



**“IF YOU WANT
TO SHINE
LIKE A SUN.
FIRST BURN
LIKE A SUN.”**

- A.P.J ABDUL KALAM



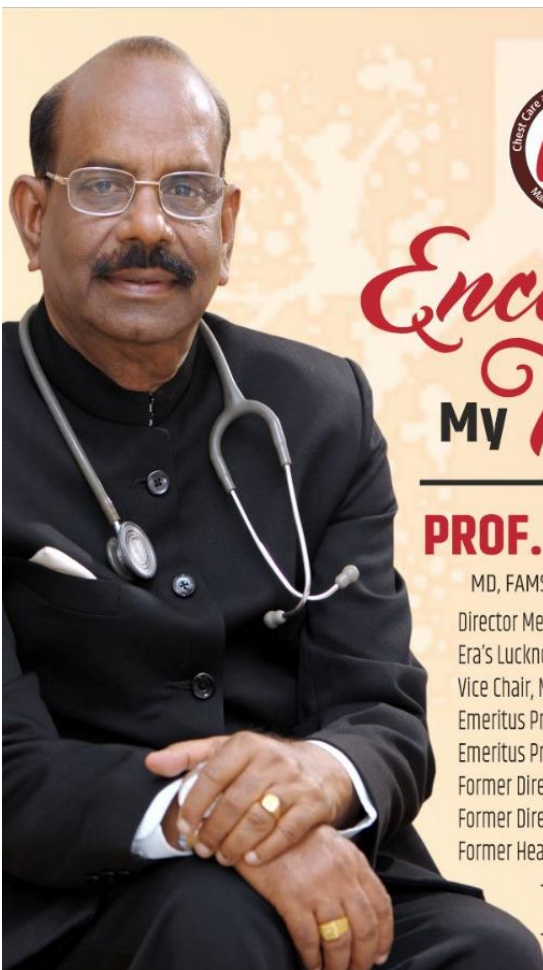
**“Better than a thousand days of diligent –
study is one day with a great teacher”**

Japanese Proverb

PROF B.K. Khanna



1 DEC 1933- 3 JAN 2018




Encounter with My Teachers

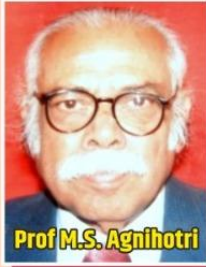
PROF. RAJENDRA PRASAD

MD, FAMS, FCCP (USA), FRCP (GLASG) FRCP (London)
Director Medical Education & Professor, Respiratory Medicine
Era's Lucknow Medical College & Hospital, Era University, Lucknow
Vice Chair, National Task Force, NTEP India
Emeritus Professor, National Academy of Medical Sciences (India)
Emeritus Professor, Indian Medical Association
Former Director: Vallabhbhai Patel Chest Institute, Delhi
Former Director: U.P. Rural Institute Of Medical Science & Research, Salfal
Former Head: Department of Pulmonary Medicine, KGMU, Lucknow

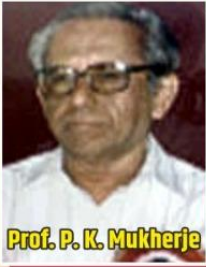
Conduct by **Vandana Tribhuwan Singh**




Prof. B.K. Khanna



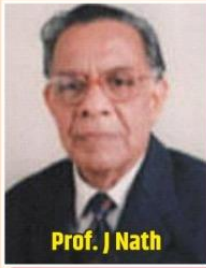
Prof M.S. Agnihotri



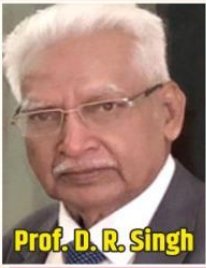
Prof. P. K. Mukherje



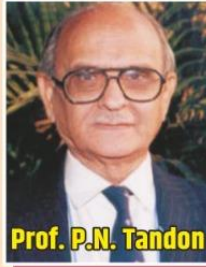
Prof. Zafar Jamil




Prof. J Nath



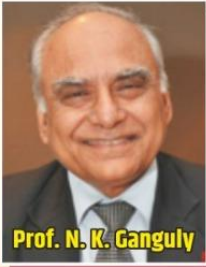
Prof. D. R. Singh



Prof. P.N. Tandon



Prof. Hari Gautam



Prof. N. K. Ganguly

& Many More who Contributed in my Academics & Career



K.G'S MEDICAL COLLEGE LUCKNOW



King George's Medical University, Lucknow



U.P. Rural Institute of Medical Sciences & Research, Saifai



Administrative Block



Academic Block



Hospital Block



Vallabhbhai Patel Chest Institute, Delhi



ERA'S LUCKNOW MEDICAL COLLEGE & HOSPITAL



National Academy of Medical Sciences (India)

DR. RAJENDRA PRASAD

MD,DTCD,FAMS,FCCP (USA) FRCP (GLASG), FRCP (London) FNCCP, FCAI,FIAB,FIMSA,FCCS,FICS,DSc.(Honoris Causa)

Dr. B.C. Roy National Awardee

Emeritus Professor National Academy of Medical Sciences, India

Director Medical Education & prof , Pulmonary Medicine

Era's Lucknow Medical College & Hospital, Lucknow

Convenor, State Chapter, Uttar Pradesh, National Academy of Medical Sciences, India

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Former Prof. & Head Pulmonary Medicine, KGMU, Lucknow

Vice-Chairman , National Task Force NTEP, India

Senior Vice Chairman, Uttar Pradesh Tuberculosis Association

E-mail: rprasadkgmc@gmail.com

- Established on 21st April, 1961 as a registered Society namely, the '*Indian Academy of Medical Sciences*' under Societies Registration Act XXI of 1860, with the objective of promoting the growth of medical sciences
- Inaugurated at New Delhi on 19th December, 1961 by Pt. Jawaharlal Nehru, the first Prime Minister of India
- First Convocation of the Academy held on 8th December, 1963 was addressed by Dr. S. Radhakrishnan, the then President of India
- The Academy was re-named National Academy of Medical Sciences (India) on 16th November, 1976 on the Working Group set up by Government of India
- NAMS is one of the unique institution which fosters and utilises academic excellence as its resource to meet the medical and social goals

- 1. Fellows (FAMS)**
- 2. Members (MAMS)**
- 3. Associate Fellow (Associate Fellow <45 years)**
- 4. Members (After DNB) (MNAMS)**
- 5. Associate Member (After MD/MS)**
- 6. Emeritus Professor**

NAMS Associate Membership

NAMS Associate Membership has been introduced for the Medical /Dental Scientists who have completed Postgraduate qualifications (MD/ MS/ MDS) or PhD/MSc Biotechnology in **SINGLE ATTEMPT** and have a postgraduate degree with Any ONE of the following:

- a. Membership of a National Professional organization in his/her specialty
- b. Publication in a Scientific Journal
- c. Presentation at the Annual Scientific Conference of National Professional organization

The application form, must be proposed by any of the following:

Head of Institution

Head of Department

Head of Unit

NAMS Fellow

Applications are accepted throughout the year.

The link for online application is as follows; <https://namsdigital.in/Home/AMAMSHome>

Current issues in Treatment of Tuberculosis

DR. RAJENDRA PRASAD

MD,DTCD,FAMS,FCCP (USA) FRCP (GLASG), FRCP (London) FNCCP, FCAI,FIAB,FIMSA,FCCS,FICS,D,Sc.(Honoris Causa)

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E-mail: rprasadkgmc@gmail.com

**Would you like your near &
dear ones to suffer/succumb
to tuberculosis**

Agenda Today

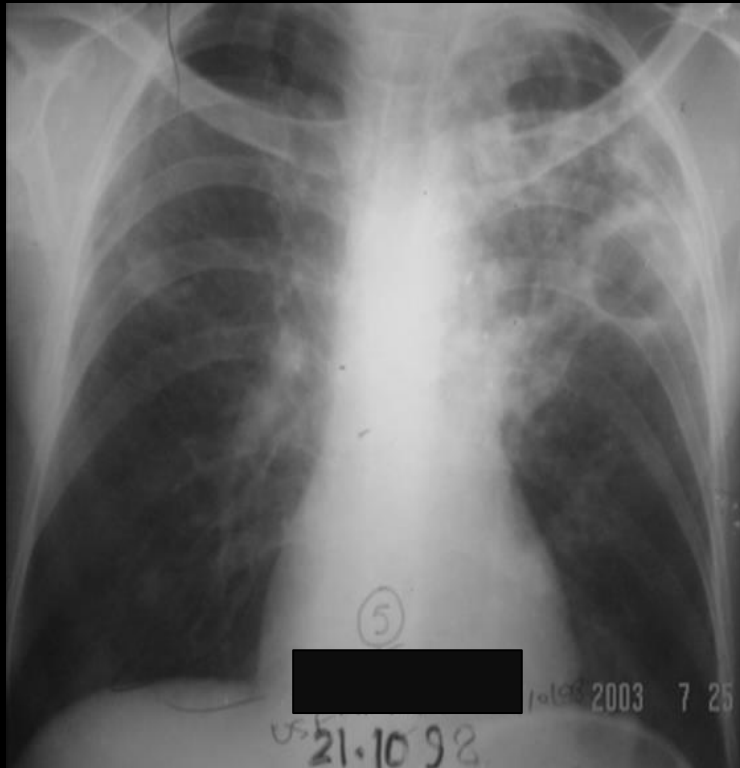
- Basic concepts in Treatment of Tuberculosis
- Update in Treatment of DS and DR Tuberculosis
- Future of Tuberculosis treatment

PATIENTS AND PROVIDERS WISH

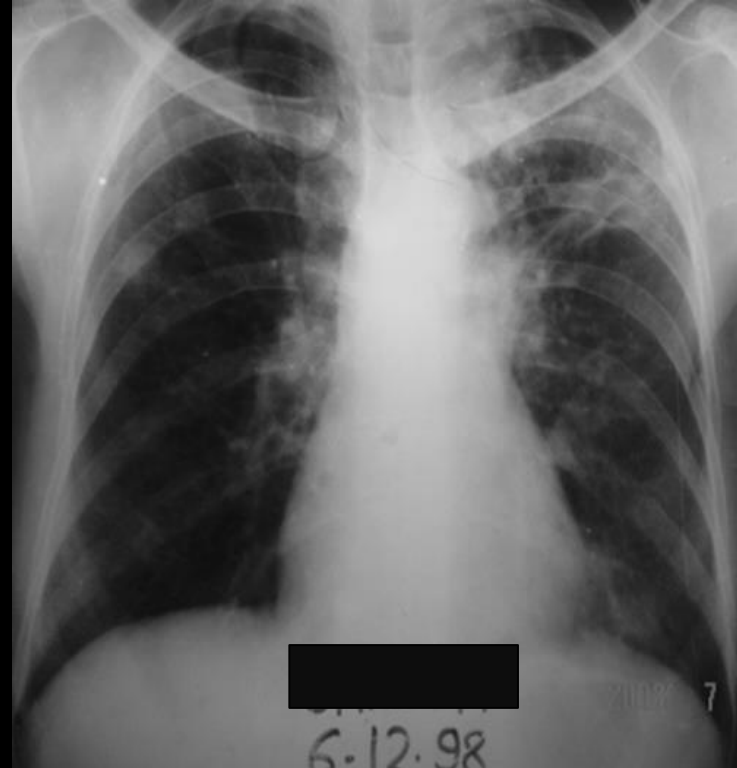
- Shorter treatment duration
- oral regimens
- reduced number of medications, reduced pill burden
- less adverse drug effects

**Lectures on TUBERCULOSIS by Professor
Rajendra Prasad from 01.01.1976 to 24.4.2025**

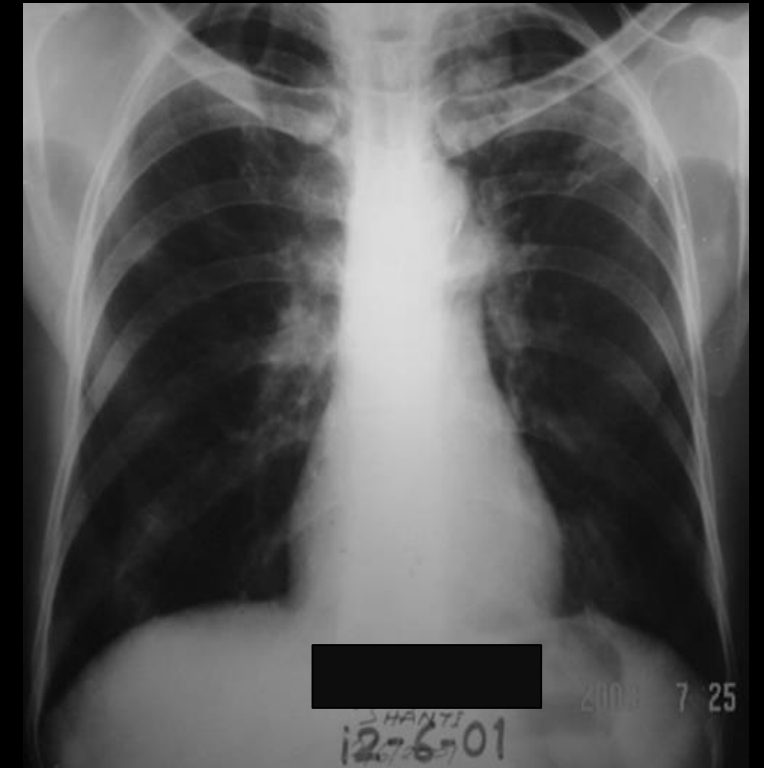
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Sputum +Ve

