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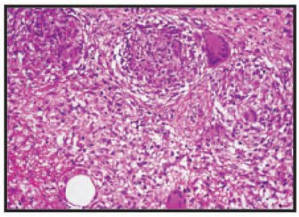

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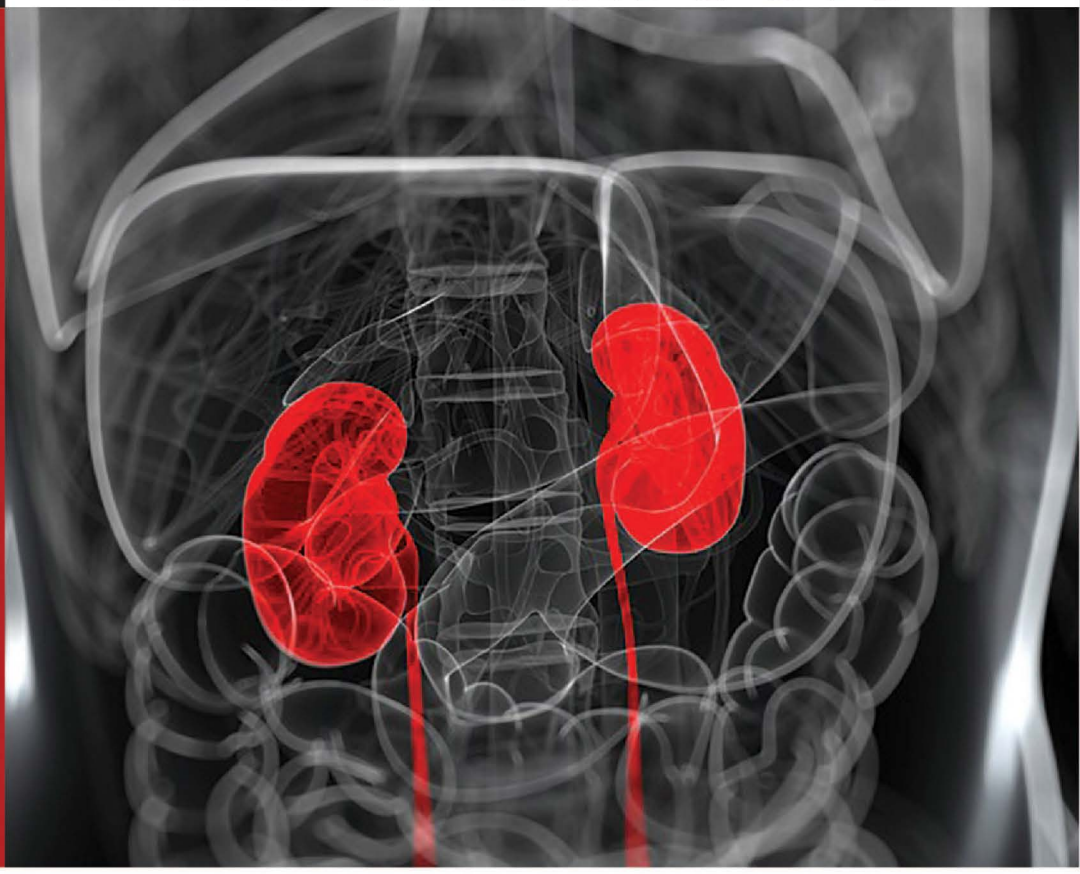

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CHAPTER 2

Excerpts from Guidelines on Management of Drug-resistant Tuberculosis

Sujata Patwardhan, Narendra Sutar

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"Taken from the Revised National Tuberculosis Control Programme, Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi."

These national guidelines are available on the internet; however, they pertain to pulmonary tuberculosis (TB).[1-5]

Not every consultant or student have time to access to this guidelines and hence certain sections relevant to genitourinary TB (GUTB) and important parts of these guidelines are included in this chapter to help in understanding of our national program and be a part of it by following the guidelines.

