chest X-rays found consistent with active pulmonary tuberculosis can be recorded as "CXR Pos.").

The sputum smear results are recorded in the "**smear**" column of the TB01 card. "NEG" is written under the smear column for negative results, and positive grading is recorded for the positive results i.e. 3+, 2+, 1+ and write exact number of AFBs in case of **(1-9 per 100 HPF).**

In case of pre-treatment examination where two sputum smears are examined, the highest positive grading obtained in any of the smears is recorded on the TB01 card. Write CXR done or not.

Writing Xpert results:

Xpert MTB/Rif test result reported as follows:

"MTB" Colum;	Det = MTB Detected;
	ND = MTB Not Detected
	INV = Invalid/Error/No Result
"RR Colum;	Det = Rifampicin Resistance Detected;
	ND = Rifampicin Resistance Not Detected;
	IND = Rifampicin Resistance Indeterminate

TB 01: BACK SIDE

- **TB Treatment-Continuation Phase:** Tick on appropriate regimen as per guidelines.
- **Treatment outcome:** Click on the appropriate outcome at the end of treatment as per guidelines.
- **Date of appointment for drug collection:** Date when appointment for drug collection is given.
- **Date of appointment for follow up:** Date when patient has to return for follow up smear/Sputum examination.
- **DST results:** Mention the DST result if done. DST can be genotypic (Xpert) and phenotypic (Culture/PSI)
- **Continuation Phase:** Record the number of tablets per dose in the relevant box for adults and children.

- **Contacts Screening:** This section is related to the contact screening. NTP recommend contacts screening of TB cases especially all smear positive TB cases. Under five children and symptomatic adults should be screened for TB by the relevant diagnostic tool and results should be recorded in this section of TB 01. There are columns for name, age, methods of screening, date and result of screening. It is suggested that Registration number for confirmed diagnosed TB cases can be written in remarks column and thus the diagnosed cases by contacts screening can be identified. In case more than eight contacts, separate paper sheet can be stitched to the TB01 card of patient.
- **Comments:** This section on lower part of backside of the TB01 is an important part of the form. The comments related to the following four main areas are recorded in this section:
    - Diagnosis: Any special measure and/or result of a test which has played a role in the diagnosis of the patient and is not recorded elsewhere in TB01. These may include X-ray finding of seriously ill patients, tests at the reference laboratory.
    - Chemotherapy: In case of TB patient this may include the date continuation phase started; comments on side effects of drugs, hyper-sensitivity to drug(s), stopping of Streptomycin at two months etc. The chemotherapy of household contacts, if done, is also recorded.
    - Follow-up: This may include comments on retrieval action taken, if any.
    - Others: Any other important event related to treatment and/or its outcome can also be recorded.

We will now move on to recording the sputum smear results, classification and type of disease on the front side of the TB01 card.

National TB Control Program Pakistan

Tuberculosis Treatment Facility Card — TB-01 (Front Side)

BMU name _____

TB Care Facility name : _____

Patient name : _____

Father / Husband Name: _____

SEX M ☐ F ☐ **DOB** **Age**

Date of Registration ☐☐/☐☐/☐☐☐☐

Patient Address _____

Occupation _____ Contact No _____

Treatment Supporter Name _____

TREATMENT SUPPORTER TYPE / CONTACT NUMBER			
Family	Community	LHW	Cell number

PATIENT IS REFERRED BY					
Self	CW	LHW	PB- HF	PVT-HF	Other

CW; community worker, LHW; lady health worker, PB-Pubic, PVT; private ;HF health facility

RISK FACTORS	**YES/NO**
Contact of B+ PTB case	
Diabetes	
Malnutrition	
HIV Infection / AIDS	
Smoking	
Health care worker (HCW)	
Other (specify also if treated for LTBI)	

INVESTIGATIONS

M	**Date**	**Examination Type**	**Lab No**	**Result**	**CXR**	**Weight (KG)**
0		AFB Smear				
		Xpert				
		HIV				
2		AFB Smear				
5		AFB Smear				
6		AFB Smear				

CXR- Chest X-ray, M-month of treatment
Use blank column to enter results of other test done (as per required, eg culture)

TB Registration No								

CNIC No. Patient ☐	Family member if <18 yrs) ☐												

DISEASE SITE:				
Pulmonary ☐	Extra Pulmonary ☐			
If EPTB Specify site				
Pleura	Lymph node	Abdomen/ Peritoneum	Bones/ joint	Other
Evidence of EPTB diagnosis (other than bacteriology)				
Histology	X-Ray	U/Sound	MRI	Other

TYPE OF PATIENT: Based on TB treatment history			
NEW	☐	Unknown previous treatment	☐
RETREATMENT	*If retreatment case tick appropriate box below*		
Relapse	☐	Treatment after Failure	☐
After loss to follow up	☐	Other previously treated	☐
TYPE OF PATIENT : Based on bacteriology results			
Bacteriology confirmed "B+"	☐	**Clinically diagnosed**	☐
B+ case; AFB smear +ve and/or Xpert(MTB) and/or culture			

TB TREATMENT -INITIAL PHASE

Regimen Type	**Drug Regimen**	**Dosage**	**Tablets**
Regimen-1 (Adult)	2HRZE	(75/150/400/275)	
Regimen-2 (Child)	2HRZ+E	(50/75/150)+100	
Regimen-3*: (Adult)-HrTB	2HRZE+Lfx	(75/150/400/275) +250	

**only for TB cases who are laboratory confirmed Rifampicin sensitive, INH-Resistant and FQ-susceptible.*

National TB Control Program Pakistan

TB-01 (Back Side)

M. TUBERCULOSIS DST RESULT*								
DATE	RIFAMPICIN	LAB.NO	Date	ISONIAZID	LAB.NO	DATE	FQ	LAB.NO

**Enter Results: R=resistant , S=Susceptible and NA =if not done FQ – flouroquinolone*

TB TREATMENT-CONTINUATION PHASE				
Regimen	**Drug Regimen**	**Dosage**	**No. of Tablets**	**Remarks**
Regimen 1A (Adult):	4HR**	(75/150)		
Regimen 1B (Adult):	4HRZE*	(75/150/400/275)		
Regimen 2 (Child):	4HR**	(50/75)		
Regimen-3; (Adult)	4HRZE + LFX	(75/150/400/275)+250		

**Only for retreatment TB cases, if patient is AFB smear positive at the end of two month. Send sample for DST and adjust treatment when DST results are available as per national guideline. **Regimen 1A and Regimen 2 - extended for 6 more months (+6 HR) in case of TB Meningitis / Bone TB*

APPOINTMENTS FOR DRUG COLLECTION AND FOLLOW UP					
	Next appointment date	Initial	**Date Patients visited**	Remark (General condition/adverse event)	Initial
1					
2					
3					
4					
5					
6					

TREATMENT OUTCOME		**Date :**
☐ **Cured**	☐ **Died**	☐ **Transferred /moved to DR-TB register**
☐ **Treatment completed**	☐ **Treatment Failure**	☐ **Re-enrolled on HrTB regimen (Regimen3)**
☐ **Not evaluated**	☐ **Lost to follow up**	

CONTACT SCREENING : Household Contacts												
Name of Contact		**Age**	**Sex**	**Symptomatic**	**Date & Result of Screening**				**If TB**	**If not TB**	**Identifier Code** (if TB, Reg. No, if PT, PT Reg No)
				If yes describe Cough, Fever, Weight loss	Date	Sm	X	CXR	P/EP	PT (Y/N)	
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10											

Comments: _____

_____

Exercise 3.1: Mr Jamil

Mr Jamil was identified as a TB presumptive case and was referred for sputum examination. He has come to the doctor at the BMU/ TB Care facility with 1+ sputum results. Today is July 03, 2019.

i) Can Jamil be diagnosed as TB case on the basis of above sputum report? Yes/ No

ii) If Yes, Is his sputum positive or a sputum negative case?

iii) If No, What further action should the doctor take to make Jamil's diagnosis?

Suggested action (Investigations and or treatment):

iv) Write the patient name, age, sex, date treatment started, in the TB01 given in the worksheet (Father name Mukhtar Saboor, Grandfather name Saboor Ahmed)

v) Record the sputum smear result in the TB01 in the worksheet.

vi) Classify the disease and record in the TB01 in the worksheet.

vii) On inquiring about previous history of drug intake Jamil was found to have not taken any anti TB drug in the past. Decide and record the type of disease on Jamil's TB01 card given in the worksheet.

Exercise 3.2: Ms. Shamim

Ms Shamim was identified as a TB presumptive case and was referred for sputum examination. She has come to the doctor at the BMU with 1 + sputum results. Today is July 14, 2019.

i) Can Shamim be diagnosed as a TB case on the basis of her sputum report? Y/ N

ii) If Yes, Is she a sputum positive or a sputum negative case?

iii) If No, What further action should the doctor take to make Shamim's diagnosis?

Suggested action (Investigations and or treatment):

iv) Write the patient name, age, sex, date treatment started, in TB01 given in the works sheet. (Husband name Arif Saleem. Father name Rafiq Ahmed)

v) Record the sputum smear result in the TB01 given in the work sheet.

vi) Classify the disease and record in the TB01 given in the work sheet.

vii) On inquiring about previous history of drug intake she stated that she was diagnosed and treated for TB during the last summer. She took medicine (including painful injections daily) for about six weeks from this hospital.

Xpert test shows RR not detected. Decide and record the type of Shamim's disease in TB01 given in the work sheet.

- REVIEW/REVISE YOUR ANSWERS WITH THE FACILITATOR
- CONTINUE NEXT EXERCISE

Exercise 3.3: Patient Types

Read the following case studies and decide the type of patient for each case.

Case A: Ayesha was treated for pulmonary tuberculosis and declared cured four years back. Now on examination her sputum smears are found positive

Type of patient (Ayesha) is: _____

Case B: Rajab was diagnosed and registered as a new sputum smear positive case of tuberculosis in a neighbouring district. He has migrated to your area with a transfer form and TB02 form.

Type of patient (Rajab) is: _____

Case C: Atif took anti-TB drugs for two months from a government hospital with a BMU/ TB Care Facility and then stopped taking treatment for about three months. He has now returning for treatment. Now on examination, his sputum results are found negative;

Type of patient (Atif) is: _____

Case D: Salma took anti-TB drugs for about six weeks from a private practitioner three months back. Now on examination her sputum smears are found positive (treatment prescription & sputum results are available with patient).

Type of patient (Salma) is: _____

Case E: Rabia was diagnosed and treated as smear positive pulmonary tuberculosis. At the end of five months of regular treatment her smears were found positive.

Type of patient (Rabia) is: _____

Case F: Shahid was diagnosed and treated as smear positive relapse case of pulmonary tuberculosis. At the end of five months of regular treatment her smears were found positive.

Type of patient (Shahid) is: _____

On the TB01 Cards, boxes for recording the prescribed drugs for new and retreatment patients are given. The abbreviated names of TB drug are written below the boxes. FDC drugs prescribed for the patient will be recorded in the box as the number of tablets prescribed e.g. 2,3, 4 etc. depending on the relevant patient weight.

Use the worksheets given at the end of the module to complete the exercises

EXERCISES: Prescribe to a TB patient (Use desk guide to complete these exercises)

Exercise A: Mr.Jamil:

Mr. Jamil has been diagnosed as sputum positive, pulmonary TB patient. He has never taken TB treatment in the past. Use your desk guide to,

Decide the treatment and record in the TB01.

Prescribe the appropriate drug regimen (intensive phase) for Jamil and record the drugs and weight in TB01 below. (Jamil weighs 52Kg and the health facility has "HRZE (75/150/400/275), HR (75/150) tablets.

Exercise B: Mrs.Shamim

Mrs Shamim has been diagnosed as a sputum positive, pulmonary, TB patient. She had taken anti-TB drugs in the past for about 6 weeks. Use your desk guide to,

Decide the treatment and record in TB01 below.

Prescribe the appropriate drug regimen (intensive phase) for Shamim and record the drugs and weight in TB01 below. (Shamim weighs 36Kg and the health facility has "HRZE (75/150/400/275), HR (75/150)" tablets.

Exercise C:Ms.Nasreen:

Ms Nasreen has been diagnosed as a sputum positive, pulmonary, TB patient. She has never taken TB medicines in the past except the antibiotics prescribed last week by you. Use your desk guide to, Decide the treatment and record this in the TB01 below.

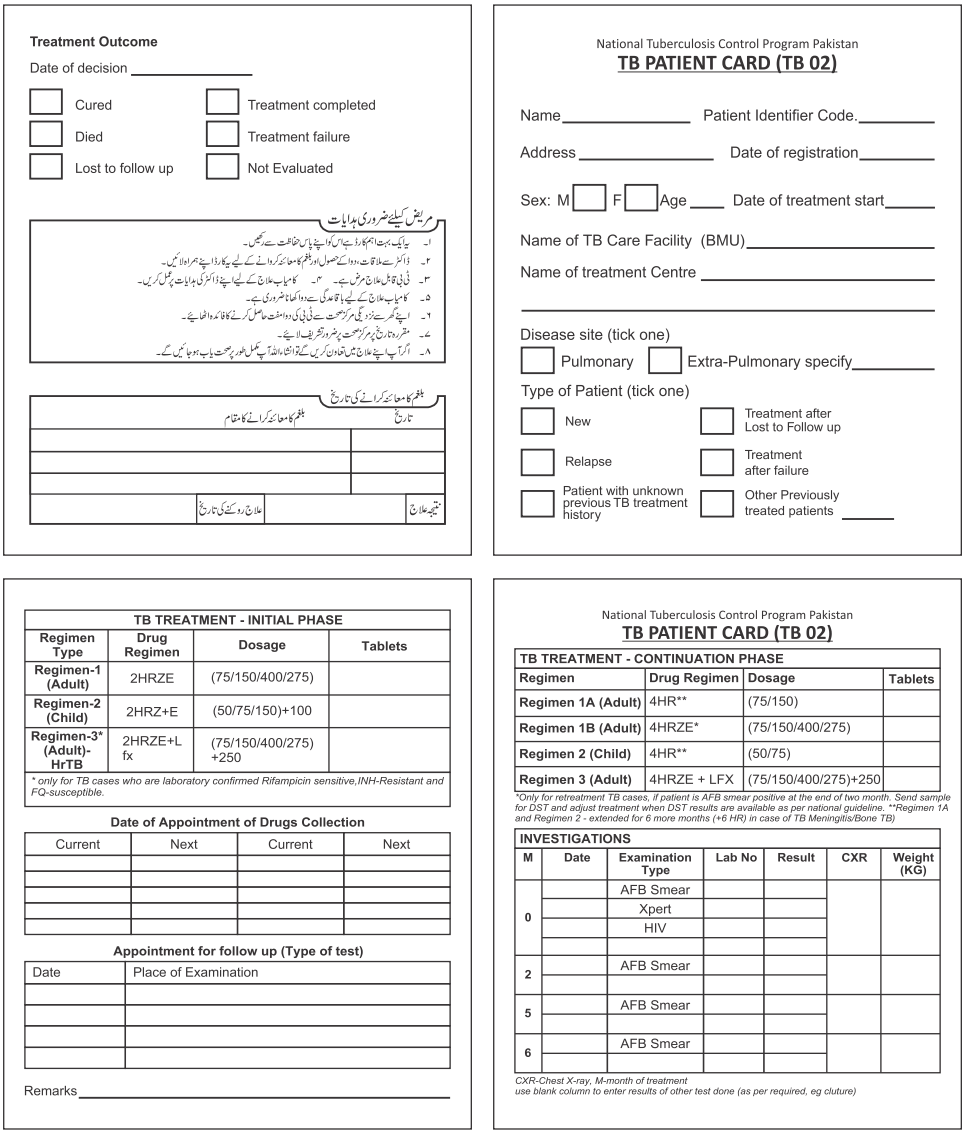
Prescribe the appropriate drug regimen for Nasreen and record the drugs and weight in the TB01 below (Nasreen weighs 58Kg and health facility has "HRZE (75/150/400/275), HR (75/150)" tablets.

Exercise D:Mr.AllahRakha

Mr Allah Rakha has been diagnosed as a sputum negative, pulmonary, TB patient. He has never taken TB medicines in the past. Use your desk guide to, Decide the treatment and record in TB01 below.

Prescribe the appropriate drug regimen (intensive phase) for Allah Rakha and record the drugs and weight in the TB01 below. (Allah Rakha weighs 51Kg and the health facility has "HRZE (75/150/400/275), HR (75/150)" tablets.

- DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD



Treatment Outcome

Date of decision _____

☐ Cured ☐ Treatment completed

☐ Died ☐ Treatment failure

☐ Lost to follow up ☐ Not Evaluated

مریض کیلئے ضروری ہدایات

۱۔ یہ ایک بہت اہم کارڈ ہے اس کو اپنے پاس حفاظت سے رکھیں۔
۲۔ ڈاکٹر سے ملاقات، دوا کے حصول اور بلغم کا معائنہ کروانے کے لیے یہ کارڈ اپنے ہمراہ لائیں۔
۳۔ ٹی بی قابل علاج مرض ہے۔ ۴۔ کامیاب علاج کے لیے اپنے ڈاکٹر کی ہدایات پر عمل کریں۔
۵۔ کامیاب علاج کے لیے باقاعدگی سے دوا کھانا ضروری ہے۔
۶۔ اپنے گھر سے نزدیکی مرکز صحت سے ٹی بی کی دوا مفت حاصل کرنے کا فائدہ اٹھایئے۔
۷۔ مقررہ تاریخ پر مرکز صحت پر ضرور تشریف لایئے۔
۸۔ اگر آپ اپنے علاج میں تعاون کریں گے تو انشاءاللہ آپ مکمل طور پر صحت یاب ہو جائیں گے۔

بلغم کا معائنہ کرانے کی تاریخ

تاریخ	بلغم کا معائنہ کرانے کا مقام

نتیجہ علاج | | علاج روکنے کی تاریخ

National Tuberculosis Control Program Pakistan

TB PATIENT CARD (TB 02)

Name _____ Patient Identifier Code. _____

Address _____ Date of registration _____

Sex: M ☐ F ☐ Age ___ Date of treatment start _____

Name of TB Care Facility (BMU) _____

Name of treatment Centre _____

_____

Disease site (tick one)

☐ Pulmonary ☐ Extra-Pulmonary specify _____

Type of Patient (tick one)

☐ New ☐ Treatment after Lost to Follow up

☐ Relapse ☐ Treatment after failure

☐ Patient with unknown previous TB treatment history ☐ Other Previously treated patients _____

TB TREATMENT - INITIAL PHASE

Regimen Type	Drug Regimen	Dosage	Tablets
Regimen-1 (Adult)	2HRZE	(75/150/400/275)	
Regimen-2 (Child)	2HRZ+E	(50/75/150)+100	
Regimen-3* (Adult)-HrTB	2HRZE+L fx	(75/150/400/275) +250	

** only for TB cases who are laboratory confirmed Rifampicin sensitive,INH-Resistant and FQ-susceptible.*

Date of Appointment of Drugs Collection

Current	Next	Current	Next

Appointment for follow up (Type of test)

Date	Place of Examination

Remarks _____

National Tuberculosis Control Program Pakistan

TB PATIENT CARD (TB 02)

TB TREATMENT - CONTINUATION PHASE

Regimen	Drug Regimen	Dosage	Tablets
Regimen 1A (Adult)	4HR**	(75/150)	
Regimen 1B (Adult)	4HRZE*	(75/150/400/275)	
Regimen 2 (Child)	4HR**	(50/75)	
Regimen 3 (Adult)	4HRZE + LFX	(75/150/400/275)+250	

**Only for retreatment TB cases, if patient is AFB smear positive at the end of two month. Send sample for DST and adjust treatment when DST results are available as per national guideline. **Regimen 1A and Regimen 2 - extended for 6 more months (+6 HR) in case of TB Meningitis/Bone TB)*

INVESTIGATIONS

M	Date	Examination Type	Lab No	Result	CXR	Weight (KG)
0		AFB Smear				
		Xpert				
		HIV				
2		AFB Smear				
5		AFB Smear				
6		AFB Smear				

CXR-Chest X-ray, M-month of treatment
use blank column to enter results of other test done (as per required, eg cluture)

3.6 TB PATIENT CARD (TB02)

The patient card (TB02) contains essential general information about the patient and specific medical information about the patient's diagnosis and treatment. This card is kept with the patient. The person (either patient or supporter or family member) who visits the treatment or the diagnostic center in relation to patient's treatment (for drug collection, advice etc.) carries this card.·

TB02: SIDE 1

This part includes the general information and part of medical information. The general information on side 1 of TB02 includes: the patient's name, address, sex, age, district TB number, name of the diagnostic center (BMU)/TB Care Facility responsible for the patient; the date treatment started. The medical information includes the disease classification and type of patient. All the information on Side1 of TB02 (both general and medical) is transferred from TB01 card to the TB02 at the time of registering a TB patient.

TB02: SIDE 2

The DOTS Facilitator will record the date of the current and next monthly appointment at the treatment center. The patient and/or his treatment supporter will visit the BMU on monthly basis, for clinical review and to collect drugs. If the patient chooses to have direct observation at the treatment center then they will come daily to see their treatment supporter, as well as this monthly visit. The date of the next appointment is calculated by adding one month to the current date of the patient's visit to the BMU. For example if a patient visits the BMU on 13th of February 2017, the date of the next appointment would be the 13th March 2017. If the 13th of March is found to be a holiday,

then the next working day should be used instead. The remarks section of TB02 is used to record stopping of streptomycin at the end of 2nd month previously treated case.

Whenever the patient visits the BMU/TB Care Facility for registration or follow-up visits, the staff at the BMU/ TB Care Facility should record the date and time of the next sputum examination. The patient is given appointment at the BMU/ TB Care Facility for the end of the 2nd and 6th for new case and for previously treated case. The date of next sputum examination is calculated by adding 2 months to the current date of the patient's visit to the BMU/ TB Care Facility. For example in the a new case the patient who is being registered on the 13th of February 2017, the date of the next sputum examination will be the 13th of April 2017. If the 13th of April is found to be a holiday, then the next working day should be used instead. If the same patient were was a previously treated patient, then the next sputum examination date would be the 13th of May 2017 (one month later).

·**TB02: SIDE 3:**

This side contains all the medical information about the patient's diagnosis and treatment, including patient type, drugs prescribed and sputum smear results. The DOTS Facilitator at the BMU /TB Care Facility will transfer all this information TB01 to TB02, at the time of registering the TB patient.

TB02: SIDE 4

Few key messages for the patient and space to record the treatment outcome (by transferring information from TB01) are also included in side 4 of the TB02.

When registering a TB patient, the TB02 card should be completed and given to the patient. The patient should keep the TB02 card and take it along to the health facility whenever he/she visits the BMU. The TB02 card helps the care provider to trace the patient's record (TB01 card) during follow-up visits. It also serves as a reminder for the patient to visit the health facility on the given/recorded date of appointment.

Use the worksheets given at the end of the module to complete the exercises

Exercise A: Mr. Jamil

Transfer the relevant data from TB01 to Jamil's TB02 (given in the worksheet at the end of module). Also record the date of the next appointment for follow-up assessment at the BMU/ TB Care Facility on TB02 below.

Exercise B:Mrs.Shamim

Transfer the relevant data from TB01 to Shamim's TB02 (given in the worksheet at the end of module). Also record the date of the next appointment for follow-up assessment at the BMU/ TB Care Facility on TB02 below.

3.7 BASIC MANAGEMENT UNIT "TB REGISTER (TB03)"

All tuberculosis patients must be registered with the programme in "Basic Management Unit TB Register (TB-03)".

Most of the information of a patient to be entered in the TB-03 is similar to TB-01 and TB02 such as; date of registration, patient identifier code, patients name/father/ husband, sex (M/F), complete address (in full), referred by, date treatment started, site (P/EP) and type.

Each BMU should maintain a TB Register to keep record of all TB patients who have been diagnosed in the center and for whom treatment has been prescribed. The patient's treatment card (TB01) is the main source of information to be recorded in TB Register (TB03). Quarterly reports on case finding and treatment outcomes are based on information obtained from the TB Register (TB03). Sample TB03 is given in subsequent pages.

Date of Registration: The date of registration refers to the date on which the patient is registered in the TB03. Usually, the patient should be registered in the TB03 on the day of initiating the treatment, in which case the date of registration would be the same as date started treatment. The date should be recorded in the format dd/mm/yy (day/month/year). Patient Identifier Code: It consist of 12 digits.

The section below described the coding system

Coding System:

Following is the proposed coding system to assign TB Registration Number to a TB patient.

Province Code	District Code	Facility Code
• A for AJ&K • B for Balochistan • K for KPK • F for FATA • G for GB • P for Punjab • S for Sindh	01 (list of all districts in all provinces/regions with their assigned codes is attached)	• H for health facility (BMU) in Public Health sector • G for solo GP clinic • P for Private Hospital • N for NGO based facility • O for Other public sector including para-statal sector facilities

TB Patient Code	Year Code	Cumulative "12 digit" code (example)
Starting from 001	15 for the year 2018	• P/01/H001/001/18 • P/01/G001/001/18 • P/01/P001/001/18 • P/01/N001/001/18 • P/01/O001/001/18

Other Information to be Recorded in the TB Register: For each newly registered patient, the TB number, name of the patient, sex, age and address of the patient, name of the BMU/TB care facility, start date of treatment, disease site and type should be recorded. This information is obtained from the TB01 card.

The date (dd/mm) treatment started and the drug regimen prescribed should be recorded in the separate box given.,

The disease site is recorded by writing "P" for pulmonary and "EP" for extra-pulmonary tuberculosis. The type of patient is recorded by using the following abbreviations: N for New; R for Relapse; F for Failure, L for Loss to follow-up, T for Transferred-in case and O for Others.

Results of Sputum Examination and the Treatment Outcome: On the right side of the register, sputum smear results at the start of treatment and completion of the 2nd, 5th, 6th for new case, and for previously treated case, treatment is recorded. The sputum results should be recorded in the relevant month column (0, 2 , 5, 6,for new case and for previously treated case and lab number is also mentioned in next column after each result. If sputum result is positive at end of month 02.

Treatment outcome: is also mentioned in the right side of the TB 03 register and date of stoppage of treatment is mentioned in the relevant column.

Moved to second-line treatment register: In case the patient is found Rifampacin resistant on X-pert testing, he/she will be referred to PMDT site and information will be recorded in this column.

- DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD
- COMPLETE EXERCISE

Exercise:

Transfer the information in already completed in TB01 (in the worksheet) into TB03.

TB CARE FACILITY (BMU) / DISTRICT TB REGISTER TB-03

Instructions

Smear results reported as follows:

Grading - ZN Microscopy

No. of AFB Observed	Report
No AFB in 100 fields	Negative
1-9 AFB in 100 fields	Record exact number of bacilli
10-99 AFB in 100 fields	1+
1-10 AFB/fields in 50 fields	2+
More than 10 AFB/field in 20 field	3+

Grading - FM Microscopy

200X	400X	Report
No AFB in one length	No AFB in one length	Negative
1-4 AFB in one length	1-2 AFB in one length	Confirmation required*
5-49 AFB in one length	3-24 AFB in one length	Scanty (exact number)
3-24 AFB in one fields	1-6 AFB in one fields	1+
25-250 AFB in one fields	7-60 AFB in one fields	2+
>250 AFB in one fields	>60 AFB in one fields	3+

* confirmation required by another technician or prepare another smear, stain and read.

Xpert MTB/Rif test result reported as follows:

"MTB" Column;	Det=MTB Detected ND=MTB Not Detected INV=Invalid/Error/No Result
"RR" Column	Det=Rifampicin Resistance Detected ND=Rifampicin Resistance Not Detected IND=Rifampicin Resistance Indeterminate

Disease type
NEW: No previous history of ATT
Previously treated
RLP : Relapse
TAF : Treatment after failure
L2FUP : Lost to follow up
H/O – History of
ATT –Anti TB treatment
UK : Unknown

Treatmnet outcome

C= CURED
TC=Treatmnet completed
D=Died
F- Faiure
NE= Not evaluated
L2FUP= Lost to follow up

TB-03 CARE FACILITY (BMU) / DISTRICT TB REGISTER **TB-03**

										Date of Registration	
										TB Registration no.	
										Patient name (First)	
										Patient name (last)	
										Gender M/F/TG	
										Age (Yrs)	
										CNIC	
										Address	
										Contact #	
										Date Treatment Started	
										Site PTB/EPTB/Both	
										NEW	
										Relapse	Previously Treated
										Treatment After Failure	
										Treatment After lost To Follow Up	
										Other	
										H/O ATT Unknown	
										Transfer In	
										HIV Test Result (R/NR/UK)	Investigations "0" Month
										AFB sm	
										MTB	Xpert
										RR	
										CXR	
										Remarks/any other investigation	

TB CARE FACILITY (BMU) / DISTRICT TB REGISTER TB-03

Regimen 1,2,3	Follow up Smear results			Other Test	DST - RESULT			End Treatment Date	Outcome						Re-enrolled on HrTB Regimen	Moved to second line treatment register	Contact Tracing NIH								Remarks
	2M	5M	6M		R	H	FQ		Cured	Treatment Completed	Died	Failure	Lost to follow up	Not Evaluated			No. of NIH Contact		No. of Contact Screening		No. of Confirmed TB Cases Detected		No. of Contacts put on presumptive Treatment		
	AFB sm	AFB sm	AFB sm																						
	Result	Result	Result		Result	Result	Result																		
	Lab No./Date	Lab No./Date	Lab No./Date		Lab No./Date	Lab No./Date	Lab No./Date										<5	5+	<5	5+	<5	5+	<5	5+	

TUBERCULOSIS REFERRAL/TRANSFER FORM (TB 10)

The TB patients from the far-off places within the district and outside district are prompted & persuaded to go to the nearest hospital/BMU/ TB Care Facility for registering collecting their medicines and for follow up visit in their own district. However patients consent is necessary. Patient must be ensured the availability of free drugs, same treatment regimen to their identified hospital/BMU/ TB Care Facility. In this way patients are prevented from being lost to follow-up and the observed treatment throughout the treatment would be ensured. Province wise directory (containing the list of BMU's by district, names of doctor's in charge with contact numbers) would be used for identifying nearest BMU/ TB Care Facility / and later transferred.

Patients are given drugs to a maximum of three days (if patient come from within district) to one week (if patient come from outside the district) to ensure early visit to the BMU/ TB Care Facility nearest to their home. A copy of TB01 is also given to the patient, who hands it over to the staff at BMU/ TB Care Facility on his/her first visit. The BMU receiving health staff will keep the TB01 updated and register the patient. If the patient is newly diagnosed and not registered yet, if on dialogue with patient agreed to go to the nearest health facility in his/her district then that patient which is referred is recorded in pre-registration referral register and patient will be registered in TB03 of receiving BMU /TB Care Facility as new case. If the patient is already registered with BMU /TB Care Facility and wanted to go to some other district or BMU / TB Care Facility then that registered patient will be registered in TB03 of receiving health facility as transferred-in patient with original registration no. In both cases the receiving health facility will fill the bottom half of the TB10 form and return it to the referring or transferring institution, as soon as the patient comes to them.

TB10 form will be used when transferring patients from one reporting unit/ centre to other. It will be filled in triplicate and one copy will be given to the patient (to hand over at the referred health facility); one copy is sent to the health facility directly and the other retained for records. The receiving health facility will fill the bottom half of the form and return it to the referring or transferring institution, as soon as the patient comes to them. This form can also be used by the private practitioner to refer his patient to the TB Control Programme. See TB10 on the next page.

TB-10

PRE-REGISTRATION REFERRAL/TRANSFER OUT FORM

Receiving Facility Copy

REASON FOR REFERRAL (Tick appropriate Box)

☐ PRE-REGISTRATION REFERRAL ☐ TRANSFER OUT ☐ REFER TO PMDT SITE

NAME OF PATIENT _____ AGE _____ GENDER _____

CNIC NUMBER _____ CELL NUMBER _____

PATIENT ADDRESS _____

TYPE OF TB PATIENT _____

☐ PTB ☐ EP-TB ☐ New ☐ Previously Treated ☐ Bacteriologically Confirmed ☐ Clinically Diagonesd

TB Registration Number _____ Date Treatment Started _____ Regimen (1,2,3 RR-TB) _____

X-RAY _____ Any Additional Information _____

Laboratory Results _____ AFB Microscopy _____ Xpert MTB/Rif _____

Document Attached ☐ TB-01 ☐ TB-05

Any Other:

	REFERRING HEALTH FACILITY	RECEIVING HEALTH FACILITY
Date Patient referred /received		
Signature		
Name heath staff		
Designation		
Name		
Adress		
District		
Province		
Contact number /Whatsapp		
E mail		

1. Pre-registration Referral (PR): *TB patient who is referred to another TB Care facility before registration made. The referred TB patient is expected to be registered and start treatment at receiving unit. The Treatment outcome will be declared by the rec eiving unit.*

2. Transfer out TB patient (TO-*Registered TB patient who is transferred out to another TB Care facility during the treatment course. The transferred out TB patient is expected to continue treatment at receiving unit. The patient TB registration number of the sending unit shall be used at the receiving unit as well.*

TB REFERRAL / TRANSFER REGISTER (TRTR)

After pre-registration referral patients from one reporting unit/center to other the patient relevant information is recorded in TB Referral/Transfer Register. See the register in the next page.

The TB patients are prompted & persuaded to go to the nearest hospital/BMU/ TB Care Facility for registering collecting their medicines and for follow up visit. In this way patients are prevented from actually becoming lost to follow-up.

Pre-registered TB patient (PR): TB patient who is referred to another health facilitybefore registration is made. The referred TB patient expects to be registered and start treatment at receiving unit.

Transfer out TB patient (TO): Registered TB patient who is transferred out to another health facility during the treatment course. The transfer out TB patient is expected to be registered as "Transferred in" case and to continue treatment as prescribed at the sending unit. The District TB case number at the sending unit shall be used at the receiving unit as well.

Exercise : Mr.Shakir:

Mr. Shakir , 38 years old from chakwal who has come to Islamabad to meet his friend. His friend presumed Shakir as TB presumptive case .Later at BMU Barakahu he has been diagnosed as sputum positive, new pulmonary TB patient i.e 4RHZE on 9th April 2019. When Shakir come to the DOTS facilitator for registration, the DOTS facilitator has a dialogue with the patient. He identifies BMU TB Care Facility /"DHQ Chakwal" from Provincial directory to be his referral BMU/ TB Care Facility. He made his TB01 form, give patient 1 week ATT drugs, made TB10 form and refer to BMU "DHQ Chakwal".

i) Fill in the Mr.Shakir TB Referral / Transfer Register (TRTR) from the above information.

ii) Mr. Shakir reached the BMU DHQ Chakwal on 17th April 2019 and gets registered. BMU Barakahu received the remaining part of the filled TB10 by post. Following information was recorded on TB10 slip. (District: Chakwal, Facility BMU DHQ Chakwal, BMU TB Register No.34/12.Name of patient. Shakir Ahmed. Record TB Register No of Mr. Shakir on Referral register (given in the work sheet)

National TB Control Program Pakistan

TB Referral / Transfer Register (TRTR)

Month: _____ Year: _____ Facility name: _____ Person in Charge _____

1 Sr. No.	2 Name	3 Phone/Cell No.	4 Type of Lab Test / Result / Lab No	5 Pre-Registered or Transferred out PR/TO	6 Date Referred/ Transfer	7 Name/ Address/ Tel No. (Receiving unit)	8 Patient identifier code at referring unit (if transfer out)	9 *** Treatment Outcome/ Unknown	10 Remarks (About Missing Patient)

Pre-registered TB patient (PR): TB patient who is referred to another health facility before registration made. The referred TB patient expects to be registered and start treatment at receiving unit.
** Transfer out TB patient (TO): Registered TB patient who is transferred out to another health facility during the treatment course. The transfer out TB patient is expected to be registered as "Transferred in" case and to continue treatment as prescribed at the sending unit. The patient TB case number at the sending unit shall be used at the receiving unit as well.
*** Treatment outcome: In case of transfer the outcome will be declared by the sending unit, and in case of pre-registration referral the outcome will be declared by the receiving unit

3.8 SUMMARY POINTS

- All patients must be grouped as one of 6 disease types: a new case, a relapse case, a failure case, a treatment after lost to follow up case, other previously treated and patients with unknown previous TB treatment history..
- Every TB patient is classified as pulmonary or extra-pulmonary TB.
- The division of TB patients i.e, new or retreatment is based on sputum examination result and history of previous TB
- The NTP recommended drug regimens are very effective and can successfully treat almost all case of tuberculosis if used in the right dosage and for the right duration.
- Anti-TB drugs are only effective if prescribed at the correct dose, according to the patient's weight
- Direct observation is essential during the full course of treatment in order to avoid developing resistance to anti-TB drugs mainly Rifampicin
- All patients diagnosed as having TB must be registered with the TB program on TB03 register
- The TB Patient Card (TB02) contains general information about the patient and medical information about the patient's diagnosis and treatment.
- TB Register (TB03) contains information on all patients diagnosed as having TB at the BMU/ TB Care Facility, their treatment and the result of follow-up sputum smear examinations. It is used for monitoring the effectiveness of the programme since quarterly reports on case finding and treatment outcomes are based on information from the TB03 register.
- TB Referral/ Transfer Register is an important tool to manage the referral of cases to BMU/ TB Care Facility in other district.