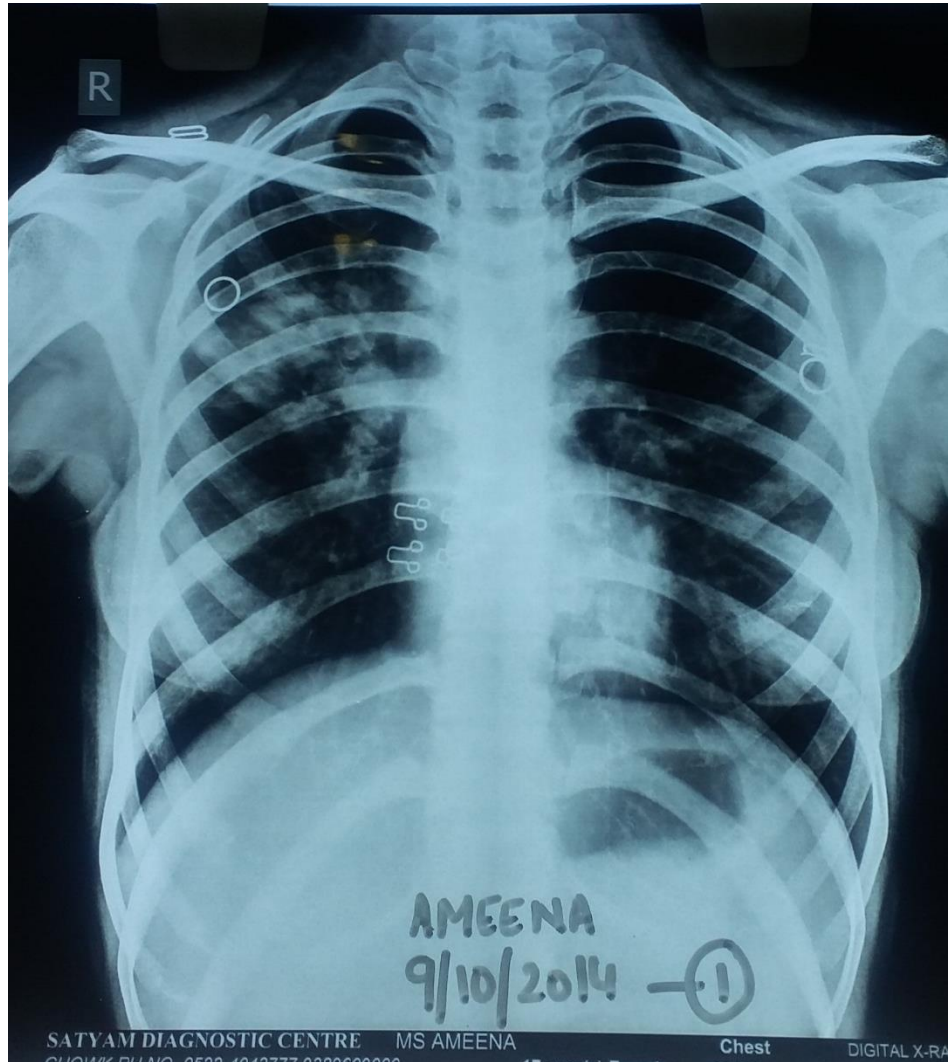


Sputum -Ve

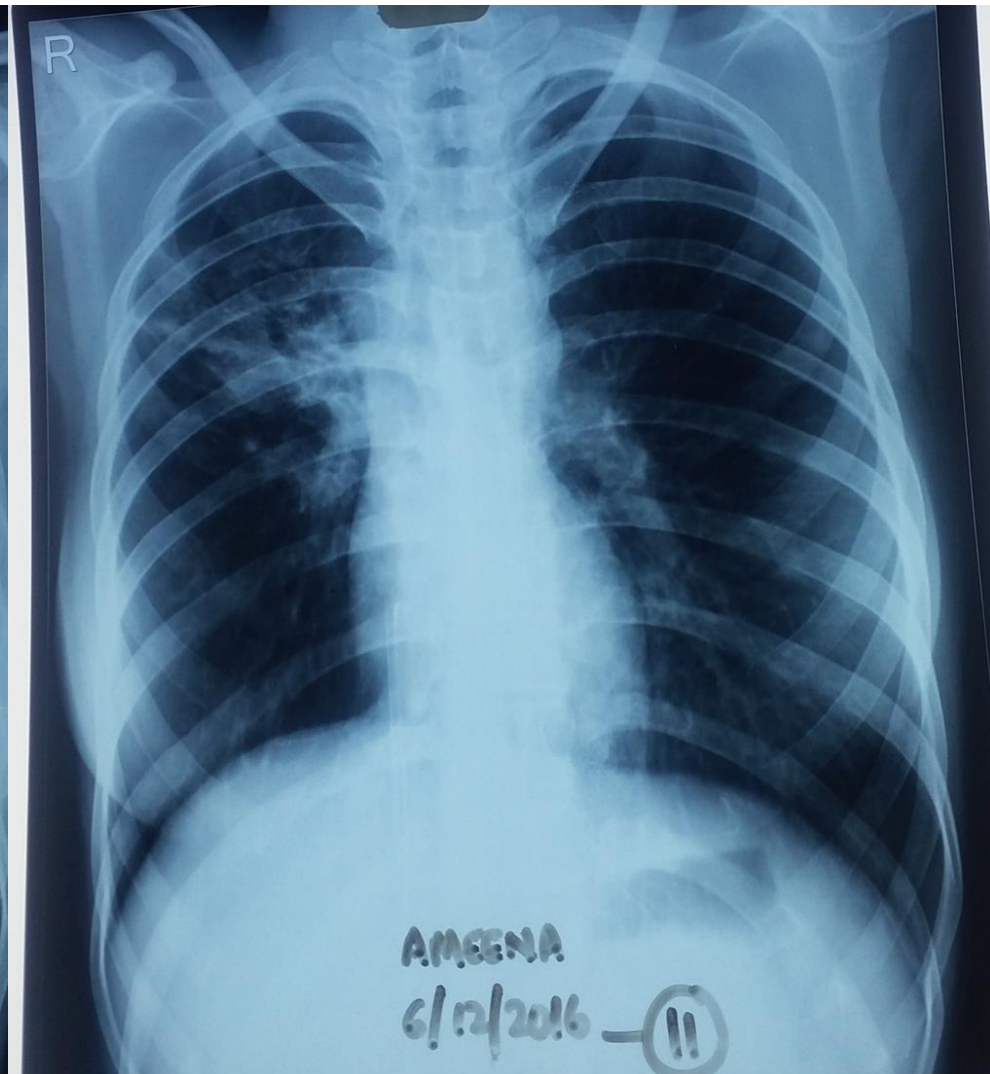
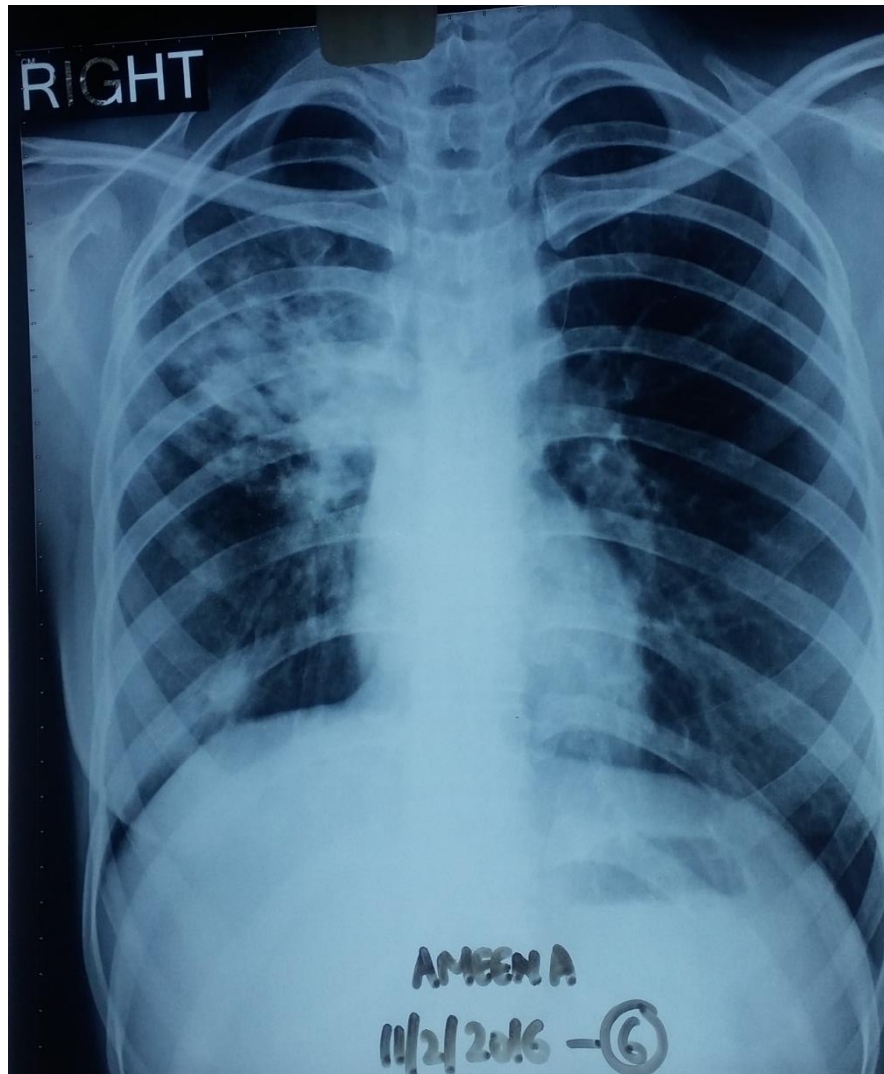


Sputum -Ve

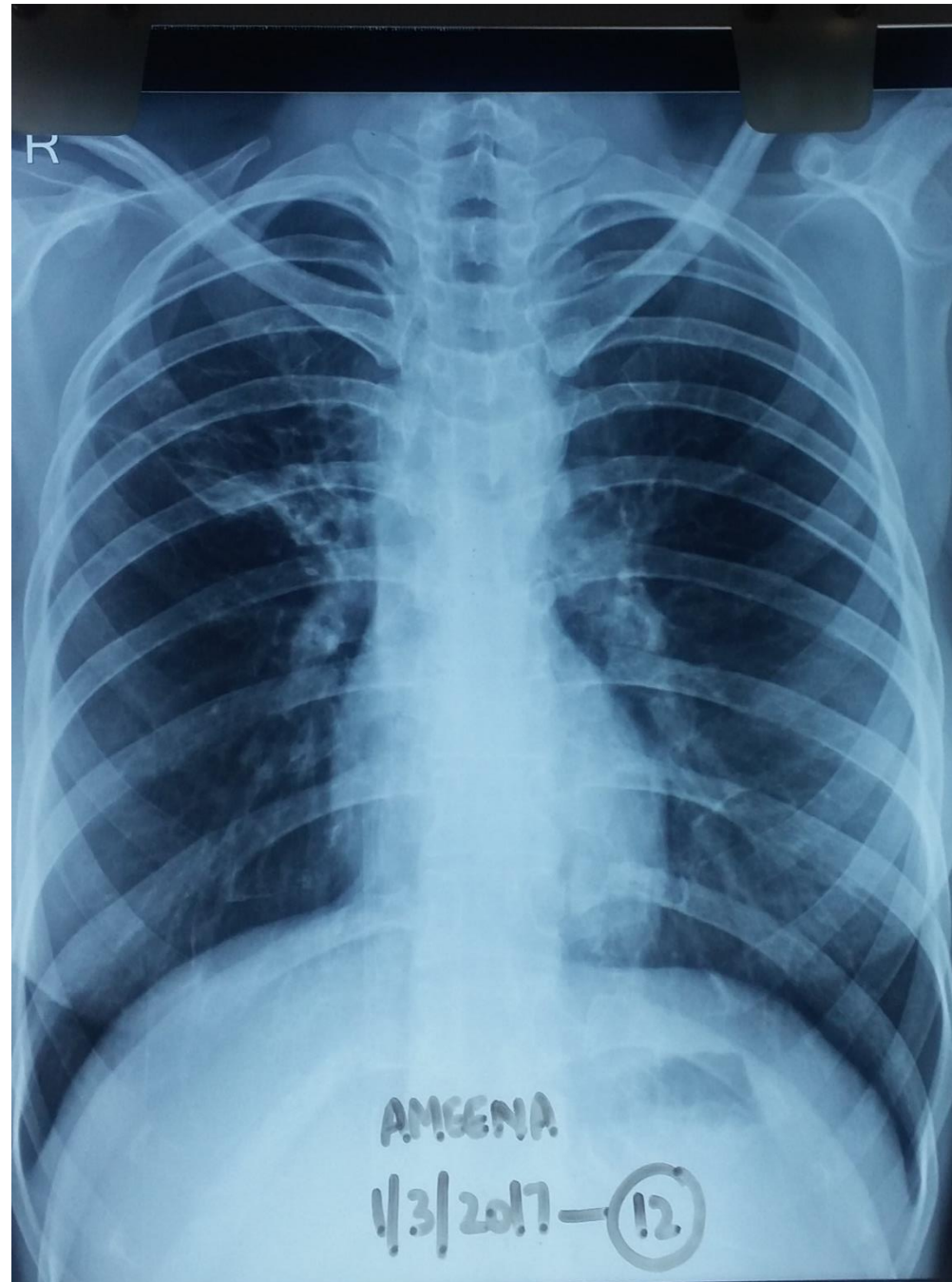
A 17 yr old female C/O-Fever,loss of weight and loss of appetite since 1 month
Sputum positive for AFB was put on 4/5 primary line ATT for 1 year without any response



Sputum Smear Positive, Gene Xpert Positive for TB and Rifampicin Resistance.
C/S showed resistance to H, Kanamycin and Oflox but sensitive to Moxi and Capreo.
9 K, Ethio, Cyclo, Moxi, Z, E, H



After 13 months of treatment(still on treatment)



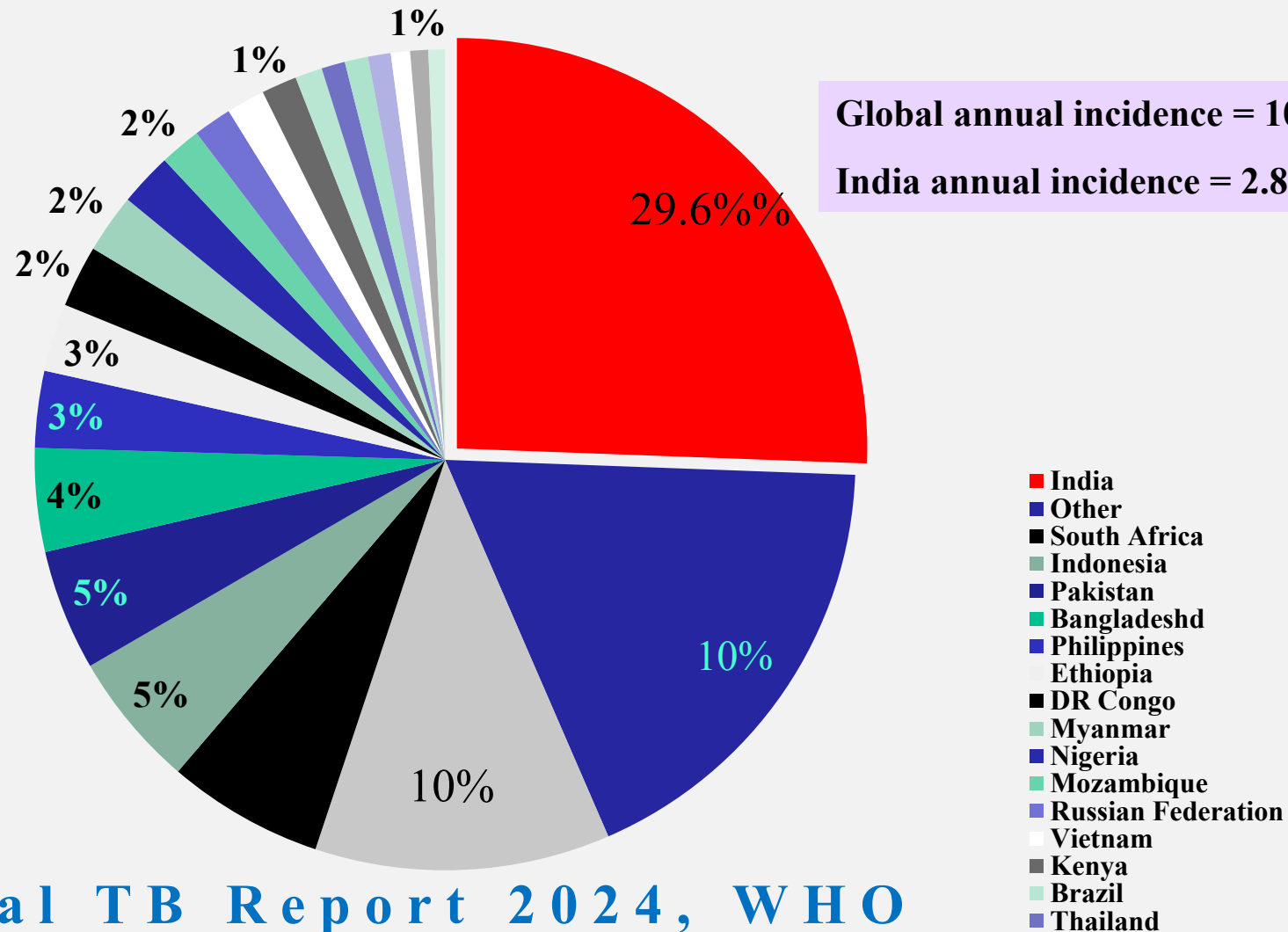


TUBERCULOSIS (TB)

Almost curable if adequate t/t prescribed & taken.

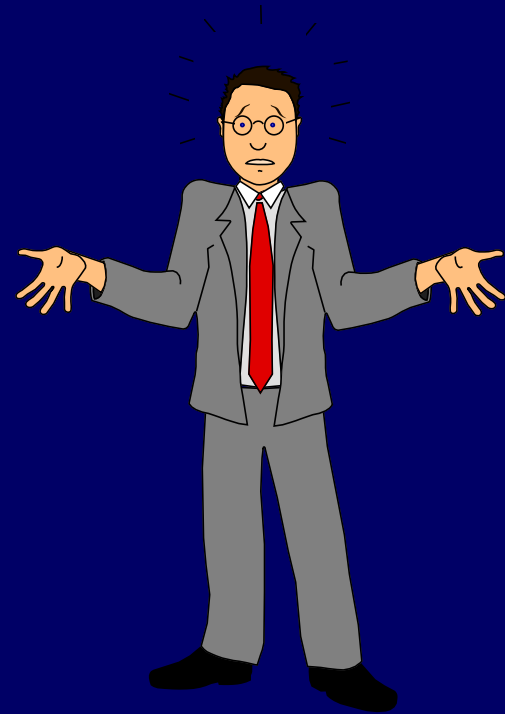
0.357 MILLION Deaths /Year

India has highest TB burden



TB/Death

WHY ?



FACTORS PROMOTING DR-TB/DEATH

POOR MANAGEMENT OF TB PATIENTS

MR. Aray Singh

D PULTB (Sputum +ve
2x)

wt - 60kgs.