The salient topics covered are:

1. Definitions and classification of drug-resistant TB (DR-TB) patients
2. State-level structure and responsibilities
3. Methods for drug-susceptibility testing (DST)
4. Choice of diagnostic technology
5. Specimen collection and transportation to culture and drug-susceptibility testing (C-DST) laboratories
6. Integrated DR-TB diagnostic algorithm
7. Treatment of drug-resistant TB
8. Newer anti-TB drugs
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10. Integrated DR-TB algorithm
11. Management of DR-TB in extrapulmonary TB patients
12. Management of contacts of DR-TB
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DEFINITIONS AND CLASSIFICATION OF DRUG-RESISTANT TUBERCULOSIS PATIENTS

The following are the definitions and classification for DR-TB patients:
Presumptive DR-TB:
It refers to the following patients in order of their risk:

- TB patients found positive on any follow-up sputum smear examination during treatment with first-line drugs including treatment failures.
- Pediatric TB nonresponders
- TB patients who are contacts of DR-TB
- Previously treated TB patients
- New TB patients with HIV co-infection
- All notified new TB patients

A patient is confirmed to have DR-TB only when the results are from a Revised National Tuberculosis Control Programme (RNTCP) quality-assured C-DST laboratory and by a RNTCP-endorsed testing method. Such patients are classified according to the following definitions:

- *Mono-resistant TB (*MR-TB*)*: A TB patient, whose biological specimen is resistant to one first line anti-TB drug only.
- *Poly-drug resistant TB* (PDR-TB): A TB patient, whose biological specimen is resistant to more than one first-line anti-TB drug, other than both H and R.

Although new TB patients from above-mentioned categories are at the lower risk of drug resistance, testing them further for presence of drug resistance at the time of diagnosis is a necessary standard of care.

- *Rifampicin resistance* (RR): A TB patient, whose biological specimen is resistant to R, detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to R, in the form of MR, poly-resistance, MDR, or XDR.
- *Multidrug resistance* (MDR): A TB patient, whose biological specimen is resistant to both H and R with or without resistance to other first-line anti-TB drugs. MDR-TB patients may also have additional resistance to any/all FQ OR any/all second-line injectable (SLI) anti-TB drugs.
- *Extensive drug resistance* (XDR): A MDR-TB patient whose biological specimen is additionally resistant to at least a FQ (Ofx, Lfx, Mfx) and a SLI anti-TB drug (Km, Am, and Cm).

It is to be noted that R resistance is quite rare without H resistance. Majority of DST results with R resistance will also be H resistant, i.e., MDR-TB. This has been substantiated in the National Drug Resistance Survey (2014–16).[6] Therefore, RNTCP has taken the programmatic decision that patients, who have any R resistance, should be managed as if they are an MDR-TB patient and this is in line with the World Health Organization (WHO) global guidelines for the programmatic management of drug-resistant TB (PMDT).

STATE-LEVEL STRUCTURE AND RESPONSIBILITIES

The National Expert Technical Working Group has developed national policies, and technical and operational guidelines. The state level is where the majority of planning

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activities, implementation, and monitoring occur. The State PMDT Committee is responsible for developing the plan of action for implementation, expansion, maintenance, and supervision, monitoring and quality enhancement of PMDT services in the respective state.

Drug-resistant Tuberculosis Center

Treatment of DR-TB is not completely based on centralized and institutionalized care for the entire duration. In fact, clinical care needs the presence of a clinical and patient support expert resource center. This is the DRTBC which is a 20–30-bedded tertiary care facility established to serve a population of approximately 10 million, with an airborne infection.

Overall PMDT structures and roles are:

- Diagnose rifampicin-resistant patients at district level
- Receive diagnostic/follow-up specimens
- Provide rapid results to district field and DR-TB center
- Maintain records and NIKSHAY
- Quality assurance of results
- Maintain ward and airborne infection control (AIC) measures
- Pretreatment evaluation
- Start MDR/XDR-TB treatment
- Consult for complications
- Clinical expert resource
- Maintain records and NIKSHAY
- Identify suspects and refer specimens
- Coordinate for test results
- Refer patients to N/DDR-TBC (nodal/district DR-TB center)
- Coordinate care and drug flow from district drug store to field level
- Maintain records, NIKSHAY, monitor, and supervise
- Prepare and ship drug boxes to district level
- Manage supply chain for diagnostics and drugs
- Maintain records, NIKSHAY, and DVDMS (Drug vaccine distribution management system)
- Initiate patient on standard DRTB regimen (MDR/RR-TB, H mono-/poly-DR-TB patients)
- Manage adverse drug reaction (ADR)
- Maintain records and NIKSHAY
- Identify presumptive case and refer specimens
- Support, supervise, and manage DR-TB patients
- Communicate results to patients
- Manage minor adverse effects
- Refer patient for the treatment initiation
- Collect and refer follow-up specimens.