- WAIT FOR INSTRUCTIONS FROM THE FACILITATOR BEFORE PROCEEDING

SESSION 4

EDUCATING TB PATIENTS AND MANAGING CONTACTS EXPLAINING DOT AND SELECTING TREATMENT SUPPORTER PREPARING TREATMENT SUPPORTER

In the previous session we learnt about registering TB patients and also how to complete the various cards and registers (TB01 card, TB02 card and TB03 register) for TB patients. We will now concentrate on another very important aspect of TB treatment i.e. education of patient and management of contacts.

SESSION OBJECTIVES

At the end of the session, participants will be able to:

Role of counselling and health education in Tuberculosis

- Be able to manage contacts of TB patient.
- Explain directly observed treatment to patients and why continued treatment is important
- Help patients to select the best treatment supporter

Role of counselling and health education in Tuberculosis

Counselling and health education should be provided to the health staff, patients and their relatives/attendants. It is often necessary to carry out such a counselling session for a patient in the presence of treatment supporter who will monitor his/her intake of drugs on a daily basis.

The patient shall be explained the importance of contact screening to bring the household members to get screened. The contact's sputum examination is done with appropriate diagnostic

Health education should be provided on continuous basis during treatment period so that s/he should understand the importance of regular intake of drugs for the complete duration and importance of follow up clinical and lab examination.

NOTES: Key messages to be provided by the Doctor/ DOTS facilitator

- Informing a TB patient about his/her diagnosis is a sensitive task. Many patients do not want to know that they have TB and they may therefore avoid facing the reality. News about their suffering from tuberculosis is generally unwanted and difficult for the patients. Tuberculosis is more than just a health problem for the individual patient. Labeling a patient as having “Tuberculosis” has social repercussions on patients and their families. Women are at a greater risk of suffering from these undesirable social consequences. The doctor and other medical staff need to understand these concerns and talk to the patients in a way that is sensitive to these concerns.
- Almost all tuberculosis cases (> 95%) are curable if the right drugs are taken for the right duration.
- Most TB patients cannot afford to buy TB drugs for the required treatment period which likely make them to stop buying drugs as soon as they feel better. Therefore, patients should be ensured that uninterrupted free anti-TB drugs would be provided to them throughout their period of treatment.
- The TB Control Program has recommended six month drug regimens for new and a retreatment cases, respectively. The symptoms of TB are likely to subside in the first two months of treatment but relief of symptoms does not signify cure. If the full course of six months is not taken, all TB bacteria will not be killed, and the patient will become ill again. The patients should be explained that incomplete treatment may lead to drug-resistance, which is an extremely difficult form of tuberculosis to treat.
- Most TB patients (about three in four) are poor and illiterate, so numerical explanation of six month treatment should be supplemented by sign-posting the treatment duration in terms of the month when the patient is expected to complete the treatment. Relating months to agricultural and local activities is preferred where possible.

- The TB patients are expected to understand and remember the number of tablets of each TB drug that they have been prescribed to take daily.
- Some patients may develop symptoms related to the side effects of TB drugs. These symptoms may range from mild nausea to severe jaundice. The education of patients helps them to detect and take action concerning these side effects promptly. Patients should be advised to consult staff at the health facility if itching of the skin, jaundice, vomiting, impaired vision etc. is noticed.
- Patients should cover their mouths when they cough. This will reduce the chances of spreading the spread of disease through droplet infection. Patients do not need to cover their mouth when they are not coughing.
- Patients should not spit close to other people. Spit into a container and then bury it or put it into the drain.
- TB bacteria are not spread by sharing dishes, plates, clothes, or through sexual contact. This is an important message, because it helps to prevent social exclusion of TB patients by avoiding unnecessary separation of his/her household belongings and activities.
- Patients are required to visit the BMU/TB Care Facility at the end of the 2nd/5th and 6th new and previously treated case.
- It is important to verify that patients have clearly understood the messages provided by asking specific questions. The patient should be given an opportunity to share his/her concerns with the care provided and the care provided should also do everything possible to deal with these concerns.

- Discuss with THE FACILITATOR to clarify points not understood
- READ "KEY HEALTH EDUCATION MESSAGES" IN THE DESKGUIDE
- THEN CONTINUE READING

- DO THE ROLE-PLAYS 4.1 – 4.2.

ROLE PLAYS

Role-play 4.1: JAMIL

Information for the participant who is the <u>care provider</u> in this role-play

*(**Note:** Patient responses are given in the next box)*

Instructions: Mr. Jamil has been diagnosed as having TB on the basis of his sputum results and treatment has been prescribed. You are the care provider. Educate the TB patient (Mr Jamil), using the desk guide.

<u>RESPONSES JAMIL 4.1</u>

Information for the participant who is the <u>patient</u> in this role-play

Instructions: You are the patient. The care provider will educate you about TB. Respond to the care provider's questions by acting as if you were Mr Jamil described in the case study below. Then end the role-play.

Case study: Mr Jamil

- I (Mr. Jamil) have been diagnosed as having TB and treatment has been prescribed
- I don't know anything about TB, its cause and transmission. In addition, I have a number of concerns:
- I am <u>not very convinced that I have TB</u>. I have a neat and clean house and we have no one in our family has ever had TB before.
- I am <u>not sure TB can be successfully treated.</u> I believe you only get better when you eat meat and fish. I am also concerned that the drugs are hot ("garam"). Can I reduce the number of tablets?

- I am worried that I'll never be cured and have to take the treatment for the rest of my life.
- I am concerned by the fact that I may not be able to have sexual contact with my wife. In addition, I fear I may lose my job because I am becoming very weak day by day.
- I am afraid that I may not afford treatment because my friend had to pay for his drugs.
- I am afraid that there will be no TB drugs at the BHU and therefore would prefer to get my drugs from the hospital instead. Last year when my child was sick, the BHU could not give me drugs because they had no drugs in stock.

END OF ROLE PLAY

COMMENTS ON WHAT THE ROLE PLAYS ILLUSTRATES

Role-play Jamil: The Jamil role play illustrate a real problem. People generally don't accept at first being diagnosed as a case of TB. They may give examples with their own knowledge and experiences of others. They usually have various concerns and miss conceptions related to drugs, sexual health etc. As most of the patients with TB belong to lower socio-economic class, so they also show their concerns related to price of drugs. They may have some past experience of the public health facility not offering the services they required.

The care provider should show concern and discuss to answer to their concerns and try to remove any misconceptions. The care provider should try to giving examples of the experience with other patients getting diagnosed and having treatment from their health facility.

MANAGING CONTACTS

Contacts are people who have been sharing the same living premises and the daily life activities with the patient. It is important to identify contacts, of a patient with sputum smear positive pulmonary tuberculosis, and manage them in order to reduce the risk of missing cases and continued transmission of TB to other family members. Priority is assigned in screening contacts that had frequent, prolonged and close contact with the patient during the infectious period, in an enclosed environment. This may include all people living in the same household or dwelling, close relatives and friends, and close work colleagues who share the same indoor small work area on daily basis.

All child contacts till 5 years must be examined for symptoms and BCG scar. The management of contacts consists of the following two steps.

1. Identifying and Retrieving Contacts

All the household members should be considered to be Contacts. All household members irrespective of age and gender need be assessed and those who need further screening at the BMU/ TB Care Facility should be identified. It is the responsibility of the DOTS Facilitator to do this preliminary screening when registering the TB patient. After interviewing the patient, the DOTS facilitator should take a decision based on the following two points:

- All children less than 5 years of age should be brought to the BMU /TB Care Facility for further assessment and management. The children below 5 year of age found not suffering from any symptoms are put on INH prophylaxis therapy (IPT). The INH is prescribed in a dosage of 5mg/kg and is given for a period of 6 months.

Child breast- fed by sputum smear-positive mother would continue breast feed and is protected by prescribing INH in same dosage for six months and is given BCG, if not already given.

- Adults and children (older than 5 years of age) with symptoms suggestive of tuberculosis i.e. cough > two weeks, weight loss, fever etc. should be asked to visit the BMU/ TB Care Facility at their earliest convenient date.

The significance of screening all Contacts should be explained to the patient and the patient should be given a list of the household members who need to visit the BMU /TB Care Facility. The patient should also be requested to encourage the household members to get screened.

1. Screening & Managing Contacts

The Contacts that visit the BMU /TB Care Facility as requested should be screened and managed according to the NTP case management guidelines.

Recording of Screened Contacts.

Write screened contacts Name, Age, Sex, Method of screening in TB presumptive case which is tuberculin for children, X-ray, DSM in TB01.Tick the household contact relevant column of TB01.

Result of the screening is recorded in the relevant test column advised i.e. NEG, POS, ND. Date tested of screening and result would be written below the result in next line. If screened contact diagnosed as TB and registered, then it is suggested to write patient registration number in remarks column of Household Contacts in Tb01. Later the number of contacts screened against index case and number of confirmed TB cases found will be recorded in TB03

CONTACT REGISTER:

Contact register containing information about Patient name, BMU/ TB Care Facility number, age, gender, nationality of the index case. After that contact information is taken. i.e. Name of contact identified, address of contact, symptoms, date of onset of symptoms.

Method of screening in TB presumptive cases is Tuberculin for children, X-Ray and Direct Smear Microscopy(DSM). Whatever is the method of screening just (tick) the relevant column. Result of the screening is recorded in the relevant test column advised. I.e. NEG, POS, ND. Date tested. Action Taken will be recorded in the Action Taken column. Which are as follow i.e. Registration for treatment, Referred, Lost to follow up , none. Results of previous treatment is recorded i.e. completed, Lost to follow up , NA.

Action taken of all contacts must be maintained in the contact register. If as a result of the TB contact investigation household contact patient is registered for TB treatment then Patient Registration number is recorded in the contact register.

Total contacts/ contacts screened and the TB patients registered for that single index case must also be recorded in TB03.

- READ "MANAGING THE HOUSEHOLD CONTACT" IN DESKGUIDE
- DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD
- COMPLETE THE EXERCISES 4.1 – 4.6

Exercises: Managing Contacts

You are the care provider. Complete these exercises by using the desk guide to manage the Contacts of the patients.

Exercise 4.1: Mr.Jamil

Mr Jamil has been diagnosed as a sputum positive, new case of pulmonary TB. Jamils household members as told by him are as follows:

NAME /RELATION	AGE	SYMPTOMS
Ms Parveen (wife)	26 years	Coughing badly for almost a month
Mr Zubair (nephew)	11 years	Headache and stomach aches for 5 days
Ms Nazia (niece)	8 years	Fever for the last few days
Mr Omar (son)	4 years	None

Does any of Jamil's house-hold contacts need further management for TB? *Y / N*

If yes, who and why?

_____

How would you manage the Contacts? Also fill below Household contacts (portion of TB01 is shown below)

Would you prescribe IPT to any contact of Mr Jamil, if yes please prescribe dose of INH (#Mr.Omar weight is 12Kg)

Exercise 4.2: Ms.Shamim

Ms Shamim has been diagnosed as a sputum positive, Relapse case. Shamim's household members as told by her are as follows:

NAME /RELATION	**AGE**	**SYMPTOMS**
Mr Arif Saleem (husband)	30 years	None
Mr Zaheer (son)	7 years	None
Mr Qasir (son)	6 years	Diarrhea for 2 days
Ms Rizwana (daughter)	1 1/2 years	None
Mr Iftikhar (son) put weight of baby	4 months (breast fed)	None

i) Does any of Shamim house-hold contacts need further management for TB? Y / N

If yes, who and why?

---

ii) How would you manage the household contact? Fill below Household contacts (portion of TB01 is shown below)

---

iii) Would you prescribe IPT to any contact of Ms Shamim, if yes please prescribe dose of INH

National TB Control Program

REGISTER FOR TB PATIENTS CONTACTS

Ministry of National Health Services Regulations & Coordination

Name Index case	Registration No. Of Index Case	Diagnosis Of Index Case	Name Of Contact[1]	Age	Sex	Address Of Contact / Cell No. / CNIC	Symptoms	Date Of Onset of Symptoms	Method of screening (tick)			Result Of Screening[2]			Action Taken[3]
									S	CXR	X	*S	**CXR	***X	

1- List All Contacts Consecutively Under The Name Of The Index Case.

2 - *S : Sputum Smear , **CXR : X-Ray , ***X : Xpert

3 - Action: *Registration for treatment, Referred, Lost to Follow up , none*

DIRECTLY OBSERVED TREATMENT

It is very important to explain the importance of "direct observation" to the patient and help the patient to identify an acceptable and affordable means of supervising his/her treatment. Direct observation of all patients taking Rifampicin (throughout whole period of treatment of new and retreatment cases)

EXPLAINING DOT AND THE IMPORTANCE OF CONTINUED TREATMENT

It is important to convince the patient that continued treatment for six months for new / previously treated cases respectively is essential in order to ensure that he/she is cured on completion of treatment. It is also important to make sure the patient appreciates the need to identify a person who can support him/her to complete treatment without interruptions.

The concept of a patient taking tablets under supervision for whole treatment period may be difficult for patients to grasp. Patients generally take time to understand, get convinced and agree to take observed treatment. Patience and tolerance is therefore required. Telling the patient you must do this is not an effective way. Rather it is necessary to discuss. Explain points, and then wait while the patient responds, and answer their questions. Don't try to persuade. Have a two-way conversation between you and the patient, respecting their views.

It is important that the patient appreciates the importance of observed treatment in order to increase the chances of the patient complying with treatment. If the patient accepts observed treatment simply as a result of pressure from the care provider or because of the ill health, he/she may eventually not complete treatment.

Directly observed treatment is important, as most TB patients forget to take tablets, especially when they start feeling well and return to work (i.e. after a few weeks of treatment). Observed treatment is especially critical during the first two months of treatment when the patient may be seriously ill, at risk of acquiring drug resistance, and most likely to transmit TB.

Treatment supporters have generally been shown to be helpful in encouraging patients to take the right tablets for the right length of time and therefore increase the chances of the patient getting cured.

Remember that imposing a very inconvenient way of directly observed treatment on the patient may lead to lost to follow up. The patient has the choice, and their opinions and constraints must be respected. By a two-way conversation between the health worker and patient, together an acceptable form of direct observation can be identified.

Directly Observed treatment (DOT) is required for entire duration of treatment in both New and previously treated TB cases to avoid the risk of drug resistance. Regular supervision is required to ensure that the patient takes all the drugs prescribed and every dose of treatment is swallowed under the direct supervision of a treatment supporter. The detailed strategy to observe community-based DOTS at all TB Care Facilities in the country is implemented and its key features are:

- Treatment services should be provided as close to the patient's home as possible
- If any health facility is not near to his/her home, he will select a treatment supporter who will observe the daily intake of drugs at a mutually agreed place.
- The treatment supporter identified by the patient will be briefed by the DOTS facilitator at the TB Care facility of the protocols of observing the intake of drugs.
- The treatment supporter accompanied by patient will collect the drugs on monthly basis from TB Care Facility where patient is registered throughout full course of treatment
- Patients are referred to the TB Care Facility management of adverse reactions if any and for follow-up sputum examinations at the end of months 2, 5 and 6 and the sputum results recorded in TB-01 & TB03.

DOT should be done at a time and place that is convenient for the patient. The following treatment administration options may be offered to patients on TB treatment:

a) Community- or home-based directly observed treatment (DOT) is recommended over health facility-based DOT or unsupervised treatment.

b) DOT administered by trained lay providers or health-care workers is recommended over DOT administered by family members or unsupervised treatment

c) Video observed treatment (VOT) can replace DOT when the video communication technology is available and can be appropriately organized and operated by health-care providers and patients.

· READ “MANAGING DOT” IN THE DESKGUIDE

HELPING THE PATIENT TO SELECT A TREATMENT SUPPORTER

According to the WHO, there can be flexibility and innovation in observing treatment, ideally that the treatment supporter is accountable to the health services and accessible to the patient.

· Identification of a suitable and acceptable treatment supporter for the patient is the key to success of directly observed treatment which should take place where the patient comes for follow-up of treatment. There are certain characteristics that are desirable in selecting a treatment supporter. These characteristics may include his/her being:

- o Accessible
- o Reliable
- o Accountable to health services and
- o Caring but capable of influencing the patient.

· The available treatment supporter options generally includes:

- o Health facility based worker i.e. health staff member at the selected treatment center
- o Lady health worker i.e. woman formally working with National Program for PHC & FP.
- o Community health worker i.e. any person formally associated with / accountable to health services and living close to patient's place
- o Family member i.e. father, mother, husband etc person which has influence on the patient.
- o Community volunteer i.e. suitable person selected from community e.g. teacher, maulvietc

· After having a two-way discussion between the DOTS Facilitator and the patient the selection of a suitable treatment supporter is possible. The decision of who to select as a treatment supporter is generally influenced by many factors including the:

- o physical condition of the patient
- o distance (where they live)
- o cost and the patient's ability to pay for transport
- o the occupation of the patient
- o social acceptability to the patient and supporter

If these factors are not adequately considered at the time of selecting the supporter, direct observation is more likely to fail or be faced with problems at a later stage.

The health facility staff and the community health worker (including the lady health worker or other health workers living in the village) can be equally good treatment supporters, provided the choice is based on the wishes and circumstances of the patient.

If a facility health worker or community health worker is not accessible or acceptable, then also consider Family member or other community volunteers, such as teachers, students, imam, shopkeeper and other community volunteers. It is very important in the case of community volunteer and family member selected as treatment supporter that an outreach health worker (such as vaccinator, sanitary patrol or any other outreach health worker) or community health worker should weekly supervise him. The identified outreach health worker is informed and oriented for the assigned task by the DOTS Facilitator at treatment center.

In the case of a health facility staff or community health worker or community volunteer supporting the treatment, the patient will have to go to the treatment supporter daily (at a mutually agreed time) for supervised intake of tablets. Community workers include lady health workers, village-based family planning workers, health facility staff living in the village or other community volunteer e.g. teacher).

Using an unacceptable or unsuitable treatment supporter can lead to patient's later deciding not to continue taking treatment or seeking care elsewhere. The quality of care from alternate care providers is likely to be poor.