R

Tab RLV 450mg OD - o

Tab Isotrex 300mg OD - o

Tab CombotoL 800mg OD - o

Tab PZA 750mg BD ::

Tab Pau-D 1 tab OD BBE

Protinex Powder 2hf BD in one glass
of water / milk

Tab Benadon 40mg 1/2 OD as --

Syr Heparin 3 2hf thr


18/03/22

Name - Mr. Ramhal
Δ - TB Epine

wt - 58 kgs

Rx

- T. Forecox 2 tabs OD
- T. Benadon 40 mg $1/2$ tabs HS
- T. Pan 40 OD BBF
- Ensure protein powder 2 tabs
- T. Becosule - 2 1 tabs ^{TDS} _{2 tabs} ^{mult} _{OD}


18.02.2022



R

Q/O Dizziness Weakness
nausea.

दिनांक 02/12/2023

H/O DM - Mother

Mrs. Shivangi
Agrahari
Age-26

w/o Rahul Sah
Aurangabad

CBC, TSH, RBS
mx

BP - $\frac{100}{70}$ mmHg

LMP - 01/12/2023

MH - $\frac{3-4}{20}$ days.

ML - 11 months

G₀ + P₀ + 0

Wt - 59.8 kg

Actv.

T Bact oint.

AK T₄ 1 R/K/day

Cap: Zincasule - 10D

cap: Rablet D - 10D

Tab: Udilive 300 10D
शिव

Tab: Stemetil MD 120 → 4 days
0 0

-15 days



Case Definition

~~TB suspect~~ – Presumptive TB

Case definition

Microbiologically confirmed

Clinically diagnosed

Anatomical site

Pulmonary

Extra pulmonary

History of ATT

New

Recurrent

Treatment after failure

Treatment after lost to follow up

Other previously treated patients

Treatment outcome

Cure

Treatment completed

Died

Failure

Lost to follow up

Change of regimen

Not evaluated

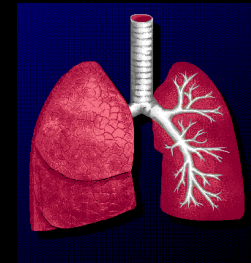
Presumptive Pulmonary TB

Presumptive Pulmonary TB refers to a person with any of the symptoms and signs suggestive of TB including:-

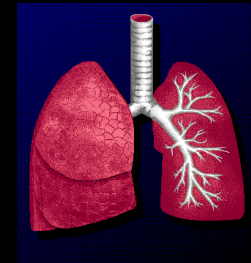
- Cough for > 2 weeks
- Haemoptysis
- Fever >2 weeks
- Significant weight loss
- Any pulmonary abnormality in chest radiograph

Note: In addition , contacts of microbiologically confirmed TB patients, PLHIV , Diabetics, Malnourished, cancer patients, patients on immuno- suppressants or steroids should be regularly screened for sign and symptoms of TB

How To Treat Tuberculosis ?



Basic Principles in Treatment of Tuberculosis



Aims Of Treatment

- Cure the patient
- Prevent complications and death
- Avoid relapse
- Reduce transmission potential to susceptible individuals
- Limit emergence and spread of drug-resistant strains

Principles of Chemotherapy

- **No single drug therapy**

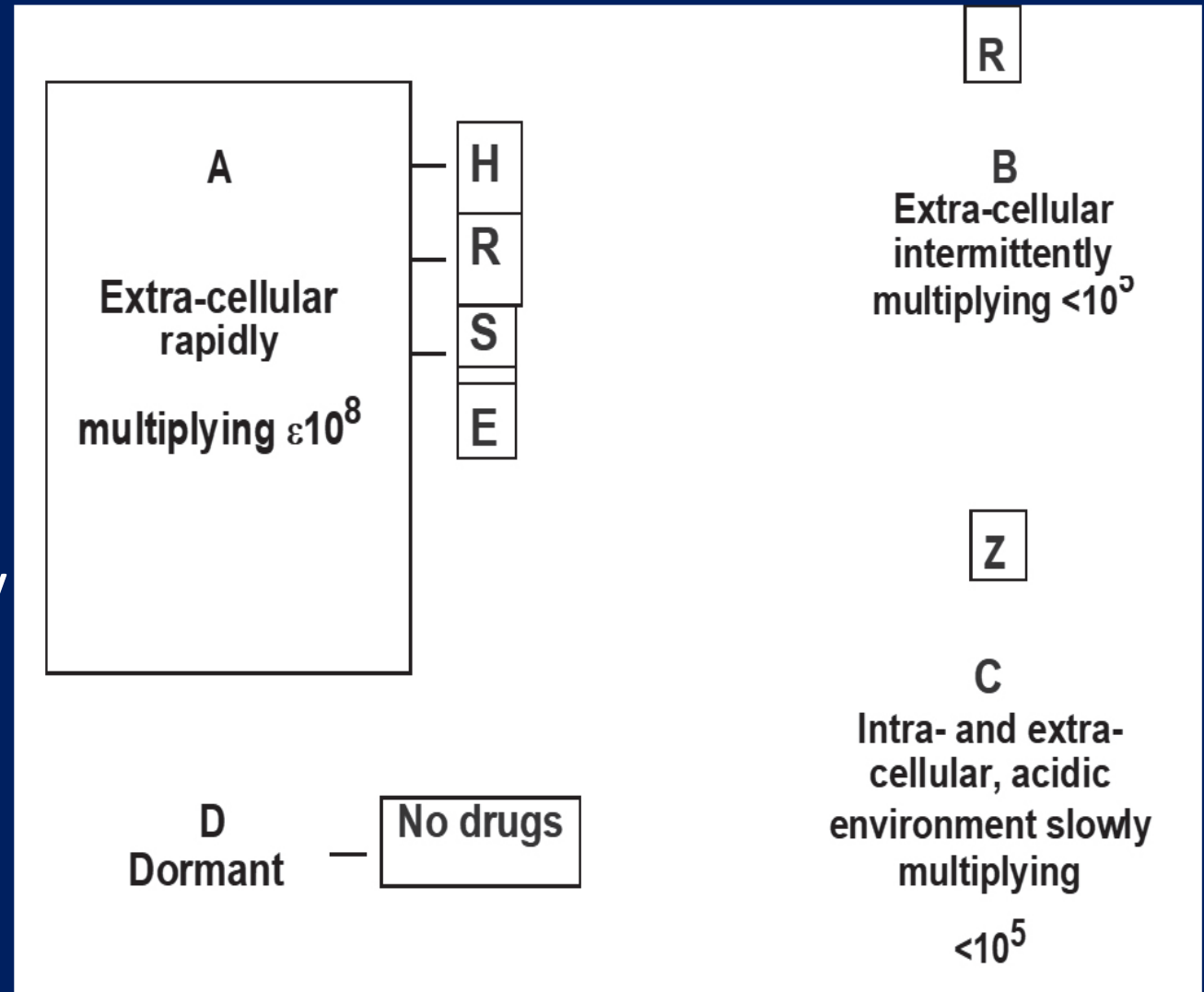
- Smear positive PTB patient there are appreciable numbers of mutant resistant to any single drug before the start of the treatment that are capable of multiplying and will not be affected by a single drug

- **Multiple drug (2, 3 or 4) to prevent the resistant mutants**

- in the initial Intensive Phase when the bacterial load is high the chances of survival and selection of drug resistant organism to any drug would be very small as mutants resistant to one drug are as a rule susceptible to other and vice versa

Bacillary subpopulations and different drugs acting on them

- Intensive phase eliminates naturally occurring drug resistant mutants and prevent the further emergence of drug resistant mutants
- Continuation phase (CP) with fewer drugs for a comparatively longer time will ensure elimination of persisters which are responsible for relapses.



- **Drugs should be given in single dose**
 - importance to achieve peak serum levels of all the drugs simultaneously, so that maximum bactericidal effect is obtained. This is achieved by administration of all the drugs at the same time
- **Drugs should be given in effective dose and adequate duration**

Directly Observed treatment (DOT):

Ensures

- Right drugs
- in the right doses
- at the right intervals
- for the right duration

FDC's Vs. separate ATT

FDC's

- SIMPLIFY TREATMENT
- MINIMIZE PRESCRIPTION ERROR
- ↑ PATIENT'S & DOCTORS COMPLIANCE
- SIMPLIFY DRUG SUPPLY MANAGEMENT
- REDUCE RISK OF MISUSE OF REGIMEN
- EXPECTED TO REDUCE DRUG RESISTANCE

FDC's

- MAJOR CONCERN - QUALITY OF FDC
- SUBSTANDARD FDC's
 - TREATMENT FAILURE
 - DRUG RESISTANCE

**IUAT-LD & WHO RECOMMENDS USE OF FDCS OF
PROVEN BIOAVAILABILITY TO ENSURE ADEQUATE
TREATMENT**

Bull WHO; 2001 : 79 (1)

6% of Nov drug samples were substandard, says CDSCO data

Govt Calls For Proactive Action To Check Making Of Spurious Meds

DurgeshNandan.Jha
@timesgroup.com

New Delhi: In the wake of deaths of some children in Gambia and Uzbekistan, allegedly linked to cough syrups manufactured by two companies in India, the government has directed drug regulatory authorities, both at the Centre and in the states, to take more proactive action to prevent malpractices and production of spurious medicines.

In November, the data



CRACKING THE WHIP

"We had a meeting with Health Minister Mansukh Mandaviya in which he informed that more action is planned to ensure that good manufacturing practices (GMP) are strictly adhered to," he added.

India is known as the pharmacy of the world because of its generic medicines and low-cost vaccines. It has the highest number of United States Food and Drug Administration (USFDA) compliant pharmaceutical plants outside of the USA.

Times of India 31.12.2024

Drug Alert: 53 Drug Samples Fail To Qualify CDSCO Test, 3 Declared Spurious



Written By Susmita...

— Published On 29 Aug 2023 2:37 PM | Updated On 31 Aug 2023 2:27 PM



Drug alert: 53 drug samples fail to qualify CDSCO test, 3 declared spu

Duration of Treatment

Duration of Treatment

DS-TB

Conventional T/t

1 - 2 years

SCC

6 - 9 months

DR-TB

6-20 months

DURATION OF TREATMENT

If Z is used during intensive phase – 6 months

2 RHEZ/ 4 RH

2 RHZ/ 4RH

2 SHRZ/ 4 RH

If continuation Phase is without R - 8 months

2 RHEZ/ 6 EH/TH

2 RHZ/ 6 EH/TH

2 SHRZ/6 EH/TH

If Z is not used in intensive phase – 9 months

2 RHE/ 7 RH

9 RHE

If R & Z is not used – 1 – 2 yrs.

2 SEH/ 10 EH

12 EH

Such duration is enough for PTB as well as EPTB

ISTC 2006, 2009,2013 , STCI 2014,2022

Standard

Any practitioner **treating a patient** for TB is assuming an important public health **responsibility**.

To fulfill this responsibility the practitioner must not only prescribe an **appropriate regimen**, but also be capable of **assessing the adherence** of the patient to the regimen and addressing poor adherence when it occurs.

By so-doing the provider will be able to ensure adherence to the regimen until treatment is completed

Clinical standards for drug-susceptible pulmonary TB

SUMMARY

BACKGROUND: The aim of these clinical standards is to provide guidance on ‘best practice’ for diagnosis, treatment and management of drug-susceptible pulmonary TB (PTB).

METHODS: A panel of 54 global experts in the field of TB care, public health, microbiology, and pharmacology were identified; 46 participated in a Delphi process. A 5-point Likert scale was used to score draft standards. The final document represents the broad consensus and was approved by all 46 participants.

RESULTS: Seven clinical standards were defined: Standard 1, all patients (adult or child) who have symptoms and signs compatible with PTB should undergo investigations to reach a diagnosis; Standard 2, adequate bacteriological tests should be conducted to exclude drug-resistant TB; Standard 3, an appropriate regimen recommended by WHO and national guidelines for the treatment of PTB should be

identified; Standard 4, health education and counseling should be provided for each patient starting treatment; Standard 5, treatment monitoring should be conducted to assess adherence, follow patient progress, identify and manage adverse events, and detect development of resistance; Standard 6, a recommended series of patient examinations should be performed at the end of treatment; Standard 7, necessary public health actions should be conducted for each patient. We also identified priorities for future research into PTB.


CONCLUSION: These consensus-based clinical standards will help to improve patient care by guiding clinicians and programme managers in planning and implementation of locally appropriate measures for optimal person-centred treatment for PTB.

KEY WORDS: pulmonary TB; management; diagnosis; treatment; education; rehabilitation; clinical standards

CLINICAL STANDARDS FOR DRUG SUSCEPTIBLE PULMONARY TB

STANDARD 4

All patients initiating treatment for PTB should be provided health education/counselling.



Consider
hospitalization
/ consultation
for presence of
any one of the
following

III

Consider Hospitalization/ Consultation for presence of any one of the following*

1. BMI < 14.0 kg/m²
2. BMI 14.0–15.9 kg/m² AND (bilateral pedal oedema OR inability to stand without support OR no appetite)
3. Severe anaemia (Hb < 7 g/dL) with or without heart failure
4. Unstable vital signs—pulse rate > 100 per minute OR RR > 24 per minute / <12/min OR oxygen saturation < 94% OR systolic blood pressure < 90 mm Hg OR poor performance status (bed-ridden or extremely limited mobility)
5. Complications of PTB—Example, moderate–massive haemoptysis, hydro–pneumothorax
6. Complications of EPTB—Example, altered consciousness, seizures, lower limb paresis/ paralysis, suspected intestinal obstruction or perforation
7. Complications to anti-TB treatment—drug induced hepatotoxicity or seizures
8. Patients with comorbidities who need inpatient care to manage these comorbidities according to the judgement of the treating physician—Example, DM, HIV, liver or renal disease, alcohol addiction/ drug abuse
9. Discretion of the Treating physician based on the clinical scenario of the patient.

*Technical Guidance For Comprehensive Package for Differentiated Care of TB patients

Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS): a field-based, open-label, cluster-randomised, controlled trial



Anurag Bhargava, Madhavi Bhargava, Ajay Meher, Andrea Benedetti, Banurekha Velayutham, G Sai Teja, Basilea Watson, Ganesh Barik, Rajeev Ranjan Pathak, Ranjit Prasad, Rakesh Dayal, Adarsh Kibballi Madhukeshwar, Vineet Chadha, Madhukar Pai, Rajendra Joshi, Dick Menzies, Soumya Swaminathan

Bhargava A et al Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS): a field-based, open-label, cluster-randomised, controlled trial. Lancet 2023; 402: 627–40

Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS)

- In India, tuberculosis and undernutrition are syndemics with a high burden of tuberculosis coexisting with a high burden of undernutrition in patients and in the population.
- This study emphasis on the effect of nutritional supplementation on tuberculosis incidence in household contacts of adults with microbiologically confirmed pulmonary tuberculosis.

Bhargava A et al Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS): a field-based, open-label, cluster-randomised, controlled trial. Lancet 2023; 402: 627–40

Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS)

- This is the first randomised trial looking at the effect of nutritional support on tuberculosis incidence in household contacts, whereby the nutritional intervention was associated with substantial (39–48%) reduction in tuberculosis incidence in the household during 2 years of follow-up.
- This biosocial intervention can accelerate reduction in tuberculosis incidence in countries or communities with a tuberculosis and undernutrition syndemic.

Bhargava A et al Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS): a field-based, open-label, cluster-randomised, controlled trial. Lancet 2023; 402: 627–40

Monitoring of Progress of Tuberculosis

- * **Bacteriological assessment:** sputum smear for AFB
- * **Radiological assessment:**
 - Progress of lesion should halt
 - Acute lesions (exudative) clear
 - Cavity - either disappear or thin wall
 - Chronic lesion - heal by fibrosis
 - Atelectasis - should shrink more
- * **Clinical assessment:** toxaemia disappear, weight gain
- * **ESR:** unsatisfactory for assessing activity or progress

CLINICAL STANDARDS FOR DRUG SUSCEPTIBLE PULMONARY TB

STANDARD 5

Treatment monitoring should be conducted to follow each patient's progress, support patients during treatment, assess treatment adherence, detect and manage adverse effects early and detect the emergence of resistance to anti-TB drugs.

Clinical standards for drug-susceptible pulmonary TB, INT J TUBERC LUNG DIS 26(7):592–604,2022 The Union

CLINICAL STANDARDS FOR DRUG SUSCEPTIBLE PULMONARY TB

TDM is at present recommended for certain patient groups:

- 1) patients who are taking several concomitant medications so as to reduce toxicity,
- 2) patients with inadequate treatment response (i.e., patients who are not smear microscopy or culture converting and/or have slow clinical and / or radiological improvement),
- 3) patients with gastrointestinal abnormalities that precipitate malabsorption,
- 4) those with renal insufficiency,
- 5) HIV coinfecting patients,
- 6) diabetic patients and
- 7) those with severe disease, including TB meningitis.

