TUBERCULOSIS CONTROL in Pakistan

MODULE FOR MBBS STUDENTS

National Tuberculosis Control Program
Pakistan
FOREWORD

It is a matter of great pleasure and satisfaction that National TB Control Program has produced "MODULE FOR M.B.B.S STUDENTS" on Community Based TB Care (DOTS).

Pakistan currently ranks fifth amongst countries with 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 231/100,000, Pakistan produces about 420,000 new cases annually. As we accelerate our pace towards the Millenium Development Golas (MDGs) by the target date of 2015, TB Control assumes a very high priority within the health sector.

National TB Control Program, working under the Ministry of Inter Provincial Coordination, Government of Pakistan, in collaboration with all Provincial/Regional TB Control Programs, endorses and implements WHO recommended Stop 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 future 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.

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TABLE OF CONTENTS

BACKGROUND AND OBJECTIVES OF THE MODULE

Session 1: INTRODUCTION: CONCEPTS OF TB & ITS EPIDEMIOLOGY

1.1. Tuberculosis
1.2. History of tuberculosis through ages
1.3. Morbidity and mortality of tuberculosis globally & in Pakistan
1.4. Epidemiological indices
1.5. Concepts of causation of tuberculosis: agent, host & environment
1.6. Dynamics of transmission of tuberculosis
1.7. Natural history of tuberculosis
1.8. Levels of prevention & control of tuberculosis

Session 2: NATIONAL TB CONTROL PROGRAM (NTP)

2.1. Background
2.2. Mission
2.3. Organizational arrangements
2.4. DOTS and Stop TB strategy
2.5. Progress made in TB control in Pakistan

Session 3: NATIONAL CASE MANAGEMENT GUIDELINES

3.1. Case detection
3.2. Treatment
3.3. Follow-up
3.4. Recording and reporting system- monitoring of TB patient

Session 4: FIELD VISIT TO TB TREATMENT CENTRE & DIAGNOSTIC CENTRE

4.1. Working arrangements

APPENDIX
BACKGROUND AND OBJECTIVES OF THE MODULE

Background:

Tuberculosis (TB) is an important public health problem that is preventable and curable. About one-third of world’s population is infected with this disease (1). If left untreated, each active TB (sputum positive) case can infects 10 to 15 people in one year(1). World Health Organization (WHO) declared TB a global emergency in 1993 after which it adopted Directly Observed Treatment, Short-course (DOTS) strategy. After the implementation of DOTS, more than 20 million patients had been treated and more than 16 million cured of TB by 2004 (2). Due to it, the mortality and incidence of TB also reduced. Nevertheless progress in this regards is slow in sub-Saharan Africa as well as the eastern Europe (2). Asia continues to bear two-third of the burden of TB. Moreover new challenges like TB/HIV co-infection, Multi Drug Resistant (MDR) TB and childhood TB have emerged which are hampering TB control efforts (2). To address all these issues, Stop TB strategy was launched by WHO in 2006 (2). One of the components of this strategy is to ‘engage all care providers’. This means that all health professionals providing care to the TB patients have to be involved. As a part of global DOTS expansion plan, attention was called to medical schools. Medical students are future doctors and medical schools play an important role in building competence and skills of these students in handling the health problems in the community. As Pakistan is 5th amongst 22 countries with highest burden of TB (3), training of medical students to combat this issue is not only imperative, but urgent.

This four days module on TB prevention and control by National Tuberculosis Control Program (NTP) is an effort to highlight the public health as well as clinical aspect of this infectious disease which can be applied practically in the hospitals, clinics and the community. Session 1 deals with the basic concepts about tuberculosis, its evolution through ages and the major events in history and its epidemiology. Session 2 reflects the role of NTP in control of TB in accordance with the global strategies for its prevention and control. Case management of a patient with TB and their recording and reporting will be dealt in session 3. These sessions will be followed by field visit to a DOTS facility.

Objectives of the module:

1. Understand the basic concepts including the case definitions, epidemiology and control of TB.
2. Discuss the role of NTP Pakistan in line with the global strategies for TB control.
3. Manage a patient with TB

References:

OBJECTIVES OF THE SESSION

A. Discuss and describe the following about TB:
   1. Historical perspective
   2. Natural history
   3. Global and national burden
   4. Etiology and concepts in causation
   5. Dynamics of transmission
   6. Basic measures for its control

B. Practice
   1. Calculation of TB morbidity and mortality
   2. Administration of BCG vaccination
   3. Conduction of mantoux test

1.1. TUBERCULOSIS

Tuberculosis or TB (short for tubercle bacillus) is an infectious bacterial disease caused by various species of mycobacterium, usually ‘Mycobacterium Tuberculosis’ in humans (1). When the infection affects the lung parenchyma, it is called ‘pulmonary tuberculosis’. When the infection affects other parts of the body, it is called ‘extra-pulmonary tuberculosis’. Examples of extra pulmonary TB includes lymphadenopathy (glandular tuberculosis), pleural effusion (pleural TB), pericardial disease (pericardial TB), miliary TB, genito-urinary TB and tuberculous meningitis. Patients usually complain of constitutional symptoms (fever, night sweat, weight loss) and local features related to the site of disease. A patient with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary TB.

1.2. HISTORY OF TUBERCULOSIS THROUGH AGES

History of TB dates back to the ancient Egypt. Examination of mummies as well as the paintings of those times reveals that TB existed in that era (around 5000 BC). Hippocrates used the word ‘pthisis’ for TB which means ‘to dry up’. The word ‘consumption’ is found in Latin history which refers to the consuming affect of the illness. Tuberculosis is also mentioned in the medical text of Chinese literature by Emperor Shenong in 2700 BCE. Rigveda, as old as 1500 BCE called TB ‘yaksma’, which was followed by the term ‘balasa’ and ‘scrofula’ in the Athurveda in the Indian literature. An epidemic of TB is reported in Europe in 17th century when it was called ‘great white plague’. A German professor of Medicine proposed the word ‘tuberculosis’ for this infectious disease in his book ‘Systematik de speziellen Pathologie und Therapie’ (2).

Robert Koch presented his discovery of the causative organism of tuberculosis, ‘Koch’s bacillus’ or ‘Mycobacterium tuberculosis’ in Berlin on 24th March 1882. Since 1882, 24th March was observed as the World’s tuberculosis day. In 1890, Koch developed tuberculin, a Purified Protein Derivative (PPD). Though it was ineffective means of immunization for TB, but Charles Mantoux in 1908 showed it to be an effective way of diagnosing TB by intra-dermal method (Mantoux test or Tuberculin test) (2). Roentgen discovered X-rays in 1895 which improved the diagnosis of TB.
Bacille Calmette Guerin (BCG), the current vaccine for TB, was first used in 1921 (3). It was not until World War II that BCG was widely used. It was introduced in Pakistan in 1949 (4). Progress in control of TB started with the discovery of Streptomycin in 1944, P-Amino-Salicylic acid (PAS) in 1946 and Isoniazid in 1951 (5).

Activity 1: Identify the events in this graph that lead to decreasing the mortality due to TB

![Graph showing mortality rate per 100,000 from 1840 to 1960](image)

1.3. MORBIDITY AND MORTALITY OF TUBERCULOSIS GLOBALLY & IN PAKISTAN

In 2009, 9.4 million incident (new) cases of TB and a prevalence of 137 cases of TB per 100,000 population were reported globally (6). Highest number of cases occurred in Asia (55%) followed by Africa (30%), Eastern Mediterranean region (7%), European region(4%) and the region of Americas (3%) (6). The five countries with largest number of cases were India, China, Afghanistan, Indonesia and Pakistan. India and China combined accounted for 35% of these new cases (6). Approximately 1300,000 people died of TB in 2009 (6).

Pakistan stands 5th among 22 countries with high burden of Tuberculosis (6). Estimated prevalence of TB in Pakistan is 350 cases per 100,000 population (7). Total new cases reported were 258,251 composed of 101,887 smear positive cases, 112,948 smear negative cases and 43,416 cases of extra-pulmonary TB (7). Sixty thousand people died of TB in Pakistan in 2009 (6).