LIST OF TREATMENT SUPPORTERS

TEHSIL/TALUKA: _____District: _____

FACILITY NAME: _____

Village/Locality	Lady Health workers	Other Community Health Workers	Community Volunteers

RECORDING THE TYPE OF SUPPORTER ON TREATMENT CARD

The identified treatment supporter's name and type should be recorded in section “type of supporter” of TB Treatment Card (TB01) and in the remarks column of the TB Register (TBO3). Following abbreviations (coding) may be used for recording the type of supporters:

HFW: Health facility based worker

LHW Lady health worker

CHW Community health worker

FM Family Member

CVT Community volunteer

The uniform use of abbreviations to record the type of treatment supporter (in TB01 and TB03) will help the programme to learn from early implementation experiences, and further refine the care delivery protocols including treatment support arrangements.

REQUEST FOR TREATMENT SUPPORT

If the patient select LHW or CMW as treatment supporter, then the DOTS facilitator will send a written request (preferably by name) to the identified treatment supporter for a meeting at the patient nearest health facility. The patient (preferably) will carry the request to the treatment supporter. The patient and the treatment supporter will attend the requested meeting with the DOTS Facilitator at his/her nearest health facility.

National Tuberculosis Control Programme

REQUEST FOR TREATMENT SUPPORT

Respected Mr./Mst._____

TB CARE, INCLUDING FREE DRUGS, IS AVAILABLE AT OUR HEALTH FACILITY
Mr./Ms. _____, resident of _____, has been diagnosed as a case of tuberculosis.

Successful treatment is important for the patient, his/her family and community.
Your support is needed to ensure success of the patient's treatment.

You are requested to contact staff at the health facility (_____), during the working hours on _____ (date), to ensure that the patient gets cured with your support.

Sincerely

(In-charge health facility)

· READ "SELECT TREATMENT SUPPORTER" IN THE DESKGUIDE

TREATMENT SUPPORT

We have already discussed the importance of treatment support and the process of identifying a suitable Treatment Supporter for a patient in the previous section. The identified Supporter is explained the importance of support to a patient and asked if he/she agrees to take responsibility for supporting the patient. If he/she agrees, it is important to enable the Treatment Supporter, by imparting certain essential knowledge and skills, so that he/she can carry out the treatment support role effectively. The treatment support role is comprised of the following seven essential components:

Collect tablets, on monthly basis, and safely store, preferably with the patient

Directly observe intake of tablets (in right number of drugs and dosage)

Record daily intake of drugs in Treatment Support Card

Remind patient to visit BMU/TB Care Facility at the completion of intensive phase

Identify possible side effects and refer

Discuss difficulties in continued treatment and help resolve them

Trace and help to retrieve late patients

The Treatment Supporter is oriented to carry out these essential tasks. The orientation is meant to impart necessary knowledge and skills for the expected role. With the introduction of new six months regimen for new case of TB patients, the role of treatment supporter has become vital to ensure direct observation till the completion of treatment. The treatment support card will remain with the supporter for complete duration of treatment and at the end of treatment it will be submitted to health facility and will be attached to patient TB01 card. Every month Treatment Support Card (TSC) will be reviewed by DOTS facilitator and comments will be written on TB01 comments column about the drug intake regularity. At start of continuation phase Treatment Supporter and patient will be re-oriented on changed drugs.

COLLECTION AND STORAGE OF DRUGS

During the whole treatment period of 6 months when the patient is on observed treatment outside his/her treatment centre, patient along with treatment supporter should collect the drugs from health facility from which the patient is diagnosed. In the case of lady health worker supervising a patient, it is suggested that the drugs should be provided to her. In the case of family member supervised patients, the drugs will be given to the family, member during his/her monthly visit to the health facility.

The drugs must be stored in a safe place (under lock, if possible) and out of reach of children. In addition, the storage place should be dry and cool.

OBSERVED INTAKE OF TABLETS

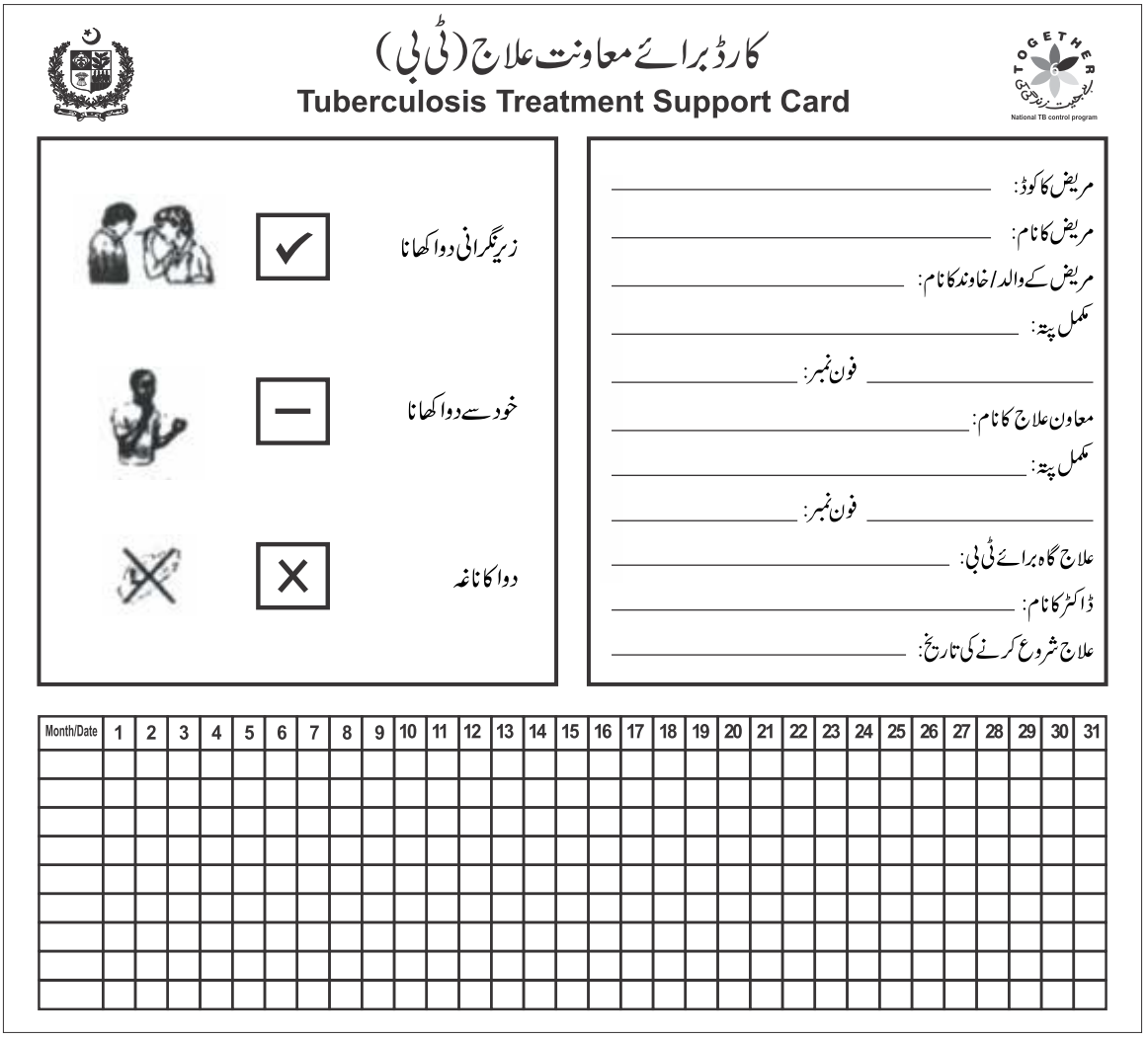
It is important for the Treatment Supporter to understand clearly the number of tablets to be taken by the patient, on daily basis. This is done by telling and showing him/her the tablets to be taken daily on empty stomach, and then confirming by asking.

The patient under DOT is expected to take maximum number of doses under supervision. However, occasionally the patient will face situation where he/she will not be able to contact Supporter for one or more days (for observed intake). These situations may include patient or supporter going out of the region for some social reasons, or a holiday. In such situations the Supporter is expected to instruct the patient about intake of tablets and give the tablets for the requested number of days. It is important to minimize the number of missed intakes.

RECORD DAILY INTAKE IN TREATMENT SUPPORT CARD

The TB Programme Pakistan has designed a Card for Treatment Supporter to record daily intake of drugs. Three symbols used to record "supervised intake", "unsupervised intake" and "missed intake" of tablets are same as used in TB01 records. It is important that Treatment Supporter understands and learns the skills for recording the intake of tablets in the Card.

The Treatment Support Card will be kept with the Treatment Supporter, who will keep record of the patient's daily intake of tablets. In case the Treatment Supporter is an illiterate family member, the Lady Health Worker on her weekly visit will verify the intake of tablets (by interviewing the Supporter and/or patient and counting the pills) and update the record on Treatment Support Card.



کارڈ برائے معاونت علاج (ٹی بی)

Tuberculosis Treatment Support Card

TOGETHER

National TB control program

زیرنگرانی دوا کھانا ✓

خود سے دوا کھانا —

دوا کا ناغہ ✗

مریض کا کوڈ: _____

مریض کا نام: _____

مریض کے والد/خاوند کا نام: _____

مکمل پتہ: _____

_____ فون نمبر: _____

معاون علاج کا نام: _____

مکمل پتہ: _____

_____ فون نمبر: _____

علاج گاہ برائے ٹی بی: _____

ڈاکٹر کا نام: _____

علاج شروع کرنے کی تاریخ: _____

Month/Date	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

معاون علاج کے لیے ہدایات

(زیرنگرانی علاج (DOT) کا طریقہ کار)

1- ٹی بی کے مریض کو خوش آمدید کہا جائے اور خوش دلی سے بات کی جائے اور دوائیں تیار کرنے سے پہلے مریض کی خیریت دریافت کی جائے اور مریض کے تاثرات کو توجہ سے سنا جائے۔

2- مریض کو دوا کھلانے سے پہلے مندرجہ ذیل تیاری مکمل کی جائے:

* اپنے دونوں ہاتھ دھو لیجئے اور اپنے مریض کے لیے گلاس میں پانی ڈالئے۔
* دوائی کا ڈبہ کھولیے۔
* مریض کا نام چیک کیجئے۔
* مریض کی دوائی کا لفافہ نکالئے، جس میں تمام دوائیں موجود ہونگی۔

3- مریض کو دوائی کھانے کے لیے کہیں اور مندرجہ ذیل باتوں کا خیال رکھیں:

* دوائیوں کا پیکٹ کھول کر ان سے گولیاں (خوراک کے مطابق) نکال کر مریض کے ہاتھ پر رکھیں اور پانی کا گلاس پیش کریں۔
* تمام گولیاں ایک ہی وقت میں کھائی جائیں گی بطور معاون علاج آپ مریض کو اپنی موجودگی میں دوا کھلائیں گے اگر مریض کو تمام دوائیاں ایک ساتھ کھانے میں دقت یا مشکل ہو رہی ہو تو اسے کچھ دیر کا وقفہ دیں لیکن مریض تمام دوائیاں آدھے گھنٹے کے اندر ضرور کھالے تاکہ وہ اپنا اثر قائم رکھ سکیں۔
* یقین کرلیں کہ مریض نے دوائیاں کھالی ہیں۔

4- دوائی کا اندراج معاون علاج کارڈ میں کریں اور یہ کارڈ اپنے پاس رکھیں۔

ٹی بی مریض کے علاج کے دوران خیال رکھنے والی باتیں

* اس بات کو یقینی بنائیں کہ تمام دوائیں محفوظ طریقے سے دھوپ اور نمی سے دور رکھی جائیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
* دوا کے نام، رنگت اور مقدار کے بارے میں معلومات رکھیں۔
* اگر مریض دوا کو نگل نہ سکے تو دوا کو پیس کر پانی کے ساتھ کھلا دیں۔
* مریض کی حوصلہ افزائی کریں، اگر وہ اداس اور مایوس ہوں اور یہ سوچتے ہوں کہ وہ صحت یاب نہیں ہوں گے تو مریض کو تسلی دیں اور بتائیں کہ اگر وہ تمام دوائیں چھ/آٹھ ماہ تک پابندی سے کھائیں گے تو مکمل طور پر صحت یاب ہو جائیں گے۔
* کسی بھی قسم کے مضر اثرات اور پیچیدگی کی صورت میں ڈاکٹر سے رجوع کریں۔
* دوا کو نمی والی جگہ سے دور رکھیں۔
* دواؤں کو فرش پر نہ گرنے دیں اگر فرش پر گر جائے تو اسے پھینک دیں۔
* ایک مریض کی دوا کو دوسرے مریض کی دوا سے تبدیل نہ کریں۔
* مریض کو روزانہ کی خوراک کم مقدار میں نہ دیں۔
* مریض پر غصہ نہ کریں۔
* تنقید سے پرہیز کریں۔ یہ بات آسان نہیں ہے کہ کوئی شخص بیمار ہو اور چھ/آٹھ ماہ کے طویل عرصے تک پابندی سے دوائی کھائے اس لیے بعض اوقات مریض مایوس اور اداس ہو جاتے ہیں۔
* دوائی کے مضر اثرات کا علاج خود سے نہ کریں۔

Back Side OF TREARMENT SUPPORT CARD

The Treatment Support Card has information on the front and back. When preparing the treatment supporter, the DOTS Facilitator will record the name of patient, name of father/husband, address, name of the treatment center, name and designation of treatment supporter, and date treatment started on the front of the card.

- **Follow-up visit to the BMU/TB Care Facility:** Treatment Supporter is explained the importance of follow-up visit to BMU **/ TB Care Facility** at the completion of the intensive phase that is after the 2nd month. This follow-up visit is important for the patient because he/she is assessed clinically, his/her sputum is examined and drugs are changed accordingly. The recorded date of appointment at BMU/TB Care Facility in TB02 helps to know when to send the patient.
- **Identify side effects and refer:** The Treatment Supporter is expected to monitor appearance of symptoms or complaints, which can potentially be due to side effects of the TB drugs. In all such cases the Supporter is expected to refer the patient, as earliest as possible, to the doctor at the treatment center. Under no circumstances the Supporter should try to suggest any measure, other than referral, for a complaint/symptom that can potentially be due to side effect of drugs.
- **Discuss difficulties and try to resolve:** The success of treatment support is based on mutual trust and confidence between the patient and the Supporter. The patient would face a wide range of socio-cultural, economic and medical problems that can potentially make him stop/discontinue the treatment. The Supporter is expected to be vigilant and sensitive to such concerns/problems of the patient. Unless these concerns and problems are properly addressed at the right time, the continued treatment of the patient may be difficult. The Treatment Supporter would help the patient to find a feasible and acceptable way to address his/her problem/difficulty.

- **Identify and retrieve late patients:** The Treatment Supporter has a key role in the early identification of interruption of drug intake and refusal to continue treatment. The Treatment Supporter should be the first person to try to convince and help the patient to continue in case of interruption or refusal. If a patient persistently refuses to continue treatment or has complaints related to the taking tablets, the Treatment Supporter should send the patient to the treatment center and inform the DOTS Facilitator as well (this is important in case the patient does not go)

- READ "PREPARE TREaTMENT SUPPORTER" IN THE DESKGUIDE
- DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD

SUMMARY POINTS

- TB patients must be educated about TB and its treatment. The key messages to be stressed by the doctor and the DOTS facilitator are found in the desk guide.
- All household members of TB patients must be assessed and those with cough more than 2weeks and/or other symptoms suggestive of TB who need to be further screened at the BMU/ TB Care Facility identified.
- Clear understanding to patient about direct observation is very important so that the patient becomes convinced about the importance of direct observation.
- Tolerance and patience is required because patients may find the concept of direct observation of treatment difficult to accept. Especially so, as this is not done for other illnesses, and is more trouble for a sick person.
- Identification of a caring, accountable, accessible and reliable treatment supporter who should be acceptable for the patient is the key to success of directly observed treatment.
- Do not try to persuade the patient to have direct observation at a place, which is not accessible. Because, although they may accept initially as they feel ill and want to be given treatment, if inconvenient they may later stop coming when they feel well. For this reason it is important to take time to discuss and choose a treatment supporter who is accessible, acceptable, as well as reliable.
- Most people who agree to be treatment supporters will have some concerns. It is important that the care provider finds out about these concerns and discusses them at the beginning of the treatment.
- All treatment supporters need to be prepared when taking on a new patient even if they have previously had some training. It is important that the Supporter agrees to take responsibility for individual patient, and drugs are handed over to the Supporter and not to the patient.
- The treatment supporter card is important as it serves as a record of treatment taken and as a detailed description of how to properly directly observe treatment
- The treatment supporter has as important role to play in the early detection of lost to follow up, patients who refuse treatment and people who are having problems with their treatment.

- wait for the facilitator to proceed further

SESSION 5
PATIENT MONTHLY REVIEW AND FOLLOW-UP AT BMU/TB CARE FACILITY

SESSION OBJECTIVES

At the end of the session, participants will be able to

- Ascertain the regularity of drug intake and identify measures to improve intake
- Issue drugs to treatment supporters or patients and record it in the TB01 card.
- Refer TB patients to the BMU/ TB Care Facility for follow-up.
- Retrieval of delayed patients
- Identify and manage the side effects of TB drugs
- Decide when and why to do smears during the follow-up
- Decide when to change the treatment (drugs) during follow-up.
- Decide what to prescribe during continuation phase

ASCERTAINING THE REGULARITY OF DRUG INTAKE

It is important that every month during the visit of patient to the health facility, the regularity of drug intake should be ascertained.

Generally, the following three methods are used to ascertain the regularity of drug intake:

- Review of the Treatment Support Card and TB 01 Card
- Interview of the patient
- Counting of the empty blisters

As already discussed in previous session, the Treatment Supporter is responsible for recording the daily intake of drugs taken by patients under his/her supervision, in the Treatment Support Card. The Treatment Supporter should bring this card along when he/she comes to the treatment center to collect the patient's drugs. After completing the full treatment, the Treatment Support Card will be attached to the TB01 card of the patient and kept at the treatment center.

- Reviewing the treatment support card to ascertain the regularity of drug intake consists of three main tasks:
    - Assess the quality of the recorded data (on daily intake of drugs) by identifying missing, unclear and incorrect entries and discussing them with the Treatment Supporter.
    - Review of the recorded data on drug intake to identify the days when drug intake was supervised, unsupervised or missed.
    - Discuss about the days when drug intake was missed or unsupervised with the Treatment Supporter and identify/agree on appropriate measures to minimize the chances of missed drug intake in future.
- Interview of the patient is the main method used to ascertain the regularity of drug intake when the Treatment Supporter fails to bring the Treatment Support Card, or the quality of data on the Support Card is poor (such as during unsupervised intake). Interview also helps to ascertain that the patient has taken the right drugs in the right dosage.

