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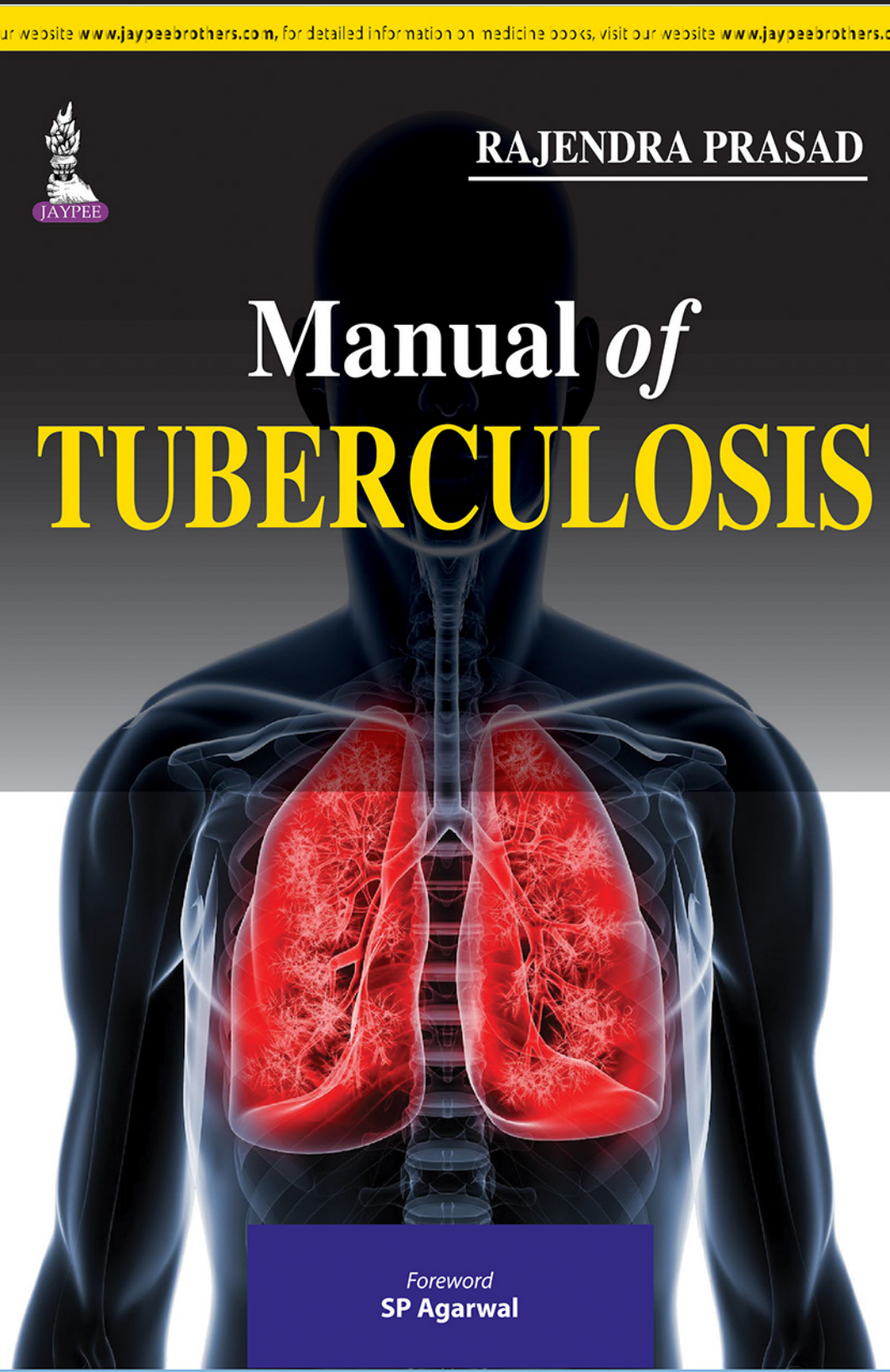
RAJENDRA PRASAD

Manual *of* TUBERCULOSIS



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SP Agarwal

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2
CHAPTER

Case Definitions in Tuberculosis

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Various definitions used in tuberculosis are described.