METHODS FOR DRUG SUSCEPTIBILITY TESTING

Presently, drug resistance detection using the following technologies is available for diagnosis of DR-TB through rapid molecular diagnostic testing:

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Line probe assay (LPA) for detection of *Mycobacterium tuberculosis* (MTB) complex and resistance to first-line drugs R, H and second-line drugs class FQ and class SLI drugs[7,8] and cartridge-based nucleic acid amplification test (CBNAAT) Xpert MTB/rifampicin testing using the GeneXpert platform for now.[8]

Growth-based phenotypic drug susceptibility testing: Culture, though a highly sensitive and specific method for TB diagnosis, requires 2–8 weeks to yield results and hence does not help in early detection. However, culture will be used for long-term follow-up of patients on DR-TB treatment and help detect early recurrence in both drug-sensitive and DR-TB. The growth-based phenotypic culture methods include automated liquid culture (LC) systems, e.g., BACTEC MGIT 960, BacT/Alert or VersaTREK, and solid [Löwenstein–Jensen (LJ)] media.

Rapid molecular drug resistance testing: LPA provides rapid diagnosis of R and H resistance as well as resistance to class FQ and class SLI drugs. LPA can yield results in 72 hours.

Nucleic acid amplification test (NAAT) provides accurate and rapid diagnosis of TB by detecting MTB and R resistance conferring mutations.[8] The test can be performed on both respiratory and nonrespiratory specimens and yield results in 2 hours. Presently, under RNTCP, its use is recommended for diagnosis of DR-TB in presumptive DR-TB patients and TB in children, extrapulmonary TB (EPTB) and in key population such as people living with HIV (PLHIV), socially and clinically vulnerable groups and for active case finding efforts.

Drug resistance status is determined by either of the following methods:

- *Drug resistance tests (DRTs) using molecular methods*: This can be performed on sputum specimen (direct) or on culture isolates (indirect) for diagnostic purpose. The methods are PCR-based and cannot be used for determining response to treatment. The tests that belong to this group include:
  - *CBNAAT*: It can be performed on smear-positive, smear-negative and EP specimens. The test detects TB and resistance to R LPA is performed on smear-positive specimen. The test detects TB and resistance to R and H [first-line LPA (FL-LPA)] as well as class FQ and class SLI [second-line LPA (SL-LPA)].
- *Drug susceptibility test*: These are growth based tests and can be performed on LJ culture isolates or in LC system mycobacteria growth indicator tube (MGIT) for both pulmonary and EP specimen. Most commonly used method for testing is the economic variant of the proportion sensitivity. MGIT is preferred method for DST and both first- and second-line anti-TB drugs can be tested. Following drugs can be tested for susceptibility by LC:
  - *First-line drugs*: R, H, Z*
  - *Second-line drugs*: Lfx, Mfx, Km, Cm, Am -
  - *Other drugs*: Lzd, Cfz*, Bdq*, Dlm*, etc.

  *When standardized, the WHO endorsed and approved for use in program.

CHOICE OF DIAGNOSTIC TECHNOLOGY

The program has substantially scaled up the laboratory capacity of various C-DST laboratories. The choice of technology to be used for diagnosis of DR-TB has been determined as per recommendations of the National Laboratory Committee. The choice of technologies is given in the following text.

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Drug Resistance Diagnostic Technology Choice

Following are the choices for drug resistance diagnostic technology:

- *First*: CBNAAT/LPA
- *Second*: LC isolation and LPA DST
- *Third*: LC isolation and liquid DST

All the follow-up cultures will be done through the LC. If the state is facing challenges, with respect to follow-up culture by LC, this may be communicated to the Central TB Division for facilitation.

Specimen Collection and Transportation to C-DST Laboratories

Obtaining good quality specimens of adequate volume is critical to ensuring correct diagnosis. Though the guidelines are specifically mentioned only sputum, the same are applicable to a collected specimen. The Laboratory technician needs to explain the process of collecting "a good-quality sputum specimen" while adhering to AIC measures. The program recommends collection of sputa one spot and one morning, OR two spot specimens collected within a gap of at least 1 hour (if the patient is coming from a long distance OR she/he is unlikely to return to give the second specimen). Ideally, a sputum specimen should have a volume of 2–5 mL and preferably be mucopurulent. Care should be taken to ensure that specimens sent for molecular testing are not heavily blood stained or contaminated. It is advisable to let the hemoptysis subside before collecting the specimen. The patient must be advised to collect the specimen in a sterile container (50-mL conical tube) after thorough rinsing of the mouth with clean water. Specimens should be transported to the laboratory as soon as possible after collection. In case of leakage or spillage of specimen during transportation leading to nontesting of specimen, special care should be taken to ensure recollection of specimen.