1.4. EPIDEMIOLOGICAL INDICES

1.4.1. Incidence of TB: Number of new cases of TB occurring in a given time period in the population at risk during that period.

1.4.2. Prevalence of TB: Number of new and old case of TB at a given time in the total population at that time.

1.4.3. Case detection rate (CDR): the term ‘case detection’ means that TB is diagnosed and notified in the National surveillance/reporting system. It is actually a ratio but the terminology ‘rate’ has become a standard terminology in context of this indicator.

1. Case detection rate for all forms of TB (CDR TOT): It is calculated as the number of new cases notified divided by the total number of estimated incident cases. Sputum Smear positive (SS +) case of TB is one in which Mycobacterium tuberculosis are visible in patient’s sputum when examined under the microscope.

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1 Asia here means the WHO regions of South-East Asia and the Western pacific. Africa means the WHO African Region.
2. Case detection rate for sputum smear positive TB (CDR SS+): It is calculated as the number of new sputum smear positive cases notified divided by the number of new smear positive cases estimated for that year, expressed as percentage.

1.4.4. Case notification rate (CNR)
1. Case notification rate all cases (CNR all cases): The number of tuberculosis cases reported per 100 000 population in a given year. Includes all forms of TB.
2. Case notification rate for sputum smear positive TB (CNR SS+): The number of new smear-positive pulmonary tuberculosis cases reported per 100 000 populations in a given year.

1.4.5. Treatment success rate (TSR): It is defined as the proportion of new smear-positive TB cases registered under DOTS in a given year that successfully completed treatment, whether with or without bacteriological evidence of success ("cured" or “treatment completed” respectively).

<table>
<thead>
<tr>
<th>Activity 2:</th>
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<tbody>
<tr>
<td>a) Number of new cases of TB in Pakistan in 1999 was 269000 and total population was 152331000. Calculate the incidence of TB in Pakistan in 1999.</td>
</tr>
<tr>
<td>b) 258251 new cases of TB were notified in Pakistan in 2009 and total incident cases were 420000. Calculate the CDR for all forms of TB.</td>
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1.5. CONCEPTS OF CAUSATION OF TUBERCULOSIS (HOST, AGENT & ENVIRONMENT):

Tuberculosis is caused by interplay of environmental and genetic factors which can be explained in the form of an epidemiological triad:

1.5.1. Agent: Agent for the casing TB is Mycobacterium tuberculosis, which is an acid-fast, gram-positive, aerobic, non-motile, rod-shaped organism. Two of its forms cause disease in humans: Human variety and the Bovine variety.

1.5.2. Host: Man is the host for TB. Host factors that makes him susceptible for the disease are as follows:

1- **Age:** Infants and children are not only more susceptible to develop TB than adults, but also suffer from the severe form of the disease e.g. Miliary tuberculosis (8). This is mainly because of their immunologic immaturity (8). Though no age is immune from TB. In Pakistan, more than 75% of active TB cases belong to the productive age group (15-59 yrs).

2- **Gender:** The incidence of TB is high in males as compared to females in all age groups except childhood, when incidence is higher in females (9).

3- **Heredity:** Some people resist TB more effectively than others. This maybe explained in part by the genetic factors related to TB (10). HLA – DR 2 has been associated with the susceptibility to TB in Asian population (10).

4- **Nutrition:** Malnutrition increases morbidity due to TB as well as its mortality, especially in resource poor settings. Poor nutrition affects the immune system and thus predisposes a person to tuberculosis (11).

5- **Education:** Lesser the education, higher is the TB prevalence. In one study it was found that in urban areas that people with no schooling suffer form TB four times than those who have tertiary level education (12).
6. **Occupation:** Working in overcrowded and ill-ventilated places increases its chances of spreading. Some occupational diseases like silicosis and anthracosis increases the susceptibility to TB (5)

1.5.3. **Environment:** Certain environmental factors prone a person to TB. These include:

1. **Overcrowding:** Overcrowding leads to poor hygienic conditions, poor ventilation and contact of infectious case with more people increasing the chances of transmission of TB.

2. **Economic status:** The association between TB and poverty is well established. Poverty can increase person's vulnerability to TB. Crowding, malnutrition, poor air ventilation and poor sanitation all are related to poverty and have been associated with increased probability of being infected with TB as well as activation of the infection (13).

### Activity 3:

35 years old male, 6 feet 1 inch in height and having weight of 55 kg, worked in a cotton industry. He lived in a slum with his 6 family members in one room. He developed cough for 6 weeks along with chest pain and night sweats. Identify the risk factors in this person for development of tuberculosis.

### 1.6. DYNAMICS OF TRANSMISSION OF TUBERCULOSIS

1.6.1. **Source of infection:** Most common source of infection is a case of tuberculosis whose sputum is positive for Mycobacterium tuberculosis, who has received no treatment or incomplete/irregular treatment. Other sources of infection are excreta of such patient, milk obtained from cows suffering from TB and material from slaughtered tuberculosis animal (5).

1.6.2. **Mode of transmission:** Tuberculosis is a droplet infection and droplet nuclei produced when a patient having tuberculosis coughs or sneezes (Figure 1). The particles must be fresh enough to contain the viable organism to be transmitted. The force and frequency of the cough or sneeze as well as the ventilation of the room affects the transmission process. TB is not transmitted by fomites, dishes or other articles used by the patient.

![Figure 1: Mode of transmission of Tuberculosis](image)

1.6.3. **Point of entry:** Nose and throat (by inhalation) are commonest point of entry. Mouth (by ingestion) is another point of entry for Mycobacterium tuberculosis.

### 1.7. NATURAL HISTORY OF TUBERCULOSIS

Once exposed to the infection, patient may either have active or latent infection. In ‘active infection’, patient has symptoms and signs produced by actively replicating tubercle bacilli. In case of pulmonary TB, patient is potentially contagious and has symptoms like cough, chest pain, shortness of breath, weight loss, fever and night sweats. Those having ‘latent
infection’ are not infectious and do not show and symptoms or signs of TB; but they are at risk of developing active tuberculosis during their lifetime.

Time during the exposure to Mycobacterium tuberculosis and development of active infection is called the incubation period. It may vary from a few months to a few years. Figure 2 depicts the natural history of TB.

**Figure 2: Natural history of TB in a newly infected host (adapted from 'Testing for Tuberculosis' by Konstantinos A (14))**

1.8. LEVELS OF PREVENTION & CONTROL OF TUBERCULOSIS:

Early diagnosis and treatment of a patient with TB is the first strategy in controlling tuberculosis. Primary, secondary and tertiary levels of prevention of TB are as follows:

1.8.1. Primary prevention

1. **Health education:** Stigma regarding TB prevails in our society. Due to this, patient suffers from discrimination, rejection and social isolation (15). TB stigma is one of the barriers to TB control (16). Even when TB is cured, the ‘label’ of having had TB sticks (16). The stigma related to TB negatively affects the life of a TB patient in the following ways (16):

- Patient does not reveal his ailment.
- People develop feeling of hatred towards the TB patient.
- It gives rise to gossip and speculations.
- Marriage prospects reduce.
- Family tensions and divorce rate may increase.
- Patient may lose his job.
- Patient and his family members are financially burdened.
- Patient worries about fulfillment of his responsibilities in the society.
- Guilt and blame of TB infection.
This stigma has public health implications. It may lead to delayed diagnosis and thus delayed treatment for TB. On the other hand, once the treatment is started, it may also lead to treatment default.

How this stigma can be addressed? Here is where health education comes into play. Focused health education about TB not only to patients but their family members may allay fears and overcome this stigma (15). Once the patient knows that he has support in society from his family, friends and the healthcare workers, TB will be diagnosed and treated early which is one of the effective strategies for TB control.

