Basic Training Module
for Doctors on
Management of Tuberculosis

National Tuberculosis Control Program
Ministry Of National Health Services, Regulations & Coordination
Government of Pakistan
www.ntp.gov.pk

Revised Edition 2015
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Pakistan
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FOREWORD

It is a matter of great pleasure and satisfaction that National TB Control Program has produced “Revised Edition” of Doctors Training Module on Community Based TB Care (DOTS).

Pakistan currently harbors fifth highest burden of Tuberculosis alongside the fourth highest burden of Drug Resistant TB globally. In an estimated population of around 180 million with annual incidence of TB being 270/100,000, Pakistan produces about 510,000-730,000 new cases annually. As we move in the era of Sustainable Development Goals (SDGs), TB Control maintains a very high priority within the health sector.

National TB Control Program, working under the Ministry of Health Services, Regulation and Coordination, Government of Pakistan, in collaboration with all Provincial/Regional TB Control Programs, endorses and implements WHO recommended The End TB Strategy for effective control of this menace. The program entails free of cost diagnosis and treatment of registered TB patients through uninterrupted provision of quality assured anti TB drugs in the country.

“DOTS” is a cost-effective way to control TB, a threat to human health and socio-economic development. The Government of Pakistan is committed to an effective TB Control Program and 100% access to TB patients nation-wide.

I am sure that this training course will enable the doctors to deliver quality TB care and reduce the burden of disease. I appreciate the efforts made by all, involved in the development of this document. I wish all success to NTP in achieving the goal of effective Tuberculosis Control in Pakistan.

Dr. Ejaz Qadeer
National Manager
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7.5 SUMMARY POINTS

WORK SHEETS
INTRODUCTION

Tuberculosis (TB) is a major public health problem in Pakistan. Pakistan ranks fourth amongst 22 high burden countries for TB in the world.\textsuperscript{1} A nationwide population-based TB prevalence survey\textsuperscript{2} in 2010-11 reported an estimated TB prevalence (all forms and all ages) of 342 cases per 100,000 populations which implies that between 510,000 - 730,000 individuals have active TB in the country at any given time. Based on this prevalence, the incidence was estimated at 272 TB cases per 100,000 populations.

OBJECTIVES OF TRAINING COURSE

The course is designed to train doctors on standard TB case management practices. The teaching methods used are participatory and skills-based; including group discussion, role-play of cases and practical exercises. The module should also be kept for reference after the course.

The specific objectives of the course are:

- To orient and update the participants on the current TB control approaches
- To provide an overview of the standard case management of TB.
- To train doctors how to use the case management desk guide.
- To strengthen their capacity in TB diagnosis, prescription, education, contact management, recording/reporting and follow-up.

NORMS SETTING

In order to ensure that the training session runs smoothly and to make the best of the course we need to agree on some norms. Following points may be taken into consideration.

\footnotesize

1\textsuperscript{WHO Global TB Report, 2014}
2 National TB Prevalence Report, NTP, Pakistan, 2010-11
NO VISITORS ALLOWED DURING THE SESSION

CERTIFICATE

No
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 DOTS strategy for control of TB in Pakistan
- Understand the organization of TB control services
- Understand the principles and importance of effective communication in health care and recognize barriers that may exist when communicating with the people
- Be able to use these communication skills learnt in their daily work
- Understand the background, significance and use of TB desk guide
- Understand different components of the 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 510,000 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.

The TB control globally and in Pakistan has been evolved in various stages. The current status is as following:

Global TB targets:

The World Health Organization in its annual report 2014 has provided a glance of Stop TB Strategy and Post-2015 Global Strategy.
The Stop TB Strategy at a glance

<table>
<thead>
<tr>
<th>VISION</th>
<th>A TB-free world</th>
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<tr>
<td>GOAL</td>
<td>To dramatically reduce the global burden of TB by 2015 in line with the Millennium Development Goals (MDGs) and the Stop TB Partnership targets</td>
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| OBJECTIVES | ■ Achieve universal access to high-quality care for all people with TB  
■ Reduce the human suffering and socioeconomic burden associated with TB  
■ Protect vulnerable populations from TB, TB/HIV and drug-resistant TB  
■ Support development of new tools and enable their timely and effective use  
■ Protect and promote human rights in TB prevention, care and control |
| TARGETS | ■ MDG 6. Target 6.c: Halt and begin to reverse the incidence of TB by 2015  
■ Targets linked to the MDGs and endorsed by the Stop TB Partnership:  
   — 2015: reduce prevalence of and deaths due to TB by 50% compared with a baseline of 1990  
   — 2050: eliminate TB as a public health problem (defined as <1 case per 1 million population per year) |

Components

1. **Pursue high-quality DOTS expansion and enhancement**  
   - Secure political commitment, with adequate and sustained financing  
   - Ensure early case detection, and diagnosis through quality-assured bacteriology  
   - Provide standardized treatment with supervision, and patient support  
   - Ensure effective drug supply and management  
   - Monitor and evaluate performance and impact

2. **Address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations**  
   - Scale up collaborative TB/HIV activities  
   - Scale up prevention and management of MDR-TB  
   - Address the needs of TB contacts, and of poor and vulnerable populations

3. **Contribute to health system strengthening based on primary health care**  
   - Help improve health policies, human resource development, financing, supplies, service delivery and information  
   - Strengthen infection control in health services, other congregate settings and households  
   - Upgrade laboratory networks, and implement the Practical Approach to Lung Health  
   - Adapt successful approaches from other fields and sectors, and foster action on the social determinants of health

4. **Engage all care providers**  
   - Involve all public, voluntary, corporate and private providers through public–private mix approaches  
   - Promote use of the International Standards for Tuberculosis Care

5. **Empower people with TB, and communities through partnership**  
   - Pursue advocacy, communication and social mobilization  
   - Foster community participation in TB care, prevention and health promotion  
   - Promote use of the Patients’ Charter for Tuberculosis Care

6. **Enable and promote research**  
   - Conduct programme-based operational research  
   - Advocate for and participate in research to develop new diagnostics, drugs and vaccines
### The post-2015 global TB strategy at a glance

| VISION | A TB-free world  
|        | — zero deaths, disease and suffering due to TB |
| GOAL   | End the global tuberculosis epidemic |
| MILESTONES FOR 2025 | — 75% reduction in TB deaths (compared with 2015)  
|        | — 50% reduction in TB incidence rate (less than 55 TB cases per 100,000 population)  
|        | — No affected families facing catastrophic costs due to TB |
| TARGETS FOR 2035 | — 95% reduction in TB deaths (compared with 2015)  
|        | — 90% reduction in TB incidence rate (less than 10 TB cases per 100,000 population)  
|        | — No affected families facing catastrophic costs due to TB |

### 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 AND COMPONENTS

#### 1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION
   A. Early diagnosis of TB including universal drug-susceptibility testing; and systematic screening of contacts and high-risk groups  
   B. Treatment of all people with TB including drug-resistant TB; and patient support  
   C. Collaborative TB/HIV activities, and management of co-morbidities  
   D. Preventive treatment of persons at high risk; and vaccination against TB

#### 2. BOLD POLICIES AND SUPPORTIVE SYSTEMS
   A. Political commitment with adequate resources for TB 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 TB

#### 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
NTP Pakistan’s Response – National TB Control Strategic Plan “Vision 2020”

The National TB Strategic Plan “Vision 2020” provided innovative strategies that will:

1. Improve the performance and impact of TB control by maximizing public sector investment and accountability in TB control activities.

2. Address sensitive and drug resistant TB by:
   A. Reducing diagnostic delays,
   B. Reducing the duration and improving the efficacy of treatment,
   C. Preventing disease, and
   D. Increasing access to DOTS and DR-TB treatment, etc.

3. Invest in new diagnostic and TB management tools and approaches that are less labor intensive, more cost-effective, and can be delivered close to patients to minimize the health workforce burden and help improve patient access, thereby increasing case detection and enhance treatment success rates.

4. Universal access to TB services, which implies expanding TB DOTS through all types of healthcare providers including the large and currently unregulated private sector

5. Prioritize research with potential to change policy and practice in TB care in the country.

The NSP vision 2020 entails achieving the following:

Vision: TB Free Pakistan

Mission: To ensure universal access to quality diagnosis and treatment for people with TB.

Goal: To reduce 50%, the prevalence of TB by 2025 in comparison to 2012.

Objectives:

i. To increase the contribution of public sector TB control Program funding at least 3 times by 2016 onwards in comparison to 2013

ii. To increase the number of notified TB cases from 298,981 in 2013 to at least 420,000 by 2020 while maintaining the treatment success rate at least at 93%

iii. To reduce, by at least 5% per year from 2018 onwards, the prevalence of MDR-TB among TB patients who have never received any TB treatment;

iv. To optimize and sustain the programmatic deliverables (technical and managerial) at operational level by 2018
1.3 TB CARE: ORGANIZATION:

1.4. LEVELS & RESPONSIBILITY:

The TB Program management roles at district, provincial and federal levels have been redefined after devolution and they are as under;

**Districts Health System:**
- Implementation of TB control interventions through public and private sector
- Coordination with other departments for effective management of Tuberculosis
- Service delivery through Basic Management unit /TB care facility (Rural Health Center/Basic Health unit)

**Provincial TB Control Program:**
- Development of province specific strategic plan and planning documents (PC-1)
- Oversight implementation of TB control interventions
- Technical assistance to districts
- Coordination with implementing & bilateral partners
- Logistic support to districts
- Data validation
- Monitoring & supervision

**National TB Control Program:**

- Coordination and Technical assistance to provinces and districts
- Development of national strategic plan and planning documents (PC-1)
- Policy formulation
- Resource generation especially foreign support
- Disease surveillance
- International representation

**TB Control service delivery in districts:**

The delivery and management of TB care has been integrated within district healthcare services so that continuing care can be provided close to the patient's home. TB care has become an integral part of healthcare at all levels starting from district hospitals to primary healthcare facilities to community health workers. This integration has made it possible to plan and carry out TB control in a district without the addition of a TB-specific care delivery staff. In the context of devolution, the district health authorities i.e. Executive District Officer Health (EDO), District Health Officer (DHO), Medical Superintendent of District Head Quarter Hospital, District TB Coordinator (nominated person), In-charge doctors, DOTS facilitators and Laboratory technician of Rural Health Centers, Basic Health Units, and the District Laboratory Supervisor are the key district personnel that are involved in TB control activities at the district level. The district EDO-H/DHO and the DTC are primarily responsible for advocating, planning, financing, implementing, and monitoring TB care services in their respective districts.

The district and sub-district hospitals, the rural health centers and selected BHUs (where needed) in public health /other health sector works as BMUs /TB care facility. A BMU / TB care facility has a laboratory with laboratory staff (not usually in the case of private sector) and a doctor/qualified medical staff who is trained to diagnose and initiate treatment. The BMU / TB care facility is also a facility where patients return for re-examination and confirmation of cure. The BMU/TB care facility maintains record on standard formats and provides periodic reports to the district coordinator including report on treatment outcome and usually patients prefers the BMU for their regular drug collection.

The tertiary/specialized hospitals, district and sub-district hospitals and TB clinics offer TB services as BMU. The district, teaching and specialized hospitals also provide care to difficult to diagnose TB and manage adult TB cases as well as childhood TB cases. Selected teaching specialized and district hospitals also offer diagnosis and case management of MDR-TB cases (with capacity enhancement and support from the program). The medical schools and post-graduate training institutions would continue contributing in the under-graduate and post-graduate training of doctors and chest specialists as well as TB related research.
TB care diagnostic and treatment facilities in private sector settings includes a variety of implementing models (including general practitioners, NGO clinics, private hospitals and other government sector hospitals)

1.5 THE ROLE OF HEALTH FACILITIES

TB Care Services at Basic Management Unit (BMU) / TB care facility

✓ 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
✓ Declare DRTB presumptive case. 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

1.6 THE ROLE OF 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 male or/ and female who will arrange treatment supporter to ensure direct observation throughout the course of
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 previously treated patients. 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.

1.7 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

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

The picture below represents few common observed barriers in communication.
Exercise 2.1

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.

1.8 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.

- **The Desk-guide:**
  - Is user-friendly for the health worker
  - Follows the logical sequence of steps to be carried out in the TB care delivery process.
  - Has sections including checklists of essential care delivery tasks, which help doctors and paramedics to provide quality care.

- **Why is the desk guide needed?**

The desk guide will help all health workers to understand the complete process of care.

TB care involves a mix of two main components:

- Medical (diagnosing, prescribing, health educating) components
- Social (including identification of treatment supporters and lost to follow up tracing) components.

The management and continuing care of TB patients depends on different health workers at different stages. Some stages are managed mainly by the doctors; others are managed mainly by the paramedics. Doctors have overall responsibility for care, especially for diagnosis and treatment and deciding whether a patient is cured or not. Paramedics have a particular responsibility for communication with patients and their families about TB and its treatment, choosing and orienting DOTS Treatment Supporters, record keeping and follow-up, and tracing of lost to follow up.
It is important that all health workers understand their role and the role of other workers in the process of caring for a person with TB

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

The desk guide should be available in the doctor’s room for ready reference

- **How is the Desk-guide organized?**

The desk-guide follows the step by step process of delivering TB care, right through from the presenting symptoms to cure. Each section of the desk-guide includes checklists of essential care delivery tasks. The sections of the desk-guide are ordered according to the process of delivering TB care as follows:

  o Identifying Presumptive TB cases (Sensitive TB & DR-TB)
  o Diagnosing and Categorizing TB Patient
  o Prescribing Drugs to TB patient
  o Registering and Educating Patient
  o Managing Household Contacts
  o Managing Directly Observed Treatment
  o Preparing treatment Supporter
  o Follow-up of TB patient at treatment centres
  o Retrieving TB Patient
  o Follow-up at BMU
  o Managing treatment interruption
  o Declaring Treatment Outcomes and Ensuring quality

There are also reference pages at the end:

  o Managing TB Patient with interrupted treatment
  o Emergency management of very ill patients
  o Definitions

Different health workers are involved in different ways in the process of care at a health facility when someone with TB symptoms comes to seek care. For this reason, some of the sections (pages) of the desk guide are more relevant to particular group of health workers than others.

It is, however, important for all health workers to understand every stage in the care of TB patient. You can refer to the desk guide at any time if you need to remind yourself of the details of any part
of the process. In all stages of care delivery good communication with the patient is essential. Good communication helps in correct diagnosis, patient friendly care and better compliance.

- **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:**

<table>
<thead>
<tr>
<th>Main step</th>
<th>This refers to a point/area under consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️ Sub-step</td>
<td>This refers to two or more points related to the main step above</td>
</tr>
<tr>
<td>☐ Condition</td>
<td>This refers to conditionality (if), and usually followed by an action statement under that particular condition</td>
</tr>
<tr>
<td>🔄 Recommended Action</td>
<td>This refers to an action, in the light of points considered above Condition</td>
</tr>
</tbody>
</table>

The use of various bullets in the desk-guide is demonstrated in the examples below.