Clinical standards for drug-susceptible pulmonary TB, INT J TUBERC LUNG DIS 26(7):592–604,2022Union

CLINICAL STANDARDS FOR DRUG SUSCEPTIBLE PULMONARY TB

STANDARD 6

At the end of treatment for PTB a set of examinations should be performed for each patient.

CLINICAL STANDARDS FOR DRUG SUSCEPTIBLE PULMONARY TB

Set of examinations to be performed at the end of treatment of each patient with PTB

Clinical assessment	Clinical history ,Symptom assessment ,Clinical examination
Imaging	Chest radiography Computed tomography if chest radiography is severely abnormal or low dyspnoea score
Microbiological evaluation	If available Sputum specimen for smear microscopy and mycobacterial culture – DST if culture-positive (if possible)
Subjective evaluation	Dyspnoea score
Functional evaluation (if dyspnoea is present)	Six-minute walk test, Spirometry, Body plethysmography Diffusion capacity assessment (DLCO, KCO) ,Tidal volume Pulse oximetry, Arterial blood gas analysis in case of low peripheral oxygen saturation , Cardiopulmonary exercise testing
Plan a follow-up 6 months after TB treatment completion (to evaluate for relapse, bronchiectasis, persisting opacification or nodules which might indicate need for rehabilitation)	

CLINICAL STANDARDS FOR DRUG SUSCEPTIBLE PULMONARY TB

STANDARD 7

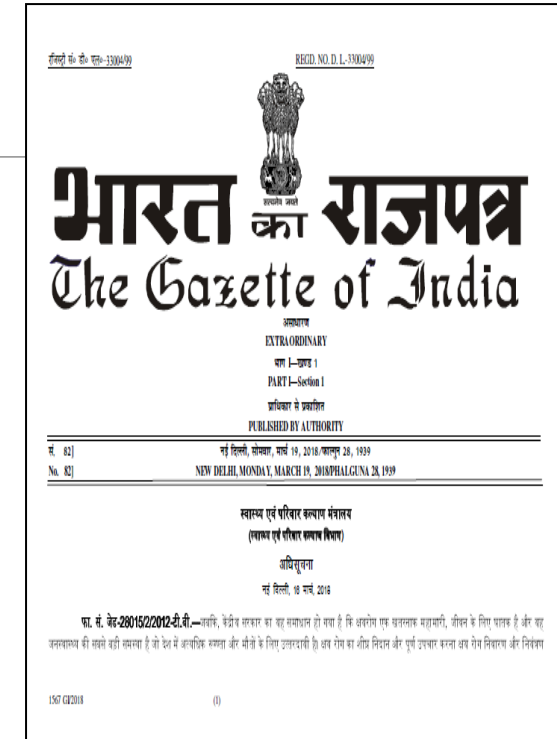
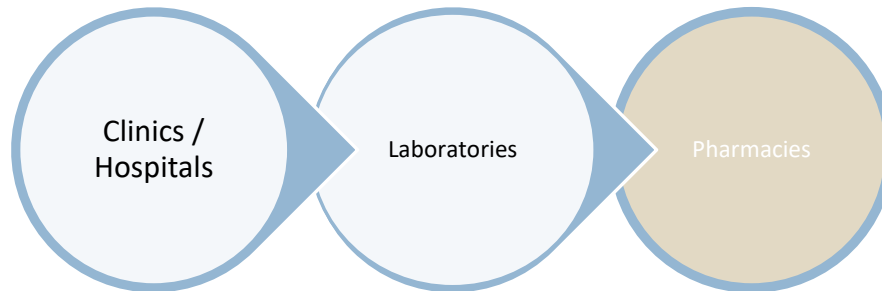
For each patient with PTB, a set of public health actions should be conducted

Clinical standards for drug-susceptible pulmonary TB, INT J TUBERC LUNG DIS 26(7):592–604,2022 The Union

Gazette on TB Notification

→ Mandatory Notification of TB patients

- 7th May 2012- First Order : Laboratories, Private practitioner
- 21st July 2015- First Amendment : Included Public Health Action
- 19th March 2018- Second Amendment: Chemists



→ Failure to take the mandated steps may attract the provisions of Sections 269 and 270 of the Indian Penal Code (IPC)

2

FIR

519

Notices

Public Health Actions

Contact Investigation:

- All household contacts should be screened for TB and evaluated for active TB disease
- In case of paediatric TB patients, reverse contact tracing for search of any active TB case in the household of the child must be undertaken
- This information must be entered in Ni-kshay



Long Term Follow Up

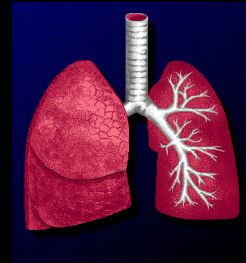
- After completion of treatment, the patients should be followed up clinically at the end of 6, 12, 18 & 24 months
- In the presence of any clinical symptom, sputum microscopy and/or culture of the biological specimen should be considered.
- This is important in detecting recurrence of TB at the earliest.



TB-Treatment

- Treatment of Drug Susceptible TB
- Treatment of Drug Resistant TB

How To Treat D S Tuberculosis ?



Treatment of drug-susceptible tuberculosis

Type of TB cases	Intensive Phase (IP)	Continuation Phase (CP)	Total duration
New/Previously treated(Hand R sensitive/unknown)	2 (RHEZ)	4 (HRE)	6 months

Treatment of drug-susceptible tuberculosis

- There is **no need to extend IP**
- **CP** in both new and previously treated cases may be extended by **3-6 months** in certain form of TB like
 - CNS TB
 - Skeletal TB
 - Disseminated TB
- Adjuvant corticosteroid treatment is recommended for TB meningitis and pericarditis.

Daily FDC Regimen Schedule for Adults

Weight Category	Type of case	Number of tablets to be consumed in Intensive phase	Number of tablets to be consumed in Continuation phase
		H R Z E (4 FDC)	H R E (3 FDC)
		75/150/400/275 mg per tab	75/150/275 mg per tab
25-34 kg	New and Previously Treated	2	2
35-49 kg		3	3
50-64 kg		4	4
65-75 kg		5	5
>75 kg*		6	6

FDC Schedule for Adults

Weight Category	Number of Tablets			
	Intensive Phase		Continuation Phase	
	HRZE 75/150/400/275 mg per tab	Doses in IP	HRE 75/150/275 mg per tab	Doses in CP
25-34 kg	2	56 doses	2	112 doses
35-49 kg	3	56 doses	3	112 doses
50-64 kg	4	56 doses	4	112 doses
65-75 kg	5	56 doses	5	112 doses
> 75 kg	6	56 doses	6	112 doses

Dose of antitubercular drugs used in treatment of Drug Susceptible Tuberculosis (DS-TB)

<i>Drugs</i>	<i>Daily</i>	
	<i>Adult</i>	<i>Children*</i>
H	5 (4–6)	10 (10–15)
R	10 (8–12)	15 (10–20)
Z	25 (20–30)	35 (30–40)
E	15 (15–20)	20 (15–25)
S	15 (12–18)	15 (12–18)

Abbreviations used: H-Isoniazid, R-Rifampicin, Z-Pyrazinamide, E-Ethambutol, S-Streptomycin

WHO 2017



INDEX- TB GUIDELINES 2016

(INDian EXtra-pulmonary Tuberculosis Guidelines 2016)



Dr Neeraj Nischal
Assistant Professor
Department of Medicine
AIIMS, New Delhi



Training Module On Extrapulmonary Tuberculosis 2023

Treatment of Extra Pulmonary TB

- Treatment regimen and schedule are same as Pulmonary TB
- Duration of continuation phase may be extended by 3 to 6 months in TB meningitis, Bone and Joint TB, Spinal TB with neurological involvement and neurological TB based on clinician's decision and clinical response.
- Adjuvant corticosteroid may be used for treatment for TB meningitis and pericarditis
- For more details may access Index TB Guidelines at <https://tbcindia.gov.in/showfile.php?lid=3245>

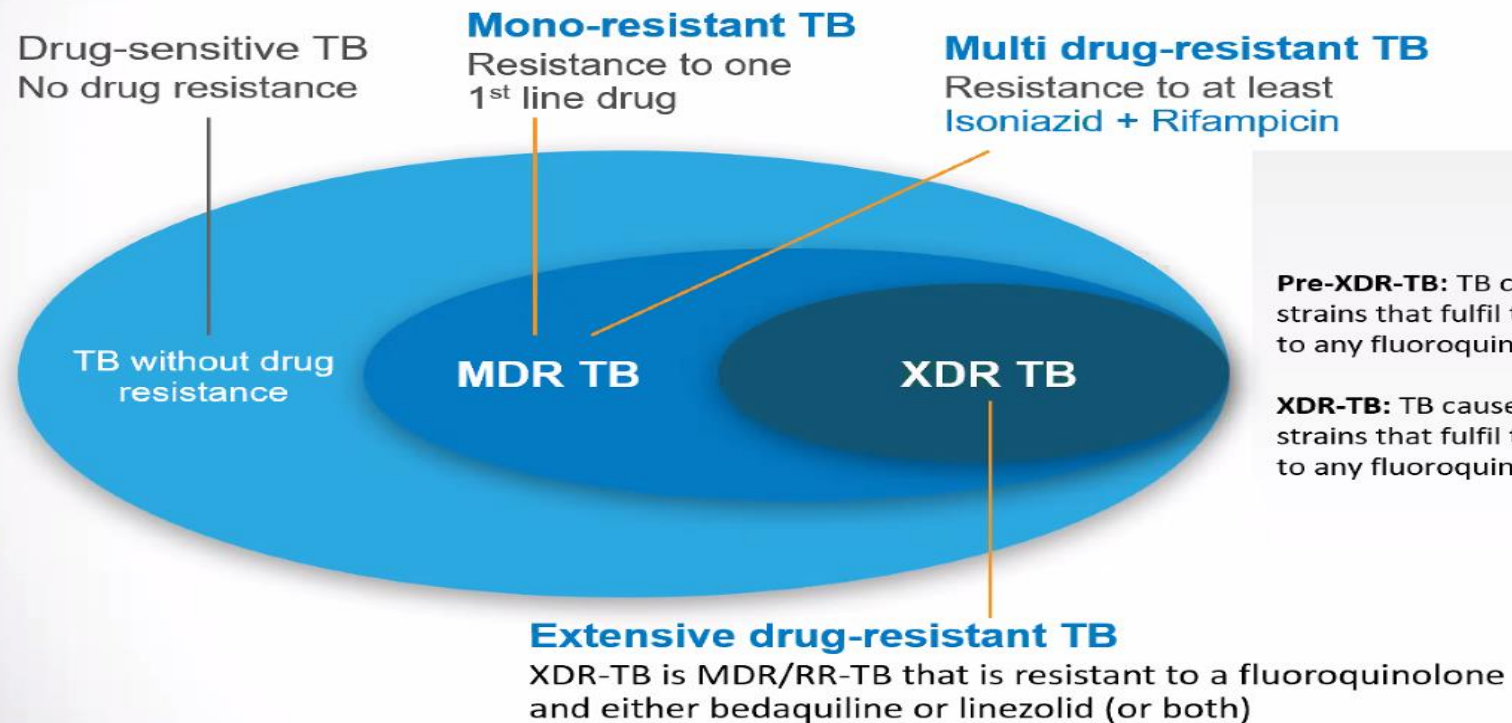
DRUG RESISTANT T.B.

A case of tuberculosis (usually pulmonary) excreting bacilli resistant to one or more anti-tuberculous drugs

DR-TB

- Primary
- Acquired

Definitions of TB Resistance



Pre-XDR-TB: TB caused by *Mycobacterium tuberculosis* (*M. tuberculosis*) strains that fulfil the definition of MDR/RR-TB and that are also resistant to any fluoroquinolone.

XDR-TB: TB caused by *Mycobacterium tuberculosis* (*M. tuberculosis*) strains that fulfil the definition of MDR/RR-TB and that are also resistant to any fluoroquinolone and at least one additional Group A drug.



MDR/RR TB - GLOBAL *R Prasad Lucknow*



Estimated MDR TB/RR Cases=4,00,000 in 2023

Available from 215 countries including all 194 WHO member states.

WHO GLOBAL TB REPORT 2024.

XDR TB- GLOBAL

Global
tuberculosis
report

2024

Out of 4,00,000 MDR-TB cases 29,000 were Pre XDR/XDR-TB

Available from 215 countries including all 194 WHO member states.

WHO GLOBAL TB REPORT 2024.

