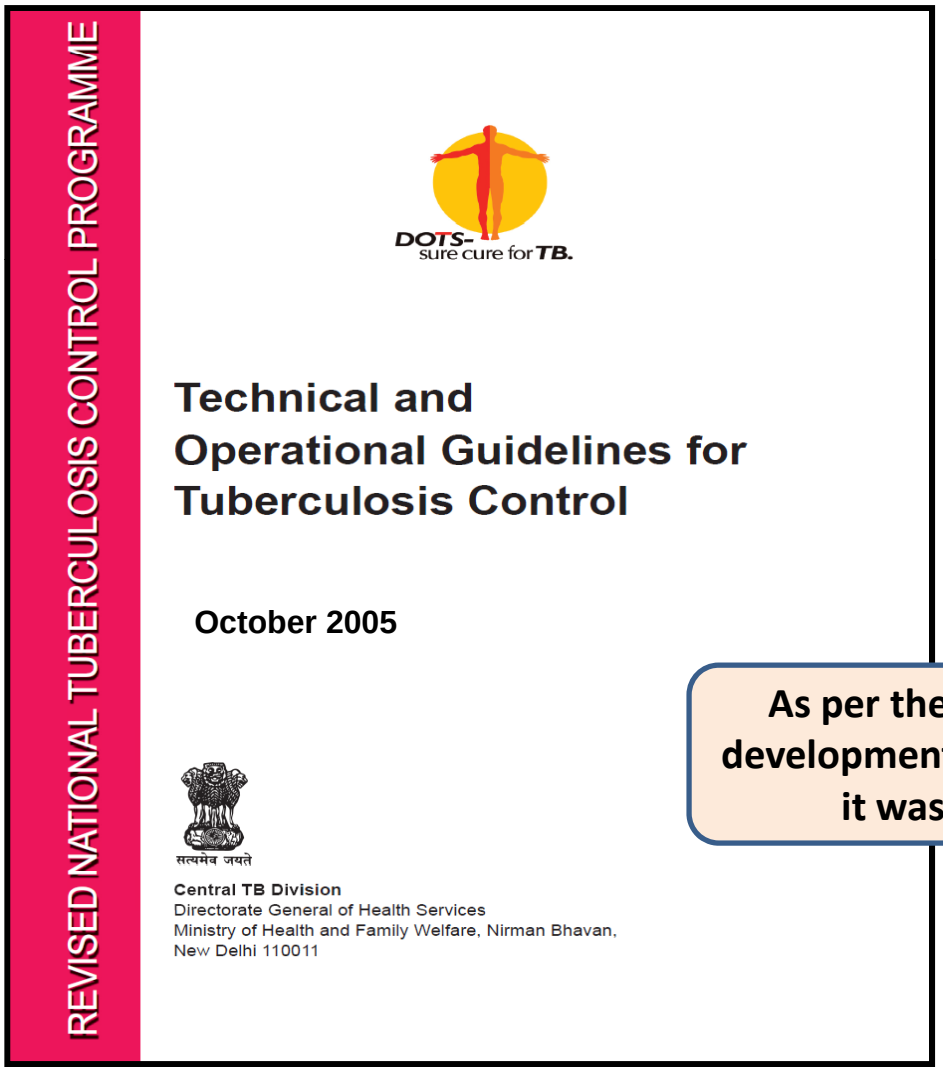
Revised National TB Control Programme

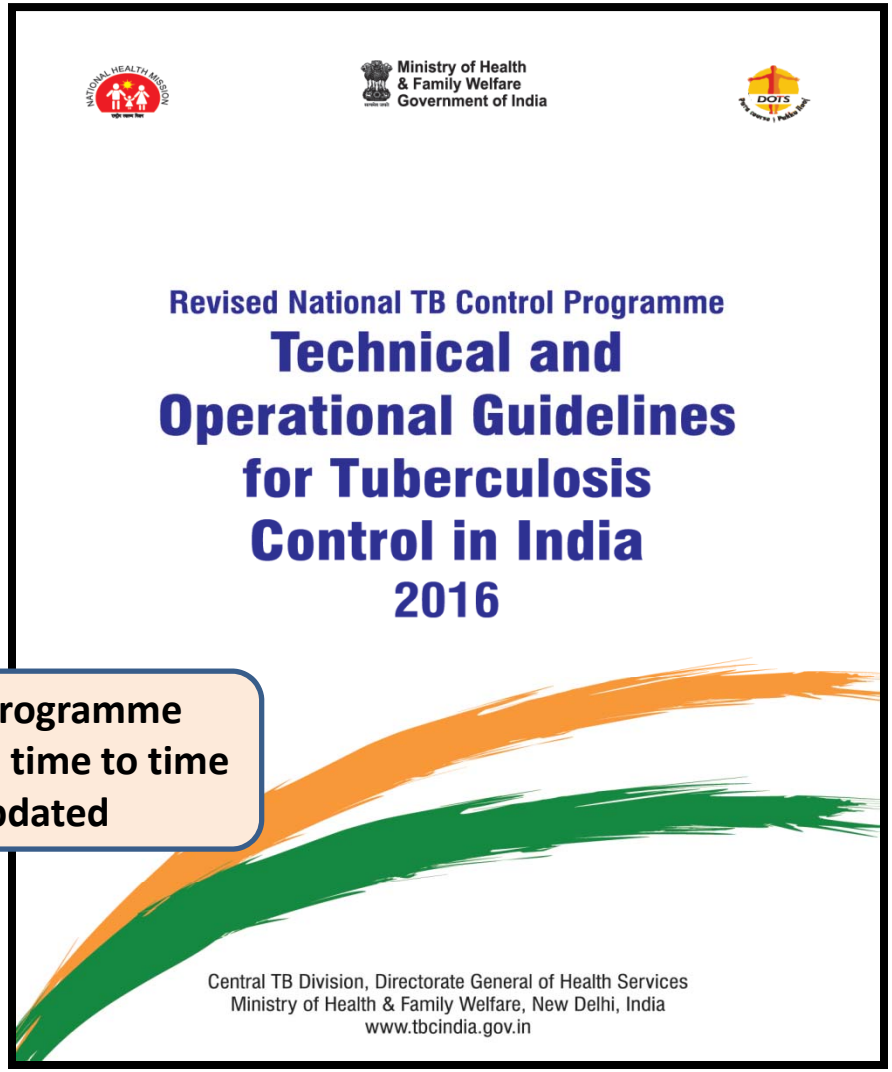
Technical & Operational Guideline

for TB Control in India

- March 2016

Why TOG and why it is required ?





As per the programme developments , time to time it was updated

Revised Technical & Operational Guideline for RNTCP

2005 - The first technical & operational guidelines for Revised National TB Control Programme (RNTCP). It was revised many a times based on need of programme

2016 - The current document outlines the guidelines on TB care in line with RNTCP National Strategic Plan for Tuberculosis Control 2012-17. It covers

- **Strategies and guidelines for diagnosis and treatment of all forms of TB** *(pulmonary, extra-pulmonary, drug resistant TB, TB with comorbidities, pediatric TB, etc.)*
- **Programme management aspects covering**
  - patient support systems,
  - human resource management,
  - partnerships for TB control,
  - advocacy, communication and social mobilization, I
  - Infection control measures,
  - planning and finance are also incorporated.
- **It is intended to be used by all programme mangers**

Ref: Standards for TB Care in India (STCI)