**Example 1:** (desk-guide page 1 “DECIDES LIKELY PROBLEM(S), ADVISE AND TREAT”) Presumptive TB if any of these present:

- ✔️ Cough more than 2 weeks, or
- ✔️ Cough less than 2 weeks or uncertain duration PLUS either
  - √ Blood stained sputum or fever at night or weight loss, or
  - √ Previous TB in the patient, family or other close contact
- 🔄 Explain importance of sputum exams and send for 2 smears

**Example 2:** (desk-guide page 2 “Diagnosing and Categorizing TB Patient”) Decide Sputum Positive or Negative Pulmonary TB:

- ☐ If one or two positive sputum smears
- 🔄 Declare sputum positive pulmonary TB
1.9 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;

- Understand how to identify presumptive Tuberculosis
- Know the common clinical presentation of a presumptive TB case
- Why risk assessment of presumptive TB case is essential
- What is the importance of monitoring TB case finding activities at BMU/TB care facility?
- What different tests are available for diagnosis of tuberculosis?
- Know the laboratory tests recommended for bacteriological diagnosis of tuberculosis.
- Understand which laboratory test can aid in clinical diagnosis of tuberculosis
- Know the laboratory test used for diagnosis of TB infection
- Know the laboratory test that should not be used for diagnosis of tuberculosis
- Understand the recommended algorithm for diagnosis of pulmonary tuberculosis for passive case finding approach.
- Know the recommendations for diagnosis of pulmonary TB (PTB) in patient at risk of DRTB
- Know the recommendation for diagnosis of extra-pulmonary Tuberculosis.
- Understand what is systematic screening for active tuberculosis
- How to request sputum examination?
  - Interpret sputum smear/ Xpert results

2.2 HOW TO IDENTIFY PRESUMPTIVE CASE OF PULMONARY TUBERCULOSIS

Most patients with pulmonary TB develop a persistent cough soon after disease onset. However, cough is not specific to pulmonary TB and is a common feature in smokers as well as in patients with acute upper or lower respiratory tract infection. Most acute respiratory infections with appropriate treatment (usually anti-biotic) resolve within 2 weeks. A patient with persistent cough (with or without other symptoms) for 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.

### 2.3 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)
- Any other condition which render these patients vulnerable to severe form of tuberculosis (HIV+ive, other immune-compromised, seriously ill and/or hospitalized and children)
**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

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

Based on prevalence survey conducted in 2010-11, it **is estimated that there are 500,000 incidents** TB cases every year whereas TB case detection rate (CDR) is 58%, this accounts for more than 200,000 TB cases missed annually in Pakistan. 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
2.5 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-03)

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-03 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.
## REGISTER FOR PRESUMPTIVE TB CASES (PTC)

<table>
<thead>
<tr>
<th>Yearly Sr. No.</th>
<th>Date (DD/MM/YY)</th>
<th>Name With Father/Husband Name</th>
<th>Address/CNIC/Phone number</th>
<th>Age</th>
<th>Sex</th>
<th>OPD Monthly OPD Number</th>
<th>Indoor Ward/Unit Bed No.</th>
<th>Examination type(S-X-C) / Result</th>
<th>Lab number</th>
<th>Remarks</th>
</tr>
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</table>
### OUT-PATIENT DEPARTMENT (OPD) REGISTER

<table>
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<tr>
<th>SEX &amp; AGE CATEGORY (tick in appropriate column)</th>
<th>( &lt;5 ) year</th>
<th>( &gt;1 ) year</th>
<th>( 1-4 )</th>
<th>( 5-14 )</th>
<th>( 15-49 )</th>
<th>( 50+ )</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMALE</td>
<td></td>
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</tr>
<tr>
<td>MALE</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Action Taken / Special Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
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</table>

<table>
<thead>
<tr>
<th>Referred from (if applicable)</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Weight for age (if child)</th>
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</thead>
<tbody>
<tr>
<td>MALNUTRITION</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Name with Father / Husband</th>
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</thead>
</table>

<table>
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<tr>
<th>Follow-Up Cases</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>(New cases) Monthly OPD Serial No.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address</th>
</tr>
</thead>
</table>

### Table of Action Taken / Special Remarks:

- Diagnosis
- Referred from (if applicable)
- Weight for age (if child)
- MALNUTRITION

### Table of Name with Father / Husband:

<table>
<thead>
<tr>
<th>Name with Father / Husband</th>
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### Table of Follow-Up Cases:

<table>
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<th>Follow-Up Cases</th>
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</table>

### Table of New Cases:

<table>
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<th>New cases</th>
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### Table of Address:

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<thead>
<tr>
<th>Address</th>
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</thead>
</table>

### Table of Action Taken / Special Remarks:

- Diagnosis
- Referred from (if applicable)
- Weight for age (if child)
- MALNUTRITION

### Table of Name with Father / Husband:

<table>
<thead>
<tr>
<th>Name with Father / Husband</th>
</tr>
</thead>
</table>

### Table of Follow-Up Cases:

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<thead>
<tr>
<th>Follow-Up Cases</th>
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</thead>
</table>

### Table of New Cases:

<table>
<thead>
<tr>
<th>New cases</th>
</tr>
</thead>
</table>

### Table of Address:

<table>
<thead>
<tr>
<th>Address</th>
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</thead>
</table>

### Table of Action Taken / Special Remarks:

- Diagnosis
- Referred from (if applicable)
- Weight for age (if child)
- MALNUTRITION
2.6 WHAT DIFFERENT TESTS ARE AVAILABLE FOR DIAGNOSIS OF TUBERCULOSIS:

There are different types of test available; some are recommended for bacteriological diagnosis of tuberculosis, some only aid in clinical diagnosis of tuberculosis, some are used for diagnosis of TB infections and some non-specific test which are NOT recommended for diagnosis of TB.

<table>
<thead>
<tr>
<th>Use</th>
<th>Test</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Bacteriological diagnosis of TB</td>
<td>AFB smear microscopy</td>
<td>Initial test for diagnosis of TB in presumptive TB case not at risk of DRTB</td>
</tr>
<tr>
<td></td>
<td>Xpert/MTB Rif assay</td>
<td>Initial test for diagnosis of TB in presumptive TB case at risk of DRTB or in vulnerable population</td>
</tr>
<tr>
<td></td>
<td>MTB culture</td>
<td>In difficult cases who are negative on smear or culture</td>
</tr>
<tr>
<td><strong>2</strong> Aid to Clinical diagnosis of TB</td>
<td>X-ray</td>
<td>As follow on test for patient who are negative of smear and/or Xpert MTB Rif assay</td>
</tr>
<tr>
<td></td>
<td>Histopathology</td>
<td></td>
</tr>
<tr>
<td><strong>3</strong> Diagnosis of TB infection</td>
<td>TST</td>
<td>Recommended only for Children under 5years</td>
</tr>
<tr>
<td></td>
<td>IGRA</td>
<td>Not recommended for low and middle income countries</td>
</tr>
<tr>
<td><strong>4</strong> Non- specific</td>
<td>Serology test</td>
<td>NOT recommended</td>
</tr>
<tr>
<td></td>
<td>Blood CBC, ESR</td>
<td>NOT Recommended</td>
</tr>
</tbody>
</table>

2.7 LABORATORY TEST RECOMMENDED FOR BACTERIOLOGICAL DIAGNOSIS OF TUBERCULOSIS:

There are three test currently recommended by NTP for bacteriological diagnosis of tuberculosis

**AFB SMEAR MICROSCOPY**

Microscopy of sputum smears is simple and inexpensive, quickly detecting infectious cases of pulmonary TB (>5000 bacilli per milliliter of sputum). Sputum specimens from patients with pulmonary TB - especially those with cavitary disease - often contain sufficiently large numbers of acid-fast bacilli to be readily detected by microscopy.

Mycobacteria are distinguished from other micro-organisms by thick lipid-containing cell-walls that retain biochemical stains despite de-colourisation by acid-containing reagents (so-called *acid-fastness*). However, Microscopy for acid-fast bacilli (AFB) cannot distinguish Mycobacterium tuberculosis from NTM, nor viable from non-viable organisms, or drug-susceptible from drug-resistant strains

**Ziehl-Neelsen (ZN) light microscopy:** is performed directly on sputum specimens and services are available in laboratories at all service levels, including Primary health care centers, (Rural health centre), Tehsil head quarter (THQ), Districts hospitals (DHQ) and Tertiary Care Hospitals.
In general, one ZN microscopy centre is considered sufficient for catchment population of 100,000.

**Fluorescent microscopy:** fluorescence microscopy is on average 10% more sensitive than ZN microscope. Conventional fluorescent microscopes required technical expertise, capital and running costs was considerable, however now **Light-emitting diode (LED) fluorescent microscopes are available which are** cost effective. WHO evaluation (2007) confirmed the diagnostic accuracy of LED microscopy and recommends that LED microscopy be phased in as an alternative for conventional ZN light microscopy in both high and low-volume laboratories. In Pakistan LED fluorescence microscopy is gradually being rolled out started from high volume centers.

**XPERT MTB/RIF ASSAY:**

The Xpert MTB/RIF is a Rapid Molecular Test for diagnosis of TB assay can detect both TB and resistance to Rifampicin in less than two hours (in a single test) and currently is the only fully automated cartridge based real-time DNA based test. It is one of WHO endorsed rapid diagnostic test (WRD). It is more sensitive than microscopy and detects MTB even when present in very small numbers and has detection limit of 136 MTB/ML of sputum. It thus has a high sensitivity in smear-negative tuberculosis. Sensitivity of a single Xpert MTB/RIF test in smear-negative/culture-positive patients is reported to be 72.5%.

### Reporting Pattern and interpretation of results of Xpert MTB Rif

<table>
<thead>
<tr>
<th>S.No</th>
<th>REPORT</th>
<th>DRTB RISK ASSESSMENT</th>
<th>INTERPRETATION</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MTB Detected Rif resistance NOT detected</td>
<td>No History of previous ATT</td>
<td>Definite TB case (B+) NO Rifampicin resistance</td>
<td>Start as new case (Cat-I)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>History of previous ATT</td>
<td>Definite TB case (B+) NO Rifampicin resistance</td>
<td>Start as previously treated case (Cat- II)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>History of previously treated (Cat-II Failure)</td>
<td>Definite TB case (B+) NO Rifampicin detected</td>
<td>Start as previously treated case (Cat-II) and transport sample/Refer patient for pheno DST</td>
</tr>
<tr>
<td>2</td>
<td>MTB Detected Rif Resistance Detected</td>
<td>No History of previous ATT</td>
<td>Definite TB case with Rif resistance</td>
<td>Repeat Xpert MTB/Rif assay – If -RR Not detected - start on FLD-Cat-I -RR detected –follow as below</td>
</tr>
<tr>
<td></td>
<td></td>
<td>History of previous ATT</td>
<td>Definite TB case with Rif resistance</td>
<td>Refer patient to MDR treatment site enroll patient on SLD and send specimen for FL and SLDST.</td>
</tr>
<tr>
<td>3</td>
<td>MTB NOT detected</td>
<td>MTB Not detected but not excluded :</td>
<td></td>
<td>Clinical evaluation /Radiology and +culture</td>
</tr>
</tbody>
</table>
The MTB/Rif assay is simple to perform with minimal training, is not prone to cross-contamination, and requires minimal bio-safety facilities (similar to sputum smear microscopy)

CULTURE AND SPECIES IDENTIFICATION

Culture is the gold standard of diagnostic testing for TB. Mycobacterial culture and identification of M. tuberculosis provide a definitive diagnosis of TB. The detection limits being around 100 organisms per ml and thus is more sensitive and can detect cases earlier (often before they become infectious). Conventional DST is done on culture isolate first identified as MTB.

Although both the sensitivity and the specificity of culture methods are better than those of sputum smear microscopy as well as Xpert MTB/Rif assay for the diagnosis of tuberculosis, but it is not recommended for use as an initial diagnostic test as it requires 2-6 weeks for results (1-2 weeks on liquid culture media and 4-8 weeks on solid culture media) besides being technically complex.

Solid and liquid culture methods are suitable for intermediate and central level (Regional /Provincial and National reference laboratories). Usually, one culture laboratory is adequate to cover 500,000 - 1 million populations. Solid culture methods are less expensive than liquid culture systems, but results are invariably delayed (2-8wks). Liquid culture increases the case yield by 10% over solid media, and results are available in days rather than weeks (7-14days). Liquid systems are, however, more prone to contamination and the manipulation of large volumes of infectious material, mandates appropriate and adequate bio-safety measures.

Use of culture is recommended in routine practice

- To obtain Culture isolates for conventional DST
- Treatment monitoring of drug resistant TB patient on second line drugs
- Smear and Xpert MTB/Rif negative presumptive TB case with difficulty in clinical diagnosis

2.8 LABORATORY TEST CAN AID IN CLINICAL DIAGNOSIS OF TB?

Histological Examination of biopsied tissue may support in clinical diagnosis of tuberculosis (caseating granulomas) when bacteriology is negative or cannot be done, however histology is non-specific.

Always ensure enough tissue is available, collected in normal saline for molecular assay or culture if TB is presumed.

The 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.

2.9 LABORATORY TEST USED FOR DIAGNOSIS OF TB INFECTION?

There are two kinds of tests that are used to determine if a person has been infected with TB bacteria: the tuberculin skin test and TB blood tests. (see Interferon Gamma release assay)
**TUBERCULIN TEST**

TST requires two patient visits, results are available in 48-72hrs, TST is not expensive, requires an injection into the skin, adequately trained staff, and no special laboratory infrastructure or supplies. BCG vaccination may cause false-positive results in younger persons.

The tuberculin test is recommended in clinical work with children under 5 years of age, where a positive test is more likely to reflect recent infection with Tuberculosis and a much higher risk of developing disease. Other than in children under 5 years, TST has a limited value in clinical work, in high prevalence countries like Pakistan. A "positive" tuberculin test is infrequently followed by disease and a "negative" tuberculin test does not exclude active tuberculosis.

**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).

IGRAs were explicitly designed to replace the tuberculin skin test (TST) in diagnosis of LTBI, and were not intended for diagnosis of active TB. Because IGRAs (like the TST) cannot distinguish LTBI from active TB, these tests are expected to have poor specificity for active TB in high-burden settings due to a high background prevalence of LTBI.

**WHO recommendation on Use of IGRA** is;

IGRAs should not be used in low and middle income countries for the diagnosis of pulmonary or extra-pulmonary TB, nor for the diagnostic work-up of adults (including HIV-positive individuals). Presumptive cases of active TB in these settings (strong recommendation).

IGRAs should not replace the TST in low and middle income countries for the diagnosis of latent TB infection in children, nor for the diagnostic work-up of children (including HIV positive children), in individuals living with HIV infection or screening of latent TB infection in adult and pediatric contacts, or in outbreak investigation.

**2.10 LABORATORY TEST NOT RECOMMENDED FOR 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. There is no evidence that existing commercial

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3 Policy statement on use of tuberculosis interferon gamma release assay in low and middle income countries WHO - 2011
serological assays improve patient-important outcomes, and high proportions of false-positive and false-negative results adversely impact patient safety. Overall data quality was graded as very low and it is strongly recommended that these tests not be used for the diagnosis of pulmonary and extra-pulmonary TB.

**BLOOD EXAMINATION (HB, CBC & ESR):**

Blood examinations are not useful tests as anaemia 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 in other conditions too. A normal result however does not exclude active TB.

**2.11 WHAT IS THE ROLE OF X-RAY IN DIAGNOSIS OF TUBERCULOSIS**

The sputum smear examination for AFB should be performed in all Presumptive TB cases as initial diagnostic test; Radiological examination is recommended for diagnosis of TB in patients with:

i. Two AFB smear negative microscopy results

ii. Children and Young adult who cannot produce sputum and

iii. Patients suffering from military or extra-pulmonary tuberculosis.

Chest X-ray plays an important role in the diagnosis of TB and non-TB chest diseases. However, the radiological diagnosis of tuberculosis is not always specific and reliable, because other chest diseases can also appear similar to tuberculosis on an X-ray and in early stages of TB patient may not have any radiological evidence of TB.