ISSUING DRUGS TO THE TREATMENT SUPPORTER ALONG WITH PATIENT & RECORDING IT:

The drugs of all patients, except patients whose treatment is observed by a health center staff, will be issued by the BMU on monthly basis.

- During the intensive phase, the drugs will be issued to the Treatment Supporters of the patients under supervised treatment. In the case of lady health worker supervised patients, the drugs will be given to the lady health worker during her routine monthly visit to the treatment center. When drugs for the next one month

have been issued, it will be recorded in the table of appointment for drug collection on TB 01 card, the first issue of the drugs will be written as "First month drugs issued", and in the next column the next date of drug collection will be entered. In the case of family member supervised patients, the drugs will be given to the family member during his/her routine monthly follow up visit.

- During the continuation phase observed treatment support will be continued, the drugs will be issued to the Treatment Supporters of the patients to supervise treatment. The monthly supply of drugs should be issued when the patient/Treatment Supporter visits the BMU/TB Care Facility.
- On each visit for treatment follow-up, the date of the current and next appointment at the health facility should also be recorded on the TB 01 and TB02 card. The date of the next appointment should also be explained to the patient.
- During the continuation phase patients continue to visit monthly along with treatment supporter for clinical review and to collect their drugs. Therefore all patients are given an appointment for one month time.
- The date of the next appointment at the health facility is calculated by adding one month to the current date of the patient's visit. For example if a patient visits the BMU/ TB Care Facility on the 13th of April 2019, the date of the next appointment at the BMU would be the 13th of May 2019. If the 13th of May is found to be a holiday, then the next working day should be used instead.

PATIENTS PERIODIC CHECKUP AT BMU /TB Care Facility:

In addition to drug collection, the patients should visit periodically to BMU/ TB Care Facility for follow-up sputum examination and treatment assessment. The details about when and why to refer for sputum examination and the treatment assessment are discussed in "PATIENT FOLLOW UP AT BMU /TB Care Facility"

5.5 RETRIEVAL OF DELAYED PATIENTS

Patients who miss visits for drug collection or sputum smear examination must be identified as early as possible. The identification of patients who have missed treatment must be followed by effective measures to retrieve the patient. Retrieving the patient consists of two main steps, accessing the patient and convincing the patient. The mechanisms adopted to access and convince a patient who has missed treatment should be socially acceptable to the patient and his/her family and administratively feasible for the health service staff.

Every effort should be made to educate the patient on the importance of adhering to his/her treatment schedule. If during an intensive phase of treatment, a patient misses his/her treatment for more than 2 consecutive days, he/she must be reminded on cell phone/SMS, and in case of no response, shall be traced by health workers or by the treatment supporter.

If during continuation phase of treatment, a patient fails to collect drugs for up to one week after the drug collection day he must be reminded on cell phone/SMS, and in case of no response shall be traced by health workers.

Assessing treatment response in New and Previously Treated Pulmonary TB patients, and acting on the results

Response to treatment in pulmonary TB patients is monitored by sputum smear examination. This recommendation applies both to new patients treated with regimens containing 6 months of rifampicin (2HRZE/4HR) and to previously treated patients receiving the 6 month regimen with first-line drugs (2HRZE). See Table-9,11,12 for a monitoring scheme with sputum smear microscopy.

New bacteriologically confirmed pulmonary TB patients with positive sputum smears and /or MTB detected on Xpert at the start of treatment. These patients should be monitored by sputum smear microscopy at the end of intensive phase and then at the completion of fifth and sixth months of treatment.

New clinically diagnosed pulmonary TB patients whose sputum smear microscopy was negative (or not done)and MTB was not detected on Xpert at the start of treatment: It is important to recheck a sputum specimen at the end of the intensive phase in case of disease progression (due to non-adherence or drug resistance) or an error at the time of initial diagnosis (i.e. a true smear-positive patient was misdiagnosed as smear-negative). Those with sputum smears negative at 2 months need no further sputum monitoring. They should be monitored clinically; body weight is a useful progress indicator.

Previously treated Bacteriologically confirmed having sputum smear-positive pulmonary TB patients and/or MTB detected on Xpert and rifampicin resistance not detected receiving first-line anti-TB drugs Sputum smear examination is performed at the end of the intensive phase of treatment (the second month), at the end of (the fifth month) and at the end of treatment (the sixth month).

Table-20: Monitoring schedule for assessing treatment response

	Method	Frequency	Remarks
Treatment Compliance			
All TB patient	DOT	Daily	
Response to treatment			
Pulmonary TB Case			
New B+	Bacteriological - AFB microscopy	Month 2,5,6 (sputum microscopy)	Record results in TB treatment card /TB register
Retreatment TB case		Month 3,5,8 (sputum microscopy)	
Clinically diagnosed		Month 2 (sputum microscopy)	
ALL TB patients PTB /EPTB (B+ and CD)	Clinical symptoms / Weight	Monthly (monitoring)	Record in TB treatment card Dosages should be adjusted if weight changes
Extra-Pulmonary TB	Clinical symptoms / Weight	Monthly (monitoring)	Record in TB treatment card

A positive sputum smear at the end of the intensive phase at any of the other points in time may indicate any of the following:

- the initial phase of therapy was poorly supervised and patient adherence was poor;
- poor quality of anti-TB drugs;
- doses of anti-TB drugs are below the recommended range;
- resolution is slow because the patient had extensive cavitation and a heavy initial bacillary load;
- there are co-morbid conditions that interfere either with adherence or with response;
- the patient may have drug-resistant M. tuberculosis that is not responding to first-line treatment;
- Non-viable bacteria remain visible by microscopy (3).

With wider availability of GeneXpert, Screening for Rifampicin resistance is recommended at time of registration. Xpert MTB/Rif assay is not recommended for monitoring response to treatment however patient may be referred for Xpert testing for diagnosis of rifampicin resistance if AFB smear is positive on follow-up examination in situation when

- Xpert testing was not performed before /start of treatment or
- Smear grading results is higher than zero month smear grade
- AFB smear was negative at start of treatment

It is unnecessary, unreliable and waste of resources to monitor the patient by chest radiograph.

5.6 IDENTIFYING & MANAGING ADVERSE EFFECTS

Screening for adverse effects of anti-tuberculosis drugs is essential part of follow-up at the BMU (hospital). It is very important component of the TB care because adverse effects are difficult to recognize. This is mostly done by interviewing attendant/patients and/or treatment Supporters when they visit the BMU (hospital).

There are two main types of adverse effects of anti-tuberculosis drugs, major and minor adverse effects.

Table-15a: Major adverse effects of TB drugs are those that give rise to serious health hazards. In this case, STOP all anti tuberculosis drugs immediately and the patient should be referred to a hospital specialist. TB drugs can cause the following major adverse effects:

Table-21: Major Adverse Effects

Major Adverse Effects		Drug(s) responsible	Management	Place of management
	Itching, rash, fever	RHZE	Stop ATT drugs	DHQ /G.P clinic
Skin Reaction	Itching, rash, fever with mucosal and systemic involvement	RHZE	Stop ATT drugs	
Hepatitis (other causes excluded)	Anorexia, nausea, vomiting, jaundice	RHZ	Stop ATT drugs	DHQ /G.P clinic
Gastritis	Anorexia, nausea, vomiting, epigastric pain	RZ	Stop ATT drugs	DHQ /G.P clinic
Peripheral Neuritis	Numbness or paranesthesia of feet & hands (even after Pyridoxin)	H	Pyridoxine 100 mg daily (Adult) Stop H	DHQ / Tertiary care facility
Visual impairment, optic neuritis (other causes excluded)	Blindness	E	Stop responsible drug	DHQ / Tertiary care facility
Arthritis	Gout-Like	Z	Stop responsible drug	DHQ / Tertiary care facility
	Disseminated SLE-Like	H	Stop responsible drug	Tertiary care facility/DHQ
Shock, thrombocytopenic purpura, acute renal failure		R	Stop responsible drug	Tertiary care facility/DHQ
Confusion (suspect drug-induced acute liver failure if there is jaundice)		Stop ATT drugs	Most anti-TB drugs	DHQ

Table-15b: Minor adverse effects of TB drugs cause only relatively little discomfort. They often respond to symptomatic or simple treatment but occasionally persist for the duration of drug treatment. In this case, anti-tuberculosis treatment should be continued and symptomatic treatment added. TB drugs can cause the following minor adverse effects:

Table-22: Minor Adverse effects

Minor Adverse effects	Drugs responsible	Management	Place of management
Anorexia, nausea, abdominal pain	Rifampicin, Pyrazinamide(Z), Isoniazid(H)	Give drugs last thing at night after 2 hrs. of meals and continue ATT. Advise patient to swallow pills slowly with small sips of water. If symptoms persist or worsen, or there is protracted vomiting or any sign of bleeding, consider the side-effect to be major and refer to treating physician urgently.	Manage at PHC/ G.P clinic
Joint pains	Pyrazinamide(Z)	Aspirin or non-steroidal anti-inflammatory drug, or paracetamol and continue ATT	Manage at PHC/ G.P clinic
Itching	All drugs	Antihistamine and continue ATT	Manage at PHC/ G.P clinic
Burning, numbness or tingling sensation in the hands or feet	Isoniazid(H)	Pyridoxine 50-100 mg daily (Adult) and continue ATT	Manage at PHC/ G.P clinic
Drowsiness	Isoniazid(H)	Reassurance. Give drugs before bedtime and continue ATT	Manage at PHC/ G.P clinic
Orange/red urine	Rifampicin®	Reassurance. Patients should be told when starting treatment that this may happen and is normal and continue ATT	Manage at PHC/ G.P clinic
Flu syndrome (fever, chills, malaise, headache, bone pain)	Intermittent dosing of Rifampicin	Twice or thrice weakly drug intake (including rifampicin) should not be used anymore in the treatment of TB. Continue ATT	Manage at PHC/ G.P clinic

The adverse effects reported by patient (and also date) are recorded in the ""Comments"" section of TB01.

Table-23: Pyridoxine (Vitamin B6) : Dosage for children on TB treatment

Weight Band (Kgs)	Dose in mg	Number of 25mg Tablets	Number of 50mg Tablets
Less than 5 Kgs	6.25 mg	Half a tablet 3 times per week	Not suitable for young infants
5.0 - 7.9 Kgs	12.5 mg	Half a tablet daily	Half of 50mg tablet 3 times per week
8.0 - 14.9 Kgs	25 mg	One a tablet daily	Half of 50 mg daily
15 Kgs and above	50 mg	Two tablets daily	One 50 mg tablet daily

5.6 PATIENT FOLLOW-UP AT BMU/ TB CARE FACILITY:

Every registered sputum smear positive TB patient must visit the BMU /TB Care Facility at the completion of 2nd , 5th and 6th for new case and previously treated TB case. During these follow-up visits sputum smears are done and patients are assessed clinically.

Every registered sputum smear negative TB patient must visit the BMU at the completion of 2nd, 5th and 6th month of treatment. During 2nd month follow-up visit sputum smear will be done and patients are assessed clinically. At the completion of 5th/6th month follow-up visit patients are only assessed clinically.

The treatment decisions during follow-up are based primarily on sputum smear results, supplemented by clinical assessment (especially for sputum smear negative patients). Weight of patient is taken as an indirect indicator of the patient's health. Gradual gain of weight is considered to be indication of the patient improving under treatment.

The three main treatment decisions, which need consideration during the follow-up, are:

- when to do sputum smear examination during routine follow-up
- when to change TB drugs (in routine and in special circumstances).
- prescription during continuation phase

SPUTUM SMEAR EXAMINATION DURING FOLLOW-UP:

Sputum smear examination is the key follow-up examination, and treatment decisions are based on sputum smear results of the patient. At least one sputum sample, preferably a morning sample should be examined on each follow-up visit.

Table-24: Sputum smear examination schedule according to classification of TB patient

AFB sputum microscopy	Xpert	Case definition	Remarks
New B+PTB			
0 Month			
Positive	Xpert-MTB/RIF Not done	B+PTB	START treatment initial phase (2HRZE)
Positive	MTB+/ RR-Not Detected	B+PTB Rifampicin resistance not detected	
Negative	MTB+/ RR-Not Detected		
NOT done	MTB+/ RR-Not Detected		
End of 2 month			
Negative		Sputum converted	START continuation phase treatment (4HR)
Positive		Failure to convert	*Do Xpert MTB/RIF if at 1)was not done at 0M or 2) AFB sm was –ve or 3)AFB sm is higher grade positive then at 0M.
	MTB+/RR-Not detected		Start continuation phase treatment.
	MTB+/RR-Detected		Refer to PMDT site for Management of DRTB
End of 5 month			
Negative			Continue continuation phase treatment
Positive		Treatment Failure	Do Xpert MTB/RIF if 1) was not done at 0M and 2M or 2) AFBsm was negative at 0M or 2M or 3) AFB sm is higher grade positive then at 0M or 2M.
	MTB+/RR-Not detected		For further management refer protocol for treatment for previously treated
	MTB+/RR-Detected	RR-TB case	Refer to PMDT site for Management of DR TB.
End of 6 month			
Negative		Cured	Stop treatment and declare treatment
Positive		Treatment Failure	*Follow protocol as mentioned above for “End of 5M”

Treatment Outcomes

The TB case facility will declare treatment outcome for registered TB patients on quarterly basis, based on the data recorded in TB01 card &TB03 register. The NTP has given definitions for various treatment outcomes of the TB patients. The definitions used are compatible with international suggestions. The treatment outcomes are explained in some detail in table below:

Cured	A patient registered as smear-positive, has completed the duration of treatment, and becomes sputum smear negative at the end of treatment and on at least one previous occasion.
Treatment completed	A smear positive patient who has completed the duration of treatment and have at least one follow up smear negative results but none at the end of treatment due to any reason.
	Smear negative and extra pulmonary cases complete six months of treatment successfully.
Treatment failure	A sputum smear positive patient who remains or becomes sputum smear positive at month five or later.
Died	A patient who dies for any reason during the course of TB treatment.
Lost to follow up	A patient whose treatment was interrupted for two consecutive months or more after last medicine intake.
Not evaluated	A TB patient for whom, no treatment outcome is assigned (includes “Transfer out” to another treatment unit and his/ her treatment outcome is unknown).

5.6 CHANGING THE TREATMENT DURING FOLLOW-UP:

The routine treatment decisions during follow-up are based primarily on sputum smear results, supplemented by clinical assessment Weight of patient is taken as an indirect indicator of the patient's health. Gradual gain of weight is considered an indicator of patient improving with treatment. The Streptomycin is generally stopped at the completion of first two months of treatment, because of increased risk of hearing loss (manifested as ringing in ears, giddiness).

The main treatment decision in light of periodic assessment is when to end intensive phase (four or more drugs) and start continuation phase (with two or more drugs). The decision is made by combining the smear results at the end of 2/3 months with the information recorded at the time of registration.

Table-25: 5.7 When to end intensive phase & start continuation phase of treatment

Category of Patient	AFB smear examination		Management
	Month	Result	
New Bacteriologically positive	0 M	positive	START treatment intensive phase (2HRZE)
	End of 2 M	Negative	START continuation phase treatment (4HR)
		positive	Do X-pert test. If RR not detected. START continuation phase treatment .If RR detected then refer to PMDT site for Management of DR TB.
	End of 5 M	Negative	Continue treatment
		positive	Declare treatment outcome as New Case- TREATMENT FAILURE For further management refer protocol for a retreatment case.
	End of 6 M	Negative	Stop treatment and declare treatment outcome. If last sputum not done, declare treatment completed
		positive	Declare treatment outcome as New case- TREATMENT FAILURE For further management refer protocol for a retreatment case.
New Bacteriologically Negative	0 M	Negative	Start intensive Phase 2HRZE
	End of 2 M	Negative	Start continuation phase treatment 4HR
		positive	Do X-pert test ,if RR not detected, start continuation phase and continue the follow up as in New case- (Smear positive)
All Previously treated cases after failure, lost to follow up or relapse	0 M	positive	Register patient for a retreatment case-
			Do X-pert before start of treatment and DST refer patient /transport specimen for X-pert testing If R resistant refer to the DR TB management unit If R sensitive, Start intensive Phase (2HRZE).
	End of 2 M	Negative	Start continuation phase treatment (4HR)
		positive	Repeat X-pert test- if DST available send specimen for DST also. If X-pert report as RR refer patient to PMDT site for management If RR not detected start continuation phase of re-treatment.
	End of 5 M	Negative	Continue continuation phase
		positive	Declare Treatment outcome Retreatment case- TREATMENT FAILURE Declare DR presumptive case. Refer Patient to DR-TBMU
	End of 6 M	Negative	Declare treatment outcome " CURE"
		positive	Declare Treatment outcome Retreatment case- TREATMENT FAILURE Declare DR presumptive case. Refer Patient to DR-TBMU

· **Prescription for continuation phase:** Two drugs (i.e. Rifampicin plus Isoniazid are given to new case, for 4 months of the continuation phase.

The dosage of each drug prescribed during the continuation phase remains the same if patient weight is in same weight range as pre-treatment range. However if patient weight changes in follow-up visit and crosses to next weight range then initially prescribed drugs dosage would be changed on the basis of current treatment weight of the patient. New and Previously Treated TB patients need frequent monitoring and observed treatment, during the continuation phase also. In both new & Previously Treated TB patients it is recommended that their treatment should be observed during the continuation phase because of continued Rifampicin intake throughout.

The tables given (page 45) helps the doctor to prescribe standardized drug regimen, in accordance with national guidelines, during the continuation phase of treatment.

RECORDING INFORMATION:

The sputum and Xpert results are recorded in the TB01 card; TB02 card and TB03 register (by copying data from the laboratory report into an appropriate box in each of these cards). The date for next sputum examination, at BMU/TB Care Facility, is also recorded in TB02. The drugs prescribed at the start of continuation phase are recorded in the TB01 and TB02 cards.

The drug delivery for the continuation phase is recorded on the TB01 and TB02 cards in the section on drug collection.

F assay

SCREENING OF DRUG RESISTANT TB: PRESUMPTIVE CASES:

The use of X-pert/MTB Rif has been recommended as a first diagnostic testing for screening to the following high risk groups (DR-TB presumptive cases)

A. ALL PREVIOUSLY TREATED TB CASES: All TB cases (AFB SS+ve or clinically diagnosed) with history of previous ATT should be tested for X-pert at month zero of enrolment. This includes:

Treatment Failure New Case

Treatment Failure Previously Treated Case

Relapse after New Case

Relapse after Previously Treated Case

Treatment after loss to follow up New Case

Treatment after loss to follow up Previously Treated Case

Other Previously treated Case

B. SYMPTOMATIC CONTACTS OF DR-TB PATIENT: All household and workplace symptomatic contacts of DR-TB patients should be screed for drug resistance. Specimen from these individuals should be processed for AFB smear and then the specimen is referred for X-pert MTB/RIF assay irrespective of smear results.