Objectives of Revised TOG RNTCP

Align with the goals of
National Strategic Plan for TB Control- 2012-2017

Vision

A TB FREE INDIA

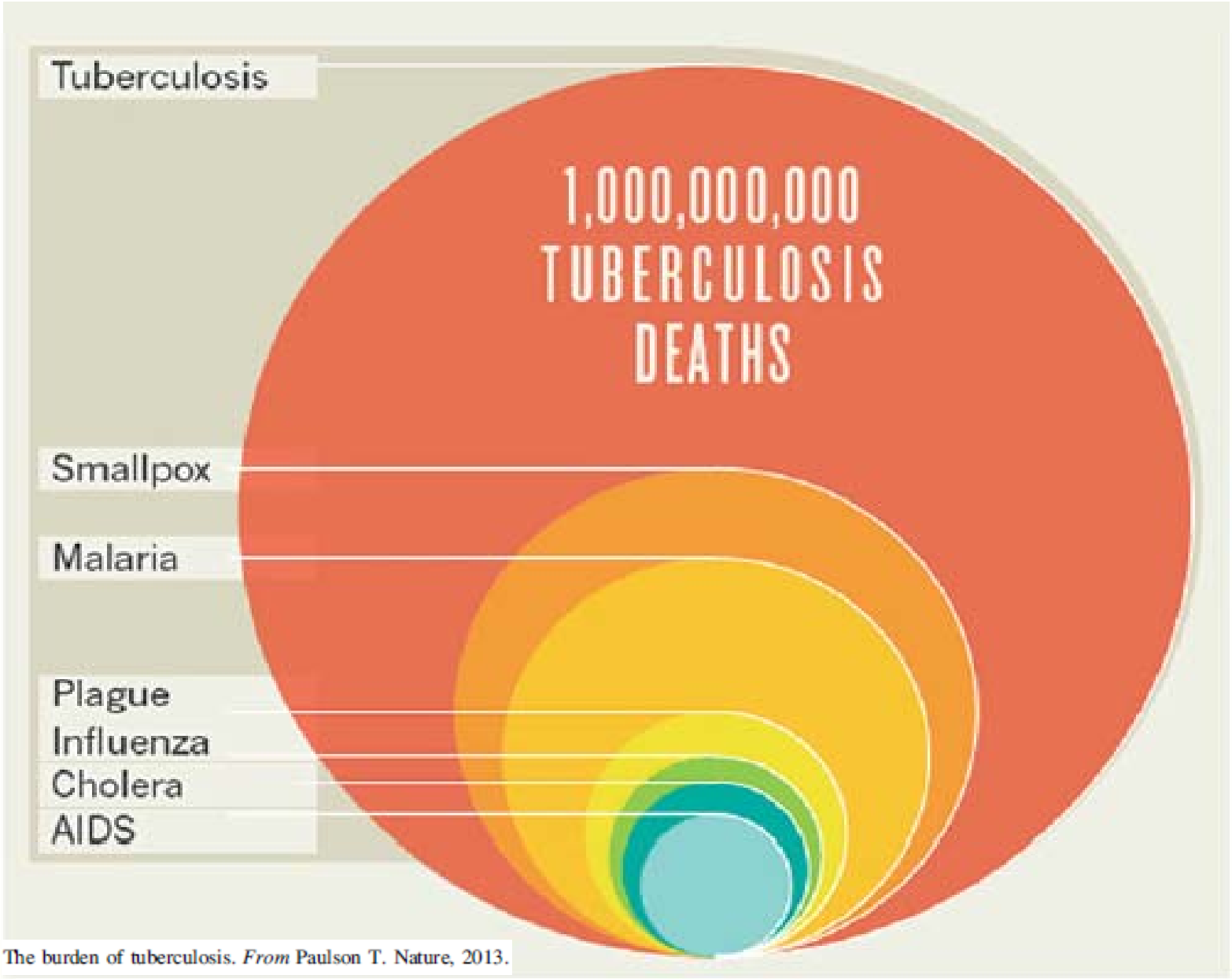
Goal

Universal Access to quality TB diagnosis & treatment for all TB patients in the community

Objectives

- **To achieve 90% notification rate for all cases**
- **To achieve 90% success rate for all new and 85% for re-treatment cases**
- **To significantly improve the successful outcomes of treatment of DR-TB Cases**
- **To achieve decreased morbidity and mortality of HIV-associated TB**
- **To improve outcomes of TB care in the private sector**

THE CAPTAIN OF ALL THESE MEN OF DEATH:
Deaths from Infectious Diseases in last 200 years



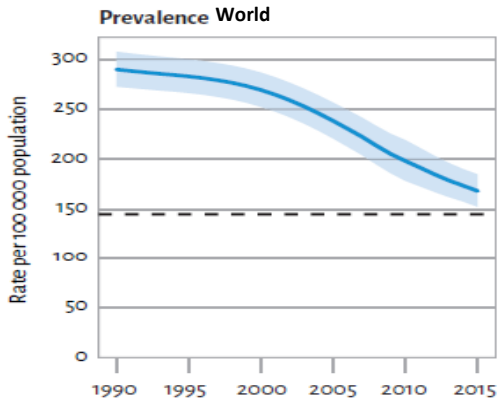
The burden of tuberculosis. *From* Paulson T. Nature, 2013.

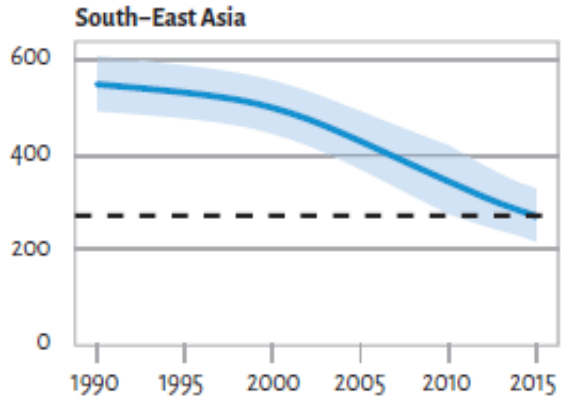
Burden of TB

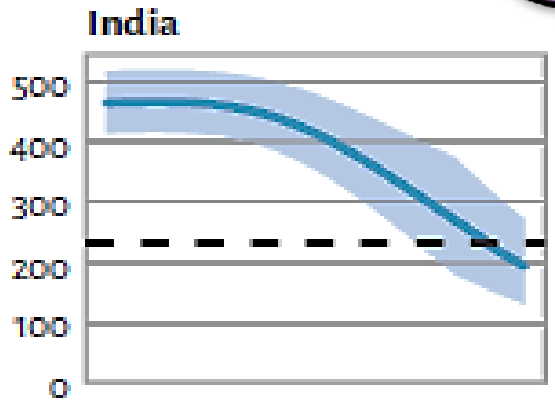
- India accounts for one fourth of the global TB burden
  - with 2.2 million out of 9.6 million new cases annually.
  - > 40% of population is infected (prevalence of infection) with *Myco. tuberculosis.*
  - In India, every day:
    - more than 6000 develop TB disease
    - more than 600 people die of TB (i.e. 2 death every 5 minutes)
- It is estimated that there are 2.5 million prevalent cases of all forms of TB disease.
- It is also estimated that about 2.2 lakhs people die due to TB annually (mortality).