“Chest X-rays can play a significant role in shortening delays in diagnosis. Furthermore, avoiding films by using digital Chest X-ray is an important advantage and Digital technology has a potential to solve most Chest X-ray problems.

“Limitations on the wider use of Chest X-ray, such as non-availability at peripheral health facilities, relatively high cost of radiological examination and the difficulty of interpreting results, even by trained physicians, need to be addressed.”

**2.12 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 outcome, health squeal and the adverse social and economic consequences of TB as well as helping to reduce TB transmission.

**Recommendations on risk groups to screen**

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

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4 Systematic screening for active Tuberculosis. Policies and recommendation WHO 2013
Three **strong recommendation** is one 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** includes four recommendations

1) Prisons and other penitentiary institutions
2) People with an untreated fibrotic Chest X-ray lesion
3) People who are seeking health care or who are in health care and who belong to selected risk groups (underweight, old age, diabetics, COPD)
4) 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:* Different screening algorithm options have been developed for adults and children. Options for the initial screening include;

1) Screening for cough lasting for longer than 2 weeks, or
2) Screening for any symptom compatible with TB, or
3) Screening with chest radiography.

**Recommendation for Systematic Screening for Active Tuberculosis in Pakistan**

NTP recommends systematic screening for active tuberculosis in;

- Health facilities /communities for House hold and other Contact of smear–Positive tuberculosis in routine practices
- Special health care facilities (HIV surveillance sites) for patient living with HIV
- Communities 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 through special organized chest camps
- Special health care facilities for screening of Tuberculosis in diabetics, chronic obstructive pulmonary disease and pregnant females
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;**
- Bacteriologically-positive pulmonary TB
- Drug-resistant TB (DR-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 DR-TB or XDR-TB.

### 2.13 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 (1st) B (2nd) 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.
National TB Control Program Pakistan
(TB 05)

REQUEST FOR SPUTUM EXAMINATION

Name of Healthcare facility: ____________________________ Date of request: ____________________________

Patient Name: ______________________________________

Age (years): ___________ Date of Birth: _____________ Sex: □ Male □ Female

CNIC #: ____________________________ Contact: ____________________________

Reason for Examination:

□ Diagnosis: If yes
□ Presumptive TB case □ Presumptive MDR TB case (specify reason)

□ Follow-up. If follow-up, month of treatment _________ Patient Identifier Code ____________________________

Clinical History

Previously treated for TB? □ No □ Yes □ Unknown

HIV infection? □ No □ Yes □ Unknown

Health care worker: □ No □ Yes ____________________________

Test(s) requested: □ Microscopy □ Xpert-MTB/RIF (if AFB sm +ve on follow up examination)

Requested by (Name and Signature): ____________________________

LABORATORY REPORT (to be completed in the laboratory)

Patient Name: ____________________________ CNIC ____________________________

Age (years): ____________ Sex: □ M □ F ____________________________ Ref by ____________________________

MICROSCOPY RESULTS

<table>
<thead>
<tr>
<th>Date sample collected</th>
<th>Specimen type</th>
<th>Laboratory Serial number(s)</th>
<th>Visual appearance (Purulent/ Mucopurulent/Mucoid/Saliva)</th>
<th>Microscopy Technique used: ZN/FM</th>
<th>Microscopy result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Xpert MTB/Rif Assay □ Not Requested □ Report attached
□ Report to follow □ Submit fresh Specimen

Reported by (Name and signature): ____________________________ Date ____________________________
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 patient’s 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.

### 2.14 SPECIMEN TRANSPORT MECHANISM:

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, 2011. 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

2.15 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:

**Reporting pattern and interpretation of AFB microscopy result**

<table>
<thead>
<tr>
<th>S.No</th>
<th>REPORT AFB smear</th>
<th>INTERPRETATION</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Positive “3+”</td>
<td>Bacteriological positive TB case (B+)</td>
<td>Start ATT.</td>
</tr>
<tr>
<td>2</td>
<td>Positive “2+”</td>
<td></td>
<td>If patient is at risk of MDR refer sample for Gene Xpert MTB/RIF assay testing.</td>
</tr>
<tr>
<td>3</td>
<td>Positive “1+”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Positive “scanty”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Negative</td>
<td>AFB not seen TB NOT excluded</td>
<td>Clinical evaluation – If vulnerable population, refer sample for Xpet/MTB Rif assay</td>
</tr>
</tbody>
</table>

*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.

2.16 RECOMMENDED ALGORITHM FOR DIAGNOSIS OF PULMONARY TUBERCULOSIS FOR PASSIVE CASE FINDING APPROACH:

All patients having symptoms suggestive of TB should be carefully assessed for:

- Presumptive TB in adults who are not at risk of having drug resistant TB
- Presumptive TB case who are at risk of having drug resistant tuberculosis (history of previous treatment, DR contact)
- Presumptive TB case who is vulnerable to have severe form of tuberculosis (HIV+ive), other immune-suppressed, seriously ill, hospitalized.
- Presumptive TB cases in Children and adults with difficulty in expectorating sputum or in cases where specimen has been collected using special procedure (Gastric aspirate, BAL, Bronchial biopsy).

2.17 HOW TO DIAGNOSE PULMONARY TB (PTB) IN ADULTS WHO ARE NOT AT RISK OF DR-TB:

All adult patients (presumptive) of having pulmonary TB should have at least two sputum specimens examined for AFB smear microscopy in a quality-assured laboratory (ISTC standard-2). All persons who had for any reason Chest-X ray done showing radiographic findings suggestive of TB should also submit sputum specimens for microbiological examination (ISTC Standard 4).

The two sputum specimen should be collected as follows

- **Spot Specimen**: Sputum sample is collected on same day as first consultation
- **Early morning Specimen**: Sputum sample is collected early morning at home next day after consultation.
Figure: Flow diagram for diagnosis of pulmonary tuberculosis

Based on the microscopy results, pulmonary TB cases are classified as Sputum smear positive TB patient (Bacteriological positive B+ive) and Sputum smear negative TB patient (clinical diagnosed) (see Chapter 3 for definition). Smear-positivity and grade indicates relative bacterial burden and correlates with disease presentation.

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

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 lymph nodes and lung parenchymal changes (atelectasis, consolidation, effusion).

- Pleural effusion

- Cavitation

- Parenchymal infiltrates

- Calcification

The non-specific signs include;

- 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:
      a) normal relationships
      b) size
      c) 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.

2.19 HOW TO DIAGNOSE PULMONARY TB (PTB) IN CHILDREN:

It is recommended that Xpert MTB/Rif should be used as initial test in preference to conventional microscopy and culture in all children presumed of having tuberculosis.

a) These recommendations apply to the use of Xpert MTB/Rif in processed and unprocessed sputum specimens.

b) These recommendations also apply to gastric lavage and aspirates.

c) Children presumed of having pulmonary TB but with a single Xpert MTB/Rif negative result should undergo further diagnostic testing, and a child with high clinical suspicion for TB should be treated even if an Xpert MTB/Rif result is negative or if the test is not available.
2.20 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.

2.21 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 retreated 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 years. Less than 5 Years

As Gene Xpert is available only at limited sites therefore for all facilities where Xpert testing is not available on site and specimen from recommended patient group requires transportation to higher level laboratory, smear microscopy should first be performed in local laboratory and same specimen should then be transported to Xpert site and patient should be managed based on microscopy results while awaiting Xpert results.

2.22 WHAT ARE THE RECOMMENDATIONS FOR DIAGNOSIS OF EXTRAPULMONARY TUBERCULOSIS:

*Diagnosis of tuberculous meningitis:* It is recommended that Xpert 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) presumed of having TB meningitis.

For CSF specimens, Xpert MTB/Rif should be preferentially used over culture if the sample volume is low or additional specimens cannot be obtained, in order to reach quick diagnosis. If sufficient volume of material is available, concentration methods should be used to increase yield.

*Diagnosis of Extra pulmonary TB at other sites:* Xpert 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 and children) presumed of having extra pulmonary TB.
• Patient (adults and Children) presumptive of having extra pulmonary TB but with a single Xpert MTB/ RIF-negative result should undergo further diagnostic testing, and those with high clinical suspicion for TB should be treated even if an Xpert 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 Xpert MTB/Rif in pleural fluid is very low. Nevertheless, any positive Xpert MTB/ Rif result based on pleural fluid should be treated for pleural TB, while those with a negative Xpert 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 Xpert MTB/Rif on theses specimens

Other test for diagnosis of Extra-pulmonary specimen: Diagnostic yield of AFB smear is low in extra-pulmonary specimen as number of bacilli in EPTB specimen (tissue, biopsy, pus, urine) is much lower compared to sputum. 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.

Depending on the organ involved, diagnosis of extra-pulmonary tuberculosis can only be made based on positive Xpert /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.

What are the recommended approaches for systematic screening for active tuberculosis?

2.23 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

• Chest X-ray will only be used in cases where two or more sputum smears are negative
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
- Ascertain previous intake of TB drugs, and decide the type of pulmonary TB patient
- Know the TB01 card (Tuberculosis Treatment Card).
- Correctly prescribe TB treatment according to the category of the patient
- Record the patient’s category and the prescribed drugs on the TB01 Card.
- Ask and record correctly the address and the contact person.
- 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)
- Record the District TB Number on the TB01 card.
- Identify & record the source of referral on TB01 card

3.2 CLASSIFYING THE DISEASE

The next step in diagnosing a case of tuberculosis is to decide whether the patient can be classified as pulmonary or extra-pulmonary tuberculosis. In case of extra-pulmonary tuberculosis, the body site mainly affected by disease is also noted. In general, recommended treatment regimens are similar irrespective of disease site.

**Pulmonary tuberculosis (PTB)** refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. Miliary TB is classified as PTB because there are lesions in the lungs. Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extra-pulmonary TB. A patient with both pulmonary and extra-pulmonary TB should be classified as a case of PTB.
Extra pulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

3.3 DECIDING THE TYPE OF TB PATIENT

After having classified the patient, the next step is to determine the type of TB patient. Ascertaining previous intake of TB drugs and defining the patient type accordingly is important for:

- Determination of treatment categories, and prescription of appropriate drugs accordingly
- Identification of patients at increased risk of acquired drug resistance
- Registration of cases;
- Notification (quarterly reports and epidemiological monitoring)

Classification based on history of previous TB treatment (patient registration group)

Classifications based on history of previous TB treatment are slightly different from those previously published. They focus only on history of previous treatment and are independent of bacteriological confirmation or site of disease.

- New patients have never been treated for TB or have taken anti-TB drugs for less than 1 month.
  - Previously treated patients have received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows:
    - Relapse patients have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by re-infection).
    - Treatment after failure patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.
    - Treatment after loss to follow-up patients have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment. (These were previously known as treatment after default patients.)
    - Other previously treated patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.
- Patients with unknown previous TB treatment history do not fit into any of the categories listed above.
New and relapse cases of TB are **incident** TB cases.

*Note.* Smear-negative pulmonary and extra-pulmonary cases may also be relapses, failures, loss to follow up or chronic cases. This should, however, be a rare event, supported by pathological or bacteriological evidence (culture).

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

### 3.4 INTRODUCTION TO TB PATIENT (TB01) CARD:

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

**TB01: FRONT SIDE**

- **Name of Diagnostic Centre (BMU)/ TB care facility:** It is the name of health facility where the laboratory services for sputum microscopy are present.

- **CNIC#:** Write patient CNIC number with age 18 and above.

- **Patient name:** Write the patient’s name in full with (S/O, W/O, D/O.) their father/husband name

- **Phone # of Patient**

- **Patient identifier code**

- **Father’s, Grandfathers /Husband’s name:** Write the father’s & G. fathers name if patient is either a male or an unmarried female. Write the fathers & 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.

- **Age:** Write the reported or estimated age of the patient.

- **Date of Registration:** Write the date on which the patient is registered and TB01 card is prepared and treatment is started e.g 20-05-2011 (*Note: if patient is “transferred in”, then record the date when he has started the treatment at first facility*)

- **Address of Patient:** Complete address of the patient where patient will live for next 6-8 months of treatment.
• **Name / Address of Contact Person:** A person name, phone number and full address who can be contacted in case patient cannot be located.

• **Name of Treatment Centre** Write down the nearest health facility from where patient will take treatment.

• **Name / Type of treatment supporter:** Write full name of treatment supporter who will ensure the intake of drug by the patient and Type of treatment supporter (e.g. LHW, CHW, HFW, FM and CVT for community volunteer e.g. teacher).
  
  o **Regimen and Dosage:** Mention new or previously-treated and number of tablets/ injections in relevant boxes.
  
  o **Referred by:** Tick the appropriate box.

  o **Recording** 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, evidence of disease confirmation (Histological and/or bacteriological). Tick the appropriate box for type of patients.

• **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.

• **Recording Smear Results/Xpert results on TB 01 Card:** In the “month” column, write the treatment month of the patient in which sputum examination is carried out NOT the calendar month. According to the NTP protocol sputum examination should be held at months: pre-treatment 0, and at the end of 2 or 3, 5, 6 and 8 months. If sputum is not done due to any reason write ND in these month sputum smear examination result column.

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.
You will learn how to ask and record the patient’s address, contact person, treatment center and district TB number in section “Registering the TB patient”, Identification and recording of Treatment Supporter, categorization and prescription, recording of supervised intake in subsequent sessions.
• **Continuation Phase:** Record the number of tablets per dose in the relevant box for adults and children. Enter the delivery of the drugs to the patients in continuation phase.

• **Contacts Management:** 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.
  
  o **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.

  o **Follow-up:** This may include comments on retrieval action taken, if any.

  o **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.

• **Treatment Outcome:** Write date of outcome and tick the appropriate box.
### CONTINUATION PHASE

<table>
<thead>
<tr>
<th>Number of tablets per dose</th>
<th>ADULT</th>
<th>CHILD</th>
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<tbody>
<tr>
<td></td>
<td>HRE  (75/150/275)</td>
<td>HR (75/150)</td>
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<tr>
<td></td>
<td>HR (60/30)</td>
<td>E (400)</td>
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<thead>
<tr>
<th>DATE OF APPOINTMENT FOR DRUG COLLECTION</th>
<th>DATE OF APPOINTMENT FOR FOLLOW UP</th>
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### (Household) CONTACTS*

<table>
<thead>
<tr>
<th>Name of Contact</th>
<th>Age</th>
<th>Sex</th>
<th>Method of Screening</th>
<th>Date &amp; Result of Screening</th>
<th>Remarks</th>
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</table>

### Treatment Outcome

- Cured
- Treatment Completed
- Died
- Treatment Failure
- Lost to follow up
- Not Evaluated

### DATE OF APPOINTMENT FOR DRUG COLLECTION

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<th>DATE OF APPOINTMENT FOR FOLLOW UP</th>
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### Comments

*Screening of all household contacts of Pulmonary TB patients
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, 2011.

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, 2011.

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 ARifSaleem. 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: __________________________
3.5 PRESCRIBING TREATMENT OF TUBERCULOSIS:

Uninterrupted availability of ATT drugs must be ensured to every TB patient free of cost. To avoid under treatment acquired drug resistance, side effect of over-treatment and to maximize cost-effective use of resources, standardized treatment fixed dose combinations (FDCs) regimen to the diagnostic category of TB patient has been recommended. The most important drugs used in the treatment of tuberculosis are Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Streptomycin (S), and Ethambutol (E). It is very important that we give the patient the full course of treatment. The patient should take the full course of anti-TB treatment so that all of the TB bacteria will be killed.