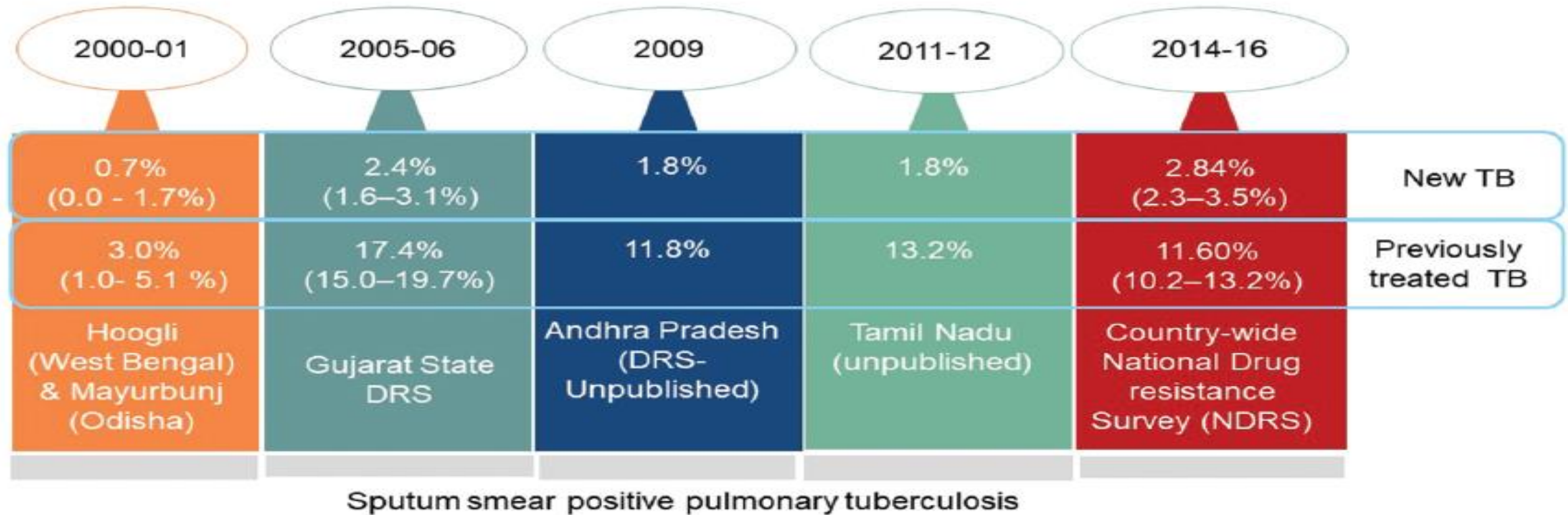
MDR/RR-TB ESTIMATE : India

1,10,000 (82,000 – 130,000)
Cases emerged in 2023

GLOBAL TUBERCULOSIS REPORT 2024

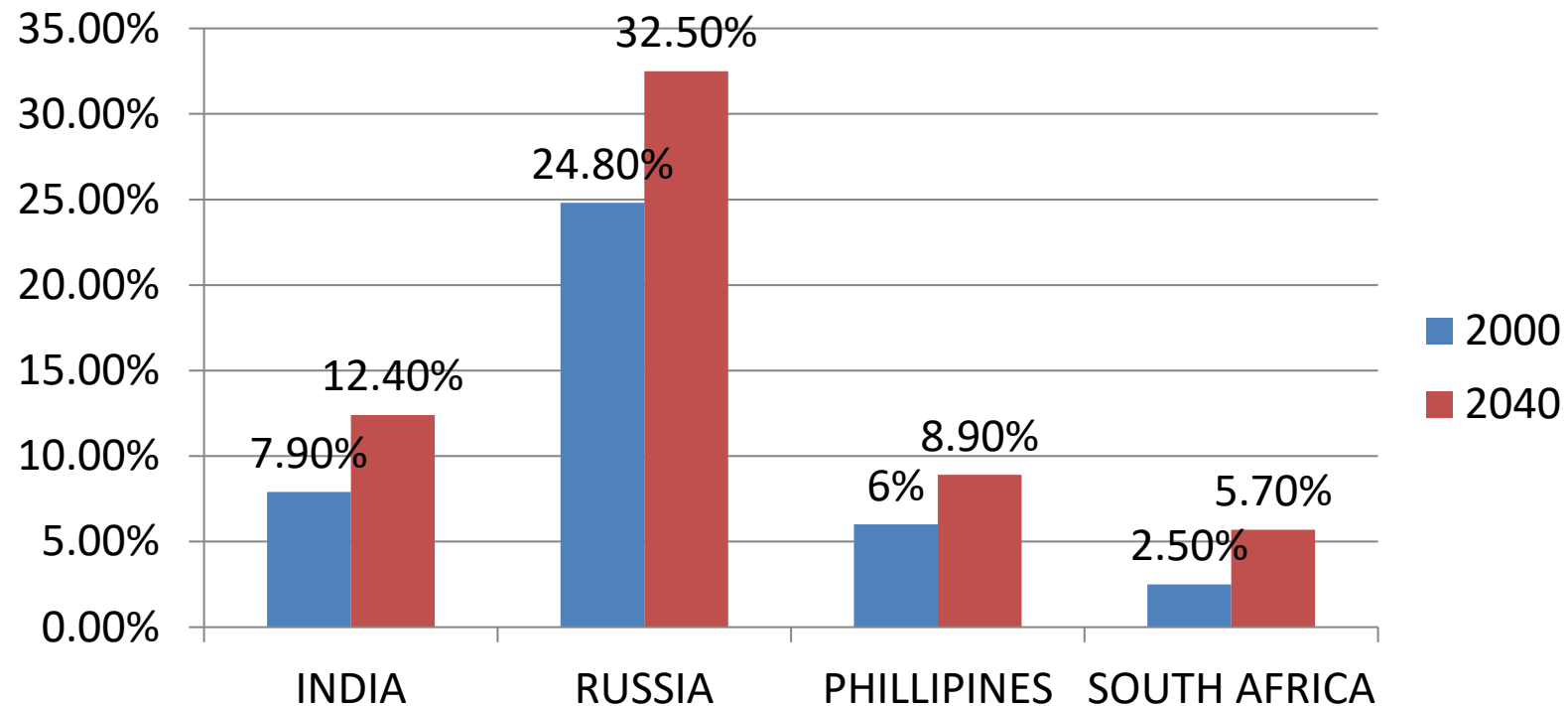


Periodic Drug Resistance Surveys in India for MDR-TB Burden Estimation Over Time

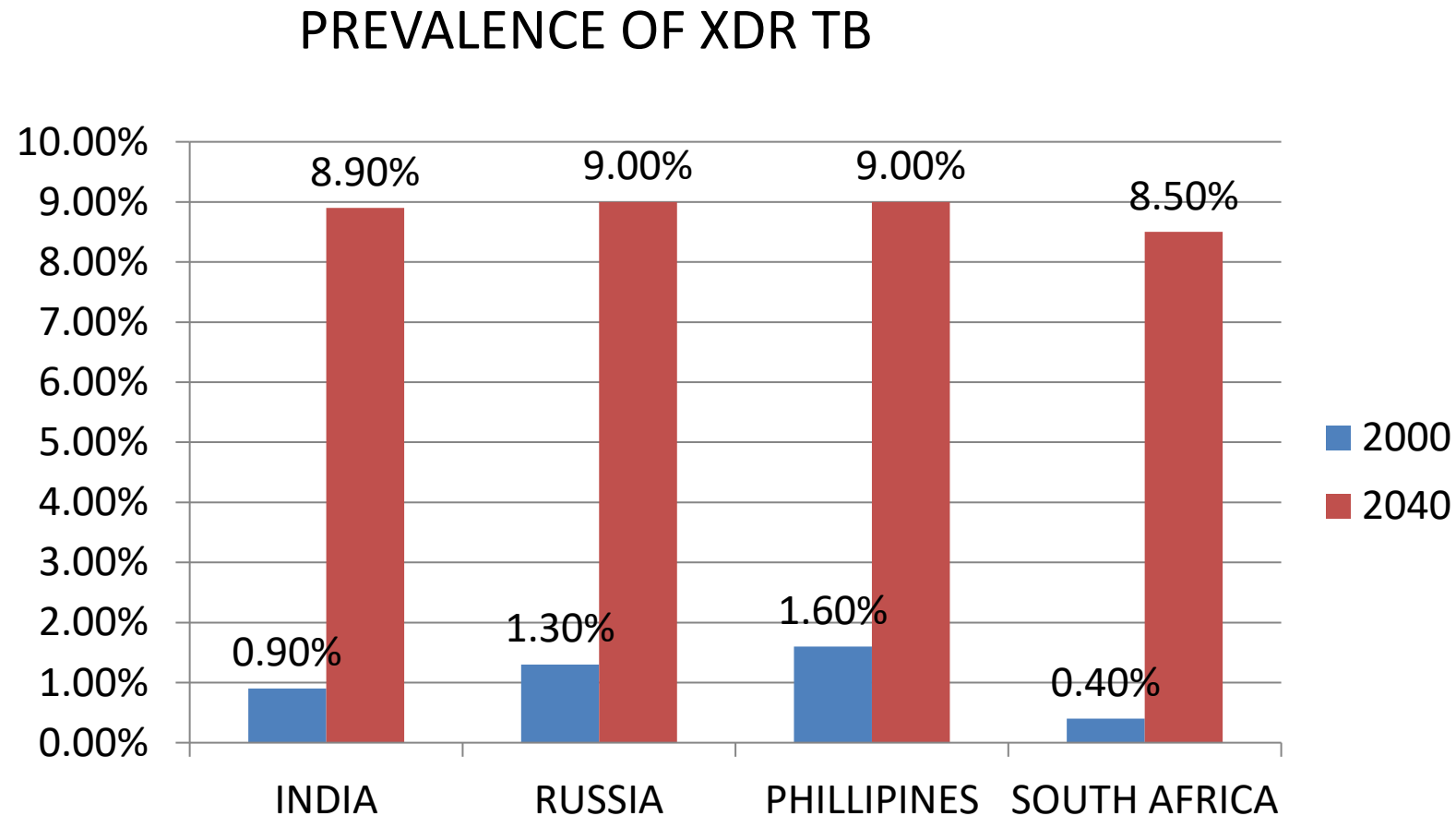


Estimating the future burden of MDR and XDR-TB TB in India, the Philippines, Russia, and South Africa: a mathematical modelling study

PREVALENCE OF MDR TB



Estimating the future burden of MDR and XDR-TB TB in India, the Philippines, Russia, and South Africa: a mathematical modelling study



Estimating the future burden of MDR and XDR-TB TB in India, the Philippines, Russia, and South Africa: a mathematical modelling study

- Cases of drug-resistant TB are forecasted to increase in the four high burden countries (India, the Philippines, Russia, and South Africa) between 2000 and 2040.
- This increase is result of **increased transmission of drug-resistant TB between people**, rather than by strains acquiring resistance to anti-TB drugs,.

Treatment of Drug Resistant TB

WHO operational handbook on tuberculosis

Module 4: Treatment

**Drug-resistant
tuberculosis treatment
2022 update**



**World Health
Organization**

NATIONAL GUIDELINES FOR MANAGEMENT OF DRUG RESISTANT TB

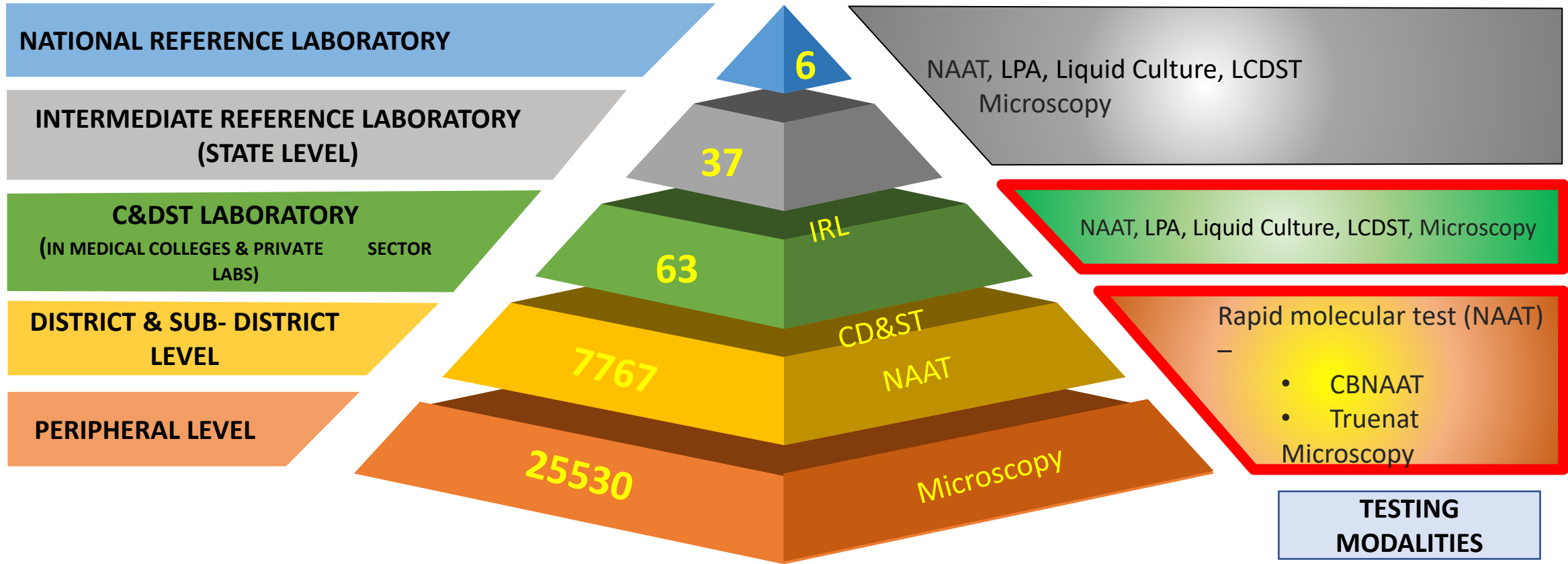


NOVEMBER 2024

**NATIONAL TB ELIMINATION
PROGRAMME**

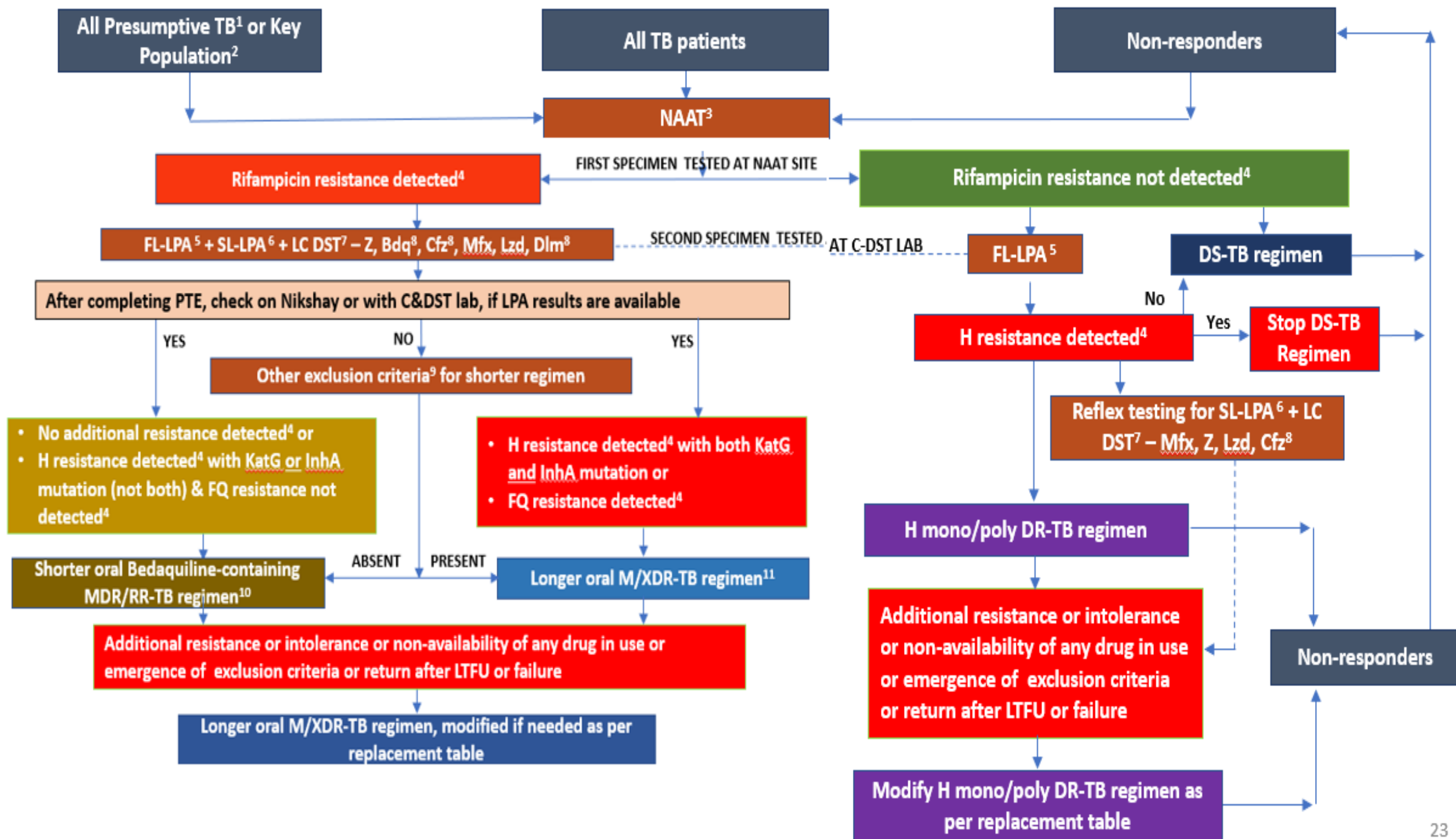
**CENTRAL TB DIVISION
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA**

NTEP Diagnostic Network



NAAT- Nucleic Acid Amplification Test; LPA- Line Probe Assay; LC DST- Liquid Culture Drug Susceptibility Testing

DR-TB treatment Centres	Functional
792	



Treatment regimen for drug-resistant TB

Treatment regimen options for DR-TB includes:

1. 6-9 months BPaLM shorter oral regimen.
2. 9-11 months shorter oral MDR/RR-TB regimen
3. 18-20 months longer oral M/XDR –TB regimen
4. 6-9 months H mono/ poly DR-TB regimen.



Guidelines for H mono/poly DRTB

6 months RZE + Levofloxacin

- Not recommended to add Inj S/M or other injectable agent (NDRS findings)
- Perform DST to other drugs of regimen and if further resistance documented then modify regimen accordingly using the replacement sequence.
- At any time, if there are signs of non-response, the patient must be subjected to NAAT again to rule out amplification of rifampicin resistance

Isoniazid (H) mono/poly DR-TB regimen

- **Change of regimen may be required in the event of:**

- additional resistance or
- intolerance to any drug or
- non-availability of any drug in use or
- return after LTFU or
- failed treatment

Extension of Treatment

Treatment may be extended till 9 months in following conditions:

- In patients with extensive disease;
- uncontrolled comorbidity;
- extra-pulmonary TB and
- if smear at the end of 4th month or culture at end of 3rd month is positive

In CNS, skeletal and milliary TB, treatment may be given up to a year

In patients who remain sputum smear positive at the end of 5-month or later of treatment, the outcome will be declared as treatment failure

Replacement sequence

Situation	Sequence of using replacement drugs
If Lfx can't be used	Replace with Mfx ^h if SL LPA pattern suggests Mut3C absent Do LC DST for detection of resistance to Mfx ^h , Z, Lzd & Cfz*
If Mfx ^h or Z can't be used	Replace with Lzd. If Lzd also cannot be given, replace with Cfz* + Cs
If both Mfx ^h and Z can't be used	Add 2 drugs of the 3 – Lzd, Cfz*, Cs in order of preference based on resistance, tolerability & availability
If R resistance	Switch to appropriate shorter or longer regimen

**whenever DST is available*

- In these situations, treat for a total duration of 9 months.
- The use of new drugs is not yet recommended in the treatment of H mono/poly DR-TB.