As per the diagnostic algorithm, two fresh specimens need to be collected at designated collection centers [designated microscopy center (DMC) or peripheral health institute (PHI) level] by trained laboratory technician (LT) and transported in a cool chain on the same day to the nearest CBNAAT laboratory for all eligible patients. At the CBNAAT site, the test is performed. For all results reported as TB [rifampicin-susceptible (RS) and RR], the second specimen needs to be repacked by the CBNAAT LT and transported to the RNTCP C-DST laboratory on the same day in cool chain. The request form (RNTCP request form for examination of biological specimen for TB) updated with the CBNAAT result should be sent along with the transported specimen. Simultaneously, the result of CBNAAT test is to be communicated to the patient and provider. At the C-DST laboratory, SL-LPA is performed for RR-TB and FL-LPA for RS-TB. All specimens need to be delivered to the RNTCP C-DST laboratory within 48–72 hours of collection. Ideally, an agency (courier/speed post) should be identified for this purpose by the concerned district TB officer (DTO). NGOs may be engaged as per partnership guidelines for specimen transportation in cool chain. If none is available, transporter need to be identified from the health system/community to transport the specimen in biosafe conditions with appropriate enablers. Models for packaging specimens are given in **Figure 2.1**. The following points are critical for the collection of fresh sputum specimens at designated collection points:

- 50-mL conical bottom tubes (made of polypropylene material) and the three-layer packing materials such as thermocol box, ice gel pack (pre-freezed at –20°C for 48 hours), request form for examination of biological specimen for TB, polythene bags, tissue paper roll as absorbent, parafilm tapes, brown tape for packaging box,

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FIG. 1: Technical specifications of transport box for sputum specimen transportation in cool chain.

permanent marker pen, labels, BIOHAZARD sticker, scissors, and spirit swab should be supplied to the DMCs for collection of sputum through the DTO.

- About 50-mL conical tubes should carry a label indicating the date of collection of the specimens along with patient's details such as name, date of specimen collection, name of DMC/District Tuberculosis Center (DTC), Lab. No:- XYZ, and specimen A or B.
- Laboratory technician at DMCs should be trained to carefully to pack the sputum specimens in the cool box to avoid spillage of the specimens.
- Laboratory technician of DMC issuing the conical tubes to the patients should give clear instructions to the patients on correct technique of collection of the sputum. Also the date of issue of the conical tubes to the patient should be recorded.
- Laboratory technician of DMC should ensure that the request form for examination of biological specimen for TB is packed in a separate plastic zip pouch and placed in the cool box before sealing the lid of the box. Also, the BIOHAZARD symbol should be pasted on the external side of the cool box along with the label indicating the postal address of the C-DST laboratory assigned.
- Laboratory technician of DMC should promptly inform the specimen transport agency such as a courier/speed post service to collect and transport the specimens.
- As per national guidelines on biomedical waste management the containers used for transporting sputum specimens to the C-DST laboratory should be labeled with a "BIOHAZARD" sticker.

INTEGRATED DR-TB DIAGNOSTIC ALGORITHM

The vision of the program is to offer DST to TB patients at the earliest time in their diagnostic process. The integrated diagnostic algorithm starts with two groups of patients who are either presumptive TB or diagnosed TB. The main objective of this algorithm is to segregate people based on risk assessment for DR-TB and offer DST-guided treatment based on drug-resistance status at least for R resistance at the time of diagnosis of TB, i.e., Universal DST. The subsequent time points when DST is offered if any of the following events occur during the course of a TB treatment schedule:

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- Bacteriologically positive after intensive phase of a course of TB/DR-TB treatment
- Failure to respond to treatment as per RNTCP definitions
- Recurrence of TB diagnosed after a course of TB treatment
- For patients who are retrieved after lost to follow-up
- For patients found to be HIV positive before or anytime during the course of TB treatment
- Any other reason as per treating physicians' advice.