Categorization of TB patients helps to simplify and standardize drug prescription, the registration of patients and the follow-up of TB cases.

Categorization of TB patients helps to simplify and standardize drug prescription, the registration of patients and the follow-up of TB cases.

3.6 TREATMENT REGIMEN FOR NEW CASE (CATEGORY I)

During the initial intensive phase, a combination of four drugs (Isoniazid, Rifampicin, Pyrazinamide and Ethambutol “HRZE”) are administered under observation daily for a period of two months (sixty doses). When the patient has completed the initial intensive phase of two months, first follow up sputum test is done, if positive, sputum will be sent / transported for Xpert examination, if RR not detected continuation phase will start irrespective of sputum smear result. Similarly, for smear negative cases initial intensive phase (HRZE) is administered for two months. Sputum smear is done at the end of 2 months, if smear is negative, the continuation phase will start. However, if sputum smear is positive, it will be tested on X-pert and if test result is Mycobacterium detected but RR not detected patient, continuation phase will start. During the continuation phase, isoniazid and Rifampicin (HR) are administered daily for four months.

**Note:** Rifampicin-containing regimens should be taken under direct observation.

3.7 TREATMENT REGIMEN FOR RE-TREATMENT CASE (CATEGORY II):

**Note:** After registration as re-treatment case & before starting treatment, all TB cases eligible for re-treatment regimen will be tested on X-pert to exclude RR. The initial intensive phase should be continued for three months. During the initial intensive phase Rifampicin, Isoniazid, Pyrazinamide and Ethambutol, supplemented with streptomycin (HRZES) are given for the first two months, followed by the same drugs without streptomycin (HRZE) for another one month administered daily under observation. If the sputum smear is negative at the end of 3rd month, the continuation phase is started. If the sputum smear is positive at the end of 3rd month, X-pert test will be repeated. If RR is detected patient will be shifted to DR register and if RR is not detected the patient should then start the continuation phase.
During the **continuation phase**, Isoniazid, Rifampicin, and Ethambutol (HRE) are administered daily for five months under observation. If the patient remains smear-positive after the end of five months, he/she is no longer eligible for the re-treatment regimen. Such patients are regarded as CAT-II treatment failure & refer to PMDT unit as MDR presumptive cases.

In the Case Management Desk guide a table is given to help the doctor in categorizing TB patients, according to the national guidelines. The table is easy to use, and method for its use is briefly described below:

- Select which row (out of the two main rows) to use, depending on the results of sputum smear examination i.e. sputum smear positive or negative.
- By using the appropriate smaller rows in disease classification and patient type to decide the category for the patient

The treatment category is recorded in the TB01 Card by putting a “tick” in the appropriate box.

**Exercise 3.4: Disease Classification**

Read the following case studies and classify the disease for each case.

**Case A:** Ahmed has cough from last 4 weeks and he is reducing weight. On investigation his sputum smear results show B+ive. He has never been treated for TB in the past. He has no other signs and symptoms of TB. Classify his disease based on site and treatment history.

Classification based on site: ________________________

Classification based on history: ________________________

**Case B:** Gulzar has cough from last 3 weeks and also complaining of blood with sputum. On investigation his sputum smear results show B+ive. He has taken ATT last year but stopped after 2 months. He has no other signs and symptoms of TB. Classify his disease based on site and treatment history.

Classification based on site: ________________________

Classification based on history: ________________________

- READ “DECIDE THE TREATMENT CATEGORY & AND PRESCRIBING DRUGS” IN THE DESKGUIDE

*The table presents the characteristics of essential anti-TB drugs.* *(See next page)*
## Table: Characteristics of essential anti-TB drugs

<table>
<thead>
<tr>
<th>Essential anti-TB drugs (Abbreviation)</th>
<th>Mode of action</th>
<th>Dosage (mg/ kg)</th>
<th>Common drug preparations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid (H)</td>
<td>Bactericidal</td>
<td>5 (4-6)</td>
<td>Tab: 100mg</td>
</tr>
<tr>
<td>Rifampicin (R)*</td>
<td>Bactericidal</td>
<td>10 (8-12)</td>
<td>Tab: 150, 300, 450mg</td>
</tr>
<tr>
<td>Pyrazinamide (Z)</td>
<td>Bactericidal</td>
<td>25 (20-30)</td>
<td>Tab: 500mg</td>
</tr>
<tr>
<td>Streptomycin (S)</td>
<td>Bactericidal</td>
<td>15 (12-18)</td>
<td>Amp: 1000mg (750 mg)</td>
</tr>
<tr>
<td>Ethambutol (E)</td>
<td>Bacteriostatic</td>
<td>15 (15-20)</td>
<td>Tab: 400mg</td>
</tr>
</tbody>
</table>

*R is almost always given in combination with H to prevent any resistance to this drug

### 3.8 STRENGTH OF INDIVIDUAL DRUGS

Ethambutol tablets are produced in single strengths of 400mg. Isoniazid is available in 100mg and 300 mg strengths. Rifampicin is available as a single tablet in three different strengths i.e. 150, 300 and 450mg. However, it is preferable that Rifampicin is used in combination with Isoniazid. Pyrazinamide is available in 500 and 400 mg strengths.

### 3.9 FIXED DOSE COMBINATION (FDC) DRUGS

FDC tablets with proven bio-availability are preferred over individual drug preparations for treating any type of TB. With FDC the prescription errors are likely to be less frequent because dosage recommendations are straight forward and adjustment of dose according to patient’s weight is easier. The number of tablets to ingest is smaller, which makes patients more adherent to treatment. Fixed dose combination drugs have also some disadvantages. If prescription error occurs and excess dose is prescribed, toxicity of all drugs will increase. Similarly, under dose prescription will lead to sub inhibitory concentrations of all drugs favoring development of drug resistance. FDC drugs also cannot be continued once there is side effects to anyone companion drug, which justify the need for separate drugs for minority of patients to be available in the stock. The recommended formulation currently used are shown in the table (See next page)
Table: Anti-TB drug strength for daily use

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Strength for daily use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid+ Rifampicin (HR)</td>
<td>100+150mg</td>
</tr>
<tr>
<td>Isoniazid+ Rifampicin+ Pyrazinamide+ Ethambutol (HRZE)</td>
<td>75+150+400+275mg</td>
</tr>
</tbody>
</table>

The table below summarizes the drugs and the duration of intensive and continuation phase in three categories of TB patients.

Table: Anti-TB drugs and duration in intensive and continuation phase strength for daily use

<table>
<thead>
<tr>
<th>Category</th>
<th>Intensive Phase</th>
<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Duration in month</td>
<td>Drugs</td>
</tr>
<tr>
<td>New case (CAT-I)</td>
<td>2</td>
<td>HRZE</td>
</tr>
<tr>
<td>Previously treated case (CAT-II)</td>
<td>3</td>
<td>HRZE +S*</td>
</tr>
</tbody>
</table>

*Streptomycin is used only for two months during intensive phase of previously treated case*

3.10 DOSAGE AND DURATION OF ANTI-TB DRUGS:

It is very important to treat TB with the correct dosage of recommended drugs for a specified period (6 months for new case and 8 months for re-treatment case of TB). Anti-TB drugs are not effective if they are not given in the correct dose and according to the weight group of the patient. If the dose prescribed is less than the recommended dose, the TB bacteria will not be killed and they may become resistant to the drugs. If the dose is higher than recommended, the drugs may cause severe toxic effects. To simplify the drug prescription process, the following three pre-treatment weight groups have been suggested in adults:

- 30 –39 kg
- 40-54kg
- 55 kg or more

The number of tablets differs only if patients fall in different weight categories otherwise it remains same for all the patients within the same range of any given weight category.
Always remember. Patient weight should be monitored each month, and dosages should be adjusted if weight changes from one weight band to another.

The number of drugs prescribed is determined by the category of the TB patient and phase of the treatment (intensive or continuation). The dosage (number of tablets) of each drug is determined by weight of the patient at the time of diagnosis.

Anti-TB drugs may need to be temporarily suspended or stopped in case of severe drug intolerance or toxicity.

The tables given in the Case Management Desk guide helps the doctors to prescribe standardized drug regimen, in accordance with national guidelines. The use of these tables is simple, as briefly outlined below:

- Select the right table out of the two given tables, according to the category of the diagnosed patient.
- Select the row of the table, according to pre-treatment weight of the patient.
- Move across the selected row and make note of the drugs/dosages (i.e. number of tablets) to be prescribed.

**READ “PRESCRIBE DRUGS TO TB PATIENT” IN THE DESKGUIDE**

**3.11 RECORDING PRESCRIPTION ON THE TB01 CARD:**

On the TB01 Cards, boxes for recording the prescribed drugs for new and previously treated case 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 3.4.-3.7

**EXERCISES: Prescribe to a TB patient (Use desk guide to complete these exercises)**
Exercise 3.4: 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 on the treatment category 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 “RHZE (150/75/400/275), RH (150/75), RHE (150/75/275), RH (60/30)” tablets).

Exercise 3.5: 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 on the treatment category 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 “RHZE (150/75/400/275), RHE (150/75/275), RH(60/30)” tablets).

Exercise 3.6: 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 category 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 “RHZE (150/75/400/275), RH (150/75), RHE (150/75/275), RH (60/30)” tablets).

Exercise 3.7: Mr. Allah Rakha

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 category 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 “RHZE (150/75/400/275), RHE (150/75/275), RH(60/30)” tablets).

• DISCUSS WITH THE FACILITATOR TO CLARIFY POINTS NOT UNDERSTOOD
3.12 REGISTERING TB PATIENTS

All tuberculosis patients must be registered with the Program 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.

Use the worksheets given at the end of the module to complete the exercises 3.8-3.9
**Exercise 3.8: Mr. Jamil**

The doctor, at the RHC BaraKahu, has diagnosed Mr. Jamil as a sputum smear positive, new case of tuberculosis. He has been a new case of TB (Cat-I). On asking, Jamil gave the following information:

Address: Village Jagiot, DakKhana Kurri, Islamabad

Name & Address of Contact person: Tabassum (farmer), Village Jagiot, DakKhana Kurri, Islamabad, PH:03009xxxxxxxx

Record the BMU, the address, and contact person’s details on Jamil’s TB01 card.

Identify & record in TB01 (worksheet given at the end of the module). Jamil has decided that he will also collect drugs from RHC Barakahu.

---

**Exercise 3.9: Mrs. Shamim**

The doctor, at the RHC BaraKahu, has diagnosed Ms. Shamim as a sputum smear positive, previously treated case of tuberculosis. She has been titled as previously treated case (Category-II). On inquiry, Shamim gave the following information:

Address: Village Sari, Dak Khana Sari, Islamabad

Name and Address of Contact person: Naheed Akhter (wife of patwari), Village Sari, DakKhana Sari, Islamabad.

Record the BMU/TB care facility, the address, and contact person’s details on shamim’s TB01 card.

Identify and record in the TB01 below (worksheet given at the end of the module). Shamim has decided that RHC Barakahu will be his treatment center.

---

**3.13 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.
Treatment Outcome

Date of decision ____________________

☐ Cured  ☐ Treatment completed
☐ Died  ☐ Treatment failure
☐ Lost to follow up  ☐ Not Evaluated

Name ____________________ Patient Identifier Code, __________

Address ____________________ Date of registration __________

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

Name of BMU/TB Care Facility ____________________

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
☐ Transfer In  ☐ Other/Unknown history ________

Date of appointment of drugs collection

Date  Current  Next  Current  Next

Date for follow up (Type of test)

Date  Place of Examination

Remarks ____________________

Initial Phase (Drug & Dosage): CAT (I, II)

<table>
<thead>
<tr>
<th>Drug</th>
<th>ADULT</th>
<th>CHILD</th>
</tr>
</thead>
<tbody>
<tr>
<td>S 750mg</td>
<td>HRZE (75/150/450/275)</td>
<td>HRZE (30/60/150)</td>
</tr>
<tr>
<td>HR (60/60)</td>
<td>E 400</td>
<td>Z 400</td>
</tr>
</tbody>
</table>

Continuation Phase

<table>
<thead>
<tr>
<th>Drug</th>
<th>ADULT</th>
<th>CHILD</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR 75/150</td>
<td>HRE 75/150/275</td>
<td>HR 30/60</td>
</tr>
<tr>
<td>E 400</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Investigations

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Examination Type</th>
<th>Lab No.</th>
<th>Result</th>
<th>CXR</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>X</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>X</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>X</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>X</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>X</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• **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 Side 1 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 2011, the date of the next appointment would be the 13th March 2011. If the 13th of March is found to be a holiday, then the next working day should be used instead. The remarks section of TB 02 is used to record stopping of streptomycin at the end of 2nd month previously treated case (Cat II).

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 (or 3rd), 5th and 6th for new case and 2nd 5th & 8th month for previously treated case. The date of next sputum examination is calculated by adding 2 or 3 months (depending on whether patient is a new or previously treated case and also depending on the number of months of treatment that have already been completed) to the current date of the patient’s visit to the BMU/ TB Care Facility. For example, in a new case Category-I the patient who is being registered on the 13th of February 2012, the date of the next sputum examination will be the 13th of April 2012. 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 being a previously treated category-II patient, then the next sputum examination date would be the 13th of May 2012 (one month later).

• **TB02: SIDE 3**

This side contains all the medical information about the patient’s diagnosis and treatment, including patient category, 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 3.10-3.11

  **Exercise 3.10: 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 3.11: 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.

3.14 **BASIC MANAGEMENT UNIT “TB REGISTER (TB03)”**

  All patients diagnosed with TB must be recorded in the TB Register. 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 consists of 12 digits.