Table-26: Reporting pattern and interpretation of results of X-pert MTB Rif

	REPORT	TB RISK ASSESSMENT	INTERPRETATION	ACTION
1	MTB Detected Rif resistance NOT detected	No previous history of ATT	Definite TB case NO Rifampicin resistance	Start New Case treatment
		History of previous ATT	Definite TB case NO Rifampicin resistance	Start Retreatment Case Treatment
		History of Failure of treatment for previous case	Definite TB case NO Rifampicin resistance	Start Retreatment Case Treatment and transport sample/Refer patient for pheno DST
2	MTB Detected Rifampicin Resistance Detected	No previous history of ATT	Definite TB case with Rifampicin resistance	Repeat X-pert MTB/Rif assay – If -RR Not detected - start on FLD- New Case treatment -RR detected –reg and start on SLD
		History of previous ATT	Definite TB case with Rifampicin resistance	Refer patient to DR treatment site enroll patient on SLD and send specimen for FL and SLDST.
3	MTB NOT detected		MTB Not detected but not excluded	Culture / clinical evaluation diagnosis

For all patient group where X-pert /MTB rif assay is recommended as preferred tool, it is recommended that for facilities where X-pert testing is not available on site and specimen requires transportation to higher level laboratory, smear microscopy should be then be performed in local laboratory and same specimen transported to X-pert site. While X-pert results are awaited , patient should be managed based on microscopy/clinical diagnosis

REFERRING DR-TB PRESUMPTIVE CASES TO THE TREATING HOSPITAL:

Those patients found to be DR-TB presumptive cases are then referred to the DR-TB hospital.

1. The doctor at referring facility records the patient name and their DR-TB risk group in the Referral Form, and sends them to DOTS Facilitator for further help.
2. The DOTS Facilitator completes the remaining details in the Referral Form (i.e. about the hospital, the referring facility and the patient).
3. The patient is advised to take to hospital: a filled Referral Form (see the form below), their TB treatment card (TB01) and/or patient card (TB02) if patient has received treatment from the referring facility), a morning sputum sample (where possible, to expedite the diagnosis and minimize the possible stay)
4. The referring Diagnostic centre keeps a copy of the two documents i.e. filled referral form and TB01 (where available), for record and future reference purposes.
5. The social and/or economic barriers to visit the hospital are identified, and patient is counseled to address the identified barrier.

National TB Control Program Pakistan
DR TB Presumptive Case Referral Form

PMDT Site (where patient is being referred): _____Date of referral (mm/dd/yy):_____

Referring Facility:_____ District:_____

Name and contact no. of the care provider (doctor): _____

Patient Name: _____ Age: _____ Sex_____

Address: _____Contact No: _____

☐ **DR-TB Risk Group** (Please tick)

☐ Failure of treatment for previously treated case

☐ Failure of treatment for new case

☐ Failure of treatment regimen used in private sector

☐ Contact of known MDR-TB case

☐ Settings with higher risk exposure e,g; in institutions with high MDR-TB (specify):

☐ Non-converters:

☐ Others (specify): _____

TB Treatment History:

TB Diagnosis and treatment			
Date Diagnosed	Facility (where)	Treatment Taken Anti-TB Drugs (with Duration)	Outcome

Attach a copy of the patient's last TB Treatment Card (where available)

For use by PMDT site to which patient has been referred:

Patient Name : _____ MDR-TB Reg. #: _____

Referring facility and address: _____

The above patient reported at this hospital on (date): _____

Signature of in-charge PMDT site: _____

Send this part back to referring facility as soon as patient reports.

INTERPRET CULTURE AND DST (R/H) RESULTS

Interpret the culture results

A positive culture requires greater than 10 colonies on solid media. If less than 10 colonies are detected in one culture, a second culture should be done. If both cultures show any number of colonies, the culture should be interpreted as positive.

Interpret the DST (R/H) Results

The hospital clinician is primarily responsible for interpreting the results of the three tests (i.e. smear, culture and DST) and initiate further necessary action accordingly.

Results, if	Interpretation	Further action
¨ DST – **resistance** to R and H, with smear positive or negative and culture positive (or result awaited, if rapid DST in-use)	DR-TB patient	¨ Register, further assess, and put patient on DR-TB treatment
¨ DST – **susceptible** to R and/or H, with smear positive or negative & culture positive (or result awaited, if rapid DST in-use)	TB but not DR-TB	¨ Manage as non-DR TB (e.g. re-treatment or mono-drug resistant TB)

If patient is found susceptible to either one or both "R" or "H", they are managed as a non-DR TB case according to national guidelines.

When patient is found resistant to both "R" and "H", they are declared as DR-TB case and further actions are taken accordingly. These actions mainly include education, baseline clinical assessment of patient followed by registration and initiation of treatment.

Exercise 5.1 Case 1: Saima

National TB Control Program Pakistan DR-TB 05
Request to Examine Sputum for Smear, Culture and DST

DR-TB Suspect #: _____ **DR-TB registration #**:
_____

Treating Hospital Date

Patient Name :

Age: Sex: **M** { } **F** { }

Address (Precise):
_____
_____

Reason for examination (check one): Diagnosis { } Follow-up examination { } Months of follow-up:_____

Test(s) requested: Smear { } Culture { } DST - R/H { } DST - Complete { }
If DST, specify risk group :_____

Signature of person requesting examination:_____

Note: Part of the form not required for the exercise has been deleted)

Today is August 31, 2010, and you have received the following rapid DST report from the hospital BSL-2 laboratory (with rapid DST facility).

DST Results

Patient: **Saima**

(The details not required for the exercise have been deleted)

Date Collected	Laboratory Specimen No.	**H**	**R**	E	Z	S	Km	Am	Cm	Ofx	Pto/Eto	Other	Other

Examined by (signature): _____ Date: _____

Why Saima is considered a DR-TB patient?

_____

_____

Case 2: Yasmin.

A 34 year old female patient, has taken 5 months of previously treated Case treatment (District TB Number is 014-2019, registered as treatment after Lost to follow up on January 24, 2019). Today is June 29, 2019, and patient is found sputum smear (+) at the completion of five months. The patient still complains of a persistent cough with back pain, hemoptysis and weight loss. The patient was also sputum smear (+) on the 2nd month of follow-up.

Other Information: Health facility: Rural Health Center Baydian, Lahore Associated treating hospital: Gulab Devi hospital, Lahore Patient Address: House 127, Street 8, Johar Town, Lahore. Past treatment: Patient took NTP recommended treatment for new case for about 4 months from the same facility (date diagnosis – April 12, 2019) HIV status: Not known.

Part-1: (at health facility)

Decide:

DR-TB presumptive case? (Yes/No)

Act:

Refer to treating hospital (i.e. fill the referral form)

5.10 SUMMARY POINTS

- When following-up patients it is important to assess:
    - the regularity of drug intake
    - adverse-effects of treatment
    - when is the next review at the BMU/TB Care Facility and give TB05 and sputum containers if necessary
- When a patient is reviewed at the BMU/TB Care Facility the sputum Xpert results and new prescription (e.g. change to the continuation phase) must be recorded in the TB01.
- The DOTS Clinic has critical role for risk assessment for DR TB and TB in vulnerable populations

National TB Control Program Pakistan

DR TB Case Referral Form

PMDT Site (where patient is being referred): _____ Date of referral (mm/dd/yy):_____

Referring Facility:_____ District:_____

Name and contact no. of the care provider (doctor): _____

Patient Name: _____ Age: _____ Sex_____

Address: _____ Contact No:_____

MDR-TB Risk Group (Please tick)

- ☐ Failure Category II
- ☐ Failure Categoryl
- ☐ Failure of treatment regimen used in private sector
- ☐ Contact of known MDR-TB case
- ☐ Settings with higher risk exposure e.g; in institutions with high MDR-TB (specify):
- ☐ Non-converters:
- ☐ Others (specify): _____

TB Treatment History:

TB Diagnosis and treatment			
Date Diagnosed	Facility (where)	Treatment Taken Anti-TB Drugs (with Duration)	Outcome

Attach a copy of the patient's last TB Treatment Card (where available)

For use by PMDT site to which patient has been referred:

Patient Name : _____ MDR-TB Reg. #: _____

Referring facility and address: _____

The above patient reported at this hospital on (date):_____

Signature of in-charge PMDT site: _____

Send this part back to referring facility as soon as patient reports.

SESSION 6
MANAGING PATIENT WHO INTERRUPT TREATMENT OUTCOMES & QUALITY OF CARE

SESSION OBJECTIVES:

At the end of the session, participants will be able to:

- Retrieve and review the records of previous treatment type, the length of treatment before interruption, and the length of interruption (from the TB01 and TB02 cards)
- Familiar with treatment outcomes in the TB01, TB02 cards and TB03 register
- Know how to work as a team at the health facility and why is it important

Managing patients who interrupt treatment and Treatment Outcomes

Review the Record of Previous Treatment: Management of patients after treatment interruption is based on review of information about treatment before interruption and current smear results and Xpert results of the patient. Record of the previous treatment (before interruption) is important to know:

- The patient's previous type
- Length of treatment before interruption
- Length of interruption

Table-27: Management of New TB patients with Interrupted Treatment

Length of interruption	Do a smear?	Result of smear	Do Xpert?	Result Xpert	Register again as	Treatment
Length of treatment			<1 month			
<2 weeks	No	-	No	-	-	Continue on same treatment for new case
2-8 weeks	No	-	No	-	-	Start again on treatment for new case
>8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	*Treatment after lost to follow-up	Start on treatment for new case If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+ MTB ND	*Treatment after lost to follow-up	Start on treatment for new case If RR+ Transfer to PMDT Send for culture & wait for result
Length of treatment			>1 month			
<2 weeks	No	-	No	-	-	Continue on same treatment for new case
2-8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+		Start again on same treatment for new case If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+ MTB ND		Start again on same treatment for new case, If RR+ Transfer to PMDT Send for Culture, Send for culture,& wait for result
>8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	*Treatment after lost to follow-up	Start on Previously treated regimen case & send sample for DST If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+ MTB ND	*Treatment after lost to follow-up	Start on Re-treatment regimen & send sample for DST If RR+ Transfer to PMDT Send for culture,& wait for result

Table-28 : Management of Previously Treated TB Patients with Interrupted Treatment

Length of interruption	Do a smear?	Result of smear	Do Xpert?	Result Xpert	Treatment
Any length of treatment					
<2 weeks	No	-	No	-	Continue on "Previously treated regimen"
2-8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	Start again treatment at "Previously treated regimen" If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+	Start again treatment for "Previously treated regimen" If RR+ Transfer to PMDT
>8 weeks	Yes	Positive	Yes	MTB+RR- MTB+RR+	Register as Treatment after lost to follow up and start treatment for "Previously treated regimen" and send sample for DST If RR+ Transfer to PMDT
		Negative	Yes	MTB+RR– MTB+RR+ MTB ND	Register as Treatment after lost to follow up and start treatment for "Previously treated regimen" and send sample for DST If RR+ Transfer to PMDT Send for culture,& wait for result

The doctor makes the decisions, on how to manage patient with interrupted treatment, by combining information about the category in which patient was registered before interrupting treatment, the length of treatment before interruption, the length of interruption and smear results/ Xpert results after interruption. The potential sources of information about treatment before interruption includes:

- **Health Facility Records:** TB01 card kept at the diagnostic center where the patient was treated previously.
- **Patient Records:** TB02 card kept by the patient.
- **Treatment supporter card**

· REFER "managing patients with interrupted treatment" in desk guide

DECIDING ON HOW TO MANAGE THE PATIENT:

The management of patients after interruption is decided by combining information about treatment before interruption and the current condition of the patient.

The tables given in the Case Management Guidelines helps the doctors to manage patents that were registered as new and/or re-treatment cases before interrupting treatment and were put on anti-TB treatment, in accordance with national guidelines.

TREATMENT OUTCOMES:

The National TB Control Programme has given a set of agreed nomenclature and definitions for various treatment outcomes (results) of TB patients. The definitions used in the programme are compatible with WHO revised definitions. The treatment outcomes are:

Cured	A patient registered as smear-positive, has completed the duration of treatment, and becomes sputum smear negative at the end of treatment and on at least one previous occasion.
Treatment completed	A smear positive patient who has completed the duration of treatment and have at least one follow up smear negative results but none at the end of treatment due to any reason.
	Smear negative and extra pulmonary cases complete six months of treatment successfully.
Treatment failure	A sputum smear positive patient who remains or becomes sputum smear positive at month five or later.
Died	A patient who dies for any reason during the course of TB treatment.
Lost to follow up	A patient whose treatment was interrupted for two consecutive months or more after last medicine intake.
Not evaluated	A TB patient for whom, no treatment outcome is assigned (includes "Transfer out" to another treatment unit and his/ her treatment outcome is unknown).

Treatment success: The sum of cured and treatment completed

DECLARING TREATMENT OUTCOMES:

- The completed TB01 is the main source of information from which treatment outcomes are determined. The doctor at the diagnostic centre /TB CARE FACILITY is responsible for declaring treatment outcomes for every registered TB patient.
- The treatment outcome can only be declared when the "date treatment stopped" is known for a patient.
- On the basis of TB01 data, including comments noted in "comments" section, the doctor at the diagnostic centre will declare the treatment outcome (i.e. when TB01 with information and remarks are available at the diagnostic centre).

√ A patient may be declared cured or treatment completed (depending upon availability of sputum results at the completion of 6th month)

A smear positive patient would be declared as treatment failure on the day he/she reports to the doctor at BMU /TB Care Facility with the follow-up smear-positive results, at the end of 5th month or later. However, if RR detected on Xpert patient will move to DR TB Register (Refer to PMDT site)

√ A patient may be is declared as lost to follow up if he/she is found to have delayed the collection of drugs for two months or more.

√ **A patient will be declared not evaluated when** no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit. Declaring outcome is the responsibility of reporting unit.

√ A patient is declared "died" when the information about patient death is received (and confirmed, where possible) during the course of treatment. Or before starting the treatment.

- √ Xpert should not be used for follow up, unless follow smear is positive to rule out RR.
- · The following information from the TB01 card is used to determine the treatment outcomes:
- ♦ Number of months for which patient has taken drugs
- ♦ Smear results at the time of registration
- ♦ Smear results during the treatment follow-up
- ♦ Comments on death, lost to follow up , not evaluated etc.
- · A table in the desk-guide helps to determine the treatment outcome on the basis of essential information from TB01. If TB treatment card (TB01) is found incomplete, the health worker concerned should be contacted as soon as possible to obtain the missing information

Follow-Up after completion of treatment

It is very unlikely and a rare event when a person successfully completes his/her full course of TB treatment and a successful treatment outcome is declared. It is therefore unnecessary to follow these patients. Patients who have successfully completed their treatment should, however, be told to report for re-examination if symptoms recur and the procedure described under "Diagnosis of Tuberculosis", should then be followed.

RECORDING THE TREATMENT OUTCOME:

- · The treatment outcome is recorded in the TB Treatment Card (TB01), TB Patient Card (TB02) and TB Register (TB03). The treatment outcome is recorded by writing “Date Treatment Stopped” in the appropriate box in these cards/forms.
- · The “date treatment stopped” is the last date the patient is expected to have taken the drugs.
- √ In case of “cured” and “treatment completed” the date of sputum examination at end of 6/8 month is recorded as treatment stopped.
- √ In case of “lost to follow up” the date treatment stopped will be the last date due for the patient's collecting his/her drugs and will be recorded after wait of two months.
- √ In case of “died” the reported date of patient's death is recorded as date stopped treatment.
- √ In case of “treatment failure” the date of doctor's examining the smear-results and declaring patient a failure is recorded as date treatment stopped (re-registration number is recorded in remarks column of TB03).
- √ In case of “not evaluated” the last date the patient is expected to have taken the drugs will be considered.

WORKING AS A TEAM AT THE HEALTH FACILITY:

Good control of TB is based on different health workers performing their individual roles in the TB care process. As well as each person working to the best of their ability it is important that they work together as a team. Communication between team members is important for the team to work well and be successful. As a team, health workers can discuss their performance, raise any problems and together find solutions.

Although team members often keep in touch informally, discussing cases and delivering messages as the need arises, it is also very important that the team meets regularly to formally review their progress. Every month the team members at each health facility should meet and hold a facility review meeting, including a review of TB services. It is best if this is held at the same time every month.

At a diagnostic facility the meeting will include the:

- Doctors
- DOTS facilitator
- LHV (if not the DOTS facilitator)
- Laboratory technician
- Dispenser

At a treatment facility the meeting may include:

- Doctor
- DOTS facilitator
- LHV (if not the DOTS facilitator)
- Dispenser

Each meeting should have a chairperson and a secretary to record the minutes of the meeting. The meeting should review the different aspects of the programme, including those listed on page 8 of the desk guide. Any problems identified should be seen as problems for the whole team and blame should not be allocated to one particular department or person. The team should as a group, look for the underlying causes of a problem and decide on how to tackle it. A good review meeting is one that is:

- Well organised
- A priority – i.e. not cancelled and all members attending
- Held regularly
- Reviews the minutes of the previous meeting, confirms that the agreed action was taken and reviews the effects of this action on the initial problem.
- Supportive
- Non-threatening

1.4 SUMMARY POINTS:

- It is important to identify patients who have interrupted treatment in order to manage them properly
- Correct management of patients who have interrupted treatment depends on the:
  - ♦ Duration of treatment before interruption
  - ♦ Length of interruption of treatment prior to interruption
- Correct management may include:
  - ♦ Doing a sputum smear / Xpert
  - ♦ Re-registering the patient
  - ♦ Changing to a different treatment regimen.
  - ♦ Continuing the previous treatment
- ####Declaring treatment outcomes is an important part of the process of monitoring the quality of the TB programme.
- #####Each treatment outcome has been clearly defined by the NTP and these are: Cured, Treatment completed, Died, Failure, lost to follow up and not evaluated.
- ######All the information on treatment outcomes should be recorded on the TB01 and TB02 cards and in the TB03 register.
- #####It is important that each individual involved in the TB care process performs his role effectively and that everyone works together as a team to that the objectives of the TB control programme are achieved.

Every month the team members at each health facility should meet and hold a facility review meeting, including a review of TB records and services.