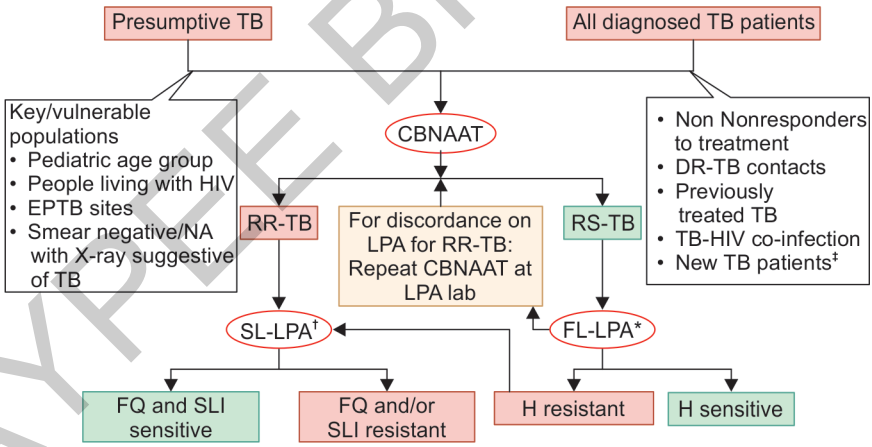
Two diagnostic specimens would be collected from the patients one early morning and one spot specimen wherever possible, but if there is a likelihood of the patient not returning for the second collection or traveling from long distance then two spot specimens may be collected with a gap of at least 1 hour. The DR-TB diagnostic algorithm is as given in **Flowchart 2.1**.

Persons presumed to have TB are:

- From this group those belonging to the pediatric age group
- PLHIV
- EP group or with a smear-negative chest X-ray suggestive of TB will be offered CBNAAT test.

By virtue of using CBNAAT as the TB diagnostic test, the R status is also available simultaneously along with TB detection.

The integrated DR-TB diagnostic algorithm 2020 guidelines has been shown in **Flowchart 2.2**.



* Offer molecular testing for H mono/poly resistance to TB patients prioritized by risk as per the available lab capacity

† LC DST (Mfx 2.0, Km, Cm, Lzd) will be done only for patients with any resistance on baseline Sl-LPA. DST to Z, Cfz, BDQ and DLM would be considered for policy in future, whenever available, standardized and WHO endorsed.

‡ States to advance in phased manner as per PMDT Scale up plan for universal DST based on lab capacity and policy on use of diagnostics.

(CBNAAT: cartridge-based nucleic acid amplification test; DR-TB: drug-resistant TB; DST: drug-susceptibility testing; EPTB: extrapulmonary TB; FL-LPA: first-line line probe assay; FQ: fluoroquinolone; LC: liquid culture; NA: not available; PMDT: programmatic management of drug-resistant TB; RR-TB: rifampicin-resistant TB; RS: rifampicin-susceptible TB; SL-LPA: second-line line probe assay; SLI: second-line injectable; TB: tuberculosis)

FLOWCHART 2.1: Drug-resistant tuberculosis diagnostic algorithm guidelines 2019.

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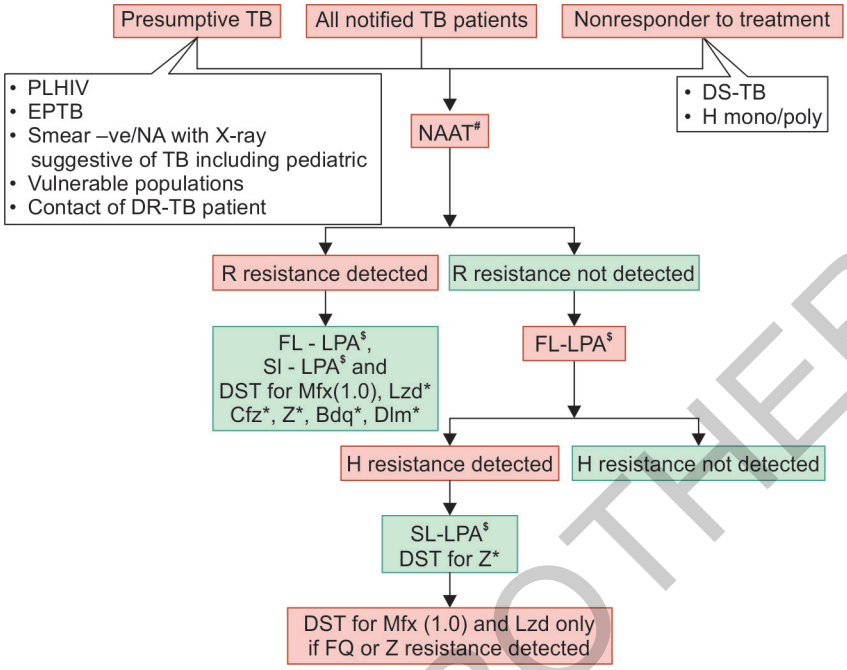