  The section described the coding system *(See next page)*
**Coding System:**

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

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

<table>
<thead>
<tr>
<th>TB Patient Code</th>
<th>Year Code</th>
<th>Cumulative “12 digit” code (example)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting from 001</td>
<td>15 for the year 2015</td>
<td>• P/01/H001/001/15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• P/01/G001/001/15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• P/01/P001/001/15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• P/01/N001/001/15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• P/01/O001/001/15</td>
</tr>
</tbody>
</table>

**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 3rd, 5th& 8th months for previously treated case, treatment is recorded. The sputum results should be
recorded in the relevant month column (0, 2/3, , 5, 6, for new case & 3\textsuperscript{rd}, 5\textsuperscript{th}, 8\textsuperscript{th} 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 3.12
**Exercise 3.12:**

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

<table>
<thead>
<tr>
<th>Site</th>
<th>Date</th>
<th>Treatment</th>
<th>Age (yrs)</th>
<th>Sex (M/F)</th>
<th>Name (Father/Husband/G. Master)</th>
<th>Registration Code</th>
<th>Complete Address (C/O &amp; Contact a)</th>
<th>Referral by</th>
<th>Follow-up</th>
<th>After failure</th>
<th>Lost to follow-up</th>
<th>Previously treated</th>
<th>Others</th>
<th>Transfer in</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
### Basic Management Unit TB Register (TB-03)

<table>
<thead>
<tr>
<th>Results with dates:</th>
<th>Enter date in relevant column</th>
<th>Moved to second line treatment (date)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smear (S) / X-pert MTB/RIF / Chest X-ray (CXR) / other examination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 month</td>
<td>End of month 2/3</td>
<td>End of month 5</td>
<td>End of month 6/8</td>
</tr>
<tr>
<td>S</td>
<td>X-pert</td>
<td>CXR</td>
<td>S</td>
</tr>
<tr>
<td>MTB</td>
<td>RR&lt;sup&gt;*&lt;/sup&gt;</td>
<td>MTB</td>
<td>RR&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>Date</td>
<td>Date</td>
<td>Date</td>
<td>Date</td>
</tr>
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</tr>
</tbody>
</table>

<sup>*</sup> MTB: Mycobacterium tuberculosis; RR: Resistance.
National TB Control Program Pakistan

Instructions
a. For diagnostic testing employing serial sputa or other specimens this is the date of receipt of the first set of specimens.
b. Y= Yes; N=No; Unk=Unknown
c. Y=Previously Treated; N= Not previously treated; Unk= unknown
d. Patient on TB treatment; indicate month of treatment at which follow-up examination is performed.
e. Smear results reported as follows:

Grading - ZN Microscopy

<table>
<thead>
<tr>
<th>No. of AFB Observed</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB in 100 fields</td>
<td>Negative</td>
</tr>
<tr>
<td>1-9 AFB in 100 fields</td>
<td>Record exact number of bacilli</td>
</tr>
<tr>
<td>10-99 AFB in 100 fields</td>
<td>1+</td>
</tr>
<tr>
<td>1-10 AFB/field in 50 fields</td>
<td>2+</td>
</tr>
<tr>
<td>More than 10 AFB/field in 20 field</td>
<td>3+</td>
</tr>
</tbody>
</table>

Grading of FM

|            | 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 field | 1-6 AFB in one field | 1+            |
| 25-250 AFB in one field | 7-60 AFB in one field | 2+            |
| >250 AFB in one field | >60 AFB in one field | 3+            |

Xpert MTB/RIF test result reported as follows:

f "MTB" Column: Det=MTB Detected; ND=MTB Not Detected; INV=Invalid/Error/No Result

g "RR" Column: Det=Rifampicin Resistance Detected; ND=Rifampicin Resistance Not Detected; IND=Rifampicin Resistance Indeterminate

- If more than one smear or Xpert MTB/RIF test is done in a month, enter the most recent positive result.
- Dates associated with the recorded examination results are dates of sample collection.
- If patient "transfers out" to another BMU, make a note in the Remarks column. If no definitive outcome is obtained, record as Not evaluated or Lost to follow-up as appropriate.
- Patients on initial treatment have follow-up sputum smear microscopy examination at 2 months. Patients on retreatment regimen have follow-up sputum smear microscopy examination at 3 months.
- *confirmation required by another technician or prepare another smear, stain and read.
3.15 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 Program. (See TB10 on the next page)
Tuberculosis Treatment Referral/Transfer

Tick for this referral or transfer: ☐ Referral\(^1\) or ☐ Transfer\(^2\) Date of referral/ transfer __________

Name/address of referring/transferring facility

From sending facility: __________________________ Sending District __________

To receiving facility: __________________________ Receiving District __________

Name of patient _____________________________ Age _____ Sex ☐ M ☐ F

Address of patient (if moving, future address): _______________________________________

Diagnosis: __________________________________________

(For Transfer) Patient Identifier Code ________________ Date TB treatment started: __________

\(^*\) CAT I, II, ______________________

Drugs patient is receiving _______________________________________________________

Remarks (e.g. side-effects observed): ______________________________________________

Name / signature of person sending the patient _______________________________________

Documented evidence of HIV tests (and results) during or before TB treatment should be reported. Please attach Form 1 (Tb05) for referral and copy of Form 3 (Tb01 card) for transfer out

For use by facility receiving referred / transferred patient)

District __________________________ Facility __________________________

Patient Identifier Code __________________ Name of patient

The above patient reported at this facility on ____________________________ (date)

Name / signature of person receiving the patient __________________________ Date __________

Return this part to sending Facility referring/ transferring patient as soon as patient has reported, at 43d3htm rqdil5y.

There are two parts of this form, Upper part is filled in triplicate. One for patient, one for DTC and one for the record. First of all tick the status of facility i.e. referring or transferring. Then mention the name and address/ address of referring / transferring facility. Name, age, sex and address and diagnosis of patients is recorded in relevant sections. In case of transfer, BMU number, date treatment started, Category and drugs should be recorded. In remarks section, side effects of drugs and other relevant information are recorded. Name / signature of person sending the Patients should be mentioned in the end.

Lower part is filled by the receiving facility and returned to the transferring facility to ensure that the process of transferring / referral has completed.

\(^1\) Referral is the process of moving a TB patient prior to registration in a BMU TB Register (TB 03) for the purpose of start of treatment (treatment closer to patient’s home). The BMU receiving a “referred” patient is responsible to inform the facility sending the patient about the care provided.

\(^2\) Transfer is the process of moving between 2 BMU a TB patient registered in a BMU Register (TB 03) to continue his treatment in another area with a different BMU TB Register. THE BMU ‘transferring-out’ a patient is responsible to report the treatment outcome, after getting the information from the BMU completing the treatment. The BMU receiving a patient; transferred-in’ is responsible for informing the BMU sending the patient (1) of the arrival of the patient and 2) at the end of the treatment, of the treatment outcome.

Note: A facility referring or transferring large numbers of patients such as large hospitals may use separate forms for referral and transfer and may have a specific register for referrals.
Tuberculosis Treatment Referral/Transfer

Tick for this referral or transfer: □ Referral\(^1\) or □ Transfer\(^2\) Date of referral/transfer _____________

Name/address of referring/transferring facility

From sending facility: ___________________ Sending District ______________

To receiving facility: ___________________ Receiving District ______________

Name of patient ___________________ Receiving District ______________

Address of patient (if moving, future address): ___________________

Diagnosis: ____________________________

(For Transfer) Patient Identifier Code ______________ Date TB treatment started: ______________

* CAT I, II, [ ]

Drugs patient is receiving __________________________

Remarks (e.g. side-effects observed): __________________________

Name / signature of person sending the patient __________________________

Documented evidence of HIV tests (and results) during or before TB treatment should be reported.

Please attach Form 1 (Tb05) for referral and copy of Form 3 (Tb01 card) for transfer out

For use be facility receiving referred / transferred patient)

District ___________________ Facility ___________________

Patient Identifier Code ______________ Name of patient ___________________

The above patient reported at this facility on ______________ (date)

Name / signature of person receiving the patient ___________________ Date ______________

Return this part to sending Facility referring/ transferring patient as soon as patient hs reported, at 43d3/1flnt rqdill5y.

There are two parts of this from, Upper part is filled in triplicate. One for patient, one for DTC and one for the record. First of all tick the status of facility i.e. referring or transferring. Then mention the sete and names/ address of referring / transferring facility. Name, age, sex and address and diagnosis of patients is recoded in relevant sections. in case of transfer, BMU number, date treatment started, Category and drugs should be recorded. in remarks section, side effects of drugs and other relevant information are recorded. Name / signature of person sending the Patients should be mentioned in the end.

Lower part is filled by the receiving facility and returned to the transferring facility to ensure that the process of transferring / referral has completed.

\(^1\)Referral is the process of moving a TB patient prior to registration in a BMU TB Register (TB 03) for the purpose of start of treatment (treatment closer to patient's home). The BMU receiving a “referred” patient is responsible to inform the facility sending the patient about the care provided.

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Note: A facility referring or transferring large numbers of patients such as large hospitals may use separate forms for referral and transfer and may have a specific register for referrals.
Tuberculosis Treatment Referral/Transfer

Tick for this referral or transfer: ☐ Referral\(^1\) or ☐ Transfer\(^2\) Date of referral/transfer ___________

Name/address of referring/transferring facility

From sending facility: __________________________ Sending District __________

To receiving facility: __________________________ Receiving District __________

Name of patient __________________________ Age _____ Sex ☐ M ☐ F

Address of patient (if moving, future address):_______________________________

Diagnosis: ______________________________________________________________

(For Transfer) Patient Identifier Code ______________ Date TB treatment started: ___________

* CAT I, II, ______________

Drugs patient is receiving ________________________________________________

Remarks (e.g. side-effects observed): _______________________________________

Name / signature of person sending the patient _________________________________

Documented evidence of HIV tests (and results) during or before TB treatment should be reported. Please attach Form 1 (TB05) for referral and copy of Form 3 (TB01 card) for transfer out

For use by facility receiving referred / transferred patient

District __________________________ Facility __________________________

Patient Identifier Code ______________ Name of patient __________________________

The above patient reported at this facility on __________________________ (date)

Name / signature of person receiving the patient __________________________ Date __________

Return this part to sending Facility referring/ transferring patient as soon as patient has reported, at 43d3/fint rqdiii5y.

There are two parts of this form, Upper part is filled in triplicate. One for patient, one for DTC and one for the record. First of all tick the status of facility i.e. referring or transferring. Then mention the site and names/address of referring / transferring facility. Name, age, sex and address and diagnosis of patients is recorded in relevant sections. In case of transfer, BMU number, date treatment started, Category and drugs should be recorded. In remarks section, side effects of drugs and other relevant information are recorded. Name / signature of person sending the Patients should be mentioned in the end.

Lower part is filled by the receiving facility and returned to the transferring facility to ensure that the process of transferring / referral has completed.

\(^1\)Referral is the process of moving a TB patient prior to **registration in a BMU TB Register** (TB 03) for the purpose of start of treatment (treatment closer to patient’s home). The BMU receiving a “referred” patient is responsible to inform the facility sending the patient about the care provided.

\(^2\)Transfer is the process of moving between 2 BMU a **TB patient registered in a BMU Register** (TB 03) to continue his treatment in another area with a different BMU TB Register. The BMU ‘transferring-out a patient is responsible to report the treatment outcome, after getting the information from the BMU completing the treatment. The BMU receiving a patient; transferred-in’ is responsible for informing the BMU sending the patient 1) of the arrival of the patient and 2) at the end of the treatment, of the treatment outcome.

Note: A facility referring or transferring large numbers of patients such as large hospitals may use separate forms for referral and transfer and may have a specific register for referrals.
Tuberculosis Treatment Referral/Transfer

Tick for this referral or transfer: ☐ Referral\(^1\) or ☐ Transfer\(^2\) Date of referral/transfer ____________

Name/address of referring/transferring facility

From sending facility: ______________________ Sending District ________________

To receiving facility: ______________________ Receiving District ________________

Name of patient ________________________ Age ____ Sex ☐ M ☐ F

Address of patient (if moving, future address): ______________________________________

Diagnosis: ___________________________________________________________________

(For Transfer) Patient Identifier Code __________________ Date TB treatment started: ____________

* CAT I, II, __________________________

Drugs patient is receiving _______________________________________________________

Remarks (e.g. side-effects observed): ____________________________

Name / signature of person sending the patient ___________________________________________________________________

---

Documented evidence of HIV tests (and results) during or before TB treatment should be reported.
Please attach Form 1 (Tb05) for referral and copy of Form 3 (Tb01 card) for transfer out

---

For use by facility receiving referred / transferred patient)

District ______________________ Facility ______________________

Patient Identifier Code __________________ Name of patient

The above patient reported at this facility on ___________________________ (date)

Name / signature of person receiving the patient __________________ Date _____________

Return this part to sending Facility referring/ transferring patient as soon as patient has reported, at 43d3flint rqdili5y.

There are two parts of this form, Upper part is filled in triplicate. One for patient, one for DTC and one for the record. First of all tick the status of facility i.e. referring or transferring. Then mention the name and address of referring / transferring facility. Name, age, sex and address and diagnosis of patients is recorded in relevant sections. In case of transfer, BMU number, date treatment started, Category and drugs should be recorded. In remarks section, side effects of drugs and other relevant information are recorded. Name / signature of person sending the Patients should be mentioned in the end.

Lower part is filled by the receiving facility and returned to the transferring facility to ensure that the process of transferring / referral has completed.

\(^1\)Referral is the process of moving a TB patient prior to registration in a BMU TB Register (TB 03) for the purpose of start of treatment (treatment closer to patient’s home). The BMU receiving a “referred” patient is responsible to inform the facility sending the patient about the care provided.

\(^2\)Transfer is the process of moving between 2 BMU a TB patient registered in a BMU Register (TB 03) to continue his treatment in another area with a different BMU TB Register. THE BMU ‘transferring-out’ a patient is responsible to report the treatment outcome, after getting the information from the BMU completing the treatment. The BMU receiving a patient; transferred-in’ is responsible for informing the BMU sending the patient (1) of the arrival of the patient and (2) at the end of the treatment, of the treatment outcome.

Note: A facility referring or transferring large numbers of patients such as large hospitals may use separate forms for referral and transfer and may have a specific register for referrals.
3.16 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 facility before 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.

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Exercise 3.13: 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 2000. 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”.

- Fill in the Mr.Shakir TB Referral / Transfer Register (TRTR) from the above information.
- Mr. Shakir reached the BMU DHQ Chakwal on 17th April 2000 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)
## TB Referral / Transfer Register (TRTR)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name</th>
<th>Phone/Cell No.</th>
<th>Type of Lab Test / Result / Lab No</th>
<th>Pre-Registered or Transferred Out PR/TO</th>
<th>Date Referred / Transfer</th>
<th>Name / Address / Tel No. (Receiving Unit)</th>
<th>Patient Identifier code at referring unit (if transfer out)</th>
<th>Treatment Outcome / Unknown</th>
<th>Remarks (About Missing Patient)</th>
</tr>
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<tbody>
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</tbody>
</table>

**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.
3.17 SUMMARY POINTS

- All patients must be grouped as one of 5 disease types: a new case, a relapse case, a failure case, a treatment after lost to follow up case, a transferred in case and other.

- Every TB patient is classified as pulmonary or extra-pulmonary TB.

- The categorization of TB patients into 2 categories 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


- 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 Program 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
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.

4.1 SESSION OBJECTIVES

- At the end of the session, participants will be able to:
- Know the key messages to be delivered to a TB patient, at the time of registration.
- Be able to deliver the key messages to TB patients.
- Be able to inquire and respond to queries and concerns of patients.
- Be able to identify and manage household contact(s) of TB patients.
- Explain directly observed treatment to patients and why continued treatment is important.
- Help patients to select the best treatment supporter.
- Make arrangements to contact the selected treatment supporter.
- Know the seven essential components of treatment support.
- Train the Supporter to carry out the following 7 essential components of treatment support.

4.2 EDUCATING TB PATIENTS:

When a TB patient has been diagnosed, the doctor should provide the patient with key messages about the diagnosis and treatment of TB which needs to be reiterated by the DOTS Facilitator.

The key messages that should be delivered by the doctor and the DOTS Facilitator at BMU/ TB Care Facility are provided in the Case Management Desk Guide. The following information presented includes key explanatory notes concerning key health education messages which are included in the desk guide. Reading these notes will help you to understand the background and the significance of each message included in the desk guide.
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/eight-month drug regimens for new and previously treated 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/eight 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/eight-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 2\textsuperscript{nd}, 5\textsuperscript{th} and 6\textsuperscript{th} case while 3\textsuperscript{rd}, 5\textsuperscript{th} & 8\textsuperscript{th} month for previously treated case of treatment.

• 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 desk guide
  • 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 care provider 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.
RESPONSES JAMIL 4.1

Information for the participant who is the patient 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 not very convinced that I have TB. I have a neat and clean house and we have no one in our family has ever had TB before.
  - I am not sure TB can be successfully treated. 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
## Role-play 4.2: SHAMIM

### Information for the participant who is the **care provider** in this role-play

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

**Instructions:** Shamim has been diagnosed as having TB on the basis of her sputum results and treatment has been prescribed. You are the care provider. Educate the TB patient (Shamim) by using the desk guide page 3 (bottom) and page 5.