SESSION 7
CASE NOTIFICATION AND TREATMENT OUTCOMES

7.1 SESSION OBJECTIVES

At the end of the session, participants will be able to:

- Know the quarterly report of case finding (TB07)
- Know the quarterly report on treatment results (TB09)

7.2 REPORT ON NEW CASES & Previously Treated Case (TB07)

- The quarterly report on new cases and previously treated of tuberculosis (TB07) is an important report in the routine recording and reporting system of the TB Control Programme. The report shows incident TB cases (New + Relapse) and Previously Treated (excluding Relapse). It provides information on the number of new pulmonary smear positive cases, relapses, other re-treatments, new pulmonary smear negative cases, and extra-pulmonary tuberculosis cases that were diagnosed and registered during a quarter of an year (i.e. 3-month period eg. Jan-Mar).
- Transferred-in cases are not included in this report as they get reported as new cases in the previous quarterly report or at another BMU/TB Care Facility.
- The TB07 report is produced during first week of every quarter, by extracting data from the TB Register (TB03) at each BMU/ TB Care Facility. All new and previously treated cases registered during the previous quarter (i.e. quarter under reporting) are identified by looking at the “date of registration” column.
- The report includes important indicators that can alert us as to whether or not the diagnostic procedures are working effectively. The reports are submitted to the District TB Coordinator (DTC) who checks the completeness and consistency of the reports received from all BMUs. The TB Coordinator then produces a district report by compiling the information from all the BMUs/ TB Care Facility's in district and submit to the province.

THE TOP of the form is used to record general information about the BMU (BMU) /TB Care Facility and the district. It allows the provincial programme to quickly determine the district and the quarter that is being reported. In case of BMU (BMU) /TB Care Facility report, the relevant column is checked and in case of consolidated report (generated at district level) total number of BMUs and No of reporting BMUs are mentioned.

National TB Control Program

QUARTERLY REPORT ON TB CASES REGISTRATION

INDIVIDUAL/CONSOLIDATED (TICK ONE)

Ministry of National Health Services Regulations & Coordination

TB-07

Name of TB Care Facility (BMU): _____ District: _____ Patients registered during: _____ Quarter of year: _____

Name of TB Coordinator/Facility incharge: _____ Date of completion of this form: _____

All TB Cases Registered	New (N)	Relapse (R)	Previous Treatment History Unknown (UK)	N+R+ UK	Previously Treated (Excluding Relapse)			Total
					Treatment after Failure	Treatment after lost to follow-up	Other previously treated	
Pulmonary, Bacteriologically Confirmed								
Pulmonary, Clinically Diagnosed								
Extra Pulmonary, Bacteriologically Confirmed								
Extra Pulmonary, Clinically Diagnosed								
Total								

Block 2: All New, Relapse and Previous treatment history unknown Cases registered during the period by Age Group and Gender

	0-4		5-14		15-24		25-34		35-44		45-54		55-64		65 & above	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Pulmonary, Bacteriologically Confirmed																
Pulmonary, Clinically Diagnosed																
Extra Pulmonary, Bacteriologically																
Extra Pulmonary, Clinically Diagnosed																

Block 3: Presumptive TB case Identification, Laboratory Diagnosis and use of WRD

Total New OPD in Quarter	No. of Presumptive TB Cases identified	No. of Presumptive TB Patients tested using AFB sm. and/or Xpert	Among Presumptive TB cases tested number reported B+ (AFB+ and/or MTB+)	Among all form TB cases registered number of B+ TB Cases (AFB+ and/or MTB+)	Among NEW, Relapse, UK TB Cases registered (B+ & CD) number tested by expert

Block 4 : TB HIV Activities

New, Relapse &UK Patients tested for HIV / or with known HIV status at the time of TB diagnosis	HIV Positive TB Patients	HIV Positive TB Patients on ART	HIV/Positive Patients on Preventive Treatment

Block 5: Bacteriologically Confirmed TB Cases with DST Result

	Rifampicin		Isoniazid		Fluoroquinolone	
	Results	Resistant	Results	Resistant	Results	Resistant
New						
Relapse						
Previously Treated						
Total						

Block 6 : Contact Tracing HH*

No. of B+ PTB (Index Cases) whose contacts are screened	No. of House Hold contacts of B+ PTB Cases screened		Among HH contact screened, No. of TB Cases diagnosed		No. of HH contact initiated on Presumptive Treatment	
	< = 5yrs	>5yrs	< = 5yrs	>5yrs	< = 5yrs	>5yrs

THE TOP: The name of BMU /TB Care Facility, date of completion of form (day/month/year) signature of the in-charge of BMU /TB Care Facility, name and number of the district are recorded in the given spaces. The quarter and the year being reported is recorded by using the following table:

Quarter	Time of Reporting (TB07)	Patient Registered During
1	First week April, 2019	January 1 – March 31, 2019
2	First week July, 2019	April 1 – June 30, 2019
3	First week October, 2019	July 1 – September 30, 2019
4	First week January, 2020	October 1 – December 31, 2019

- **BLOCK 1** is subdivided into 9 columns:
  - 1st column is to classify the patients (Pulmonary Bacteriologically confirmed , Pulmonary Clinically Diagnosed, Extrapulmonary Bacteriologically confirmed and or clinically diagnosed. Sex i.e. male and female.
  - 2nd column is for New : There are four rows
    - Row 1 : Pulmonary bacteriologically Diagnosed
    - Row 2 : Pulmonary clinically diagnosed
    - Row 3 : Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed
    - Row 4 : Total
  - 3rd column is for Relapse :
    - Row 1 : Pulmonary bacteriologically Diagnosed
    - Row 2 : Pulmonary clinically diagnosed
    - Row 3 : Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed
    - Row 4 : Total
  - 4th column is total of NEW + Relapse :
    - Row 1 : Pulmonary bacteriologically Diagnosed
    - Row 2 : Pulmonary clinically diagnosed
    - Row 3 : Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed
    - Row 4 : Total
  - Column 5 to 8 is for Previously treated excluding relapse (Treatment after failure + lost to follow up + Others + Previous treatment history Unknown). Each column has four rows :
    - Row 1 : Pulmonary bacteriologically Diagnosed
    - Row 2 : Pulmonary clinically diagnosed
    - Row 3 : Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed
    - Row 4 : Total

- Column 9 is for the TOTAL : There are four rows:
  - Row 1 : Pulmonary bacteriologically Diagnosed
  - Row 2 Pulmonary clinically diagnosed
  - Row 3 : Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed
  - Row 4 : Total

- **BLOCK 2** presents male and female patients (New + Incident) presented by specific age groups. The age groups used in Block 2 are internationally recognized age groups.
  - When the report is completed, the total number in the BLOCK 2 c TOTAL should correspond to the total number in Block 1 Column 4 (New + Relapse) .

  There are two main reasons for reporting new pulmonary smear positive cases of tuberculosis by sex and age groups:
  - To evaluate case finding: To see if sex distribution of Incident cases is unexpectedly high (or unexpectedly low) in particular age group(s). Also if age distribution of incident cases is similar (or dissimilar) to the national or regional distribution.
  - To determine the trend of tuberculosis: To see if the number of cases for either sex, in a particular age group is increasing or decreasing. In successful programmes, there is a shift in age distribution towards older age groups.
- **BLOCK 3** this block will be completed for evaluation of laboratory activities. No of PTCs (examined for diagnosis) and number of TB presumptive cases with positive bacteriological resultswill be recorded in relevant columns. Record the total # of OPD for respective quarter.
- **BLOCK 4** Report the diagnosed cases through contacts screening from TB03 and mention the exact figure of total contacts in column 1 , contacts screened cases in column.2 In the 3rd column mention the exact figure of confirmed TB cases out of total screened out cases (the cases are included in block1).

7.1 QUARTERLY REPORTING ON SMEAR CONVERSION (TB08)

- The Quarterly report on smear conversion (TB08) is an important report form in the routine recording and reporting system of TB Control Programme. The report indicates how many pulmonary smear positive (new and relapses and other re-treatment) cases, registered 3 to 6 months earlier, have been converted to smear negative (or have died, or Lost to follow or transferred to another diagnostic center) at the completion of 2/3 months of their treatment. The report also tells how many sputum smear negative cases, registered 3 to 6 months earlier, have died, or Lost to follow, or transferred out by the completion of 2/3 months of their treatment.
- The report is produced, by extracting data on new cases and previously treated cases from the previous report on new cases and previously treated (TB07). This is done at each BMU/ TB Care Facility during the first week of every quarter. The pages of the TB03 register to be reviewed for the quarter is located by examining the “date of registration” column and identifying the pages with cases registered during the quarter 3 to 6 months earlier.
- The report includes important indicators that can alert us that diagnostic and treatment arrangements are/ are not working effectively. The report also identifies early Lost to follow and deaths among registered TB patients. The report is submitted to the District TB Coordinator who checks the consistency and completeness of reports received from all diagnostic centers. The TB Coordinator also produces a district report by compiling the reports from all BMU/ TB Care Facility in the district.

National TB Control Program Pakistan

QUARTERLY REPORT ON SPUTUM CONVERSION OF TB CASES REGISTERED ONE QUARTER EARLIER
INDIVIDUAL BMU / CONSOLIDATED (TICK ONE)

TB-08

Name of BMU/TB Care Facility_____**District:** _____	**Patients registered during**_____ **Quarter of year**_____
Name of TB Coordinator:_____ **Signature:** _____	**Date of completion of this form:** _____

Block 1: All TB cases registered during the quarter (except for TB cases moved to the second -line treatment register)

TB patient type	Number of cases registered	Smear Negative	Smear positive	Died	Lost to follow-up	Not evaluated	TOTAL
Bacteriologically confirmed (New and Relapse)							
Clinically diagnosed (New and Relapse)							
Extrapulmonary (bacteriologically confirmed and/or clinically diagnosed)							
Retreatment (excluding relapse)							

The **top part** of the form contains general information about the BMU/TB care Facility and district. It allows the provincial programme to quickly determine which district and quarter is being reported on.

The **lower part** of the form is divided into seven columns.

- **Cases Registered (1)**: The number of new (bacteriologically positive and negative) and previously treated cases (relapses ,treatment after failure, treatment after Lost to follow up , and others SS+ive, Others SS-ive) registered during the quarter being reported are taken from the quarterly report on new cases and previously treated for the quarter being reported on (i.e. column , 2,3,4,5 and 6 of TB07). Columns “M” and “F” are meant for recording the number of male and female patients, whereas column “T” is meant for recording the total number of male and female patients.
- **Smear Negative (2):** Number of patients who are found to be smear negative at the completion of 2 months of treatment. This is recorded separately for new cases (smear positive and negative) and previously treated (relapses ,treatment after failure, treatment after Lost to follow up, and others SS+ive, Others SS-I've).
- **Smear Positive (3):** Number of patients who are found to be smear positive at the completion of 2 months of treatment. This is recorded separately for new cases (smear positive and negative) and previously treated (relapses ,treatment after failure, treatment after default Lost to follow up, and others SS+ive, Others SS-I've).
- **Died (4):** Number of patients (out of those under review) who died during the period being reported on.
- **Lost to follow-up (5):** Number of patients (out of those under review) whose treatment was interrupted for two consecutive months or more after registration.
- **Not evaluted (6):** Number of patients (out of those under review) whom no treatment outcome is assigned (includes “Transfer out” to another treatment unit and whose treatment outcome is unknown).

Total (7): Total number of patients evaluated (i.e. sum of column 3, 4, 5, and 6).

7.1 THE QUARTERLY REPORT ON TREATMENT RESULTS (TB09)

- The quarterly report on treatment results (TB09) is an important report form in routine recording and reporting system of TB Control Programme. The report tells how many of the pulmonary tuberculosis cases, out of total registered 12 to 15 months earlier, and has successfully or unsuccessfully completed their treatment. The successful treatment results include cured and treatment completed, whereas unsuccessful treatment results include treatment failure, Lost to follow up, died, transferred out.
- The report is produced, by extracting data from TB Register (TB03) for the quarter under reporting, at each BMU/TB Care Facility in the first week of every quarter. The section of TB03 to be reviewed for the quarter is located by examining the “date of registration” column and identifying the pages with cases registered during the quarter 12 to 15 months earlier. So the report gives treatment outcomes for the cases registered and reported in case finding report 12-15 months earlier.
- The report includes important indicators that can alert us that treatment arrangements are working/not working effectively. The report is submitted to District TB Coordinator who checks the consistency and completeness of reports received from all BMUs/TB Care Facility's , and produce a district report by compiling reports from all BMUs /TB Care Facility's in district.

TB-09

National TB Control Program

QUARTERLY REPORT ON TREATMENT OUTCOMES
INDIVIDUAL BMU / CONSOLIDATED (TICK ONE)

Ministry of National Health Services Regulations & Coordination

Name of TB Care Facility (BMU): _____ District: _____	Patients registered during: _____ Quarter of year: _____
Name of TB Coordinator/Facility incharge: _____	Date of completion of this form: _____
Signature: _____	

Block-1: All TB cases registered during the quarter

TB Patient Type	Number of TB Cases registered (X)	TREATMENT OUTCOMES						Re-enrolled on HrTB Treatment (Y)	Moved/ Transfered to the DR-TB register (Z)	Total Evaluated (X-Y-Z)
		Cured	Treatment completed	Treatment failed	Died	Loss to follow-up	Not evaluated			
A. Pulmonary TB Bacteriologically confirmed (New + Relapse + Previously treated History Unknown)										
B. Pulmonary TB Clinically Diagnosed (New + Relapse + Previously treated History Unknown)										
C. Extra Pulmonary TB Bacteriologically confirmed/Clinically diagnosed (New + Relapse + Previously treated History Unknown)										
D. Retreatment (Excluding Relapse)										
Treatment outcome of subset of patients										
A-1: HIV - Positive PTB and EPTB (New + Relapse + Previously treated History Unknown)										
A-2: Children <15 - PTB and EPTB (New + Relapse + Previously treated History Unknown)										

Block 2: Bacteriologically Confirmed TB Cases with DST Result

	Rifampicin		Isoniazid		Fluoroquinolone	
	Results	Resistant	Results	Resistant	Results	Resistant
New						
Relapse						
Previously Treated						
Total						

Block 3 :

	No. of Patient put on treatment
Regimen 1: 2HRZE/4HR	
Regimen 2: 6HRZE	
Regimen 3: 6HRZE + LFX	
Total	

THE TOP SECTION: The name of BMU/TB Care Facility, date of completion of form (day/month/year), signature in-charge BMU/TB Care Facility, name and number of district are recorded in the given spaces. The quarter and the year under reporting is recorded by using the following table:

Time of Reporting (TB09)	Patients Registered During
First week April, 2019	January 1 – March31, 2019 (i.e. quarter1, 2019)
First week July, 2019	April 1 – June 30, 2019 (i.e. quarter 2, 2019)
First week October, 2019	July 1 – September 30, 2019 (i.e. quarter 3, 2019)
First week January, 2020	October 1 – December 31, 2019 (i.e. quarter 4,2019)

The **lower part**of the form is divided into 2 main columns.

- **Number of cases registered (during the quarter under review):**It covers the total cases registered for B+ive (new and relapse), clinically diagnosed (new and relapse), extrapulmonary and previously treated (excluding the relapse)
- **Treatment outcomes (which is further divided into six columns):**This column is to put the figures against the six possible outcomes expected among the patients registered during the quarter under review.The outcomes to be reported includes;
- **Cured:** A patient registered as smear-positive, has completed the duration of treatment, and becomes sputum smear negative at the end of treatment and on at least one previous occasion.
- **Treatment completed:** A smear positive patient who has completed the duration of treatment and have at least one follow up smear negative results but none at the end of treatment due to any reason Smear negative and extra pulmonary cases complete six months of treatment successfully
- **Treatment failure:** A sputum smear positive patient who remains or becomes sputum smear positive at month five or later.
- **Died:** A patient who dies for any reason during the course of treatment.
- **Lost to follow up:** A patient whose treatment was interrupted for two consecutive months or more after registration

Not evaluated: A TB patient for whom,no treatment outcome is assigned (includes "Transfer out" to another treatment unit and whose treatment outcome is unknown).

7.1 SUMMARY POINTS

- The TB07 is the quarterly reporting form used to report the details of new and re-treatment cases of TB
- Transferred in cases should not be reported on the TB07
- The aim of the TB07 is to allow the district TB Coordinator to monitor the diagnostic procedures of the TB Programme. This is done by comparing each quarter's data with previous data from that area, expected percentages and percentages from neighboring areas.
- The TB08 is the quarterly report on smear conversion and it provides information on whether the diagnostic and treatment arrangements are/are not working effectively.
- The main indicators used are the smear conversion rate among sputum positive cases and the proportion of patients who die, Lost to follow up or are transferred out before the 2^{nd}/3^{rd} month of treatment
- The TB08 allows the TB Coordinator to monitor the treatment of patients registered with the program. This is done by comparing each quarter's data with previous data from that area, expected percentages and percentages from neighboring areas.

- Having identified variations/problems the District TB Coordinator can then investigate the problem and identify ways of addressing the problems.
- The quarterly report on treatment results (TB09) provides information on the number of patients who have successfully completed their treatment.
- The report includes important indicators that can alert us that the treatment arrangements are working/not working effectively.
- The main indicators used are the cure rates, treatment completion rates, treatment failure rates for all patients, in addition to the proportion of patients who die, lost to follow-up or not evaluated at the end of treatment.

SESSION 8
MANAGEMENT OF LATENT TB INFECTION

Background

Latent tuberculosis infection (LTBI) is defined as a state of persistent immune response to stimulation by Mycobacterium tuberculosis antigens with no evidence of clinically manifest active TB[21]. As there is no "gold standard" test for LTBI, the global burden is not known with certainty; however, up to one third of the world's population is estimated to be infected with M. tuberculosis[22] and the vast majority have no signs or symptoms of TB disease and are not infectious, although they are at risk for active TB disease and for becoming infectious. Several studies have shown that, on average, 5–10% of those infected will develop active TB disease over the course of their lives, usually within the first 5 years after initial infection[23]. The risk for active TB disease after infection depends on several factors, the most important being immunological status.

Prevention of active TB disease by treatment of LTBI is a critical component of the WHO End TB Strategy[24]. The efficacy of currently available treatments ranges from 60% to 90%. Mass, population-wide LTBI testing and treatment are not feasible because the tests are imperfect, there are risks of serious and fatal Side-effects, and the cost would be high, for an unproven public health impact. For infected individuals in population groups in which the risk for progression to active disease significantly exceeds that of the general population, however, the benefits are greater than the harm.