2- **Specific protection:** Certain measures can be taken to protect a person from tuberculosis. These are:

   a. **Vaccination:** Bacille Calmette Geurin (BCG) is the vaccine used for the control of TB. It contains live attenuated strain of Mycobacterium bovis that uses shared antigens to stimulate cross-immunity against Mycobacterium tuberculosis and Mycobacterium leprae (17). It reduces the risk of all forms of TB by 50% (18). It also reduces severe, non-pulmonary forms such as childhood meningitis by 70% (19). In Pakistan it is a part of the Extended Program of Immunization (EPI) and is administered at birth. Immunity induced by it lasts from 3-12 years and 5-8 years on an average. BCG vaccine (dose of 0.05 ml for infants) is injected intradermally in the deltoid region (figure 3) of the arm or the gluteal region. A nodule is produced at the site of vaccination in about 6-12 weeks and then it disappears slowly. A post-vaccination tuberculin test is given 12 weeks later; it the person is still tuberculin negative, BCG vaccination is repeated.

   b. **Chemoprophylaxis:** It is recommended for those at risk of tuberculosis such as malnourished individuals and those in contact of established tuberculosis case. Isoniazid (INH) is used in as the chemoprophylactic agent.

   ![Figure 3: BCG Vaccination](20)

1.8.2. **Secondary prevention:**

1- **Early diagnosis:** TB is an insidious disease and may not produce violent symptoms. By the time typical symptoms of TB like cough, fever, weight loss and night sweats develop, the person has infected many others. Therefore it is necessary to find a case of TB early for effective control of the infection. On finding the case of TB early, treatment can be started early and thus he can be prevented from becoming infectious and spreading the disease to others. Following investigations are performed to detect a case of TB:

   a. **Sputum examination:** Sputum microscopy for AFB is regarded as the most effective method for diagnosis of infective case of TB (5). By sputum examination, a patient of TB can be distinguished in the following categories:

      i. Sputum smear positive
      ii. Sputum smear negative
b. Tuberculin test: It is easy to perform and tells whether the patient has had tubercular infection. In this test tuberculin reaction is elicited, universal method of which is by Mantoux test. This test consists of injecting 0.1 ml (5 i.u) of Purified Protein Derivative (PPD) solution intra-dermally on the outer surface of the forearm four finger breadths below the elbow. The reaction is measured after 72 hours. If the reaction is positive, a wheal is raised measuring 5 mm or more surrounded by the zone of erythema. Only induration has to be measured (5). The specificity of Mantoux test for pulmonary as well as extra-pulmonary TB increases as the size of induration increases reaching 86% at induration of more than 15 mm (21).

c. X-Ray examination: By X-ray examination of the chest, tuberculin positive cases can be divided into those who have healed TB requiring no treatment or are suffering from active tuberculosis.

2- Prompt treatment: It is the most important preventive measure against TB. In order to control TB, it is important to control the reservoir (the infected TB patient). The only quick way for it is to treat the infectious patient to render him non-infectious.

1.8.3. Tertiary prevention

It consists of disability limitation and rehabilitation of the TB patient. Tuberculosis patient due to his disease may develop disability in respiratory functions such as chest wall deformity and decreased exercise endurance due to which his daily activities may be restricted. These disabilities can be limited by adequate treatment and rehabilitation can be provided in the form of physical therapy as well as social support.

Activity 4:
(a) What is the most effective strategy for controlling tuberculosis?
(b) What is the first line test in diagnosing a patient of TB?
(c) At what time the BCG vaccination is administered in the EPI schedule in Pakistan; what is the dose and mode of its administration?
(d) Which drug is used in chemoprophylaxis of TB?
(e) How is the tuberculin test done and what does it show?

REFERENCES


Answers to the activities

**Session 1:**

**Activity 1:**
Event A: TB Bacillus identified,
Event B: Tuberculin test,
Event C: BCG vaccine,
Event D: TB Antibiotics

**Activity 2:**
- a) 177 TB cases per 100,000 population;
- b) 61.5%

**Activity 3:** Male gender, malnutrition, occupation, overcrowding and poor hygienic conditions

**Activity 4:**
- a) Early diagnosis and prompt treatment of the TB case;
- b) Sputum smear microscopy;
- c) 0.05 ml intradermal injection at birth in the deltoid or gluteal region;
- d) Isoniazid (INH);
- e) 0.1 ml of PPD is injected intradermally on the outer surface of the forearm 4 finger breadths below the elbow. It is read 48-72 hrs after the injection. An induration of more than 5 mm shows that a person has active infection. More the induration, more are the chances of active disease.
OBJECTIVES OF THE SESSION:

1. Understand the mission and organizational arrangements of NTP
2. Describe the objectives and components of the STOP TB strategy
3. Discuss the progress in TB control

2.1. BACKGROUND OF NATIONAL TUBERCULOSIS CONTROL PROGRAM (NTP)

National Tuberculosis Control Program (NTP) is a national body, under the Ministry of Inter-Provincial Coordination (MoIPC), formerly Ministry of Health (MoH), Pakistan formed in 1995 in response to the declaration of global emergency of tuberculosis by World Health Organization (WHO) in 1993 (1). Under this program, national guidelines were developed and piloted in various regions of Pakistan. The program remained dormant due to abolition of National Tuberculosis Directorate in 1996 and its progress remained slow in the first three years i.e. 1995 to 1998. In 1998, the roles and relationship between the national and provincial TB control program were re-defined (1).

2.2. MISSION OF NTP

Mission of NTP is to achieve country wide tuberculosis control by Directly Observed Treatment-Short course (DOTS) strategy and by ensuring quality tuberculosis care through public sector health services and enhance the role of other partners, including private sector and Non-Governmental Organizations (NGOs) (2).

2.3. ORGANIZATIONAL ARRANGEMENTS

2.3.1. National Tuberculosis control Program (NTP)

NTP has very strong management capacity and is actively involved in policy planning, decision making and coordination with MoH, Provincial TB Control Programs (PTPs) and national and international partners. It also has capability for financial management for public sector. The major sources of its funding are USAID, GFATM, FIDELIS, CIDA and JPRM (2). NTP is responsible for:

1. Policy formulation and strategic planning
2. Technical support, supervision, monitoring and evaluation support to the provinces
3. Coordination and communication with the partners
4. Research

2.3.2. Provincial Tuberculosis Control Program (PTP)

The Provincial/Regional Tuberculosis Control Programs (PTP), under their respective departments of health, are responsible for coordinating the planning, implementing, managing and financing of the tuberculosis control activities in their respective provinces/regions. The PTPs are involved in supporting the district health services, and other partners, for effective implementation of DOTS in the districts (2). The main responsibilities of the PTP include:

1. Participation in strategic, Program and operational planning
2. Technical support, supervision, monitoring and evaluation support to the districts
3. Coordination and communication with partners
4. Operational research
2.3.3. District and Facility level Arrangements

The district authorities, in context of devolution, are primarily responsible for advocating, planning, financing, implementing, and monitoring TB care services in their respective 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 (2). There are two types of centres:

1. Basic Management Unit (BMU)/Diagnostic centre: The BMU/diagnostic centre is responsible for diagnosis, registration, treatment initiation, follow-up examination, cure confirmation and quarterly report preparation. The hospitals and rural health centres work as diagnostic centres for TB patients (2).

2. Treatment centre: The treatment centre supplies anti-TB drugs and ensures that the “direct observation” is carried out through appropriately selected supporter. The basic health units and dispensaries work as treatment centres (2).

2.4. DOTS AND STOP TB STRATEGY

In 1994, a global strategy for the control of TB, later named DOTS was launched. There are five main components of this DOTS strategy, which were implemented in 182 countries. The five components of DOTS strategy were:

1. Commitment of government to the national tuberculosis control
2. Case detection through smear microscopy by passive case finding
3. Standardized treatment of TB cases through DOTS
4. Regular uninterrupted drug supply
5. A monitoring (recording and reporting) system for program supervision and evaluation

The Stop TB strategy was implemented in 2006 (3). It builds on the DOTS strategy (which is now the first component of Stop TB strategy) to meet the Millennium Development Goal (MDG) of reducing the global burden (prevalence and mortality) of tuberculosis by half till 2015.