NAAT include CBNAAT and TruNAAT
* Whenever available
$ Culture isolated to be subjected to LPA for smear negative specimens

FLOWCHART 2.2: The integrated DR-TB diagnostic algorithm guidelines 2020.

TREATMENT OF DRUG-RESISTANT TUBERCULSOSIS

This section provides guidance on the treatment of all forms of DR-TB patients.

Classes of Anti-TB Drugs Recommended for Treatment of DR-TB Patients

The anti-TB drugs recommended for treatment of MDR/RR-TB patients are grouped based on efficacy, experience of use, and drug class and aligned with revised classification as per the WHO PMDT Guidelines 2016. The same is explained in **Table 2.1**.[9]

Newer Anti-TB Drugs

After almost five decades of discovery of rifampicin, the first new drug named bedaquiline (Bdq) with anti-TB effect was approved for treatment of MDR-TB by the US Food and Drug Administration (FDA) in late 2012.[10] This was followed by the approval of another new drug delamanid (DLM) by the stringent regulatory authority of various countries.[11] The drug development pipeline of new and repurposed drug has gained momentum in the recent past and more new molecules are expected to be approved in the future.

Bedaquiline is a new class of drug, diarylquinoline, that specifically targets mycobacterial ATP synthase, an enzyme essential for the supply of energy to MTB. Strong bactericidal and sterilizing activities against MTB have been shown in preclinical,

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TABLE 2.1: Recommended anti-TB drugs for treat of MDR-/RR-TB patients.[3]

New grouping of drugs		
A. Fluoroquinolones	Levofloxacin Moxifloxacin Gatifloxacin	Lfx Mfx Gfx
B. Second-line injectable agents	Amikacin Capreomycin Kanamycin (Streptomycin)	Am Cm Km (S)
C. Other second-line agents	Ethionamide/Prothionamide Cycloserine/Terizidone Linezolid Clofazimine	Eto/Pto Cs/Trd Lzd Cfz
D. Add-on agents (not part of the core MDR-TB regimen)	D1 Pyrazinamide Ethambutol High-dose isoniazid	Z E H[h]
	D2 Bedaquiline Delamanid	Bdq Dim
	D3 p-aminosalicylic acid Imipenem-cilastatin Meropenem Amoxicillin-clavulanate (Thioacetazone)	PAS Ipm/Cls Mpm Amx-Clv (T)

(MDR-TB: multidrug-resistant tuberculosis; RR-TB: rifampicin-resistant TB)

laboratory, and animal experiments. The drug has a high volume of distribution, with extensive tissue distribution, highly bound to plasma proteins and is hepatically metabolized. The drug has an extended half-life, which means that it is still present in the plasma up to 5.5 months post stopping Bdq. The dosing schedule has been established after extensive pharmacokinetic/pharmacodynamic (PK/PD) studies in animals and humans and hence needs to be administered as per the manufacturer's advice. Bdq has shown significant benefits in improving the time to culture conversion in MDR-TB patients.[10]

Delamanid, as per an interim policy guidance document released by the WHO in 2014, may be added to a WHO-recommended regimen in adult patients with pulmonary MDR-TB.[11] The process for introduction of DLM under RNTCP is ongoing and guidance for the same will be released subsequently as an addendum to these guidelines.

Regulatory Approvals for Bedaquiline in India

On December 24, 2014, the Apex Committee under the Ministry of Health and Family Welfare, Government of India for supervising clinical trials on new chemical entities in the light of directions of the Supreme Court of India approved the use of Bdq (100 mg) in adults aged 18 years and above as part of a combination therapy of pulmonary TB due to MDR-TB.

Considering MDR-TB as a serious condition with high mortality and a disease of special relevance in the Indian health scenario, the committee recommended waiver of local

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clinical trials at this stage and approved Bdq with restriction that it shall be used under the RNTCP framework for conditional access through the PMDT program for treatment of MDR-TB patients only.