MDR/RR- TB Regimens

- In accordance with the latest recommendations, MDR/RR-TB patients are to be offered one of the MDR/RR-TB regimens in the ***preference of order*** as per integrated algorithm (based on the eligibility criteria) is given below:

1. 6-9 months BPaLM shorter oral regimen.
2. 9-11 months shorter oral MDR/RR-TB regimen
3. 18-20 months longer oral M/XDR -TB regimen



BPaLM/BPaL regimen

- **Bedaquiline is a diarylquinoline**
 - inhibits mycobacterial ATP synthase.
- **Pretomanid(Pa), a nitroimidazooxazine**
 - Inhibits mycolic acid biosynthesis, blocks mycobacterial cell-wall production,
 - Acts as a respiratory poison against nonreplicating bacteria after nitric oxide release under anaerobic conditions.
 - Pa has been approved to use only with the BPaLM/BPaL.
- **Linezolid,**
 - an oxazolidinone that disrupts protein synthesis
- **Moxifloxacin,**
 - inhibit DNA synthesis

BPaLM Regimen

- **First choice of treatment** in eligible patients ≥ 14 years age with MDR / RR TB regardless of their FQ resistance status or HIV status
- Mfx is a part of regimen full course, irrespective of resistance pattern to FQ at baseline or during the course of regimen. ..

Inclusion Criteria

- Person with age 14 years & above with new microbiologically confirmed MDR/ RRTB
- H/o of Drug Exposure: less than one month intake of Bdq,Lzd and/ or Pa in the past
- or
- Person with exposure of more than one month intake of Bdq, Lzd and/ or Pa and documented sensitivity to these drugs

Inclusion Criteria

- QTcF in ECG is ≤ 450 ms in males and ≤ 470 ms in females

or

- when serum electrolytes are abnormal and QTcF is >450 ms in males & QTcF is >470 ms in females in baseline ECG, after correcting the electrolytes, QTcF in repeat ECG is ≤ 450 ms in males and ≤ 470 ms in females
- Nonlactating women /non Pregnant women

Exclusion criteria and contraindications

Person with age < 14 years.

Documented resistance to Bdq, LZD
and/or Pa.

Person with significant liver dysfunction
>3x upper Limit of normal.

Person with severe form of EP- MDR TB.

Significant cardiac conduction
abnormalities

Note: In case of extensive pulmonary TB, BPaLM regimen may be given, if eligible

Relative Contraindications

Concurrent use of medications that have known interactions	<ul style="list-style-type: none">• use of strong inhibitors/ inducers of cytochrome P450.• Drugs that prolong QT interval• MAO inhibitors and TCAs• Concomitant use of any drug that is known to cause myelosuppression.
Severe anemia, thrombocytopenia or leukopenia	<ul style="list-style-type: none">• Hb < 8 mg/dL• P/C < 750000/mm³• ANC < 1000/mm³
Significant hepatic dysfunction	<ul style="list-style-type: none">• AST/ALT > 3.0 x ULN, irrespective of symptoms• T. Bilirubin > 2.0 X ULN
Severe renal failure	<ul style="list-style-type: none">• S. creat > 3.0 x ULN
Severe neuropathy	Peripheral neuropathy of grade 3 or Grade 4

Pre-Treatment Evaluation (PTE) for MDR/ RR-TB

Clinical evaluation

- History and physical examination (including previous drug use, alcohol/substance abuse, family planning methods etc.)
- Previous history of ATT taken, especially Bdq, Pa, Dlm and Lzd (defined as more than one month exposure).
- A thorough clinical examination
- Assess nutritional status [Height (m), Weight (kg), BMI]
- Neurological evaluation, if required
- **Ophthalmic evaluation, visual acuity, and color vision test**

Laboratory-based evaluation

- Random blood sugar (**RBS**)
- **HIV** testing following counselling
- Complete **blood** count (Hb, TLC, DLC, platelet count)
- **Liver** function tests#
- Serum **electrolytes** (Na, K, Mg, Ca)
- Urine **pregnancy** test (in women of reproductive age group)
- Chest **X-ray**
- **ECG**

HBsAG and other viral markers (Hepatitis A, C and E) to be done in case of jaundice

Regimen, dosage and administration

- BPaLM regimen is to be administered orally using dosages as follows :

- Bedaquiline
 - Weeks one to two: 400 mg once daily
 - Weeks 3 to 26/39*: 200 mg 3 times a week; plus
- Pretomanid: - Weeks one to 26/39*: 200 mg daily; plus
- Linezolid: - Weeks one to 26/39*: 600 mg once daily
- Moxifloxacin: - Weeks one to 26/39*: 400 mg once daily

**Extension criteria has been described in subsequent section*

- All patients above 14 years of age would receive the above standard dosage.
- **There will be no weight bands.**

Extension Criteria :

Dose reduction of lzd to 300mg in case of grade 3-4 intolerance → extend upto 39 weeks.

In case of grade 3-4 intolerance to Mfx, drop the drug and continue as BPaL upto 39 weeks.

Extension upto 39 weeks with strict clinical evaluation and smear and culture microbiological follow up at monthly interval.

Those initiated on BPaLM, in case of baseline resistance to Bdq, Lzd, Pa , the Tx needs to be changed to 9 month shorter/ longer MDR/RR TB regimen and outcome to be given as TREATMENT REGIMEN CHANGED.

Pyridoxine - Regimen, dosage and administration

- Pyridoxine (Pdx) will be administered as per weight band given below: (Reference: for the entire duration of treatment as per weight band in line with the Guidelines for PMDT in India -- 2021).

Drugs	16-29 kg	>30 kg
Pyridoxine (Pdx)	50 mg	100 mg

- Pyridoxine supplementation has been shown to reduce the incidence of neuropathy in patients, supporting its inclusion in treatment protocols to mitigate drug-induced neuropathy.
- Pyridoxine to be used in the BPaLM regimen to provide added protection against neuropathy.

BPaLM: Follow-up

Follow-up assessments	Timeline
Duration	26 weeks (extended up to 39 weeks)
Clinical review, including weight and BMI, concomitant medication, adherence, signs/symptoms suggesting adverse events	Monthly
CBC (with Hb, platelets) and ECG	Day 15, 30, then monthly till month six, and more frequently if clinically indicated
Visual acuity, and color vision test	Week 09, 13, 26 and more frequently if clinically indicated
Smear microscopy	With culture at the C&DST lab
Culture	<p>Monthly from month two onwards (i.e., at month 2, 3,4,5,6).</p> <p>If the culture results of month 4 or later are positive, collect one repeat specimen immediately and send it for culture to rapidly ascertain bacteriological conversion or reversion and if the repeat specimen is culture negative, then collect and send the subsequent monthly or end-of- treatment specimen.</p>
DST	NAAT MTB/XDR or FL and SL LPA (Lfx, Mfx, Am, Eto) and LC DST (Mfx 1.0, Lzd, Z, Bdq, Pa*, Dlm*) if culture +ve at the end of month 4, end of Rx and as and when clinically indicated during treatment
Urine pregnancy test	As and when clinically indicated
Chest X-Ray and LFT#	At the end of month three, the end of treatment, as and when clinically indicated
S. Electrolytes (Na, K, Mg, Ca)	As and when clinically indicated in case of any QTcF prolongation
Specialist (Ophthalmic, Neurological) consultation	As and when clinically indicated
Surgical evaluation	After culture conversion
Long term follow-up	At 06, 12, 18, and 24 months after completion of treatment (Clinical, CXR, Smear and C&DST, if symptomatic) and whenever the patient returns to the health system

9-11 month shorter oral MDR/RR-TB regimen



9-11 month shorter oral MDR/RR-TB regimen

- To be given to eligible persons as per integrated algorithm in chapter 2,
- In patients 14 years or more with MDR/RR TB, BPaLM is first preference
- The 9-11 month, shorter oral, Bdq-containing regimen is to be **preferred over the 18-20 months longer** regimen in adults and children with MDR/RR-TB.
- Till Bdq is available for the use in children below five years, Bdq is replaced by inj Amikacin, and other
- modifications as per the PMDT guidelines 2021.
- Access to rapid DRT for ruling out FQ resistance is required before starting a patient.
- The program has adopted 9-11 month shorter oral regimen "with Lzd" for two months replacing "4 months of Eto" in IP phase, the rest of the medicine and duration



Eligibility Criteria- 9-11 Month Shorter Oral MDR/RR-TB regimen.(1)

- i. Rifampicin resistance detected.
- ii. MDR/RR-TB with FQ resistance not detected
- iii. No history of exposure to previous treatment with second-line medicines in the regimen (Bdq, Lfx, Cfz or Lzd as applicable) for more than one month (unless susceptibility to these medicines is confirmed)
- iv. No extensive TB disease
- v. No severe forms of extra-pulmonary MDR TB like CNS TB, Spinal/ skeletal TB (miliary TB with multi organ involvement or disseminated TB)
- vi. Non-pregnant , non lactating pregnant women with <20 or < 24 weeks gestation and is willing for MTP, if Eto is considered in the regimen.



Eligibility Criteria- 9-11 Month Shorter Oral MDR/RR-TB regimen.

- As **Eto has been replaced by Lzd** in the regimen therefore the 9-11 months shorter oral MDR/RR- TB regimen with Lzd **can be given to pregnant** women irrespective of the gestational age with appropriate safety monitoring in consultation with the patient. Further, if Z resistance is detected during initial phase (IP), the patient will be switched to an individualized longer oral M/XDR-TB regimen
- For the Lzd containing regimen, thyroid function test is not required in pre-treatment evaluation.
- InhA mutation and/or KatG mutation:
 - Lzd containing shorter oral MDR/RR-TB regimen can be given even in case of both KatG & InhA mutations are present.
 - In case of both KatG & InhA mutation, Eto containing shorter oral MDR/RR-TB regimen cannot be given



Shorter 09 month: Considerations

(2) Lzd (4-6) Lfx Cfz Z E H ^h (6-9) Bdq	(5) Lfx Cfz Z E	(4-6) Lfx Cfz Eto Z E H ^h (6-9) Bdq	(5) Lfx Cfz Z E
--	-----------------	--	-----------------

- Bdq** is usually given for **six** months but could be extended to **nine** months, particularly if the IP is extended from four to six months due to a positive sputum smear result at month 4.
- Lzd is only given for two months** (instead of 4-6 months of Eto). If occasional doses (upto 14 days) of Lzd are missed, the missed doses can be added on the end of the 2-month.
- In case of **Lzd intolerance** leading to permanent discontinuation of Lzd 600 mg within **the initial two months period**, replace Lzd with four-six months of **Eto** to complete the regimen, still if the regimen cannot be continued because of any reason, declare the outcome as “treatment failed” and switch to an individualized longer oral M/XDR-TB regimen without Lzd after reassessment.
- If, for any reason, a patient **is unable to tolerate Z or E, then drop one (but only one)** of these drugs **during CP** and complete the treatment duration. If two or more of these drugs or any of the other drugs (Bdq, Lfx/Mfx, Lzd/Eto, or Cfz) are stopped due to intolerance or emergence of drug resistance, declare the outcome as “treatment regimen changed” and switch the patient to an individualized longer oral M/ XDR-TB regimen after reassessment.



Regimen, dosage, and administration

- The regimen would be as follows:

(2) Lzd (4-6) Lfx Cfz Z E H ^h (6-9) Bdq	(5) Lfx Cfz Z E
--	-----------------

(4-6) Lfx Cfz Eto Z E H ^h (6-9) Bdq	(5) Lfx Cfz Z E
--	-----------------

- The dosage of Lzd is 600 mg for 14 years & above.
- For children <14 years is as per weight band as given below:

Medicine	Weight- based Daily dose	Formulation	Weight bands among patients under 15 years old							Usual upper Daily dose
			5–6 kg	7–9 kg	10–15 kg	16–23 kg	24–30 kg	31–34 kg	>34 kg	
Linezolid	15 mg/kg od in 1–15 kg	20 mg /mL susp	4 mL	6 mL	8 mL	11 mL	14 mL	15 mL	20 mL	600 mg
	10–12 mg/kg od in >15 kg	600 mg tab	0.25	0.25	0.25	0.5	0.5	0.5	0.75	

Regimen, dosage, and administration

- Clinical and haematological monitoring are crucial to detect early Lzd-associated AEs, particularly sudden or significant drop in Hb(>10%), neutrophils or platelets.
- If sputum smear microscopy is positive by the end of the month 04, then FL-LPA and SL-LPA, culture & DST should be offered and the IP should be extended. IP can be extended to month 05 or 06 based on smear results at the end of month 04 or 05 of treatment. This will be done for a maximum of 2 months (i.e., total duration of IP is not more than 6 months).
- If additional resistant to Z is detected in the baseline sample on C&DST or FQ/InhA & KatG mutation is detected in month 04 sample, the patient needs to be reassessed at N/DDR-TBC for stopping shorter oral Bedaquiline-containing MDR/RR-TB regimen and initiation of longer oral M/XDR-TB regimen, immediately on receiving the report.



Dosage of 9-11 months shorter MDR/RR-TB regimen drugs for adults

Drugs	16-29 kg	30-45 kg	46-70 kg	>70 kg
High dose H (Hh)	300 mg	600 mg	900 mg	900 mg
Ethambutol(E)	400 mg	800 mg	1200 mg	1600 mg
Pyrazinamide(Z)	750 mg	1250 mg	1750 mg	2000 mg
Levofloxacin (Lfx)	250 mg	750 mg	1000 mg	1000 mg
Bedaquiline (Bdq)	Week 0–2: Bdq 400 mg daily ; Week 3–24: Bdq 200 mg 3 times per week			
Clofazimine (Cfz)	50 mg	100 mg	100 mg	200 mg
Ethionamide (Eto)*	375 mg	500 mg	750 mg	1000 mg
Pyridoxine (Pdx)	50 mg	100 mg	100 mg	100 mg



Longer oral M/XDR-TB regimen



18-20 months Longer oral M/XDR-TB regimen

- (6 or longer) Bdq + (18-20) Lfx Lzd Cfz Cs
- As per integrated algorithm, patients who cannot be initiated on BPaLM or 9-11 month shorter oral MDR/RR-TB regimen due to reasons of ineligibility, additional resistance, intolerance, non-availability of any drug in use or emergence of exclusion criteria will be managed with an longer oral M/XDR-TB regimen modified in accordance with the replacement sequence.
- Repeat NAAT for H, FQ, SLI, Eto resistance detection or FL and SL LPA (Lfx, Mfx, Am, Eto) and LC DST (Mfx 1.0, Lzd, Z, Bdq, Pa*, Dlm*) (*whenever available) if culture is positive sent at the end of month six or any time beyond.
- For XDR-TB patients the duration of longer oral XDR-TB regimen would be for 20 months.

(For further details, refer to **Guidelines for PMDT in India – 2021.**)



Grouping of anti-TB drugs for longer M/XDR regimen

Group A:

- Levofloxacin (Lfx) OR Moxifloxacin (Mfx)
- Bedaquiline (Bdq)
- Linezolid (Lzd)

Group B:

- Clofazimine (Cfz)
- Cycloserine (Cs) OR Terizidone (Trd)

Group C:

- Ethambutol (E)
- Delamanid (Dlm)
- Pyrazinamide (Z)
- Imipenem-cilastatin (Ipm-Cln) OR Meropenem (Mpm)
- Amikacin (Am) OR Streptomycin (S)
- Ethionamide (Eto) OR Prothionamide
- *p*-aminosalicylic acid

Group C: Drugs are in decreasing order of usual preference

Longer oral M/XDR-TB regimen

- As per WHO 2020 recommendations, all three Group A agents (Levofloxacin/Moxifloxacin, Bedaquiline, Linezolid) and at least one Group B agent (Clofazimine, Cycloserine/Trizidone) should be included to ensure that treatment starts with at least four TB agents likely to be effective and that at least three agents are included for rest of the treatment if Bdq is stopped.
- However, in India the experts concurred to start with all 5 drugs of Group A and B and continue with 4 drugs in the latter part of the regimen (beyond 6-8 months) if the patient can tolerate the drugs and for operational ease in the field.