CASE DEFINITIONS

- **Tuberculosis suspect:** Any person who presents with symptoms or signs suggestive of TB. The most common symptom of pulmonary TB is productive cough for more than 2 weeks, which may be accompanied by other respiratory symptoms (shortness of breath, chest pains, hemoptysis) and/or constitutional symptoms (loss of appetite, weight loss, fever, night sweats, and fatigue).
- **Case of tuberculosis:** A definite case of TB (defined below) or one in which a clinician or other medical practitioner has diagnosed TB and has decided to treat the patients with full course of TB treatment. Any person given treatment for tuberculosis should be recorded as a case. Incomplete trial tuberculosis treatment should not be given as a method for diagnosis.
- **Definite case of tuberculosis:** A patient with *Mycobacterium tuberculosis* complex identified from a clinical specimen, either by culture or by a newer method such as molecular line probe assay. In countries that lack the laboratory capacity to routinely identify *M. tuberculosis*, a pulmonary case with one or more initial sputum smear examinations positive for acid-fast bacilli is also considered to be a "definite" case, provided that there is a functional external quality assurance (EQA) system with blind rechecking.

The determinants of case definition are:

1. Site of TB disease
2. Bacteriology (result of sputum smear)
3. Severity of TB disease
4. History of previous treatment of TB
5. HIV status of the patients.

DISEASE CLASSIFICATION

TB cases are classified as pulmonary and extra-pulmonary:

Pulmonary TB

- Tuberculosis involving only the lung parenchyma.

Pulmonary TB is further classified as smear-positive and smear-negative.

Smear-positive Patient

A case of pulmonary TB is considered to be smear-positive if one or more sputum smear specimens at the start of treatment is positive for AFB (provided that there is a functional external quality assurance (EQA) system with blind rechecking).

A patient with a new sputum smear-positive pulmonary TB is at least one sputum sample in countries with a well functioning EQA system.

In countries without functional EQA, the definition of a smear-positive pulmonary TB case was defined as one with:

- Two or more initial sputum smear examinations (direct smear microscopy) positive for acid-fast bacilli (AFB);

OR

- A patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating clinician and other medical practioner.

OR

- A patient with one sputum specimen positive for AFB and culture-positive for *M. tuberculosis*.

Smear-negative Patient

A patient having symptoms suggestive of TB with at least 2 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating clinician and other medical practioner, followed by a decision to treat the patient with a full course of anti-TB therapy;

OR

A patient whose diagnosis is based on culture-positive for *M. tuberculosis* but sputum smear examinations negative for AFB.

The following forms of smear-negative pulmonary TB are classified as seriously ill:

Seriously ill Smear-negative TB

- Miliary TB
- Extensive parenchymal infiltration
- Co-infection with HIV
- Pulmonary disease with cavitations

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- All forms of pediatric sputum smear-negative pulmonary TB except primary complex.

Diagnosis of extra-pulmonary TB should be based on:

1. One culture-positive specimen from the site of disease, or
2. Histological evidence of TB, or
3. Strong clinical evidence, consistent with active extrapulmonary TB, followed by the diagnosing medical practitioner's decision to treat the patient with a full course of anti-TB treatment. Depending upon the site of the infection, various diagnostic tools may be used. For example, FNAC/biopsy is used for diagnosing TB lymphadenitis.

Extrapulmonary TB

- Tuberculosis of organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges. Tuberculous intrathoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, therefore constitutes a case of extrapulmonary TB (EPTB). The definition of an extrapulmonary case with several sites affected depends on the site representing the most severe form of disease. Patients with both pulmonary and extrapulmonary TB should be classified as a case of pulmonary TB.

Certain forms of EPTB are considered as seriously ill:

Seriously ill EPTB

- Meningitis
- Pericarditis
- Peritonitis
- Bilateral or extensive pleural effusion
- Spinal TB with neurological involvement
- Intestinal
- Genitourinary
- Co-infection with HIV
- All forms of pediatric extrapulmonary TB other than lymph node TB and unilateral pleural effusion are considered to be seriously ill.

Not Seriously ill EPTB

- Lymph node
- Pleural effusion (unilateral)
- Peripheral joints
- Skin
- Adrenal gland

Any patient, with pulmonary or extrapulmonary TB, who is known to be HIV-positive based on voluntary sharing of results and/or history of anti-retroviral therapy, is considered as seriously ill. For the purpose of categorization, HIV testing should not be done.

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TYPES OF TUBERCULOSIS PATIENTS

New

A TB patient who has never had treatment for TB or one who has taken anti-TB drugs for less than one month.

Relapse

It is defined in a person previously treated for TB who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture) tuberculosis.

Treatment after Default

A TB patient who received anti-TB treatment for one month or more from any source and returns to treatment after having defaulted, i.e. not taken anti-TB drugs consecutively for two months or more, and who is found to be sputum smear-positive.

Failure

Any TB patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear-positive during treatment.

Chronic

A TB patient who remains smear-positive after completing a retreatment regimen.