Criteria for Patients to Receive Bedaquiline

Inclusion criteria: The criterion for patients to receive Bdq as approved by the Apex Committee is—adults aged >18 years having pulmonary MDR-TB.

Additional requirements:

- Nonpregnant females or females not on hormonal birth control methods are eligible. They should be willing to continue practicing birth control methods throughout the treatment period or have been postmenopausal for past 2 years.
- Patients with controlled stable arrhythmia can be considered after obtaining cardiac consultation.

Exclusion criteria:

- Currently having uncontrolled cardiac arrhythmia that requires medication
- Having any of the following QT/QTc interval characteristics at screening—marked prolongation of QT/QTc interval, e.g., repeated demonstration of QTcF (Fredericia correction) interval >450 ms; and history of additional risk factors for Torsade de Pointes, e.g., heart failure, hypokalemia, family history of long QT syndrome.

Bedaquiline is provided along with a background regimen based on DST results. Certain conditions as listed below should be taken into consideration while choosing the drugs for the background regimen in patients who:

- Have evidence of chorioretinitis, optic neuritis, or uveitis at screening which precludes long-term Lzd therapy.
- Have the following laboratory abnormalities (DAIDS grading of adverse events):
  - Creatinine grade 2 or greater, i.e., >1.5 times the upper limit of normal (ULN);
  - Hemoglobin grade 4 (<6.5 g/dL)
  - Platelet count grade 3 or greater (≤49,999/mm^3);
  - Absolute neutrophils count grade 3 or greater (≤749/mm^3);
  - Aspartate aminotransferase (AST) grade 2 or greater (>2.5 times ULN)
  - Alanine aminotransferase (ALT) grade 2 or greater (>2.5 times ULN)
  - Total bilirubin grade 2 or greater (>1.6 times ULN)
  - Lipase grade 2 (with no signs or symptoms of pancreatitis) or greater (>1.5 times ULN).

Note: If results of the serum chemistry panel, hematology or urinalysis are outside the normal reference range (including above-listed parameters), the patient may still be considered if the physician judges abnormalities or deviations from normal to be not clinically significant or to be appropriate and reasonable. Hypokalemia, hypomagnesaemia, and hypocalcaemia should be corrected prior to a patient receiving Bdq.

Patients who are not found to be eligible for a Bdq-containing regimen would have DST results for the key first-line and second-line drugs and managed with DST-guided regimens.

Bedaquiline is indicated in adult MDR-TB patients not eligible for the newly WHO-recommended shorter regimen.[12]

These may include:

- MDR-/RR-TB patients with resistance to any/all FQ *OR* to any/all SLI
- XDR-TB patients

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- Mixed pattern-resistant TB patients
- Treatment failures of MDR-TB + FQ/SLI resistance *OR* XDR-TB
- MDR-/RR-TB patients with extensive pulmonary lesions, advanced disease and others deemed at higher baseline risk for poor outcomes.[12]

Caution must be exercised that Bdq is not added to a failing regimen in any patient already on DR-TB treatment.

Integrated Drug-resistant Tuberculosis Algorithm

The integrated DR-TB algorithm (**Flowchart 2.1**) clearly indicates the management strategies to be followed right from the day the results of CBNAAT test are available. These management strategies are described in subsequent sections of this document. The program is improving laboratory capacity to offer DST for all TB patients (Universal DST). An integrated algorithm offers FL-LPA for the presumptive DR-TB found R sensitive on CBNAAT. The LPA will be primarily utilized to do DST for second-line drugs and to test FL-LPA to detect H mono-resistance as per the available laboratory capacity. The program would continue building capacity of the laboratories to eventually test all R-sensitive patients on LPA to detect H mono-resistance that would serve as a surrogate for poly-drug resistance. These patients would be managed as per the algorithm. Within the first 2–3 months, patients would receive the LC-DST results, reach their final classification, and treated with the appropriate regimen.

MANAGEMENT OF DR-TB IN EXTRAPULMONARY TB PATIENTS

Management of bacteriologically confirmed EP DR-TB patients will be considered by the program provided the diagnosis is made by an RNTCP C-DST laboratory. **Treatment regimen and schedule for EP DR-TB patients will remain the same as for pulmonary DR-TB**. Patients must be registered in the PMDT register and the treatment outcome of treatment completed will be considered.