Group A = Lfx/Mfx, BDQ, Lzd

Group B = Cfz, Cs

Group C = E, Dlm, Z, Ipm/Mpm, Am, Eto, PAS

Regimen and duration

(18-20) Bdq (6 month or longer) Lfx Lzd[#] Cfz Cs

#dose of Lzd will be tapered to 300 mg after the initial 6–8 months of treatment

- Duration: 18 – 20 months
- No separate IP and CP
- *Bdq will be given for 6 months & extended beyond 6 months as an exception*
- *Pyridoxine to be given to all DR-TB patients as per weight band*
- *For Pre-XDR-TB and XDR-TB patients the duration would be for 20 months*

Principles of replacement drugs as per PMDT 2021.....2

- *Replacement Sequence: the order of - delamanid, amikacin*, pyrazinamide*, ethionamide*, PAS, ethambutol, Imp/Cln or Mpm + Amx/Clv (*if sensitive)*
- Combined use of Bdq and Dlm in the regimen is recommended if an appropriate regimen cannot be designed using all 5 drugs from Group A and B
- Dlm and Am will not be started in the final 12 months of treatment
- No replacement if any drug is dropped in final 12 months of treatment
- **Use of Bedaquiline/Delamanid beyond 24 weeks** if only 2 drugs of 5 are available from Groups A & B, and adequate number of Group C drugs are not available due to high background resistance, non-availability or unreliability of DST

Dosage of M/XDR-TB drugs for adults in longer oral M/XDR-TB regimen (with replacement drugs)

SN	Drugs	16-29 kg	30-45 kg	46-70 kg	>70 kg
1	Levofloxacin (Lfx)	250 mg	750 mg	1000 mg	1000 mg
2	Moxifloxacin (Mfx)	200 mg	400 mg	400 mg	400 mg
3	High dose Mfx (Mfx ⁿ)	400mg	600mg	800mg	800mg
4	Bedaquiline (Bdq)	Week 0–2: Bdq 400 mg daily Week 3–24: Bdq 200 mg 3 times per week			
5	Clofazimine (Cfz)	50 mg	100 mg	100 mg	200 mg
6	Cycloserine (Cs) ³	250 mg	500 mg	750 mg	1000 mg
7	Linezolid (Lzd)	300 mg	600 mg	600 mg	600 mg
8	Delamanid (Dlm)	50 mg twice daily (100 mg) for 24 weeks in 6-11 years of age 100 mg twice daily (200 mg) for 24 weeks for ≥12 years of age			
9	Amikacin (Am) ¹	500 mg	750 mg	750 mg	1000 mg
10	Pyrazinamide (Z)	750 mg	1250 mg	1750 mg	2000 mg
11	Ethionamide (Eto) ³	375 mg	500 mg	750 mg	1000 mg
12	Na - PAS (60% weight/vol) ^{2,3}	10 gm	14 gm	16 gm	22 gm
13	Ethambutol (E)	400 mg	800 mg	1200 mg	1600 mg
14	Imipenem-Cilastatin (Imp-Cln) ³	2 vials (1g + 1g) bd (to be used with Clavulanic acid)			
15	Meropenems (Mpm) ³	1000 mg three times daily (alternative dosing is 2000 mg twice daily) (to be used with Clavulanic acid)			
16	Amoxicillin-Clavulanate (Amx-Clv) (to be given with carbapenems only)	875/125 mg bd	875/125 mg bd	875/125 mg bd	875/125 mg bd
17	Pyridoxine (Pdx)	50 mg	100 mg	100 mg	100 mg

DR TB TREATMENT

All oral H mono-poly DR TB regimen

(6/9) Lfx R E Z

Shorter MDR TB regimen

4-6 Bdq(6)LfxEtoCfzZH(high dose)E / 5-LfxCfzZE

All oral longer MDR TB regimen@

(18-20) Bdq(6) Lfx Lzd[#] Cfz Cs

Newer Regimen for MDR and XDR TB

B P a L /B P a L M Regimen

Treatment regimen for drug-resistant TB

Treatment regimen options for DR-TB includes:

1. 6-9 months BPaLM shorter oral regimen.
2. 9-11 months shorter oral MDR/RR-TB regimen
3. 18-20 months longer oral M/XDR –TB regimen
4. 6-9 months H mono/ poly DR-TB regimen.



MDR/RR- TB Regimens

- In accordance with the latest recommendations, MDR/RR-TB patients are to be offered one of the MDR/RR-TB regimens in the ***preference of order*** as per integrated algorithm (based on the eligibility criteria) is given below:

1. 6-9 months BPaLM shorter oral regimen.
2. 9-11 months shorter oral MDR/RR-TB regimen
3. 18-20 months longer oral M/XDR –TB regimen



Role of surgery in management of DR-TB

- In patients with localized disease, surgery, as an adjunct to chemotherapy, can improve outcomes
- When unilateral resectable disease is present, surgery should be considered for the following cases:
 - *Absence of clinical or bacteriological response to chemotherapy*
 - *High risk of failure or relapse*
 - *Morbid complications of parenchymal disease*
 - *Recurrence of positive culture*
 - *Relapse after completion of anti-tuberculosis treatment*

TB TREATMENT:FUTURE ?

TREATMENT OF DS-TB:FUTURE ?

WHO consolidated guidelines
on Drug-susceptible
tuberculosis treatment- 2022

WHO
consolidated
guidelines on
tuberculosis

Module 4: Treatment

**Drug-susceptible
tuberculosis treatment**

Treatment of drug-susceptible TB using 4-month regimens

- People aged 12 years or older with DS pulmonary TB may receive a 4-month regimen of isoniazid, rifapentine, moxifloxacin and pyrazinamide (2HPMZ/2HPM)– new recommendation.
- In children and adolescents between 3 months and 16 years of age with non-severe TB (without suspicion or evidence of MDR/RR-TB), a 4-month treatment regimen (2HRZ(E)/2HR) should be used – new recommendation

Four-month rifapentine regimens with or without moxifloxacin for tuberculosis. N Engl J Med. 2021

WHO consolidated guidelines on Drug-susceptible tuberculosis treatment- 2022

Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis

Nonsevere TB

- peripheral lymph node TB
- intrathoracic lymph node TB without airway obstruction
- uncomplicated TB pleural effusion
- paucibacillary and noncavitary disease confined to one lobe of the lungs or without a miliary pattern.

Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis , American Journal of Respiratory and Critical Care Medicine Volume 211 Number 1 | January 2025

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Treatment Strategy for Rifampin-Susceptible Tuberculosis

Nicholas I. Paton, M.D., Christopher Cousins, M.B., Ch.B., Celina Suresh, B.Sc., Erlina Burhan, M.D., Ka Lip Chew, F.R.C.P.A., Victoria B. Dalay, M.D., Qingshu Lu, Ph.D., Tutik Kusmiati, M.D., Vincent M. Balanag, M.D., Shu Ling Lee, B.Sc., Rovina Ruslami, Ph.D., Yogesh Pokharkar, M.Sc., Irawaty Djaharuddin, M.D., Jani J.R. Sugiri, M.D., Rholine S. Veto, M.D., Christine Sekaggya-Wiltshire, Ph.D., Anchalee Avihingsanon, M.D., Rohit Sarin, M.D., Padmasayee Papineni, F.R.C.P., Andrew J. Nunn, M.Sc., and Angela M. Crook, Ph.D., for the TRUNCATE-TB Trial Team*

ABSTRACT

BACKGROUND

Tuberculosis is usually treated with a 6-month rifampin-based regimen. Whether a strategy involving shorter initial treatment may lead to similar outcomes is unclear.

METHODS

In this adaptive, open-label, noninferiority trial, we randomly assigned participants with rifampin-susceptible pulmonary tuberculosis to undergo either standard treatment (rifampin and isoniazid for 24 weeks with pyrazinamide and ethambutol for the first 8 weeks) or a strategy involving initial treatment with an 8-week regimen, extended treatment for persistent clinical disease, monitoring after treatment, and retreatment for relapse. There were four strategy groups with different initial regimens; noninferiority was assessed in the two strategy groups with complete enrollment, which had initial regimens of high-dose rifampin–linezolid and bedaquiline–linezolid (each with isoniazid, pyrazinamide, and ethambutol). The primary outcome was a composite of death, ongoing treatment, or active disease at week 96. The noninferiority margin was 12 percentage points.

RESULTS

Of the 674 participants in the intention-to-treat population, 4 (0.6%) withdrew consent or were lost to follow-up. A primary-outcome event occurred in 7 of the 181 participants (3.9%) in the standard-treatment group, as compared with 21 of the 184 participants (11.4%) in the strategy group with an initial rifampin–linezolid regimen (adjusted difference, 7.4 percentage points; 97.5% confidence interval [CI], 1.7 to 13.2; noninferiority not met) and 11 of the 189 participants (5.8%) in the strategy group with an initial bedaquiline–linezolid regimen (adjusted difference, 0.8 percentage points; 97.5% CI, –3.4 to 5.1; noninferiority met). The mean total duration of treatment was 180 days in the standard-treatment group, 106 days in the rifampin–linezolid strategy group, and 85 days in the bedaquiline–linezolid strategy group. The incidences of grade 3 or 4 adverse events and serious adverse events were similar in the three groups.

CONCLUSIONS

A strategy involving initial treatment with an 8-week bedaquiline–linezolid regimen was noninferior to standard treatment for tuberculosis with respect to clinical outcomes. The strategy was associated with a shorter total duration of treatment and with no evident safety concerns. (Funded by the Singapore National Medical Research Council and others; TRUNCATE-TB ClinicalTrials.gov number, NCT03474198.)

The authors' affiliations are listed in the Appendix. Prof. Paton can be contacted at nick_paton@nus.edu.sg or at Yong Loo Lin School of Medicine, NUHS Tower Block Level 10, 1E Kent Ridge Rd., Singapore 119228.

*A complete list of members of the TRUNCATE-TB Trial Team is provided in the Supplementary Appendix, available at [NEJM.org](https://www.nejm.org).

This article was published on February 20, 2023, at [NEJM.org](https://www.nejm.org).

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TREATMENT OF DR-TB:FUTURE ?

Editorial

Are We Moving Towards Development of Universal Drug Regimen for Treatment of Tuberculosis?

Tuberculosis (TB) is considered to be a major global health problem and an important cause of morbidity and mortality in high burden countries including India. There were an estimated 10 million TB cases with 1.5 million deaths worldwide in 2018.¹ Around 4000 people die and 30,000 people fall ill every day. There were an estimated 2.7 million TB cases in India with 0.45 million deaths in 2018.¹ Rifampin (R), isoniazid (H), ethambutol (E), pyrazinamide (Z) in combination, remains the mainstay of the treatment for the drug sensitive TB (DS-TB) with a success rate of 85%.¹ The concept of drug-resistant TB (DR-TB) has come into existence by the development of acquired and also transmitted resistance, creating important forms – rifampicin-resistant-TB (RR-TB), multidrug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB). 3.4% of newly diagnosed and 18% of previously treated TB cases worldwide had MDR-TB in 2018. In India, 2.8% of newly diagnosed and 14% of previously treated TB cases estimated to have MDR-TB. Multidrug and rifampicin resistant TB (MDR-RR-TB) and XDR-TB are now posing

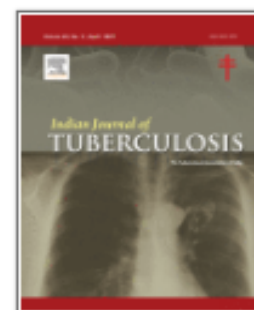
and repurposed drugs for improving outcome.³ Shorter treatment regimen was also introduced with duration of 9-12 months for MDR-/RR-TB with an aim to reduce the cost and duration of the treatment, thereby, improving the compliance and outcome.⁴⁻⁶ It is indicated in subset of MDR-/RR-TB patients who either have not been previously exposed to second-line drugs or no documented resistance to fluoroquinolones and second-line injectable agents at baseline. Shorter regimen reported to have statistically-significant higher likelihood of treatment success than those received longer conventional regimens (83% *versus* 56%).⁶ A phase 3 randomised control trial (RCT) STREAM (Standard Treatment Regimen of Anti-TB Drugs for Patients with MDR-TB) Stage-1 also reported that a shorter regimen was non-inferior with respect to primary efficacy outcome (78.8% *versus* 79.8%) and was similar to the longer regimen in terms of safety in patients with MDR-/RR-TB.^{7,8} However, there are various shortcomings associated even with approved shorter regimen. The shorter regimen still requires a minimum four months of treatment in an



Indian Journal of Tuberculosis

Available online 23 June 2022

In Press, Journal Pre-proof ?



Editorial

Can Pan-TB shorter regimens be a promising hope for ending TB in India by 2025 in ongoing COVID-19 era?

Rajendra Prasad (Director Medical Education & Head of Dept)¹  , Abhijeet Singh², Nikhil Gupta³

3

TB TREATMENT:FUTURE ?

Universal Regimen

CURRENT ISSUES IN T/T OF TUBERCULOSIS

Take Home Messages- 1

**Better not to treat
than to mal treat**

CURRENT ISSUES IN T/T OF TUBERCULOSIS

Take Home Messages- 2

- **Diagnosis must be firm.**
- **Use most appropriate regimen**
- **Use drugs in correct doses and duration**
- **Use quality medicines**
- **Use FDCs of proven bioavailability**
- **Ensure regular intake of drugs**
- **Do not experiment in suspected resistant cases.**

Take Home Messages- 3

- **DS-TB** – 6 months RHEZ/RHE
- **H mono/ poly DR-TB regimen-** -6-9 months- REZ +Levo
- **MDR/XDR-TB**

6-9 months BPaLM shorter oral regimen

9-11 months shorter oral MDR/RR-TB regimen

18-20 months longer oral M/XDR -TB regimen



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Recent changes in Treatment of TB

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Recent Changes in Treatment of TB