Others

TB patients who do not fit into the above-mentioned types. Reasons for putting a patient in this type must be specified.

DOT

Directly observed treatment means that an observer watches the patient swallowing their tablets, in a way that is sensitive and supportive to the patient's needs. This ensures that a TB patient takes the right antitubercular drugs, in the right doses and at the right intervals.

DOTS-plus

It is an integral component of RNTCP to manage MDR-TB which is to be implemented through program infrastructure of the DOTS program. The strategy

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is designed to manage MDR-TB using second-line anti-TB drugs within the DOTS strategy in low- and middle-income countries like India.

Treatment Outcomes of DOTS

In RNTCP, every patient registered has one and only one of the following six outcomes. This needs to be reported in individual treatment cards. The possible treatment outcomes are as follows:

Cured

Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at the end of treatment.

Treatment Completed

A sputum smear-positive patient who has completed treatment, with negative smears at the end of intensive phase (IP) but none at the end of treatment; or a sputum smear-negative patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment; or an EPTB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

Death

Patient who dies during the course of treatment, regardless of the cause of death.

Failure

It is defined on the basis of two aspects bacteriologically, i.e. on sputum smear and culture status. In low- and middle-income countries like India where cultures are less frequently used, sputum smears are used to define failures. Failure for initially smear-positive patients (CAT I and CAT II) is defined as sputum smear-positive at the end of the fifth month of treatment or later. Failure for initially smear-negative patients (Category III) regimen is defined as who became smear-positive during treatment.

Based on culture, failure is defined as the reappearance, whilst the patient is receiving treatment and after the negative conversion of cultures, of bacteriological activity. It is also considered treatment failure when cultures do not become negative during the course of treatment.

Defaulted

A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment.

Transferred Out

A patient who has been transferred to another TB unit or district and for whom the treatment result (outcome) is not known.

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Drug Resistant TB

Drug resistant tuberculosis is defined as a case of tuberculosis excreting bacilli resistant to one or more antitubercular drugs. DR-TB is confirmed through laboratory tests that show that the infecting isolates of *M.tuberculosis* grow in vitro in the presence of one or more antituberculosis drugs. Four different categories of drug resistance have been established:

Mono-resistance

Resistance to one antituberculosis drug.

Poly-resistance

Resistance to more than one antituberculosis drug, other than both isoniazid and rifampicin.

Multidrug-resistant TB (MDR-TB)

Resistant to isoniazid (H) and rifampicin (R) with or without resistance to other drugs.

MDR-TB Suspect

A TB patient who fails an RNTCP Category I or III treatment regimen and any RNTCP Category II patient who is sputum smear-positive at the end of the fourth month of treatment or later. Recently criteria for defining an MDR TB suspect has been divided into three groups under programmatic management of drug resistant tuberculosis. The program uses a strategy that screens patients with initially a very high-risk of MDR-TB using drug susceptibility test (DST). As laboratory and treatment capacity builds, the program will scale up to achieve universal access to quality assured DST. The MDR suspects have been divided into 3 criteria based on the risk of MDR TB. Criteria A includes all failures of new TB cases, smear +ve previously treated cases who remain smear positive at 4th month onward, all pulmonary TB cases who are contacts of known MDR-TB case. Criteria B includes in addition to Criteria A all smear +ve previously treated pulmonary TB cases at diagnosis, any smear +ve follow up result in new or previously treated cases. Criteria C includes in addition to Criteria B all smear –ve previously treated pulmonary TB cases at diagnosis and HIV TB co-infected cases at diagnosis. Initially DST will be performed in those patients fulfilling Criteria A and as capacity builds up it will progress to Criteria B and then C.

Confirmed MDR-TB Case

A TB patient whose sputum is culture positive for *Mycobacterium tuberculosis* and is resistant in-vitro to isoniazid and rifampicin with or without other antitubercular drugs based on DST results from an RNTCP-certified Culture & DST

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Laboratory. An "MDR-TB suspect" confirmed by an RNTCP-certified Culture & DST Laboratory to have MDR-TB, or any rifampicin resistance, will be treated with the RNTCP regimen for MDR-TB.

Extensively Drug-resistant TB (XDR-TB)

The term extensively drug resistant TB (XDR-TB) is a new term which was provisionally defined as those persons with TB whose isolates were resistant to isoniazid and rifampicin and at least three of the six main classes of second-line drugs (SLDs) (aminoglycosides, polypeptides, fluoroquinolones, thioamides, cycloserine, and para-aminosalicylic acid). But in October 2006, the World Health Organization revised the case definition of XDR-TB as TB with resistance to at least isoniazid and rifampicin as well as further resistance to a fluroquinolone and a second-line injectable agent (kanamycin, amikacin or capreomycin).