2.4.1. Vision

- A world Free of TB

2.4.2. Goal

- To reduce dramatically the global burden of TB by 2015 in line with the Millennium Development Goals and the Stop TB Partnership targets

2.4.3. Objectives

- To achieve universal access to high-quality diagnosis and patient-centred treatment
- To reduce the suffering and socioeconomic burden associated with TB
- To protect poor and vulnerable populations from TB, TB/HIV and MDR-TB
- To support development of new tools and enable their timely and effective use

2.4.4. Targets

- Detect at a least 70% of new sputum smear positive cases and cure at a least 85% of these cases by 2005
- Reduce the TB prevalence and death rate by 50% (relative to that in 1990) by 2015
- Eliminate TB as a public health problem by 2050 (< 1 case per million population) by 2050
2.4.5. Components - The Stop TB strategy has six components (3):

1. **Pursue quality DOTS expansion and enhancement**
   a) Political commitment with increased and sustained financing
   b) Case detection through quality assured bacteriology
   c) Standardized treatment with supervision and patient support
   d) Effective drug supply system
   e) Monitoring system and impact evaluation

2. **Address TB/HIV, MDR-TB and Other special challenges**
   a) TB/HIV collaborative activities
   b) Prevention and control of drug-resistant TB including DOTS Plus
   c) Addressing risk groups and special situations

3. **Contribute to health system strengthening**
   a) Active participation in country-led and global efforts
   b) TB control innovations that strengthen systems
   c) Adapting innovations from other fields to strengthen TB control
   d) Practical Approach to Lung Health - extending TB care to respiratory care

4. **Engage all care providers**
   a) Public-Private Mix approaches
   b) International Standards for TB care

5. **Empower patients and communities**
   a) Community TB care
   b) Advocacy, communication and social mobilization
   c) Patients’ Charter for Tuberculosis Care

6. **Enable and promote research**
   a) Program based operational research
   b) Research to develop new diagnosis, drugs and vaccine

2.5. PROGRESS MADE IN TB CONTROL IN PAKISTAN

Remarkable progress was made in Case Detection Rate (CDR) as well as Treatment Success Rate (TSR) by adopting DOTS followed by Stop TB strategy in Pakistan. This can be seen in figure 1 and 2.
Activity 1:

Refer to figure 1:

a) What is this graph telling? Explain in detail

b) What does the CDR SS+ of 70% at the end of 2010 indicate?
Activity 2:

Refer to figure 2 and 3:

a) What is this graph in figure 2 telling? Explain in detail

b) In which province TSR is the lowest and in which province the highest?

REFERENCES:

2. NTP. National strategic plan for tuberculosis control in Pakistan; 2004

Answers to the activities

Session 2:

Activity 1:

a) The graph is telling about the trends in case detection rate (CDR) in Pakistan in the last 10 years. Years are given on x-axis and the percentage of CDR on y-axis. Red line shows the CDR for all cases and blue line shows CDR for sputum smear positive (SS+) cases. Over the years it has increased but still remained low till 2006. In late 2010, CDR for all cases is 82% and that for SS+ cases is 70%.

b) The CDR SS + of 70% indicate that the target of MDG 6 of this CDR has been achieved in 2010 instead of 2005 in Pakistan

Activity 2:

a) This graph is telling about the trend of Treatment Success rate (TSR) in Pakistan from 2001 to 2009. Years are shown on x-axis and percentage of TSR on y-axis. It shows that TSR has increased from 77% in 2001 to 91% in 2009.

b) TSR is the lowest in FATA (Federally administered tribal areas) and highest in GB( Gilgit Baltistan).
OBJECTIVES OF THE SESSION:

At the end of the session, the student will be able to discuss and describe the following about tuberculosis:

1. Case detection
2. Treatment
3. Follow-up
4. Recording and reporting system

3.1. CASE DETECTION:

Making the diagnosis of TB follows the basic principles of detailed history, examination and investigations.

3.1.1. History: The following symptoms have to be asked about:
1-Cough: Duration, whether more or less than two weeks.
2-Sputum: Its colour and whether blood stained.
3- Fever: Its intensity, duration, timing, i.e in day or night. Whether associated with night sweats.
4-Weight: Any weight reduction/loss and change in appetite.
5-Smoking: Duration and frequency.
6-Family history: Does any close contact or family members suffers (or has suffered) from TB.
7- History of medication: Inquire if the patient has taken:
   - TB treatment, if yes, for how long? (also verify records if possible)
   - Streptomycin (powder/dry) injections, if yes, for what? for how long?
   - Tablets which make urine color red (show if possible), if yes, for what? & for how long?

3.1.2. Examination: Look and listen for these signs:
1-Count the pulse
2-Take the temperature
3- Listen with a stethoscope, asking the patient to breathe deeply

Suspect TB if any of these present:

- Cough more than 2 weeks, or
- Cough less than 2 weeks or of 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

3.1.3. Investigations:
1-Sputum smear examination: It is the first line test for the diagnosis of TB. Sputum examination is the most specific, cost effective and reliable test for diagnosis of pulmonary TB. Sputum microscopy is available in BMUs (hospitals and RHCs). The National TB Control Program has recommended training laboratory technicians in all the diagnostic centres. All TB
suspects should submit at least two sputum specimens for microscopic examination. When possible, at least one early morning specimen should be obtained, as sputum collected at this time has the highest yield. These two specimens are collected at the following times:

(a) Spot: This is collected on first consultation
(b) Early morning: This is collected at home and this is the early morning sputum sample collected the day after consultation.

2. Chest X-ray: The chest X-ray is no longer the best first line investigation for Pulmonary TB and most patients with TB who are diagnosed by sputum smears do not need a chest X-ray. The chest X-ray appearances are not specific to TB. If X-ray is used as the first line investigation for TB there will be an over diagnosis of TB. Chest X-ray is only indicated if a patient is found to be sputum smear negative, and we need to rule out smear negative pulmonary TB. Refer to figure 1.

FIGURE 1: MANAGEMENT OF TB SUSPECT

TB Suspect

Two Sputum Smear microscopy (Spot-morning)

One or 2 Sputum Smear positive

Declare Sputum positive pulmonary TB & Start Treatment

Both Sputum Smear negative

Give broad-spectrum antibiotic for 7 – 10 days and re-assess

If no response to antibiotics, do chest X-Ray (CXR).

CXR consistent with active pulmonary TB

Declare smear negative pulmonary TB & start treatment

CXR not consistent with active pulmonary TB

If responds to antibiotics then re-assure

Refer to pulmonary specialist/District physician
3.1.4. Decide the Type of Pulmonary TB Patient:

- Decide the “patient type” on basis of history* of TB drug intake in past:

<table>
<thead>
<tr>
<th>History of drug intake</th>
<th>Smear result now</th>
<th>Type of patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Never taken TB drugs in past</td>
<td>Smear positive</td>
<td>New case</td>
</tr>
<tr>
<td>- Taken TB drugs for less than 4 weeks in past and not registered with the Program.</td>
<td>Smear negative</td>
<td></td>
</tr>
<tr>
<td>- Taken full course of TB treatment in past and declared cured or treatment completed.</td>
<td>Smear positive</td>
<td>Relapse</td>
</tr>
<tr>
<td>- Taken TB drugs and transferred from another TB Register</td>
<td>-</td>
<td>Transferred-in</td>
</tr>
<tr>
<td>- Smear positive patient taken TB drugs for 5 months or more</td>
<td>Smear positive</td>
<td>Treatment After Failure</td>
</tr>
<tr>
<td>- Smear negative patient taken drugs for 2 months</td>
<td>Smear Negative</td>
<td>Others</td>
</tr>
<tr>
<td>- Taken drugs for a certain period then interrupted for 2/or more consecutive months</td>
<td>Smear positive</td>
<td>Treatment after default</td>
</tr>
<tr>
<td>- Taken drugs for a certain period then interrupted for 2/or more consecutive months</td>
<td>Smear Negative</td>
<td>Others</td>
</tr>
<tr>
<td>- Taken drug for more than 4 weeks from outside Program, pulmonary or extra-pulmonary TB patient, Previous treatment outcome unknown.</td>
<td>Smear positive</td>
<td>Others’ Positive</td>
</tr>
<tr>
<td></td>
<td>Smear negative</td>
<td>Others’ Negative</td>
</tr>
</tbody>
</table>

1 Others. Smear-negative pulmonary and extra-pulmonary cases may also be relapses, failures, returns after default or chronic cases. This should, however, be a rare event, supported by pathological or bacteriological evidence (culture).