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Former Director, Vallabhbhai Patel Chest Institute, University of Delhi
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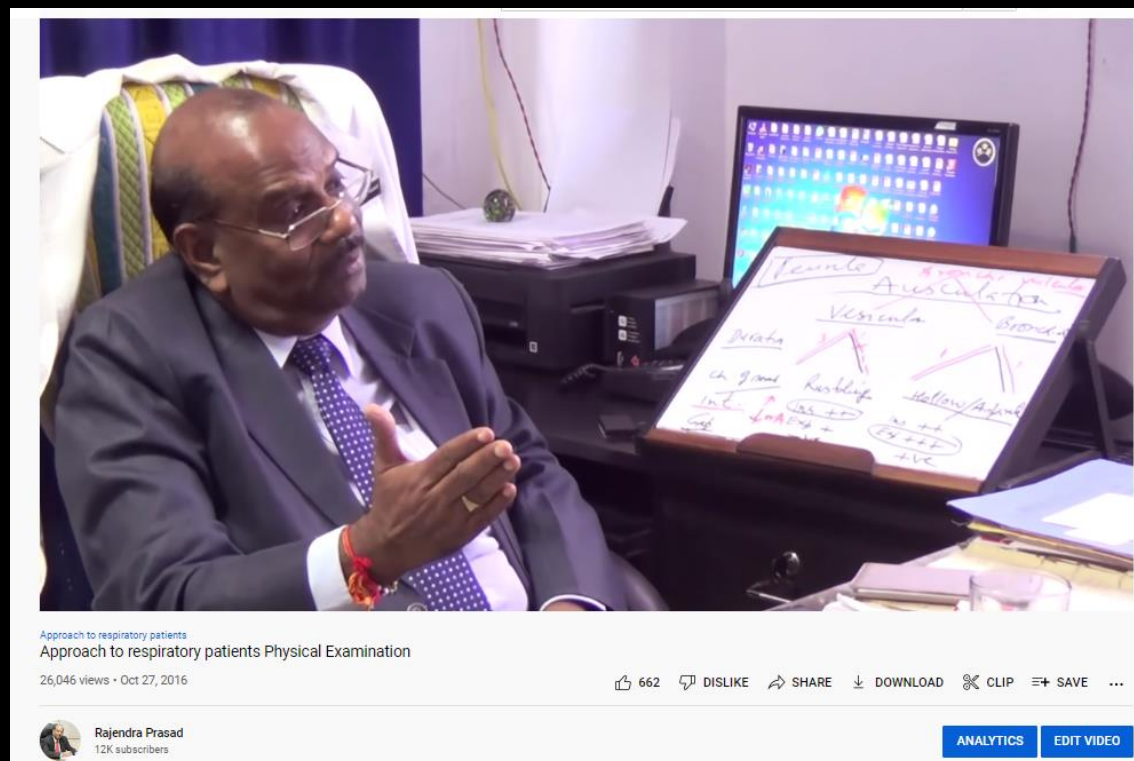
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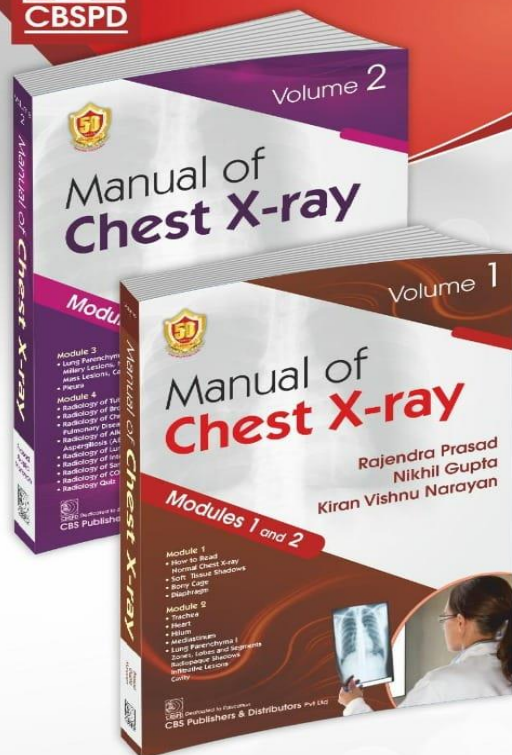
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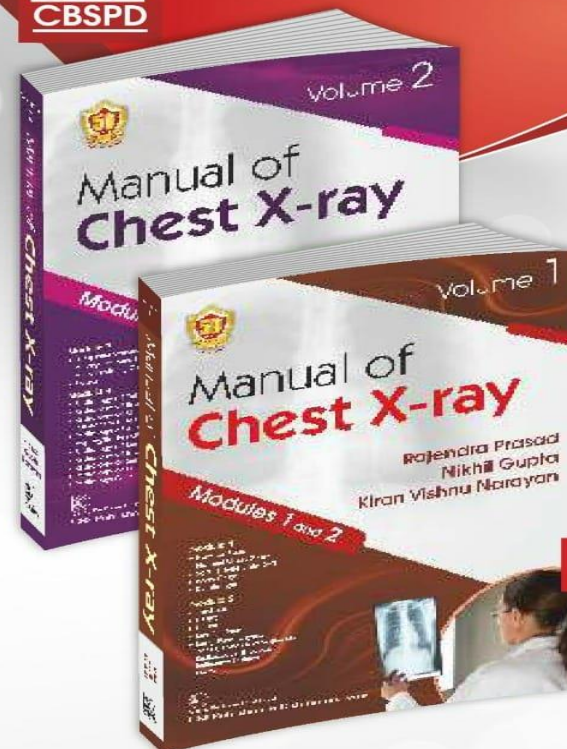
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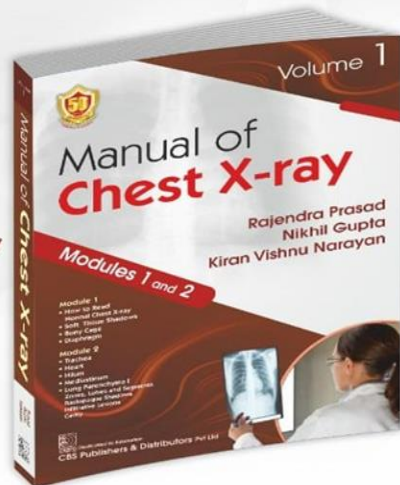
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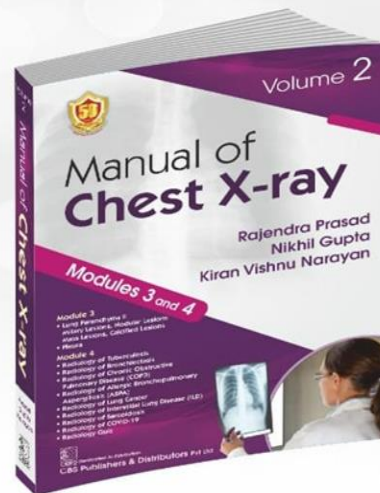
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Module 4

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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 extra-pulmonary 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 manager in TB control will find this book as practical guide.

Prof. Rajendra Prasad MD DCC (FAMS) FCCP (USA) FRCPT (CAN) FRCR (UK) FRCR (INDIA) DSC (Honorary) Casual Director, Vallabhbhai Patel Chest Institute, University of Delhi, Delhi (India). Former Professor & Head, Department of Pulmonary Medicine, King George's Medical University, Lucknow and Former Director, UP Rural Institute of Medical Sciences & Research, Saifai, Etawah, did his MBBS in 1974 & MD in 1979 from King, George's, Medical College, Lucknow. He received advance training in Pulmonary Medicine including clinical tuberculosis and TB control from Japan. He is also honorary consultant to Armed Forces Medical Services, India in Respiratory Diseases. Professor Prasad is currently Vice President of South Asia Association of Allergy, Asthma and Applied Immunology. He has been International Governor of American College of Chest Physicians (USA). He has unique distinction of being president of all major scientific bodies in the field of Pulmonary Medicine in India. Besides several prestigious fellowship of reputed National and International organization, he was awarded Fellowship of the National Academy of Medical Sciences India. He has supervised about 150 Researches and Published 225 Articles in reputed National and International Journals and books. He has presented over 1200 guest lectures, scientific papers at various National and International meetings.

Prof. Rajendra Prasad is a nationally acclaimed chest physician and tuberculosis expert, possessing nearly 4 decades' illustrious teaching and research experience with proven excellence in quality patient care. Apart from being a clinician par excellence, he is also a very popular medical teacher in Pulmonary Medicine. Prof. Prasad's contribution in the field of Tuberculosis and Multidrug Resistant Tuberculosis (MDR-TB) are widely acclaimed. He took keen interest in Revised National Tuberculosis Control Programme (RNTCP) from its inception. His dynamic leadership in academic and administrative areas has earned him a large number of awards from various International and National Scientific societies. He has been mentor of many students who are now assuming important positions in pulmonary medicine.

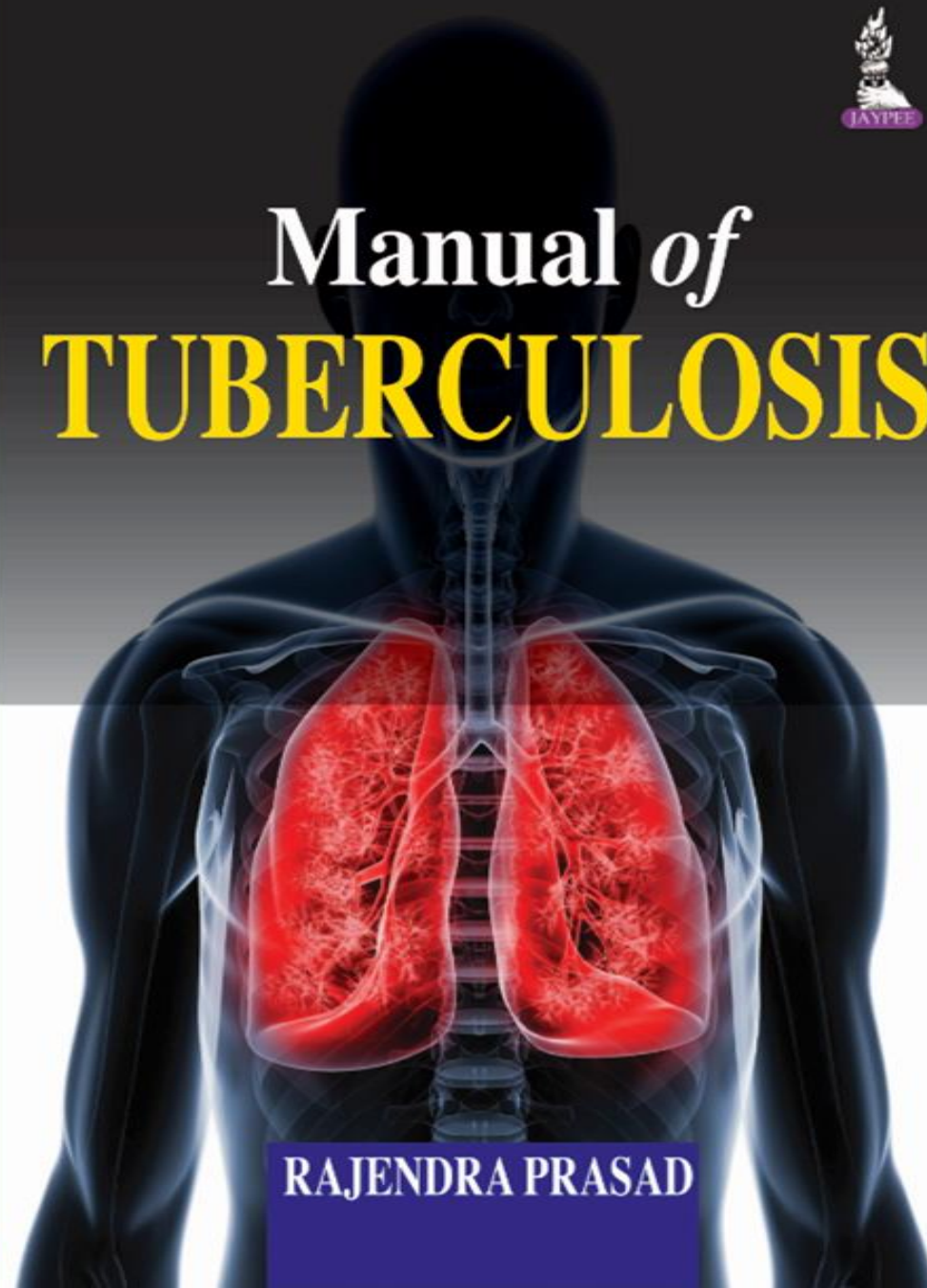


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MDR & XDR Tuberculosis

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Prof. Rajendra Prasad MD DTCO FAMS FCCP (USA) FNCCP FCAI FIAB FIMS DSC (Honoris Causa) Director, Vallabhbhai Patel Chest Institute, University of Delhi, Delhi (India), Former Professor & Head, Department of Pulmonary Medicine, King George's Medical University, Lucknow and Former Director, UP Rural Institute of Medical Sciences & Research, Saifai, Etawah, did his MBBS in 1974 & MD in 1979 from King George's Medical College, Lucknow. He received advance training in Pulmonary Medicine including clinical tuberculosis and TB control from Japan. He is also honorary consultant to Armed Forces Medical Services, India in Respiratory Diseases. He has been International Governor of American College of Chest Physicians (USA). He has unique distinction of being president of all major scientific bodies in the field of Pulmonary Medicine in India like National College of Chest Physicians India, Indian Chest Society, Indian College of Allergy, Asthma & Applied Immunology, Indian Association for Bronchology and chairman, Standing Technical Committee, Tuberculosis Association of India. Besides several prestigious fellowship of reputed National and International organization, he was awarded Fellowship of the National Academy of Medical Sciences India. He has supervised about 150 Researches, and Published 225 Articles in reputed National and International Journals and Books. He has presented over 1200 guest lectures, scientific papers at various National and International meetings.

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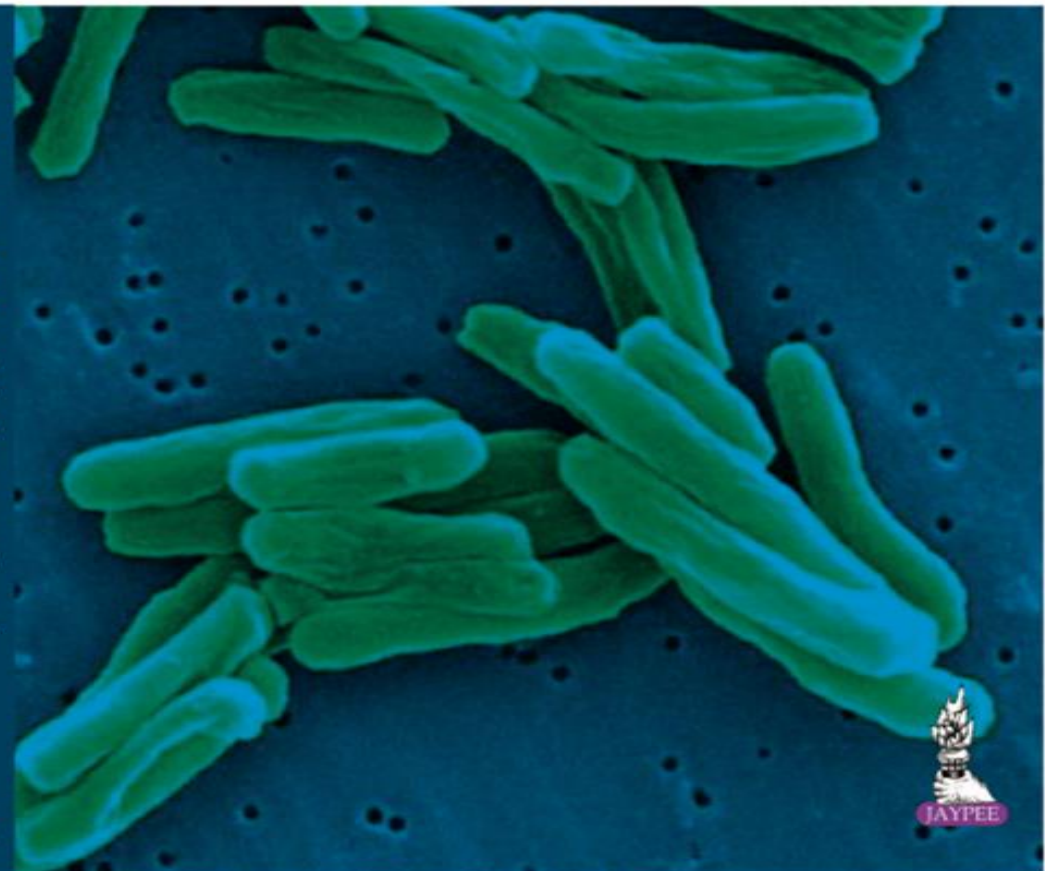


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Handbook on Adverse DRUG REACTIONS in TB Treatment

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- Serves as a practical guide for undergraduate and postgraduate medical students, practitioners, program managers and healthcare workers in TB control.

Rajendra Prasad MD DTCF FAMS FCCP (USA) FRCP (Glas) FNCCP FICS FCAI FIAB FIMS FCS DSc (Honoris Causa) is the Director of Medical Education and Professor and Head, Department of Pulmonary Medicine, Era's Lucknow Medical College and Hospital, Era University, Lucknow, Uttar Pradesh, India. He was the Director, Vallabhbhai Patel Chest Institute, University of Delhi, New Delhi; Professor and Head, Department of Pulmonary Medicine, King George's Medical University, Lucknow; and the Director, UP Rural Institute of Medical Sciences and Research, Saifai, Etawah, Uttar Pradesh. He has been International Governor of American College of Chest Physicians, USA. He has unique distinction of being President of all major scientific bodies in the field of pulmonary medicine in India. He was awarded Fellowship of the National Academy of Medical Sciences, India, American College of Chest Physicians, USA and Royal College of Physicians and Surgeons, Glasgow. He has supervised about 180 researches, and published 340 original articles, reviews and book chapters. He has written 8 books including 4 books on Tuberculosis and an Atlas on Fiber Optic Bronchoscopy based exclusively on Indian patients and presented over 1,600 guest lectures and scientific papers at various national and international meetings. He is recipient of Dr BC Roy National Award for devolving and popularizing pulmonary medicine in India.



Nikhil Gupta MD (Medicine) is an Assistant Professor, Department of General Medicine, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow, Uttar Pradesh, India. He was an Assistant Professor, Department of Medicine, Era's Lucknow Medical College and Hospital, Era University, Lucknow from 2012 to 2017. He has more than 30 guest lectures and scientific papers, supervised 15 researches and published 35 original articles, review articles, case reports and book chapters. He has also co-authored 3 books on tuberculosis.



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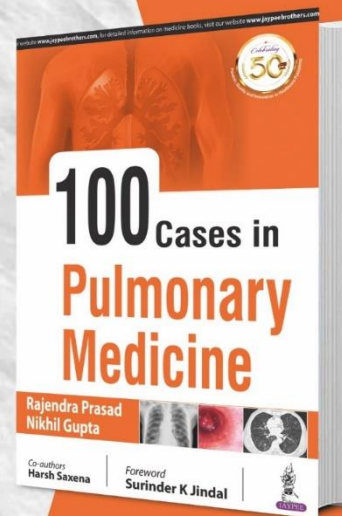
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


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
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“Anyone who keeps learning stays young”
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I am Still Learning.....



Thank You

Questions