Rationale

Current WHO guidelines on LTBI are based on the probability that the condition will progress to active TB disease in specific risk groups, on the underlying epidemiology and burden of TB, the availability of resources and the likelihood of a broader public health impact. Therefore, management of LTBI is recommended for people living with HIV[25] Thailand, between August 2002 and September 2003. During the study period, 342 index cases with sputum smear positive pulmonary tuberculosis patients were recruited into the study and their 500 household contacts aged under 15 years were identified. The prevalence of tuberculosis infection among household contacts was found to be 47.80% (95%CI = 43.41-52.19 and for children under 5 years who are household contacts of people with pulmonary TB[26] and for adult contacts of people with TB and other clinical risk groups living in settings with a low TB incidence (estimated annual TB incidence rate < 100 per 100 000 population)[27,28] 5562 contacts of INH-susceptible and 779 contacts of INH-resistant patients and 246,845 persons with no TB case in the home were followed for 15 years, with surveys every 2.5 years comprising radiographic and sputum examination, selective follow-up of high-risk individuals and passive surveillance. If a new case developed, the household members were assigned to the 'INH-susceptible' (n = 7088).

Table-29: The difference between Latent TB Infection and TB disease

A Person with Latent TB Infection	A Person with TB Disease
Has no symptoms	Has symptoms that may include a cough that lasts 2 weeks or longer, coughing up blood or sputum, weakness or fatigue, weight loss, no appetite, chills, fever, sweating at night, pain in the chest.
Does not feel sick	Usually feels sick
Cannot spread TB bacteria to others	May spread TB bacteria to others
Usually has a skin test or blood test result indicating TB infection	Usually has a skin test or blood test result indicating TB infection
Has a normal chest x-ray and a negative sputum smear	May have an abnormal chest x-ray, or positive sputum smear or culture
Needs treatment for latent TB infection to prevent TB disease	Needs treatment for TB disease

Eligibility for Programmatic management of LTBI

Not all individuals infected with M. tuberculosis develop active TB. It is estimated that the lifetime risk of an individual with LTBI for progression to active TB is 5–10%[23]. The risk is particularly high among children under the age of 5 years and among people with compromised immunity[21]. As preventive treatment entails risks and costs, preventive treatment of M. tuberculosis infection should be selectively targeted to the population groups at highest

Management of LTBI involves a comprehensive package of interventions: identifying and testing those individuals who should be tested, delivering effective, safe treatment in such a way that the majority of those starting a treatment regimen will complete it with no or minimal risk of adverse events, and monitoring and evaluation of the process.

Preventive treatment is recommended for:

- All contacts of bacteriologically confirmed pulmonary TB case
- PLHIV and
- Well specified other high-risk groups which include, in the context of Pakistan:
  - patients initiating anti-tumor necrosis factor-α treatment
  - patients on hemodialysis
  - patients preparing for an organ or hematological transplant
  - patients on cancer chemotherapy
  - current and former workers in workplaces with exposure to silica dust

Note: LTBI testing and treatment is NOT recommended to be systematically carried out in diabetes patients, tobacco smokers, people with harmful alcohol use or who are underweight unless they are included in one of the above high-risk groups.

Who does not require a diagnosis of LTBI before initiation of preventive treatment?

The TB contacts **do not** require a diagnosis of LTBI for initiation of preventive treatment however these groups must be evaluated to exclude active TB disease before the initiation of preventive treatment.

Adults, adolescents, children and infants living with HIV

Adults and adolescents living with HIV, with unknown or a positive tuberculin skin test (TST) and are unlikely to have TB disease should receive preventive treatment of TB as part of a comprehensive package of HIV care. Treatment should be given to these individuals irrespective of the degree of immunosuppression and also to those on antiretroviral treatment (ART), those who have previously been treated for TB and pregnant women.

Infants aged < 12 months living with HIV who are in contact with a case of TB and are investigated for TB should receive 6 months of isoniazid preventive treatment (IPT) if the investigation shows no TB disease.

Children aged more than 12 months living with HIV who are considered unlikely to have TB disease on the basis of screening for symptoms and who have no contact with a case of TB should be offered 6 months of IPT as part of a comprehensive package of HIV prevention and care if they live in a setting with a high prevalence of TB.

All children living with HIV who have successfully completed treatment for TB disease may receive isoniazid for an additional 6 months.

Other HIV-negative at-risk groups

The systematic testing for and treatment of LTBI may be considered for prisoners, health workers, immigrants, homeless people and people who use illicit drugs.

Systematic testing for LTBI is not recommended for people with diabetes, people with harmful alcohol use, tobacco smokers and underweight people unless they are already included in the above recommendations.

Diagnosing Latent TB Infection & Disease

Most persons, but not everyone, with TB disease have one or more symptoms of TB disease. All persons with either symptoms or a positive TB test result should be evaluated for TB disease. If a person has symptoms, but a negative TB test result, they should still be evaluated for TB disease.

A. Diagnosis of Latent TB Infection

A diagnosis of latent TB infection is made if a person has a positive TB test result and a medical evaluation does not indicate TB disease. The decision about treatment for latent TB infection will be based on a person's chances of developing TB disease by considering their risk factors.

Medical History. Clinicians should ask about the patient's history of TB exposure, infection, or disease. It is also important to consider demographic factors age, ethnic or racial group, occupation that may increase the patient's risk for exposure to TB or to drug-resistant TB. Also, clinicians should determine whether the patient has medical conditions, such as HIV infection or diabetes that increase the risk of latent TB infection progressing to TB disease.

Physical Examination. A physical exam can provide valuable information about the patient's overall condition and other factors that may affect how TB is treated, such as HIV infection or other illnesses.

Test for TB Infection. The Mantoux tuberculin skin test (TST) or the IGRA may be used to test for *M. tuberculosis* infection. Additional tests are required to confirm /exclude TB disease.

Chest Radiograph. A posterior-anterior chest radiograph is used to detect chest abnormalities. Lesions may appear anywhere in the lungs and may differ in size, shape, density, and cavitation. These abnormalities may suggest TB, but cannot be used to definitively diagnose TB. However, a chest radiograph may be used to rule out the possibility of pulmonary TB in a person who has had a positive reaction to a TST or TB blood test and no symptoms of disease.

Deciding When to Treat Latent TB Infection

People with latent TB infection do not have symptoms, and they cannot spread TB bacteria to others. However, if latent TB bacteria become active in the body and multiply, the person will go from having latent TB infection to being sick with TB disease. For this reason, people with latent TB infection should be treated to prevent them from developing TB disease. Treatment of latent TB infection should start after excluding the possibility of TB disease.

a.Every adult and adolescent should be evaluated for eligibility to receive ART. Infection control measures should be prioritized to reduce M. tuberculosis transmission in all settings in which care is provided.

b.Chest radiography can be done if available, particularly for people living with HIV on ART, but is not required to classify patients into TB and non-TB groups. In settings with a high HIV prevalence and a high TB prevalence among people living with HIV (e.g. > 10%), strong consideration should be given to adding other, sensitive investigations.

c.Contraindications include: active hepatitis (acute or chronic), regular and heavy alcohol consumption and symptoms of peripheral neuropathy. History of TB and current pregnancy should not be contraindications for starting preventive treatment. Although LTBI testing is not a requirement for initiating preventive treatment, it may be done as a part of eligibility screening where feasible.

d.Xpert MTB/RIF should be used as the initial diagnostic test for TB. Detailed algorithms for people living with HIV

suspected of having TB are available in the WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection

e.Resume regular screening for TB after completion of treatment for active disease.

B. Testing for LTBI

Either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) may be used to test for LTBI. People living with HIV who have a positive test for LTBI benefit more from preventive treatment than those who have a negative LTBI test; LTBI testing can be used, where feasible, to identify such individuals.

(http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf).

LTBI testing by TST or IGRA is not a requirement for initiating preventive treatment in people living with HIV or child household contacts aged < 5 years.

C. Treatment options for LTBI

Isoniazid monotherapy for 6 months is recommended for treatment of LTBI in both adults and children

Rifampicin plus isoniazid daily for 3 months should be offered as an alternative to 6 months of isoniazid monotherapy as preventive treatment for children and adolescents aged < 15 years

Rifapentine and isoniazid weekly for 3 months may be offered as an alternative to 6 months of isoniazid monotherapy as preventive treatment for both adults and children more than 2 years

The adults and adolescents living with HIV who have an unknown or a positive TST and are unlikely to have active TB disease should receive at least 36 months of IPT, regardless of whether they are receiving ART. IPT should also be given irrespective of the degree of immunosuppression, history of previous TB treatment and pregnancy.

D. Preventive treatment for contacts of patients with multidrug-resistant-TB

In selected high-risk household contacts of patients with multidrug-resistant tuberculosis, preventive treatment may be considered based on individualized risk assessment and a sound clinical justification.

SESSION 9
DRUG RESISTANT TUBERCULOSIS

Anti-tuberculosis (TB) drug resistance is a major public health problem that threatens progress made in TB care and control worldwide. Drug resistance arises due to improper use of antibiotics in drug-susceptible TB patients. This improper use is a result of number of actions including, administration of improper treatment, failure to ensure that patients complete the whole course. Essentially, drug resistance arises in areas with weak TB Programs. A patient who develops active disease with resistant TB strain can transmit this form of TB to other individual.

Types of Drug Resistant Tuberculosis

Mono-resistance TB: resistance to one first-line anti-TB drug only.

Poly-resistance TB: resistance to more than one first-line anti-TB drug, other than both isoniazid and rifampicin together.

Multi-drug-resistance TB (MDR-TB): resistance to at least both isoniazid and rifampicin.

Rifampicin-Resistant TB (RR-TB): resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether mono-resistance, multidrug resistance, poly-drug resistance or extensive drug resistance.

Extensive drug-resistance TB (XDR-TB): Resistance to any Fluoroquinolone (FQ) and at least one of the injectable second-line drugs SLIs (Amikacin or Streptomycin) in addition to multidrug resistance.

Drugs used in treatment of drug resistant TB

WHO has recently revised treatment guideline and second line drugs are regrouped as follows (29):

Group-A	Levofloxacin OR Moxifloxacin, Bedaquiline and Linezolid.
Group-B	Clofazimine, Cycloserine OR Terizidone
Group-C	Ethambutol, Delamanid, Pyrazinamide, Imipenem-cilastatin, Meropenem, Amikacin (Streptomycin), Ethionamide/Prothionamide, *p*-aminosalicylic acid

New drugs in MDR TB treatment

Bedaquiline & Delamanid are new drugs recently introduced. Bedaquiline has strong bactericidal and sterilizing activity against M. tuberculosis organisms and is now recommended as core drugs in longer treatment regimen.

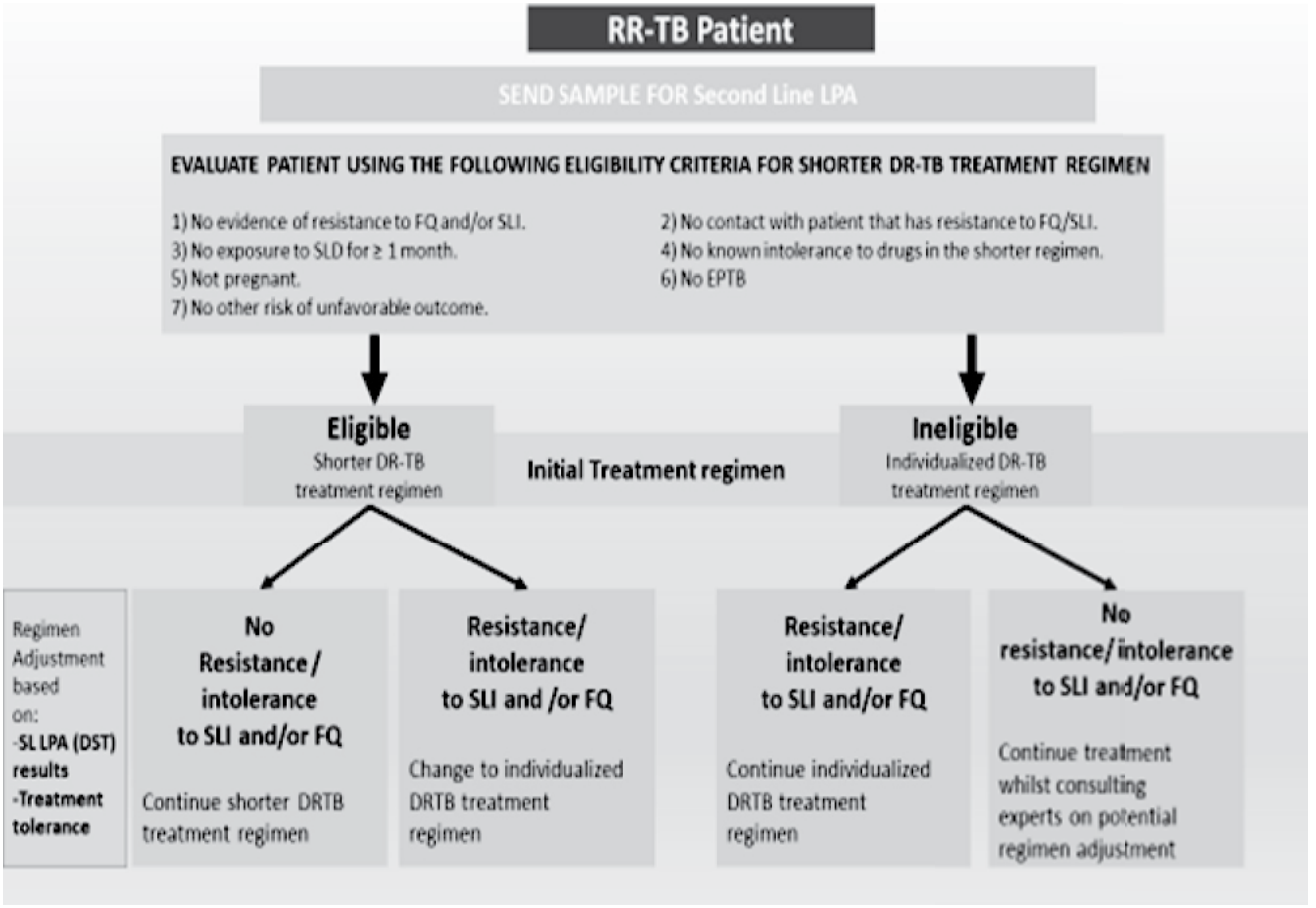
Medicines no longer recommended are Kanamycin and Capreomycin, because of increased risk of treatment failure and relapse associated with their use in longer MDR-TB regimens.

DR-TB treatment regimens

Two treatment regimens are recommended subject to drug resistance profile of Individual patients.

Longer MDR-TB Treatment regimen: Treatment duration is 20-24 months.

Short Treatment regimen (STR): In 2015 WHO released recommendation on the programmatic use of the short-course regimen for MDR TB cases (9-11 months' duration). STR is recommended for DRTB patients whose strains are susceptible to second line drugs including Fluoroquinolone and second line injectable (SLI).
Following criteria is used as guiding principles in treatment selection.



For further details on different treatment regimens refer to relevant Chapter of National Guidelines for the programmatic management of drug-resistant tuberculosis (PMDT).

DR-TB Disease Burden and Treatment Services in Pakistan

Pakistan ranks 4th among 30 high Drug Resistant (DR) TB burden countries in the world with estimated 27,000 cases DR-TB cases in 2017. It is estimated that there were 15,000 MDR/RR TB cases among pulmonary TB cases notified in 2017, based on 4.2% RR/MDR in new TB cases and 16% among previously treated cases[6].

Currently, there are 33 DR-TB Treatment Sites (public and private sectors) across the country where DR-TB patients are being managed under Programmatic Management of Drug Resistant TB (PMDT). Provision of free of cost services are ensured at these designated Treatment Sites where team of trained health professionals manage DRTB patients in collaboration with technical assistance from central level. Package of comprehensive care is provided which include proper diagnosis, precise treatment prescription by trained medical providers and comprehensive psycho-social support care. The DR-TB patients are managed as per DR-TB protocols laid down in National Guidelines to avoid risks related with misdiagnosis, use of inappropriate treatment, use of suboptimal quality drugs and improper management of adverse events related with these drugs. It is suggested that the treatment may be confined to designated PMDT Treatment Sites for provision of best possible care to patients.

Ambulatory Based-Model of Care

Majority of the DR-TB patients are managed through ambulatory care model of treatment. After careful clinical assessment, treatment supporters are identified and information is provided of nearby public sector TB care facility. All DR-TB patients visit PMDT Treatment Sites on monthly basis for follow-up assessments, including clinical monitoring, drug compliance and sputum cultures for monitoring of treatment response.

Hospital-Based Model of Care

All PMDT site are equipped with facilities of indoor management. Although hospitalization is not prerequisite for initiating DR-TB treatment, but some of the newly diagnosed DR-TB patients may require hospitalization (at PMDT Treatment Site) to make clinical assessment, observe poor clinical condition and initial response to the prescribed second line drugs (SLDs) and to make satisfactory arrangements for ambulatory-based management of DR-TB patient.

Social Support Package

The compliance to DR-TB treatment is a significant challenge for the patient & care givers/families due to length of treatment and adverse events related with DR-TB drugs. In addition, long distance travels are required to access quality care resulting high out of pocket expenditure. Keeping in view these barriers and constraints to successful treatment, social support package is provided to DR-TB patient and the treatment supporter. This enables the patient to improve their nutritional status and cover the travel expenses. The mobile cash-based disbursement mechanism through Easy Paisa is implemented to ensure timely and transparent distribution of cash incentives.

Management of Contacts of DR-TB Patients

All close contacts of DR-TB cases are at high risk of DR-TB due to transmission of drug resistant strains from index case. Risk increase with delay in the diagnosis and smear positivity of the index case. It is therefore very important that all contact should be identified and screened for TB/ Drug resistance TB soon after the diagnosis/enrolment of DRTB patient. If any contact is reported symptomatic or has abnormal shadows on CXR, they should be immediately investigated using Xpert/MTB/RIF testing. If rifampicin resistance is detected, then the patient should be referred immediately to the nearest PMDT Treatment site for enrolment and effective treatment.

National TB Control Program

PRESUMPTIVE TB CASE REGISTER

Ministry of National Health Services Regulations & Coordination

Sr. No.	Date (DD/MM/YY)	Name with Father's Name / Husband Name	Address / Cell No. / CNIC	Age	Gender	Contact of Known TB Case Yes/No	If contact TB Registration No. of Index Case	Patient Identified In		Type of Facility			Persumptive TB Case identified base on			Refer to Laboratory		Remarks
								OPD	Indoor	Chest	General	Other	Cough	Other (F, WL, NS)	CXR	Same Facility	Other	

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