---

## RESPONSES SHAMIM 4.2

### Information for the participant who is the **patient** 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 Ms Shamim described in the case study below.

**Case study: Ms Shamim**

- I (Ms. Shamim) have been diagnosed as having TB and treatment has been prescribed.
- I know the cause of TB and how it is transmitted. However, I have a number of concerns.
- I had taken TB treatment for one and a half month in the past and stopped.
- I therefore do not understand why I have TB again.
- I realized that I am feeling very ill but I want to know where the TB has been hiding in my body.
- I am not sure TB can be treated and believe that 8 months of treatment is too long since one of my friends took treatment only for 3 months.
- I am concerned that I may not be able to take injections for 2 months.
- I fear I may not be able to perform my day’s work because I am becoming weak day by day.
- I’m worried about breast feeding my baby while taking these tablets.
- I am afraid that I may not afford treatment because one of my friends had to pay for her drugs.
- I am worried that I cannot afford to come to the RHC every day for the injections. I therefore want the care provider to give me tablets.

**END OF ROLE PLAY**
4.3 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.

Role-play Shamim: The Shamim role play illustrate a real problem. People usually show their concerns related to the duration of treatment. They are not very convinced of their diagnosis if they develop the same complaints again. Women are usually afraid of taking injections and also having frequent visits to the facility because of many social reasons.

The care provider should show concern and discuss to answer to their concerns. In case of shamim as she has developed TB again because she previously left the treatment incomplete. She needs streptomycin injections daily for two months. It is very vital for her to get these injections and tablets for the required duration; otherwise the chances of her becoming multi-drug resistance will be increased to many folds.

4.4 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.

2. 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 (provided on page 6 of the desk guide).

**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, TB 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:

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

*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:

<table>
<thead>
<tr>
<th>NAME /RELATION</th>
<th>AGE</th>
<th>SYMPTOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr ARif Saleem (husband)</td>
<td>30 years</td>
<td>None</td>
</tr>
<tr>
<td>Mr Zaheer (son)</td>
<td>7 years</td>
<td>None</td>
</tr>
<tr>
<td>Mr Qasir (son)</td>
<td>6 years</td>
<td>Diarrhea for 2 days</td>
</tr>
<tr>
<td>Ms Rizwana (daughter)</td>
<td>1 1/2 years</td>
<td>None</td>
</tr>
<tr>
<td>Mr Iftikhar (son) put weight of baby</td>
<td>4 months (breast fed)</td>
<td>None</td>
</tr>
</tbody>
</table>

i. Does any of Shamim household 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

   ________________________________________________________________

98
<table>
<thead>
<tr>
<th>National TB Control Program Pakistan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Register of TB Contacts</strong></td>
</tr>
<tr>
<td>1. Name of Contact</td>
</tr>
<tr>
<td>2. Age, Sex</td>
</tr>
<tr>
<td>3. Result of screening</td>
</tr>
<tr>
<td>Symptons</td>
</tr>
<tr>
<td>Date of onset of symptoms</td>
</tr>
<tr>
<td>Method of screening</td>
</tr>
<tr>
<td>Smear</td>
</tr>
<tr>
<td>CXR</td>
</tr>
<tr>
<td>GXR</td>
</tr>
<tr>
<td>3. Action taken</td>
</tr>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Registration number of index case</td>
</tr>
</tbody>
</table>

1. List all contacts consecutively under the name of the index case (all pulmonary TB cases)
2. Clinically diagnosed, bacteriologically confirmed
3. Action: Registration for treatment, Refered, Dotted, none
4.5  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 previously treated cases)

4.6  EXPLAINING DOT AND THE IMPORTANCE OF CONTINUED TREATMENT

- It is important to convince the patient that continued treatment for six/eight 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.

  • READ “MANAGING DOT” IN THE DESKGUIDE
4.7 HELPING THE PATIENT TO SELECTING 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:
  - Accessible
  - Reliable
  - Accountable to health services
  - Caring but capable of influencing the patient.

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

- 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:
  - physical condition of the patient
  - distance (where they live)
  - cost and the patient’s ability to pay for transport
  - the occupation of the patient
  - 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.

<table>
<thead>
<tr>
<th>LIST OF TREATMENT SUPPORTERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEHSIL/TALUKA: _____________</td>
</tr>
<tr>
<td>FACILITY NAME: ______________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Village/Locality</th>
<th>Lady Health workers</th>
<th>Other Community Health Workers</th>
<th>Community Volunteers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.8 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 Program to learn from early implementation experiences, and further refine the care delivery protocols including treatment support arrangements.

4.9 REQUEST FOR TREATMENT SUPPORT

If the patient selects 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.
REQUEST FOR TREATMENT SUPPORT

Respected Mr./Ms. __________________________________________________________

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

4.10 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
impacting 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
- 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.

4.11 COLLECTION AND STORAGE OF DRUGS

During the whole treatment period of 6/8 months when the patient is on observed treatment outside his/her treatment center, 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.

4.12 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, 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.

4.13 RECORD DAILY INTAKE IN TREATMENT SUPPORT CARD

The TB Program 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.

![Tuberculosis Treatment Support Card](image)
How to Directly Observe TB Treatment

1. **Greet** and welcome the patient. Ask how he or she is and listen to the response while you begin to prepare the medicines.
2. **Prepare** for Observed Intake:
   - ✓ Wash your hands and pour a glass of water for your patient.
   - ✓ Open your box of medicines.
   - ✓ Check the patient’s name and surname.
   - ✓ Take out the patient’s treatment envelope, which contains all his or her medicines.
3. **Observe** the Intake:
   - ✓ Open the packet and pour the tablets directly onto the hand of the patient (avoid touching) and offer him or her a glass of water.
   - ✓ The tablets must all be taken one at a time, while you, the TB Treatment Supporter, watch your patient swallow them. If your patient finds it difficult to swallow them one after the others, let him or her take a short breathing space. The medicines must be taken within half an hour to make sure that they work together.
   - ✓ Talk to your patient while he or she swallows the tablets. Make sure (s)he swallows the tablets.
4. **Record** on the Treatment Supporter Card (kept with supporter).

<table>
<thead>
<tr>
<th>DO</th>
<th>DO NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Make sure the medicines are locked away and safe.</td>
<td>Do not store tablets in dump places.</td>
</tr>
<tr>
<td>Keep medicines out of reach of children.</td>
<td>Do not drop tablets on floor. (Throw away tablets, which fall on the floor).</td>
</tr>
<tr>
<td>Know the name, color and strength of each tablet.</td>
<td>Do not replace one patient’s tablets for another’s.</td>
</tr>
<tr>
<td>If the patient cannot swallow the tablets, crush them. The patient may swallow the tablets with water.</td>
<td>Do not give only part of the daily medicines.</td>
</tr>
<tr>
<td>Encourage them when they are feeling depressed, or like they are not going to get better.</td>
<td>Do not criticise,</td>
</tr>
<tr>
<td>Say that if they take tablets every day for the full 6/8 months - they will get completely well.</td>
<td>Do not get angry or shout at them - it is not easy being ill and taking tablets for 6/8 months. Everyone gets frustrated sometimes.</td>
</tr>
<tr>
<td>Refer all complications and side effects to the health worker.</td>
<td>Do not treat side effects.</td>
</tr>
</tbody>
</table>

BACK SIDE OF TREATMENT 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 (or 3rd month if a previously treated case). 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
4.14 SUMMERY 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 2 weeks 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

5.1 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.
- Identify and manage the side effects of TB drugs
- Identify and retrieve late patients
- 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
- Record relevant data in the TB01 card, TB02 card and TB03 register

5.2 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
- Interview of the patient
- Count 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:

  o 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.

  o Review of the recorded data on drug intake to identify the days when drug intake was supervised, unsupervised or missed.

  o 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.

5.3 ISSUING DRUGS TO THE TREATMENT SUPPORTER & 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 2011, the date of the next appointment at the BMU would be the 13th of May 2011. If the 13th of May is found to be a holiday, then the next working day should be used instead.

5.4 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 IDENTIFYING & MANAGING SIDE EFFECTS

Screening for side effects of anti-tuberculosis drugs is essential part of follow-up at BMU/ TB Care Facility. This is mostly done by interviewing patients and/or Treatment Supporters when they visit the BMU/ TB Care Facility.

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

• Major Side Effects: are those that give rise to serious health hazards. In this case, discontinuation of anti-tuberculosis drugs is mandatory and the patient should be referred to a hospital specialist. TB drugs can cause the following major side effects:

<table>
<thead>
<tr>
<th>MAJOR SIDE EFFECTS</th>
<th>LIKELY CAUSATIVE DRUGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin rash</td>
<td>Thiacetazone, Streptomycin</td>
</tr>
<tr>
<td>Deafness</td>
<td>Streptomycin</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Streptomycin</td>
</tr>
<tr>
<td>Jaundice</td>
<td>Isoniazid, Rifampicin, Pyrazinamide</td>
</tr>
<tr>
<td>Visual Impairment</td>
<td>Ethambutal</td>
</tr>
<tr>
<td>Shock</td>
<td>Rifampicin</td>
</tr>
<tr>
<td>Purpura</td>
<td>Rifampicin</td>
</tr>
</tbody>
</table>
• **Minor Side Effects:** Minor side effects 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 side effects:

<table>
<thead>
<tr>
<th>MINOR SIDE EFFECTS</th>
<th>LIKELY CAUSATIVE DRUGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anorexia, nausea, abdominal pain</td>
<td>Rifampicin</td>
</tr>
<tr>
<td>Joint pain</td>
<td>Pyrazinamide</td>
</tr>
<tr>
<td>eddish change in urine colour</td>
<td>Rifampicin</td>
</tr>
<tr>
<td>Burning sensation in feet</td>
<td>Isoniazid</td>
</tr>
<tr>
<td>Itching of skin</td>
<td>Isoniazid, Rifampicin, Pyrazinamide</td>
</tr>
</tbody>
</table>

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

5.6 IDENTIFYING AND RETRIEVING PATIENTS WHO HAVE MISSED TREATMENT:

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.

5.7 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 2\(^{nd}\), 5\(^{th}\) and 6\(^{th}\) for new case while 3\(^{rd}\),5\(^{th}\) & 8\(^{th}\) month for previously treated case -CAT II), /month of treatment. 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 2\(^{nd}\), 5\(^{th}\) and 6\(^{th}\) month of treatment. During 2\(^{nd}\) 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

5.8 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.

The sputum smear examination schedule differs slightly according to category of the TB patient:

<table>
<thead>
<tr>
<th>Patient Category</th>
<th>End of month 2</th>
<th>End of month 3</th>
<th>End of month 5</th>
<th>End of month 6</th>
<th>End of month 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Case</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smear Positive</td>
<td>Yes</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
</tr>
<tr>
<td>Smear Negative</td>
<td>Yes</td>
<td>NA</td>
<td>Only clinical assessment</td>
<td>Only clinical assessment</td>
<td>NA</td>
</tr>
<tr>
<td>Previously treated case</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

- Broadly speaking, completion of treatment months refers to the number of doses taken (e.g. 60 or 90 doses of TB drugs during intensive phase), rather than calendar month (in its strict sense). This means patient is generally send for the first follow-up sputum examination on his/her completing 60 (New case) or 90 (Previously treated) doses of TB drugs.
- The examination of sputum smears at the completion of the intensive phase of treatment is
the best indicator that the drugs prescribed have been taken regularly and that they are effective.

- More than 80% of new pulmonary smear-positive cases should be smear negative after the initial 2 months of treatment. In addition, 75% of previously treated cases should also be sputum negative after 3 months of treatment. It is for this reason that sputum smears are done at the end of month 2 for new TB patients and at the end of month 3 for previously treated TB patients.

- Sputum smear negative pulmonary cases must also have their sputum examined after 2 months of treatment in order to make sure that they have not become smear positive or that they were not falsely registered as sputum negative cases

- All TB cases found to be sputum smear-positive at the start of treatment should also have their sputum examined at the end of month 5 (new case and previously treated case). The sputum examination at the end of the 5th month is to identify TB patients who are not responding to the prescribed drugs, either due to ineffective regimen and/or irregular intake of drugs.

- All TB cases found to be sputum smear-positive at the start of treatment should also have their sputum examined at the end of month 6 (new case) and month 8 (previously treated case). The sputum examination at the end of 6th/8th month accordingly by category is important to determine the outcome of treatment i.e. whether the patient is cured or not.

5.9 CHANGING THE TREATMENT DURING FOLLOW-UP:

The routine 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 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.

### 5.10 WHEN TO END INTENSIVE PHASE & START CONTINUATION PHASE OF TREATMENT

<table>
<thead>
<tr>
<th>Category of Patient</th>
<th>AFB smear examination</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Month</td>
<td>Result</td>
</tr>
<tr>
<td>New Bacteriologically positive</td>
<td>0Month</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 2Month</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>End of 5Month</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>End of 6Month</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>New Bacteriologically Negative</td>
<td>0Month</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 2Month</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive</td>
</tr>
</tbody>
</table>
### All retreatment cases after failure, lost to follow up or relapse

| 0Month | Positive | Register patient for Previously treated case- CAT II  
Do X-pert before start of treatment  
refer patient /transport specimen for X-pert testing  
If R resistant refer to the DR TB management unit  
If R sensitive, Start intensive Phase (2HRZES 1HRZE). |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>End of 3Month</td>
<td>Negative</td>
<td>Start continuation phase treatment (5HRE)</td>
</tr>
</tbody>
</table>
| | 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 5Month | Negative | Declare Treatment Outcome Previously treated case- CAT II TREATMENT FAILURE  
Declare DR presumptive case. Refer Patient to DR-TBMU |
| | Positive | Continue continuation phase |
| End of 8Month | Negative | Declare treatment outcome “CURE” |
| | Positive | Declare Treatment Outcome Previously treated case- CAT II 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. For previously treated, three drugs (i.e. Isoniazid, Ethambutal and Rifampicin) are given for five 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 Re-treatment patients need frequent monitoring and observed treatment, during the continuation phase also. In both new & previously
treated patients it is recommended that their treatment should be observed during the continuation phase because of continued Rifampicin intake throughout.

The tables given in the desk guide helps the doctor to prescribe standardized drug regimen, in accordance with national guidelines, during the continuation phase of treatment.

5.11 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.

In case Streptomycin is stopped at completion of 2 months, information note is recorded in the remark section of TB02. The treatment outcome, if declared, is also recorded in the TB01 card, TB02 card and TB03 register, by writing the “date treatment stopped” in the appropriate box for the outcome.

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

5.12 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 (Cat-I)
- Treatment Failure Previously Treated Case (Cat-II)
- Relapse after New Case (Cat-I)
- Relapse after Previously Treated Case (Cat-II)
- Treatment after loss to follow up New Case (Cat-I)
- Treatment after loss to follow up Previously Treated Case (Cat-II)
- Other previously treated Case

B. SYMPTOMATIC CONTACTS OF DR-TB PATIENT: All household and workplace symptomatic contacts of DR-TB patients should be screened 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.
C. TB PATIENTS UNDER TREATMENT WHO FAIL TO CONVERT AT THE END OF INTENSIVE PHASE

- B+ive patient on New Case (Cat-1 who fail to convert at the end of month 2 of treatment.
- B+ive patient on Previously Treated Case (Cat- II who fail to convert at the end of 3 months.
- B-ive Patient who is reported AFB smear positive at the end of intensive phase

*Comprehensive First and second line DST:* All patient who are reported Rifampicin resistant on X-pert/MTB Rif assay should be referred to DR treatment site and specimen should be referred to quality assured DST laboratory for comprehensive first and second line DST before start of treatment.