Investigations and Pretreatment Evaluation

Patients would be sent to the DR-TBC for pretreatment evaluation and treatment initiation. EP DR-TB patients will undergo all those pretreatment investigations as done for pulmonary DR-TB patients as part of pretreatment evaluation prior to initiating regimen for DR-TB.

In addition, ultrasound of abdomen of the patient will also be done, if necessary, to rule out involvement of other organs and abdominal nodes. If required, additional imaging investigation will be done to rule out any other conditions.

Initiation of Treatment

After pretreatment evaluation, treatment for EP DR-TB should be initiated based on weight of the patient. Treatment regimen, weight band, and schedule for EP DR-TB patients will remain the same as for pulmonary DR-TB.

Monitoring Progress During Treatment and Follow-up

Post treatment monitoring and follow up recommended for MDR/RR-TB patients both pulmonary and extra pulmonary as well as for paediatric TB cases are based on classification as per the WHO PMDT guidelines 2016. The same is explained in **Table 2.2**.

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TABLE 2.2: Follow-up schedule.

Type of cases	Follow-up schedule	Extension of treatment	Action on follow-up positive	Long-term follow-up
Drug-sensitive pulmonary TB (New and Previously treated TB)	• Microbiological: One specimen at the time of completion of the intensive phase of treatment • Weight: Monthly • Chest X-ray: If required • Physician evaluation: Whenever required	Extension of IP is not required	If the sputum smear is positive in follow-up at any time during treatment, DST should be done as per presumptive DR-TB case	After completion of treatment the patients should be followed up with clinical and/or sputum examination at the end of 6, 12, 18, and 24 months
Multidrug-resistant pulmonary TB (with or without additional drug resistance)	• Microbiological: One sputum specimen will be collected and examined by culture at least 30 days apart from the 3rd to 7th month of treatment (i.e., at the end of the months 3, 4, 5, 6, and 7) and at 3-monthly intervals from the 9th month onwards till the completion of treatment (i.e., at the end of the months 9, 12, 15, 18, 21, and 24). If any culture during CP or end of treatment is positive then it should be followed by monthly culture for 3 months • Weight: Monthly • Chest X-ray: At the end of IP, end of treatment and whenever clinically indicated • Physician evaluation including adverse drug reaction monitoring every month for 6 months, then every 3 months for 2 years	• In MDR-TB cases IP can be extended for maximum 3 months (maximum duration of IP: 9 months). • In all MDR-TB with additional drug resistant cases (including XDR-TB) patients, IP can be extended for maximum 6 months (maximum duration of IP: 12 months)	On follow-up, if sputum culture is found to be positive at 6 months or later, repeat DST for second-line drugs to decide on further course of action. DST to other additional second line drugs may also be done if laboratory facilities are available to guide treatment	

Continued

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Genitourinary Tuberculosis

Genitourinary Tuberculosis or, more precisely, urinary TB is commonly misdiagnosed and mistreated in our country. Most urology textbooks cover this topic from the western perspective and students do not have a clear clinical picture of this disease.

Combining the experience and clinical expertise of this topic with actual cases from a tertiary care center would be justice to the topic of urinary TB.

We have covered all related information from pathology, microbiology, radiology, clinical presentation, and medical and surgical management of urinary TB in detail. We wish this to be used as a reference book by consultants and a book to refer for urinary TB by the students.

Ganesh Gopalakrishnan A hardcore teacher and a good human being with expert surgical hands are the three phrases contribute to describe Dr Ganesh Gopalakrishnan. He is an undergraduate from CMC Vellore. MS from Safdarjung (Delhi University) and MCH (URO) from Vellore with many academic achievements. He was the President of Urological Society of India from 2009 to 2010. Best known as an untiring surgeon with keen interest in reconstructive surgery, Dr Ganesh Gopalakrishnan is a retired HOD from CMC Vellore and is presently working in Vedanayagam Hospital, Coimbatore, Tamil Nadu. His vast experience in GU Koch is reflected in this book.

Sujata Patwardhan is a Professor and Head at one of the best Departments of Urology. She has a keen interest in teaching and reconstructive surgery.

Being a non-PG student of Dr Ganesh Gopalakrishnan, she continued to learn the skills of reconstructive surgery from him. The variety of cases seen in Mumbai and the challenges in treating them needed to be expressed and shared with others interested in this topic.

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