*Ascertain history of TB drug intake in the past by Asking: Ever taken?
- TB treatment, if yes, for how long? (also verify records if possible)
- Streptomycin (powder/dry) injections, if yes, for what? for how long?
- Tablets which make urine color red (show if possible), if yes, for what? & for how long?

Activity 1

You are the care provider sitting at a BHU chirrah. Mrs. Nasreen is a 44-year-old housewife who comes along with her husband to consult you. She lives in the village chirrah and she has come to the BHU with a bad cough and fever. She used to have cough occasionally but usually it subsides with local remedy. But this time it is not going away. She doesn’t know the exact number of days but she thinks that it has been present for the last 2 weeks. She also coughs up yellow-white sputum. However there is no blood in the sputum. She is not very sure how long she has had fever but she thinks it has been present for about 2 weeks. The fever is worse at night. She has lost some weight. Her mother in law who used to live with her was very ill and died a few weeks back. She used to have severe cough and sometimes coughs up blood with sputum. She took treatment from a Hakim but did not recover. Nasreen does not smoke and she has not taken any medicines yet. On examination her pulse was 92/min and temperature was 99.6° F.

(a) Do you think Ms. Nasreen is a TB suspect, and if so why?

(b) What is the action required?

3.2. TREATMENT:

TB patients must be treated with the anti-tuberculosis drug regimens recommended by National TB Control Program (NTP) Pakistan. The NTP recommended drug regimens are very effective and can treat successfully almost all cases of tuberculosis if used in the right dosage and for the right duration.
3.2.1. Duration of therapy:
It is very important that we give the patient the full course of treatment, which lasts 6 months for Cat-1 and 8 months for Cat-II. If the patient does not take the full course of treatment, not all of the TB bacteria will be killed. Treatment regimens have an initial (intensive) and a continuation phase.

The initial (intensive) phase lasts usually for 2 months in cat-1 patients and three months in cat-2 cases. Four or five anti-TB drugs (including Rifampicin) are given to kill TB bacilli rapidly. The vast majority of patients become non-infectious and symptoms improve within 2 months. Directly Observed Treatment (DOT) ensures that TB drugs are taken and prevents the development of resistance to Rifampicin. The risk of drug resistance is higher during the early stages of anti-TB drug treatment when there are more TB bacilli.

The continuation phase lasts usually for 4 – 5 months. Fewer drugs (i.e. two or more) are required to eliminate the remaining TB bacilli. Direct observation during continuation phase (both in new & re-treatment cases) helps to ensure success. The risk of drug resistance is less during the continuation phase when there are fewer TB bacilli.

3.2.2. Anti-TB drugs:
The six essential anti-TB drugs used in the Program, with their mode of action and dosage (in mg per kg body weight), are given in the table below.

<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</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

3.2.3. Decide the Treatment Category:
TB patients are put into one of 2 treatment categories on the basis of smear results, disease classification and type of patient.

<table>
<thead>
<tr>
<th>Smear Results</th>
<th>Disease Classification</th>
<th>Patient Type</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Pulmonary</td>
<td>New</td>
<td>CAT-I</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Re-treatment:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Relapse</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Rx.after failure</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Rx.after default</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Other (S+ only)</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Pulmonary or Extra-pulmonary</td>
<td>New &amp; Others (S- Only)</td>
<td>CAT-I</td>
</tr>
</tbody>
</table>


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

<table>
<thead>
<tr>
<th>Treatment category</th>
<th>Initial intensive phase</th>
<th>Continuation Phase daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>FDC containing Rifampicin 150 mg Isoniazid 75 mg, Pyrazinamide 400 mg, Ethambutol 275 mg (RHZE) for 2 months according to body weight bands</td>
<td>FDC containing Rifampicin 150 mg Isoniazid 75 mg (RH) for 4 months according to body weight bands</td>
</tr>
<tr>
<td>Category 2</td>
<td>FDC containing Rifampicin 150 mg Isoniazid 75 mg Pyrazinamide 400 mg Ethambutol 275 mg and Inj Streptomycin (500-750 mg) (RHZES) for 2 months AND Rifampicin, Isoniazid, Pyrazinamide, Ethambutol (RHZE) for 1 month according to body weight bands</td>
<td>FDC containing Rifampicin, Isoniazid, Ethambutol (RHE) for 5 months according to body weight bands</td>
</tr>
</tbody>
</table>

In more simplified form given below.

<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>CAT-I</td>
<td>2</td>
<td>HRZE</td>
</tr>
<tr>
<td>CAT-II</td>
<td>3</td>
<td>HRZE +S**</td>
</tr>
</tbody>
</table>

*Intensive phase extended for one more month, in which case duration of continuation phase is accordingly reduced to complete eight months of treatment.

#Streptomycin used in category-I, where Ethambutal in not available or not suitable.

It is very important to treat TB with the correct dosage of recommended drugs. TB medicines 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. The dosage (number of tablets) of each drug is determined by weight of the patient at the time of diagnosis.

Activity 2:

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

(a) Decide the treatment category.

(b) Which drugs will you prescribe in the intensive and continuation phase and for what duration?

3.3. FOLLOW-UP:

TB patient is being followed up for the following reasons:
1- Compliance of the patient: Regularity of drug intake is ascertained. If patient is not taking it regularly, then reasons for it is enquired and the problem is sorted out.

2- Identification and management of side effects: Symptoms related to drug toxicity is inquired and patients are managed accordingly.

<table>
<thead>
<tr>
<th>Minor adverse effects;</th>
<th>Then Manage as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Anorexia, nausea, abdominal pain</td>
<td>Continue anti-TB drugs and:</td>
</tr>
<tr>
<td>✓ Joint pains</td>
<td>Give drugs last thing at night</td>
</tr>
<tr>
<td>✓ Burning sensation in the feet</td>
<td>Aspirin</td>
</tr>
<tr>
<td>✓ Itching of skin</td>
<td>Pyridoxine 100 mg daily</td>
</tr>
<tr>
<td></td>
<td>Anti histamine</td>
</tr>
</tbody>
</table>

**If no response refer**

<table>
<thead>
<tr>
<th>Major adverse effects;</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Skin rash</td>
<td>Stop anti-TB drugs.</td>
</tr>
<tr>
<td>✓ Deafness</td>
<td>Refer to a Specialist</td>
</tr>
<tr>
<td>✓ Dizziness (vertigo &amp; nystagmus)</td>
<td></td>
</tr>
<tr>
<td>✓ Jaundice</td>
<td></td>
</tr>
<tr>
<td>✓ Visual impairment (other causes excluded)</td>
<td></td>
</tr>
<tr>
<td>✓ Shock, purpura, acute renal failure</td>
<td></td>
</tr>
</tbody>
</table>

3- Checking the effect of TB treatment: Sputum smear examination is done at 2 months after starting treatment in order to verify if the treatment is working. Its algorithm is as follows.

<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>CATEGORY I (NEW SMEAR POSITIVE no history of previous ATT)</td>
<td>0</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>End of 2M</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 2M</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>End of 5M</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 5M</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>End of 6M</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 6M</td>
<td>Positive</td>
</tr>
<tr>
<td>Category I (smear negative)</td>
<td>0-month</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 2M</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>End of 2M</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>End of 2M</td>
<td>Positive</td>
</tr>
<tr>
<td>Category II</td>
<td>0.Month*</td>
<td>0.3 Month#</td>
</tr>
<tr>
<td>-------------</td>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td>All retreatment cases after failure, default or relapse</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Register Patient for Cat-11, and start intensive phase</td>
<td>Start continuation phase treatment (5RHE)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Where possible, send for: Gene Xpert: if R sensitive – treat as cat-II, if R resistant – refer to DR-TB unit, OR Conventional DST, and start cat-II intensive phase treatment

# Where possible, send for Gene Xpert: if R sensitive – continue as cat-II, if R resistant – refer to DR-TB unit, (If conventional DST done at the start: R sensitive – continue cat-II)

3.3.1. Treatment Outcomes:

**Cured:** A patient registered as smear-positive, has completed the duration of treatment, becomes sputum smear negative in the last month of treatment and on at least one previous occasion.