If patient is reported Rifampicin sensitive on X-pert MTB/Rif assay but is clinically considered at high risk of DR (e.g. Cat-II-failure), patient may be referred for phenotypic drug susceptibility testing as small number of Rifampicin resistant are not detected by X-pert MTB/Rif assay

**Reporting pattern and interpretation of results of X-pert MTB Rif**

<table>
<thead>
<tr>
<th>REPORT</th>
<th>DR-TB RISK ASSESSMENT</th>
<th>INTERPRETATION</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 MTB Detected Rif resistance NOT detected</td>
<td>No previous history of ATT</td>
<td>Definite TB case NO Rifampicin resistance</td>
<td>Start New Case treatment Cat-I</td>
</tr>
<tr>
<td>1 MTB Detected Rif resistance NOT detected</td>
<td>History of previous ATT</td>
<td>Definite TB case NO Rifampicin resistance</td>
<td>Start Previously treated Case Treatment Cat- II</td>
</tr>
<tr>
<td>1 MTB Detected Rif resistance NOT detected</td>
<td>History of Cat-II Failure</td>
<td>Definite TB case No Rifampicin resistance</td>
<td>Start Previously treated Case Treatment Cat- II and transport sample/Refer patient for pheno DST</td>
</tr>
</tbody>
</table>
| 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 Cat-I 
-RR detected –reg and start on SLD |
| 2 MTB Detected Rifampicin Resistance Detected | 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 | MTB Not detected but not excluded | Culture / clinical evaluation diagnosis |

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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 being 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

5.13 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.

<table>
<thead>
<tr>
<th>National TB Control Program Pakistan</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR TB Presumptive Case Referral Form</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PMDT Site (where patient is being referred):</th>
<th>Date of referral (mm/dd/yy):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referring Facility:</td>
<td>District:</td>
</tr>
<tr>
<td>Name and contact no. of the care provider (doctor):</td>
<td></td>
</tr>
<tr>
<td>Patient Name:</td>
<td>Age:</td>
</tr>
<tr>
<td>Address:</td>
<td>Contact No:</td>
</tr>
</tbody>
</table>

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DR-TB Risk Group (Please tick)

☐ Failure Category II
☐ Failure Category-I
☐ 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:

<table>
<thead>
<tr>
<th>TB Diagnosis and treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Diagnosed</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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.

5.14 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.

<table>
<thead>
<tr>
<th>Results, if</th>
<th>Interpretation</th>
<th>Further action</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ DST – <strong>resistance</strong> to R and H, with smear positive or negative and culture positive (or result awaited, if rapid DST in-use)</td>
<td>DR-TB patient</td>
<td>♦ Register, further assess, and put patient on DR-TB treatment</td>
</tr>
<tr>
<td>♦ DST – <strong>susceptible</strong> to R and/or H, with smear positive or negative &amp; culture positive (or result awaited, if rapid DST in-use)</td>
<td>TB but not DR-TB</td>
<td>♦ Manage as non-DR TB (e.g. re-treatment or mono-drug resistant TB)</td>
</tr>
</tbody>
</table>

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.
Case 1: Saima

National TB Control Program Pakistan
MDR TB Suspect Referral Form

Hospital (where patient is being sent): ________________________________
Date of referral: (mm/dd/yy) ______________________________________

Referring Facility
Name and Address: __________________________________________________
District: ____________________________

Patient:
Name: ____________________________ Birth Date: __________ Age: _______ Sex: ______
Address: ________________________________________________________ Tel: __________

Brief Medical History: ____________________________________________
________________________________________________________________
________________________________________________________________

MDR-TB Risk Group (Please tick)
□ Failure Category II □ Failure Category-I
□ Failure of treatment regimen used in private sector □ Contact of known MDR-TB case
□ Settings with higher risk exposure eg in institutions with high MDR-TB (specify):
□ Others (specify) ______________________________

TB Treatment History:

<table>
<thead>
<tr>
<th>Date Diagnosed</th>
<th>Facility (where)</th>
<th>Treatment Taken</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Xpert MTB/RIF test result

<table>
<thead>
<tr>
<th>M. tuberculosis</th>
<th>Rifampicin resistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected</td>
<td>Detected</td>
</tr>
<tr>
<td>Not detected</td>
<td>Not detected</td>
</tr>
<tr>
<td>No result / Invalid / Error</td>
<td>Indeterminate result</td>
</tr>
</tbody>
</table>

Examined by (Name & signature): ____________________________ Date of result: ____________________________

For use by hospital to which patient has been referred:

Patient Name: ________________________________________________

Referring facility and address: __________________________________

The above patient reported at this hospital on ____________ (date):
MDR-TB Suspect Reg. #: ____________________________

Signature ____________________________ Position ____________________________

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

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

Patient: **Saima**

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

<table>
<thead>
<tr>
<th>DST RESULTS:</th>
<th></th>
<th>H</th>
<th>R</th>
<th>E</th>
<th>Z</th>
<th>S</th>
<th>K</th>
<th>A</th>
<th>C</th>
<th>O</th>
<th>Pto/Eto</th>
<th>Other</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Collected</td>
<td>Laboratory Specimen No.</td>
<td></td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>August 22, 2010</td>
<td></td>
<td></td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 (Category II) treatment (District TB Number is 014-2010, registered as treatment after Lost to follow up on January 24, 2010). Today is June 29, 2010, 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:

<table>
<thead>
<tr>
<th>Health facility:</th>
<th>Rural Health CenterBaydian, Lahore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associated treating hospital:</td>
<td>Gulab Devi hospital, Lahore</td>
</tr>
<tr>
<td>Patient Address:</td>
<td>House 127, Street 8, Johar Town, Lahore.</td>
</tr>
<tr>
<td>Past treatment:</td>
<td>Patient took NTP recommended CAT-I treatment for about 4 months from the same facility (date diagnosis – April 12, 2009)</td>
</tr>
<tr>
<td>HIV status:</td>
<td>Not known.</td>
</tr>
</tbody>
</table>

Part-1: (at health facility)

Decide: DR-TB presumptive case? (Yes/No)

Act: Refer to treating hospital (i.e. fill the referral form)
National TB Control Program Pakistan
MDR TB Suspect Referral Form

Hospital (where patient is being sent): ____________________________
Date of referral: (mm/dd/yy) ____________________________

Referring Facility
Name and Address: ________________________________________
District: ________________________________________________

Patient:
Name: ___________________________________ Birth Date: __________ Age: ______ Sex: ______
Address: ____________________________________________ Tel: ____________________________

Brief Medical History: ____________________________________________
__________________________________________________________________________
__________________________________________________________________________

MDR-TB Risk Group (Please tick)
☐ Failure Category II ☐ Failure Category-I
☐ Failure of treatment regimen used in private sector ☐ Contact of known MDR-TB case
☐ Settings with higher risk exposure eg in institutions with high MDR-TB (specify):
☐ Others (specify) ______________________________________________________________

TB Treatment History:

<table>
<thead>
<tr>
<th>TB Diagnosis and treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Diagnosed</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Anti-TB Drugs (with Duration)</td>
</tr>
</tbody>
</table>

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

Xpert MTB/RIF test result

<table>
<thead>
<tr>
<th>M. tuberculosis</th>
<th>Rifampicin resistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected</td>
<td>Not detected</td>
</tr>
</tbody>
</table>

Examined by (Name & signature): ____________________________ Date of result: ____________________________

For use by hospital to which patient has been referred:

Patient Name: ______________________________________
Referring facility and address: ____________________________

The above patient reported at this hospital on ___________ (date):
MDR-TB Suspect Reg. #: __________________________________

Signature: ____________________________ Position: ____________________________

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

- When following-up patients it is important to assess:
  - the regularity of drug intake
  - side-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
6.1 SESSION OBJECTIVES:

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

- Retrieve and review the records of previous treatment category, the length of treatment before interruption, and the length of interruption (from the TB01 and TB02 cards)
- Decide about sputum smear examination, Xpert testing, patient re-registration treatment or referral, according to NTP protocols.
- Review the relevant data on the TB01 card and declare the treatment outcome accordingly
- Record 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

6.2 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 category**: This data is clearly indicated on both the TB01 and TB02 cards and there is no difficulty in getting this information. The patient’s category before interruption of treatment will affect the treatment prescribed after interruption of treatment.

- **Length of treatment before interruption**: This is estimated by comparing the date when the patient started previous treatment with the last date due for his/her collecting the pills from the treatment center. Both these dates can be found on the TB01 and TB02 cards.

- **Length of interruption**: This is estimated by comparing the last date due for patient’s collecting the pills from treatment center with the current date of the visit. The last date due for collection of tablets at the treatment center can be found on the TB01 and TB02 cards.

The table below gives the details of the management protocol in case of interruption of treatment:
## Management of New TB Patient with Interrupted Treatment

<table>
<thead>
<tr>
<th>Length of treatment</th>
<th>Length of interruption</th>
<th>Do a smear?</th>
<th>Result of smear</th>
<th>Do Xpert?</th>
<th>Result Xpert</th>
<th>Register again as</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 month</td>
<td>&lt; 2 weeks</td>
<td>No</td>
<td>-</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>Continue on same CAT I</td>
</tr>
<tr>
<td></td>
<td>2-8 weeks</td>
<td>No</td>
<td>-</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>Start again on same CAT I</td>
</tr>
<tr>
<td></td>
<td>&gt; 8 weeks</td>
<td>Positive</td>
<td>Yes</td>
<td>MTB + RR</td>
<td>MTB + RR +</td>
<td>*Treatment after Loss to Follow-up</td>
<td>Start CAT II Ref to PMDT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>Yes</td>
<td>MTB + RR</td>
<td>MTB + RR+</td>
<td>*Treatment after Loss to Follow-up</td>
<td>Start CAT II Ref to PMDT Send for culture Ref to Specialist</td>
</tr>
<tr>
<td>&gt; 1 month</td>
<td>&lt; 2 weeks</td>
<td>NO</td>
<td>-</td>
<td>NO</td>
<td>-</td>
<td>-</td>
<td>Continue on same CAT I</td>
</tr>
<tr>
<td></td>
<td>2-8 weeks</td>
<td>Yes</td>
<td>Positive</td>
<td>MTB + RR</td>
<td>MTB + RR+</td>
<td>-</td>
<td>Start again on same CAT I Ref to PMDT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>Yes</td>
<td>MTB + RR</td>
<td>MTB + RR+</td>
<td>-</td>
<td>Start again on same CAT I Ref to PMDT Send for Culture Ref to Specialist</td>
</tr>
<tr>
<td></td>
<td>&gt; 8 weeks</td>
<td>Yes</td>
<td>Positive</td>
<td>MTB + RR</td>
<td>MTB + RR+</td>
<td>*Treatment after Loss to follow-up</td>
<td>Start CAT II Ref to PMDT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>Yes</td>
<td>MTB + RR</td>
<td>MTB + RR+</td>
<td>*Treatment after Loss to follow-up</td>
<td>Start CAT II Ref to PMDT Send for Culture Ref to Specialist</td>
</tr>
</tbody>
</table>
Management of Previously Treated TB Patient with Interrupted Treatment

<table>
<thead>
<tr>
<th>Length of treatment</th>
<th>Length of interruption</th>
<th>Do a smear?</th>
<th>Result of smear</th>
<th>Do Xpert</th>
<th>Result of Xpert</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Length of RX</td>
<td>&lt; 2 weeks</td>
<td>No</td>
<td>-</td>
<td>No</td>
<td>-</td>
<td>Continue on same CAT II</td>
</tr>
<tr>
<td></td>
<td>2-8 weeks</td>
<td>Yes</td>
<td>Positive</td>
<td>Yes</td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to PMDT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Negative</td>
<td>Yes</td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to specialist</td>
</tr>
<tr>
<td></td>
<td>&gt; 8 weeks</td>
<td>Yes</td>
<td>Positive</td>
<td>Yes</td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to PMDT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Negative</td>
<td>Yes</td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MTB + RR – MTB + RR+</td>
<td>Ref to PMDT</td>
</tr>
</tbody>
</table>

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.

- REFER “MANAGING PATIENTS WITH INTERRUPTED TREATMENT” IN THE DESKGUIDE

### 6.3 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.

6.4 TREATMENT OUTCOMES:

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

Cured: A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment
who was smear- or culture-negative in the last month of treatment and on at least one previous
occasion.

Treatment completed: A TB patient who completed treatment without evidence of failure BUT

with no record to show that sputum smear or culture results in the last month of treatment and on at
least one previous occasion were negative, either because tests were not done or because results are
unavailable.

Treatment failed: A TB patient whose sputum smear or culture is positive at month 5 or later
during treatment.

Died: A TB patient who dies for any reason before starting or during the course of treatment.

Lost to follow-up: A TB patient who did not start treatment or whose treatment was interrupted for
2 consecutive months or more.

Not evaluated: A TB patient for whom 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.

Treatment success: The sum of cured and treatment completed

6.5 DECLARING TREATMENT OUTCOMES:

• The completed TB01 is the main source of information from which treatment outcomes are
determined. The doctor at the diagnostic center 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 center will declare the treatment outcome (i.e. when TB01 with information
and remarks are available at the diagnostic center).

✓ A patient may be declared cured or treatment completed (depending upon availability
of sputum results at the completion of 6th/8th month)
A smear positive patient would be declared as treatment failure on the day he/she reports to the doctor at diagnostic center with the follow-up smear-positive results, at the end of 5th month or later.

A patient may be 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.

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

- 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

6.6 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.

6.7 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 Program. 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 organized
- 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

6.8 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
  ◆ Category of treatment prior to interruption

• Correct management may include:
  ◆ Doing a sputum smear / Xpert
  ◆ Re-registering the patient
  ◆ Changing to a different treatment category
  ◆ Continuing the previous treatment

• Declaring treatment outcomes is an important part of the process of monitoring the quality of the TB Program.