XDR-TB Suspect

If the 6th month follow-up culture of MDR patients under DOTS plus treatment is found to be positive, then at this time culture isolate should be sent for second-line DST.

Extremely Drug-resistant TB (XXDR-TB) or Total drug-resistant (TDR-TB)

The term XXDR-TB or TDR-TB has been proposed for cases resistant to all available first- and second-line drugs. The term "totally drug resistant" tuberculosis is not yet recognized by the WHO. For now, these cases are defined as extensively drug resistant tuberculosis (XDR-TB), according to WHO definitions.

Treatment Outcomes in DOTS-plus

Standardized treatment outcome definitions are to be used following treatment of an MDR-TB case and are as follows:

Cure

An MDR-TB patient who has completed treatment and has been consistently culture negative (with at least 5 consecutive negative results in the last 12 to 15 months). If one follow-up positive culture is reported during the last three quarters, patient will still be considered cured provided this positive culture is followed by at least 3 consecutive negative cultures, taken at least 30 days apart, provided that there is clinical evidence of improvement.

Treatment Completed

An MDR-TB patient who has completed treatment according to guidelines but does not meet the definition for cure or treatment failure due to lack of bacteriological results.

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Death

An MDR-TB patient who dies for any reason during the course of MDR-TB treatment.

Treatment Failure

Treatment will be considered to have failed if two or more of the five cultures recorded in the final 12–15 months are positive, or if any of the final three cultures are positive.

Treatment Default

An MDR-TB patient whose MDR-TB treatment was interrupted for two or more consecutive months for any reasons.

Transfer Out

An MDR-TB patient who has been transferred to another reporting unit and for whom the treatment outcome is not known.

Treatment Stopped due to Adverse Drug Reactions

A patient on MDR-TB treatment who develops severe adverse reactions and could not continue the MDR-TB treatment in spite of the management of the adverse reactions as per the defined protocols and decision has been taken by the DOTS-plus site committee to stop treatment.

Treatment Stopped due to Other Reasons

A patient on MDR-TB treatment who could not continue the MDR-TB treatment for any other medical reason (than adverse drug reactions), and a decision has been taken by the DOTS-plus site committee to stop treatment.

Still on Treatment

An MDR-TB patient who, for any reason, is still receiving their RNTCP CAT IV treatment at the time of the submission of the RNTCP DOTS-plus Treatment Outcome Report.

HIV SETTING CASE DEFINITIONS

The following are suggested case definitions for use in HIV-prevalent settings:

Smear-positive Pulmonary Tuberculosis

- One sputum smear examination positive for acid-fast bacilli (AFB) and
- Laboratory confirmation of HIV infection or
- Strong clinical evidence of HIV infection.

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Smear-negative Pulmonary Tuberculosis

- At least two sputum specimens negative for AFB and
- Radiographical abnormalities consistent with active tuberculosis and
- Laboratory confirmation of HIV infection or
- Strong clinical evidence of HIV infection and
- Decision by a clinician to treat with a full course of antituberculosis chemotherapy

OR

- A patient with AFB smear-negative sputum which is culture-positive for *M. tuberculosis*.

Extrapulmonary Tuberculosis

- One specimen from an extrapulmonary site culture-positive for *Mycobacterium tuberculosis* or smear-positive for AFB

OR

- Histological or strong clinical evidence consistent laboratory confirmation of HIV infection or
- Strong clinical evidence of HIV infection and
- Decision by a clinician to treat with a full course of antituberculosis chemotherapy with active extrapulmonary tuberculosis.

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Manual *of* TUBERCULOSIS

This book *Manual of Tuberculosis* is written with the aim of defining a practical approach to every aspect of tuberculosis. Chapters practically covers all the aspects of tuberculosis ranging from epidemiology, diagnosis and practical approach to the treatment of pulmonary as well as common extrapulmonary tuberculosis including HIV and TB. It also covers practical approach to drug resistant including multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis. Chapters also include prevention of tuberculosis and TB control in India. Pharmacokinetics of antituberculosis used in new and retreatment cases of tuberculosis including their doses, regimens and adverse effects are highlighted. Special chapters on case-based approach to treatment of tuberculosis in special situation and MDR-TB have also been included. Chapters have been written in the background of current literature and practical experience gained from day-to-day dealing with different patients suffering from tuberculosis. Undergraduate, postgraduate medical students, practitioners and program managers in TB control will find this book as practical guide.



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