**Completed:** A smear positive patient who has completed the duration of treatment and have follow up smear negative results but none at the end of treatment due to any reason OR Smear negative and extra pulmonary cases complete six months of treatment successfully

**Failure:** A sputum smear positive patient who remains or becomes sputum smear positive at five months or later OR Also a patient who was initially smear negative before starting treatment and became smear positive after completing the initial phase of treatment

**Defaulted:** A patient whose treatment was interrupted for two consecutive months or more after registration

**Transferred out:** A patient, who has been transferred to another BMU and for whom, the treatment outcome is not known.

**Died:** A patient who dies for any reason during the course of treatment (based on information gathered and recorded by a responsible health worker)
Activity 3:
For each of the following situations, name the appropriate treatment outcome:

(a) A TB patient with a skin rash is referred from a health facility to a private physician. The patient never returns to the health facility.

(b) A TB patient is moving to a new residence and needs to transfer to another health facility. You give the patient a Tuberculosis Referral/Transfer Form for the new facility. After a month, the receiving health facility has not confirmed that the patient has reported.

(c) A TB patient transfers to a new health facility. The original health facility contacts the new health facility and finds that the patient has indeed reported for treatment. At the appropriate time, the new health facility reports to the original facility that the patient has been proven cured.

(d) Smear positive TB patient became smear negative at the end of 2\textsuperscript{nd} month. He again became sputum smear positive at the 6\textsuperscript{th} month of treatment.

3.4. RECORDING AND REPORTING SYSTEM- MONITORING OF TB PATIENT:

Recording and reporting is done for every TB suspect and patient who presents to the TB centre. These systems consist of TB cards, register and forms. It is important for the following reasons:

1- To follow-up the patient
2- To determine the outcomes of the patient
3- To calculate the indicators like Case notification rate and treatment success rate
4- Evaluation and monitoring of the activities of NTP.

Answers to the activities Session 3:

Activity 1:
(a) Yes, she is a TB suspect because of the following reasons:
- Cough less than 2 weeks, PLUS
- fever at night
- weight loss
- Previous TB in the family

(b) Sputum smear microscopy will be done for confirmation of TB. Algorithm will be followed as in figure 1.

Activity 2:
(a) Category I
(b) Intensive phase for 2 months, FDC containing Rifampicin 150mg, Isoniazid 75mg, Pyrazinamide 400mg, and Ethambutol 275 mg (RHZE) according to body weight; Continuation phase for 6 months, FDC containing Rifampicin 150mg, and Isoniazid 75mg (RH) for 4 months according to body weight.

Activity 3:
(a) Defaulter
(b) Transferred out
(c) Cured
(d) Treatment failure
OBJECTIVES OF THE FIELD VISIT:

1. Physical structures and service stations
2. Case management activities at different service stations
3. Recording and reporting system

4.1. WHAT TO NOTE:
There are generally four key service stations for TB care provision. Each TB patient, during the care process needs:

1. Clinical consultation (i.e. doctor),
2. Health education and treatment management support services (i.e. nurse/ DOTS facilitator),
3. Investigation services (i.e. laboratory), and
4. Drug store (i.e. pharmacy)

4.1.1. Clinical consultation (Doctor): Patient with respiratory symptoms presents to the doctor who takes detailed history and examination. If patient is found to be a TB suspect, he is sent to the DOTS facilitator. When sputum smear examination is reported by the lab, patient goes to the DOTS facilitator, who then send him to doctor for confirmation of TB and is prescribed treatment accordingly. Students should observe the following at DOTS clinic.

Ask and observe:
 Settings
 Location: sign posting/visibility and physical proximity to key service stations (i.e. laboratory/radiology, health education and pharmacy) within the facility premises.
 Infection Control: Administrative triage in waiting room, personal protection (masks/cough etiquettes etc)
 Environmental arrangements: ventilation, air flow, sunlight
 Staff: availability & training of Doctor
 Equipment: availability and functionality (e.g. BP apparatus, Weighing Scale etc)
 Supplies: availability of print materials (e.g. Desk guide for TB management for doctors)
 Practices: registration, prescription, recording reporting etc

4.1.2. Health education and treatment management support services (i.e. by nurse/ DOTS facilitator): TB suspect is registered at this station by the DOTS facilitator in a register. Patient is given a lab form for the sputum smear examination after which he is sent to the laboratory. If suspicion of TB is confirmed, patient is followed up by the DOTS facilitator.

Ask and observe:
 Setting: Location, sign posting, waiting arrangement, infection control practices (e.g. use of face masks), space, ventilation, client/care provider position, privacy
 Supplies: Education materials, print material (e.g. TB patient cards . lab form and registers)
 Practice: Communication method, content/messages and client responses, registration of the patient, filling of patient card, filling of lab forms and recording patient outcome.

4.1.3. Investigation services (laboratory): Patient is sent to the laboratory for sputum smear examination.

Ask and observe:
Settings: Location, waiting arrangement, space, ventilation, infection control, waste disposal, protection against chemicals

Lab Supplies: reagents-mainly include methylene blue, carbol fuchsin and sulphuric acid., sputum cups and glass slides , other laboratory supplies mainly include slide storage boxes, diamond pen, wire loop, immersion oil, xylene or toluene etc.Binocular microscope – availability and functioning is checked and recorded

Practice: Collection of sputum sample, staining of the slides, labeling of the slides, microscopic examination of the slide for Acid fast bacillus

4.1.4. Drug store (Pharmacy): Anti-TB drugs are stored at the Pharmacy or the drug store. At some facilities, theses drugs are kept with the DOTS facilitator.

Ask and observe:

Settings: Location, waiting arrangement, space, ventilation

Storage: Space and environment (temperature, sunlight, humidity, pest control)

Stocks: Stock register for anti-TB drugs

Practice: Communication with clients and client responses

Figure 1: Case management practices at TB centre
Activity: What are your observations and take home message at each service station? You can use the following table to record your observations

<table>
<thead>
<tr>
<th>Service station</th>
<th>Observations</th>
<th>Strengths</th>
<th>Limitations</th>
<th>Take home message</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Recording and reporting is done for every TB suspect and patient who presents to the hospital or health centre. These systems consist of TB cards, register and forms. It is important for the following reasons:

- To follow-up the patient
- To determine the outcomes of the patient
- To calculate the indicators like Case notification rate and treatment success rate
- Evaluation and monitoring of the activities of NTP.
- A brief description of the various forms used along with the format of each form is provided.

**TB01 card**

TB01 card is filled for every diagnosed TB patient. This card contains important administrative and technical details about the patient and his/her treatment. Data from TB01 form is transferred to the TB03 Register, by DOTS facilitator, which forms the basis of Program monitoring and quarterly reporting. Front and back side of the form is given on next page.

**TB02 card**

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 hospital/clinic in relation to patient’s treatment (for drug collection, advice etc.) must bring this card.

**TB Register (TB03)**

The TB register helps to keep track of all the TB patients in the area/district. All Children diagnosed with TB must also be recorded in the TB Register. The patient’s treatment card (TB01) is the main source of information to be recorded in TB Register (TB03). Quarterly reports on case finding, sputum conversions and treatment outcomes are based on information obtained from the TB Register (TB03).

**TB Laboratory Register (TB04)**

TB04 is maintained at the laboratory for recording results of the TB suspects who are referred for sputum smear microscopy for diagnosis purposes and also for the follow-up sputum smear microscopy of TB patients already registered.

**TB laboratory form: request for sputum smear examination (TB05)**

The TB05 form is used to send a request for sputum microscopy and to receive results for diagnosis and follow-up.
TB01 FRONT SIDE

National Tuberculosis Control Program

Tuberculosis Treatment Card

Name of diagnostic centre (BMU)
CNIC #:
Name of Patient (S/o; D/o; W/o)
Father / G Father Name
Sex □ M □ F Age Date of registration
Address of patient
Name/address of contact person
Phone No.
Name of treatment center
Address
Name/Type of treatment supporter with phone No.