• 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 Program 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 smear conversion (TB08)
- 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 Program. 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 Program 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 Pakistan

**QUARTERLY REPORT ON TB CASE REGISTERED DURING PRECEDING QUARTER**

**INDIVIDUAL BMU / CONSOLIDATED (TICK ONE)**

<table>
<thead>
<tr>
<th>Name of BMU/TB Card Facility</th>
<th>District:</th>
<th>Patients registered during Quarter of year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of TB Coordinator:</td>
<td>Signature:</td>
<td>Date of completion of this form:</td>
</tr>
</tbody>
</table>

#### Block 1: All TB cases registered during the quarter

<table>
<thead>
<tr>
<th></th>
<th>New</th>
<th>Relapse</th>
<th>(N+R)</th>
<th>Treatment after failure</th>
<th>Lost to follow up</th>
<th>Others</th>
<th>Previous treatment history unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary (bacteriologically confirmed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary (clinically diagnosed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Block 2. All new and relapse cases from total of N+R column above (including bacteriologically confirmed and/or clinically diagnosed) by age group and sex

<table>
<thead>
<tr>
<th></th>
<th>0-4</th>
<th>5-14</th>
<th>15-24</th>
<th>25-34</th>
<th>35-44</th>
<th>45-54</th>
<th>55-64</th>
<th>&gt;65</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Block 3: Laboratory diagnostic activity

<table>
<thead>
<tr>
<th>Total No. of all new from OPD in quarter</th>
<th>No. of presumptive TB cases identified</th>
<th>Patients with presumptive TB under going bacteriological examination</th>
<th>Patients with presumptive TB with positive bacteriological examination result</th>
</tr>
</thead>
</table>

#### Block 4: HH Contacts*

<table>
<thead>
<tr>
<th>Total HH contacts</th>
<th>No. of HH contacts screened</th>
<th>No. of confirmed TB cases detected</th>
</tr>
</thead>
</table>

---

*HH Contacts updates from TB-01
Transferred in cases are excluded.
Data aggregated from the TB laboratory register based on Date specimen received, and excluding patients examined for follow-up...
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:

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Time of Reporting (TB07)</th>
<th>Patient Registered During</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>First week April, 2011</td>
<td>January 1 – March 31, 2011</td>
</tr>
<tr>
<td>2</td>
<td>First week July, 2011</td>
<td>April 1 – June 30, 2011</td>
</tr>
<tr>
<td>3</td>
<td>First week October, 2011</td>
<td>July 1 – September 30, 2011</td>
</tr>
<tr>
<td>4</td>
<td>First week January, 2012</td>
<td>October 1 – December 31, 2011</td>
</tr>
</tbody>
</table>

- **BLOCK 1** is subdivided into 9 columns:
  - 1\textsuperscript{st} column is to classify the patients (Pulmonary Bacteriologically confirmed, Pulmonary Clinically Diagnosed, Extra pulmonary bacteriologically confirmed and or clinically diagnosed. Sex i.e. male and female.
  - 2\textsuperscript{nd} 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 diagnose
    - Row 4: Total
  - 3\textsuperscript{rd} 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
  - 4\textsuperscript{th} 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
o 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

o 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.
  o When the report is completed, the total number in the BLOCK 2 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:

o **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.

o **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 Programs, 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 results will 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).
7.3 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 Program. 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)

Name of BMU/TB Care Facility: __________________________ District: __________________________

Name of TB Coordinator: __________________________ Signature: __________________________

Patients registered during _______ Quarter of year _______

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)

<table>
<thead>
<tr>
<th>TB patient type</th>
<th>Number of cases registered</th>
<th>Smear Negative</th>
<th>Smear positive</th>
<th>Died</th>
<th>Lost to follow-up</th>
<th>Not evaluated</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriologically confirmed (New and Relapse)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinically diagnosed (New and Relapse)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extrapulmonary (bacteriologically confirmed and/or clinically diagnosed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retreatment (excluding relapse)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The top part of the form contains general information about the BMU/TB care Facility and district. It allows the provincial Program 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 2/3 months of treatment. This is recorded separately for new cases (smear positive and negative) and re-treatments (relapses, treatment after failure, treatment after Lost to follow up, and others SS+ive, Others SS-ive).

- **Smear Positive (3):** Number of patients who are found to be smear positive at the completion of 2/3 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-ive).

- **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 evaluated (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).

### 7.4 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 Program. 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.
National TB Control Program Pakistan

QUARTERLY REPORT ON TREATMENT OUTCOME OF TB CASES REGISTERED 04 QUARTERS EARLIER
INDIVIDUAL BMU/CONSOLIDATED (TICK ONE)

Name of BMU/TB Care Facility: __________________ District: ____________
Name of TB Coordinator: ________________ Signature: ________________

Patients registered during ______ Quarter of year ______
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)

<table>
<thead>
<tr>
<th>TB patient type</th>
<th>Number of cases registered</th>
<th>Treatment outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cured</td>
</tr>
<tr>
<td>Bacteriologically confirmed (New and Relapse)</td>
<td></td>
<td>Treatment completed</td>
</tr>
<tr>
<td>Clinically diagnosed (New and Relapse)</td>
<td></td>
<td>Treatment failed</td>
</tr>
<tr>
<td>Extra-pulmonary (bacteriologically confirmed and/or clinically diagnosed)</td>
<td></td>
<td>Died</td>
</tr>
<tr>
<td>Retreatment (excluding relapse)</td>
<td></td>
<td>Lost to follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not evaluated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Time of Reporting (TB09)</th>
<th>Patients Registered During</th>
</tr>
</thead>
<tbody>
<tr>
<td>First week April, 2012</td>
<td>January 1 – March 31, 2011 (i.e. quarter 1, 2011)</td>
</tr>
<tr>
<td>First week July, 2012</td>
<td>April 1 – June 30, 2011 (i.e. quarter 2, 2011)</td>
</tr>
<tr>
<td>First week October, 2012</td>
<td>July 1 – September 30, 2011 (i.e. quarter 3, 2011)</td>
</tr>
<tr>
<td>First week January, 2013</td>
<td>October 1 – December 31, 2011 (i.e. quarter 4, 2011)</td>
</tr>
</tbody>
</table>

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), extra pulmonary 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).
7.5 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 Program. 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 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 2nd/3rd 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.
Tuberculosis Treatment Facility Card

National TB Control Program Pakistan

Name of diagnostic centre (BMU)

Patient Identifier Code

CNIC #: of patient (of family member if <18 yrs):

Disease site  (tick one)

Name of Patient

Pulmonary

Father / G Father Name

Extra pulmonary specify

Sex  M [ ] F [ ]  Age  [ ] Date of registration [ ]

Confirmatory evidence  Yes/No

Address of patient

If yes (tick) Histopathology/Bacteriology

Phone No

Type of patient  (check one)

Name of treatment center

New  [ ] Treatment after Lost to Follow up

Name/Type of treatment supporter with phone No.

Relapse  [ ] Treatment after failure

I. INITIAL PHASE  CAT (I,II)  [ ]

Transfer in  [ ] Other/Unknown History

Number of tablets (per doze) and Dosage of S:

<table>
<thead>
<tr>
<th>Tablet Type</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tablet Type</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRZ</td>
<td>(150/75/400/275)</td>
</tr>
<tr>
<td></td>
<td>(75/150/400/275)</td>
</tr>
<tr>
<td>HRZ</td>
<td>(30/60/150)</td>
</tr>
<tr>
<td>HR</td>
<td>(60/60)</td>
</tr>
<tr>
<td>Z</td>
<td>(400)</td>
</tr>
<tr>
<td>E</td>
<td>(400)</td>
</tr>
</tbody>
</table>

| Others |

Referral

Self-referral

Community member

Public facility

Private facility/provider

LHW

DATE OF APPOINTMENT FOR DRUG COLLECTION

DATE OF APPOINTMENT FOR FOLLOW UP

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Examination type</th>
<th>Lab No.</th>
<th>Result</th>
<th>CXR</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

148
**CONTINUATION PHASE**

<table>
<thead>
<tr>
<th>ADULT</th>
<th>CHILD</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRE (75/150/275)</td>
<td>HR (75/150)</td>
</tr>
<tr>
<td></td>
<td>HR (60/30)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE OF APPOINTMENT FOR DRUG COLLECTION</th>
<th>DATE OF APPOINTMENT FOR FOLLOW UP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Household CONTACTS**

<table>
<thead>
<tr>
<th>Name of Contact</th>
<th>Age</th>
<th>Sex</th>
<th>Method of Screening</th>
<th>Date &amp; Result of Screening</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

**Treatment Outcome**

- Cured
- Treatment Completed
- Died
- Treatment Failure
- Lost to follow up
- Not Evaluated

<table>
<thead>
<tr>
<th>DATE OF APPOINTMENT FOR DRUG COLLECTION</th>
<th>DATE OF APPOINTMENT FOR FOLLOW UP</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

Comments: ___________________________________________________________________

*Screening of all household contacts of Pulmonary TB patients*
Tuberculosis Treatment Facility Card

National TB Control Program Pakistan

TB01 (Front Side)

Name of diagnostic centre (BMU) ________________________________

CNIC #: of patient (of family member if < 18 yrs):

Name of Patient ________________________________

Father / G Father Name ________________________________

Sex M F Age ______ Date of registration ______

Address of patient ________________________________

Phone No ________________________________

Name of treatment center ________________________________

Name/Type of treatment supporter with phone No. ________________________________

I. INITIAL PHASE

CAT (I,II) □

Number of tablets (per doze) and Dosage of S:

<table>
<thead>
<tr>
<th>ADULT</th>
<th>HRZE (150/75/400/275)</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHILD</th>
<th>HRZ (30/60/150)</th>
<th>HR (30/60)</th>
<th>HR (60/60)</th>
<th>Z (400)</th>
<th>E (400)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

DATE OF APPOINTMENT FOR DRUG COLLECTION

DATE OF APPOINTMENT FOR FOLLOW UP

Patient Identifier Code ________________________________

Disease site (tick one)

- Pulmonary
- Extra pulmonary specify ________________________________

Confirmatory evidence Yes/No

If yes (tick) Histopathology/Bacteriology

Type of patient (check one)

- New
- Treatment after Lost to Follow up
- Relapse
- Treatment after failure
- Transfer in
- Other/Unknown History ________________________________

Month Date Examination type Lab No. Result CXR Weight

S

X

S

X

S

S

X

S

X

S

X

150
### Continuation Phase

#### Number of tablets (per dose)

<table>
<thead>
<tr>
<th>Adult</th>
<th>Child</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRE (75/150/275)</td>
<td>HR (75/150)</td>
</tr>
<tr>
<td>HR (60/30)</td>
<td>E (400)</td>
</tr>
</tbody>
</table>

#### Date of Appointment for Drug Collection

<table>
<thead>
<tr>
<th>Date of Appointment for Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

#### (Household) Contacts*

<table>
<thead>
<tr>
<th>Name of Contact</th>
<th>Age</th>
<th>Sex</th>
<th>Method of Screening</th>
<th>Date &amp; Result of Screening</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>S</td>
<td>X</td>
<td>C</td>
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<td></td>
</tr>
</tbody>
</table>

#### Treatment Outcome

- Cured
- Treatment Completed
- Died
- Treatment Failure
- Lost to follow up
- Not Evaluated

#### Date of Appointment for Drug Collection

<table>
<thead>
<tr>
<th>Date of Appointment for Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Comments

*Screening of all household contacts of Plumonary TB patients
### Treatment Outcome

<table>
<thead>
<tr>
<th>Date of decision</th>
<th>Treatment completed</th>
<th>Died</th>
<th>Treatment failure</th>
<th>Lost to follow up</th>
<th>Not Evaluated</th>
</tr>
</thead>
</table>

### Personal Information

- **Name:**
- **Patient Identifier Code:**
- **Address:**
- **Date of registration:**
- **Sex:** M/F
- **Age:**
- **Date of treatment start:**
- **Name of BMU/TB Care Facility:**
- **Name of treatment Centre:**

### Disease Site

- [ ] Pulmonary
- [ ] Extra-Pulmonary

### Type of Patient

- [ ] New
- [ ] Treatment after lost to follow up
- [ ] Relapse
- [ ] Treatment after failure
- [ ] Transfer In
- [ ] Other/Unknown history

### Initial Phase (Drugs & Dosage)

<table>
<thead>
<tr>
<th>CAT (I,II)</th>
</tr>
</thead>
</table>

#### ADULT
- **SRZ** 75/150
- **HRZE** 400/275

#### CHILD
- **HRZE** 30/60
- **HR** 60/60
- **E** 400
- **Z** 400

### Continuation Phase (Drugs & Dosage)

#### ADULT
- **HR** 75/150
- **HRE** 75/150/275

#### CHILD
- **HR** 30/60
- **E** 400

### Investigations

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Examination Type</th>
<th>Lab No.</th>
<th>Result</th>
<th>CXR</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
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</tr>
</tbody>
</table>

### Appointment for follow up (Type of test)

<table>
<thead>
<tr>
<th>Date</th>
<th>Place of Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Remarks

---

153
<table>
<thead>
<tr>
<th>Patient Registration Code</th>
<th>Date of Registration</th>
<th>Name (Father/ Husband/ G. father)</th>
<th>Sex (M/F)</th>
<th>Age (Yrs)</th>
<th>Complete Address (CNIC # / contact #)</th>
<th>Returned BY</th>
<th>Date treatment started</th>
<th>Site (P/EP)</th>
<th>New</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
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<td>Treatment After failure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lost to follow-up</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Others</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Previously treated (unknown History)</td>
</tr>
</tbody>
</table>

Transfer in
<table>
<thead>
<tr>
<th>Results with dates:</th>
<th>Enter date in relevant column</th>
<th>Moved to second-line treatment register (date)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smear (S) / X-pert MTB/RIF / Chest X-ray (CXR) / other examination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 month</td>
<td>End of month 2/3</td>
<td>End of month 5</td>
<td>End of month 6/9</td>
</tr>
<tr>
<td>$</td>
<td>X-pert</td>
<td>CXR</td>
<td>$</td>
</tr>
<tr>
<td>MTB</td>
<td>RR²</td>
<td>MTB</td>
<td>RR²</td>
</tr>
<tr>
<td>Date</td>
<td>Date</td>
<td>Date</td>
<td>Date</td>
</tr>
</tbody>
</table>
National TB Control Program Pakistan

**Instructions**
- For diagnostic testing employing serial sputa or other specimens this is the date of receipt of the first set of specimens.
- Y=Yes; N=No; Unk=Unknown
- Y=Previously Treated; N= Not previously treated; Unk= unknown
- Patient on TB treatment; indicate month of treatment at which follow-up examination is performed.
- Smear results reported as follows:

**Grading - ZN Microscopy**

<table>
<thead>
<tr>
<th>No. of AFB Observed</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB in 100 fields</td>
<td>Negative</td>
</tr>
<tr>
<td>1-9 AFB in 100 fields</td>
<td>Record exact number of bacilli</td>
</tr>
<tr>
<td>10-99 AFB in 100 fields</td>
<td>1+</td>
</tr>
<tr>
<td>1-10 AFB/field in 50 fields</td>
<td>2+</td>
</tr>
<tr>
<td>More than 10 AFB/field in 20 field</td>
<td>3+</td>
</tr>
</tbody>
</table>

**Grading of FM**

<table>
<thead>
<tr>
<th>200X</th>
<th>400X</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB in one length</td>
<td>No AFB in one length</td>
<td>Negative</td>
</tr>
<tr>
<td>1-4 AFB in one length</td>
<td>1-2 AFB in one length</td>
<td>Confirmation required*</td>
</tr>
<tr>
<td>5-49 AFB in one length</td>
<td>3-24 AFB in one length</td>
<td>Scanty (exact number)</td>
</tr>
<tr>
<td>3-24 AFB in one field</td>
<td>1-6 AFB in one field</td>
<td>1+</td>
</tr>
<tr>
<td>25-250 AFB in one field</td>
<td>7-60 AFB in one field</td>
<td>2+</td>
</tr>
<tr>
<td>&gt;250 AFB in one field</td>
<td>&gt;60 AFB in one field</td>
<td>3+</td>
</tr>
</tbody>
</table>

Xpert MTB/RIF test result reported as follows:
- **MTB** Column:
  - Del=MTB Detected;
  - ND=MTB Not Detected
  - INV=Invalid/Error/No Result
- **RR** Column:
  - Del=Rifampicin Resistance Detected;
  - ND=Rifampicin Resistance Not Detected;
  - IND=Rifampicin Resistance Indeterminate

*If more than one smear or Xpert MTB/RIF test is done in a month, enter the most recent positive result.
*Dates associated with the recorded examination results are dates of sample collection.
*If patient "transfers out" to another BMU, make a note in the Remarks column. If no definitive outcome is obtained, record as Not evaluated or Lost to follow-up as appropriate.
*Patients on initial treatment have follow-up sputum smear microscopy examination at 2 months. Patients on retreatment regimen have follow-up sputum smear microscopy examination at 3 months.
*confirmation required by another technician or prepare another.
*smear, stain and read.