I. INITIAL PHASE

Referral by
CAT (I,II) □
Number of tablets (per doze) and Dosage of S:

ADULT
RHZE (150/75/400/275) □
S □

CHILD
RHZ (60/30/150) □
RH (60/30) □
S □

Tick appropriate box after the drugs have been administered

Daily supply: enter ✓ Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—) through the number of days supplied. O = drugs not taken

Sputum smear microscopy
Weight (kg) CXR

Month Date Lab No. Result

| Month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|-------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
National Tuberculosis Control Program

II. CONTINUATION PHASE

<table>
<thead>
<tr>
<th>Number of tablets per dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADULT</td>
</tr>
<tr>
<td>RH (150/75)</td>
</tr>
</tbody>
</table>

Daily supply: enter ✓ Periodic supply: enter X on day when drugs are collected and draw a horizontal line (——) through the number of days supplied. O = drugs not taken

<table>
<thead>
<tr>
<th>(Household) CONTACTS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of contact</td>
</tr>
<tr>
<td>Tub X-ray DSM</td>
</tr>
<tr>
<td>Tub X-ray DSM</td>
</tr>
</tbody>
</table>

Treatment outcome:
- Cure
- Treatment complete
- Died
- Treatment failure
- Default
- Default
- Transfer out

*Joint International Review mission (July 2008) recommended screening of all Sputum Smear Positive (SS+) contacts.
TB PATIENT CARD (TB02)

National Tuberculosis Control Program

Tuberculosis Identity Card

Name ___________________ Patient Identifier Code. _____
Address __________________ Date of registration _____
Sex ☐ M ☐ F Age _____ Date of treatment start _____
Name of diagnostic center (BMU) __________________
Name of treatment center __________________

Side 1

Date of appointment for drugs collection

<table>
<thead>
<tr>
<th>Current</th>
<th>Next</th>
<th>Current</th>
<th>Next</th>
</tr>
</thead>
</table>

Appointment for follow-up sputum examination

<table>
<thead>
<tr>
<th>Date</th>
<th>Place of examination</th>
</tr>
</thead>
</table>

Side 2

Type of patient (tick one)

☐ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other, specify ______

Remarks: ____________________________________________

Side 3

Disease site (tick one)

☐ pulmonary ☐ Extra-Pulmonary specify ______

Side 4

I. INITIAL PHASE

<table>
<thead>
<tr>
<th>CAT (I, II)</th>
<th>ADULT</th>
<th>RHZE</th>
<th>S</th>
<th>RHZ</th>
<th>RH</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>drugs &amp; dosage</td>
<td>150/75/400/275</td>
<td>60/30/150</td>
<td>60/30</td>
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</tbody>
</table>

II. CONTINUATION PHASE

<table>
<thead>
<tr>
<th>RH</th>
<th>RHE</th>
<th>RH</th>
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</thead>
<tbody>
<tr>
<td>150/75</td>
<td>150/75/275</td>
<td>60/30</td>
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</tbody>
</table>

Sputum smear microscopy

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Lab No.</th>
<th>Result</th>
</tr>
</thead>
</table>

Weight (kg)

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Lab No.</th>
<th>Result</th>
</tr>
</thead>
</table>

Important Instructions for the patient

1. This is an important card, keep it with care.
2. Bring this card when you come to see doctor, collect drugs or get sputum examined.
3. TB is a curable disease.
5. Regular intake of drugs is essential for the success of treatment.
6. Get TB drugs, free of cost, from the health facility nearest to your place.
7. Must visit the health facility on due date of appointment
8. If you cooperate, you will get cured (Insha-Allah)
# SUSPECT REGISTER

**Name of Examination:** ________________  
**Month:** ____________  
**Year:** ____________

<table>
<thead>
<tr>
<th>Monthly Sr.No.</th>
<th>Date</th>
<th>Name With Father/Husband Name</th>
<th>Address/Phone number</th>
<th>Age</th>
<th>Sex</th>
<th>OPD Number</th>
<th>Indoor Ward/U nit/Bed No.</th>
<th>AFB Result</th>
<th>Lab number</th>
<th>Remarks</th>
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</table>
### TB Referral / Transfer Register (TRTR)

<table>
<thead>
<tr>
<th>Ser No.</th>
<th>Name</th>
<th>Phone/Cell No.</th>
<th>Smear Exam Result with lab. No</th>
<th>Pre-Registered or Transferred out PR/TO Patient TB Case no. If TO</th>
<th>Date Referred/Transfer</th>
<th>Name/Address/Tel No. (Receiving unit)</th>
<th>Patient Identifier Code (receiving unit)</th>
<th>Treat Outcome / Unknown</th>
<th>Remarks (About Missing Patient)</th>
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</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.
Register of TB Contacts

<table>
<thead>
<tr>
<th>Name of index case</th>
<th>Patient Identifier Code</th>
<th>Diagnosis of index case</th>
<th>Age</th>
<th>Gender</th>
<th>Nationality</th>
<th>TBM U No</th>
<th>Name of contact</th>
<th>Address of contact</th>
<th>Symptoms</th>
<th>Date of onset of symptoms</th>
<th>Method of screening (tick)</th>
<th>Result of screening 2</th>
<th>Action taken 3</th>
<th>Results of Pv treatment 4</th>
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1 List all contacts consecutively under the name of the index case. (Definition of contact is to be included.)

2 NEG; POS; ND

3 **Action**: Registration for treatment, Referred, Defaulted, none

4 **Result**: Completed, Defaulted, NA
## TUBERCULOSIS REGISTER (TB03)

**National Tuberculosis Control Program**

**TB03**

### Year: ______________

<table>
<thead>
<tr>
<th>Date of registration</th>
<th>Patient Identifier Code</th>
<th>Name (S/o; D/o; W/o) &amp; CNIC #</th>
<th>Father &amp; G. Father Name</th>
<th>F=Father G=Grand Father (encircle relevant information F/G)</th>
<th>Sex M/F</th>
<th>Age</th>
<th>Complete Address</th>
<th>Name of Treatment Center</th>
<th>Date treatment started</th>
<th>Treatment category</th>
<th>Site P/EP</th>
<th>Type of Patient**</th>
<th>Results of sputum smear microscopy</th>
<th>Date Treatment Stopped***</th>
<th>No of TB cases detected through contacts screening</th>
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### Remarks

- **F/G**
- **Results of sputum smear microscopy**
  - Sputum Smear Microscopy Before treatment
  - Follow Up Sputum Examinations
  - Date Treatment Stopped

### Notes

- **Type of Patient**: I, II, III, IV
- **Site**: P/EP
- **Sex**: M/F
- **Age**
- **Complete Address**
- **Name of Treatment Center**
- **Date treatment started**
- **Treatment category**
- **Site**: P/EP
- **Type of Patient**: I, II, III, IV
- **Results of sputum smear microscopy**
- **Date Treatment Stopped***
- **No of TB cases detected through contacts screening**
1. First follow up at the end of 2\textsuperscript{nd} month for NSS+ cases and at the end of 3 month for those NSS+ not converted at 2 month and for CAT 2 patients.

2. Mention the result as NEG.1- 9, 1+, 2+, 3+. ND for smear not done.

3. Last follow-up at the end of 6\textsuperscript{th} month for CAT-1 cases and for CAT-II at the end of 8\textsuperscript{th} month will be recorded in the same column accordingly.

4. Write Father and G.father name in case of male and female unmarried & fathers and husband name in case of married female
<table>
<thead>
<tr>
<th>Lab. Serial No.</th>
<th>Date Specimen received</th>
<th>Name (S/O; D/O; W/O) &amp; CNIC#</th>
<th>Sex (M/F)</th>
<th>Age</th>
<th>Complete address with Cell Number (Patient for Diagnosis)</th>
<th>Name of referring facility</th>
<th>Reason for Sputum Smear Microscopy Examination</th>
<th>Results of Sputum Smear Microscopy Examinations</th>
<th>Patient Identifier Code (after registration)</th>
<th>Remarks</th>
<th>Signature</th>
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**TB LABORATORY FORM: REQUEST FOR SPUTUM SMEAR EXAMINATION (TB05)**

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<tr>
<th>Name of BMU (Diagnostic Center)</th>
<th>Date</th>
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<th>Age</th>
<th>Sex</th>
<th>M</th>
<th>F</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Complete address</th>
<th></th>
</tr>
</thead>
</table>

Reason for sputum smear microscopy examination
- Diagnosis
- Follow-up

Number of month of treatment

Patient Identifier Code

Name and signature of person requesting examination

1. Including all public and private health facility/providers
2. Be sure to enter the patient’s BMU TB Register No. for follow-up of patients on chemotherapy

---

**RESULTS (to be completed in the laboratory)**

<table>
<thead>
<tr>
<th>Laboratory Serial No.</th>
<th>Date Examined</th>
<th>Sputum Specimen</th>
<th>Visual appearance</th>
<th>NEG</th>
<th>(1 – 9)</th>
<th>+</th>
<th>(+++)</th>
<th>(++++)</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

3. To be completed by the person collecting the sputum
4. Blood-stained, muco-purulent, saliva

Examined by

Date ____________________ Signature ____________________
National TB Control Program Pakistan
MDR TB Suspect Referral Form

Hospital (where patient is being send):

Date of referral: (mm/dd/yy)

Referring Facility
Name and Address:
District: ____________________________ Tel. No.: ____________________________

Patient:
Name: ________________________________________________________________
Age: ____________________________ Sex: ____________________________
Address: ________________________________________________________________ Tel No.: ____________________________

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>Anti-TB Drugs (with Duration)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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

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.
National Tuberculosis Control Program

QUARTERLY REPORT ON TB CASE REGISTRATION

INDIVIDUAL/CONSOLIDATED REPORT (tick one) In case of consolidated report: Functional Reporting centres

Name of district Name of BMU (Diagnostic Center) Patients registered during Quarter of year

Name of TB Coordinator Signature Date of completion of this form

Block 1: All TB cases registered

<table>
<thead>
<tr>
<th>Sex</th>
<th>Pulmonary sputum smear microscopy positive</th>
<th>New pulmonary sputum smear microscopy negative</th>
<th>New pulmonary sputum smear not done</th>
<th>New extra pulmonary</th>
<th>Others 6 previously treated (SS Neg. &amp; EP)</th>
<th>Total 7 all cases (Col. 2-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Previously treated</td>
<td>New pulmonary sputum smear microscopy positive</td>
<td>New pulmonary sputum smear microscopy negative</td>
<td>New pulmonary sputum smear not done</td>
<td>New extra pulmonary</td>
<td>Others 6 previously treated (SS Neg. &amp; EP)</td>
</tr>
<tr>
<td></td>
<td>Relapses</td>
<td>After failure</td>
<td>After default</td>
<td>Others (SS+)</td>
<td>0-4 yrs</td>
<td>5-14 yrs</td>
</tr>
<tr>
<td>Male</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<td>4</td>
</tr>
</tbody>
</table>

Block 2: New pulmonary sputum smear microscopy positive cases – Age group

<table>
<thead>
<tr>
<th>Sex</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>≥ 65</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Block 3: Laboratory active – sputum smear microscopy

<table>
<thead>
<tr>
<th>No. of TB suspects examined for diagnosis by sputum smear microscopy</th>
<th>No. of TB suspects with positive sputum smear microscopy result</th>
<th>Total OPD</th>
</tr>
</thead>
</table>

Block 4: Contacts screening

<table>
<thead>
<tr>
<th>Total No. of contacts screened out through different screening tools</th>
<th>No. of confirmed TB cases detected through contacts screening</th>
</tr>
</thead>
</table>
### QUARTERLY REPORT ON THE SPUTUM CONVERSION AFTER 2 AND/ OR 3 MONTHS TREATMENTS OF PULMONARY TUBERCULOSIS SMEAR-POSITIVE PATIENTS REGISTERED 3 TO 6 MONTHS EARLIER

**INDIVIDUAL/CONSOLIDATED REPORT** (tick one). In case of Consolidated report: Functional____ Reporting ____centre

<table>
<thead>
<tr>
<th>Name of District: _________________</th>
<th>HMIS District No: _____</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of BMU(Diagnostic Center):________________________</td>
<td></td>
</tr>
<tr>
<td>Tehsil:______________________________________________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients registered during Quarter of 20</th>
<th>Date of completion of this form: ___________________20 ____</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature: ____________________________</td>
<td>-----------------------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients Registered(1)</th>
<th>Type of Patient</th>
<th>Smear Negative 3</th>
<th>Smear Positive 4</th>
<th>Died 5</th>
<th>Defaulted (6)</th>
<th>Transferred Out 7</th>
<th>Total Patients Evaluated (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Cases</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M  F  T**</td>
<td>1. New Cases:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.1 Smear Positive</td>
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<td></td>
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<tr>
<td></td>
<td>1.2 Smear Negative</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>1.3 Extra-Pulmonary</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1.4 Smear Not Done</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Re-treatments</strong></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>M  F  T**</td>
<td>2. Re-treatments</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>2.1 Relapses</td>
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<td></td>
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<td></td>
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<tr>
<td></td>
<td>2.2 Treatment After Failure</td>
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<td></td>
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<tr>
<td></td>
<td>2.3 Treatment After Default</td>
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<tr>
<td></td>
<td>2.4 Others SS +ve Previously Treated</td>
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<tr>
<td></td>
<td>2.5 Others SS-ve Previously Treated</td>
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<td>Total</td>
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</tbody>
</table>

* From the quarterly Report on New, Relapses and Treatment after Failure and Treatment after Default Cases (TB07)

** Of the New Cases _________ (number) were excluded from evaluation of chemotherapy because:

*** Of the Re-treatments _________ (number) were excluded from evaluation of chemotherapy because:
# QUARTERLY REPORT ON THE RESULTS OF TREATMENT OF PULMONARY TUBERCULOSIS PATIENTS REGISTERED 12-15 MONTHS EARLIER

**INDIVIDUAL/CONSOLIDATED REPORT** (tick one). In case of Consolidated report: Functional ____ Reporting ____ centre

- Name of District: ____________________________
- HMIS District No: __________
- Patients registered during __________ of __________
- Date of completion of this form: __________ 20____
- Name: ____________________________
- Signature: ____________________________

<table>
<thead>
<tr>
<th>Type of Patient</th>
<th>Cured (1)</th>
<th>Treatment completed (2)</th>
<th>Died (3)</th>
<th>Treatment failure (4)</th>
<th>Defaulted (5)</th>
<th>Transferred out (6)</th>
<th>Total evaluated (Column 1-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Cases</td>
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<td>M</td>
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<td>T**</td>
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<td>1. New Cases:</td>
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<tr>
<td>1.1 Smear Positive</td>
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<tr>
<td>1.2 Smear Negative</td>
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<tr>
<td>1.3 Extra-Pulmonary</td>
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<tr>
<td>1.4 Smear Not Done</td>
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</tr>
<tr>
<td>Re-treatments</td>
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<td>T***</td>
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<tr>
<td>2. Re-treatments</td>
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<tr>
<td>2.1 Relapses</td>
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<tr>
<td>2.2 Treatment After Failure</td>
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<tr>
<td>2.3 Treatment After Default</td>
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<td></td>
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<tr>
<td>2.4 Others SS +ve Previously Treated</td>
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<tr>
<td>2.5 Others SS-ve Previously Treated</td>
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<td>Total</td>
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</tbody>
</table>

* From the quarterly Report on New, Relapses and Treatment after Failure and Treatment after Default Cases (TB07)

** Of the New Cases ________ (number) were excluded from evaluation of chemotherapy because:

______________________________
** Of the Re-treatments _________ (number) were excluded from evaluation of chemotherapy because: ________________________________

________________________________________________________________________
Tuberculosis Treatment Referral/Transfer

(Complete top part in triplicate)

Tick for this referral or transfer: □ Referral or □ Transfer 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)

Referral is the process of moving a TB patient prior to registration in a BMU TB Register 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.

Transfer is the process of moving between 2 BMU a TB patient registered in a BMU TB Register 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.
Return this part to facility sending referred / transferred patient as soon as patient has reported.

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 state 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.

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.