	Incidence	Prevalence	Mortality
Global	9.6 million (176/lakh/year)	13 million (227/lakh/year)	1.1 million (21 /lakh/year)
India	2.2 million	2.5 million	2.2 lakhs
	(167/lakh/year)	(195/lakh/year)	(17/lakh/year)

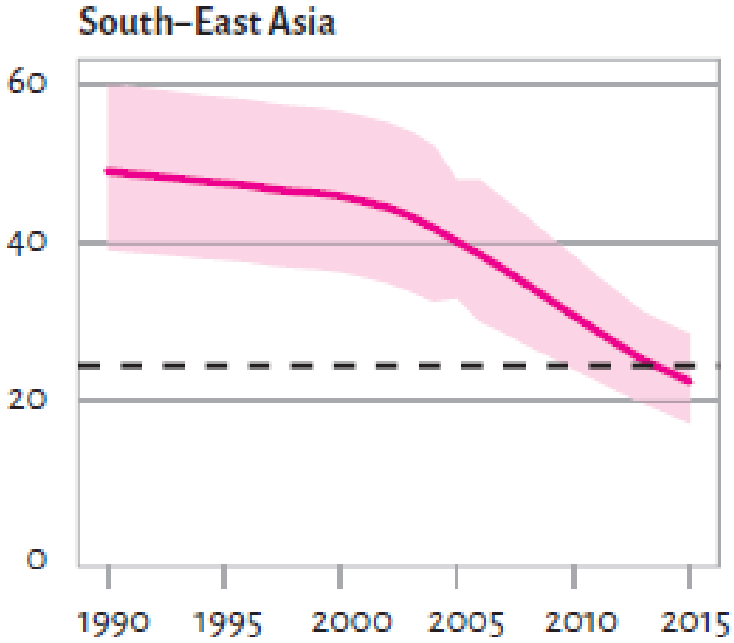
Estimated TB prevalence rates

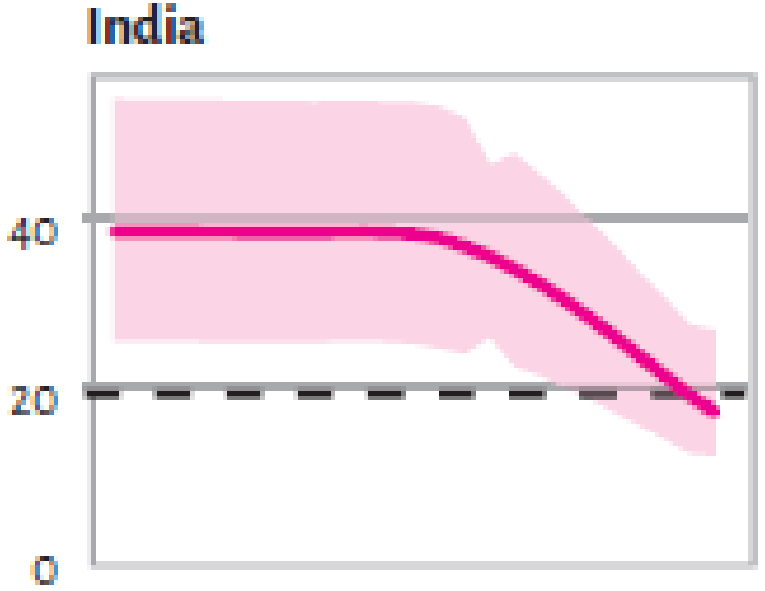






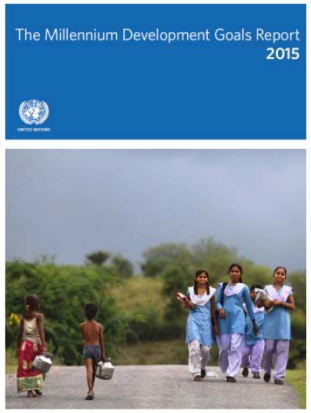
Estimated TB mortality rates





Goal 6:
Combat HIV/AIDS, malaria and other diseases

India: MDG6 TB target achieved

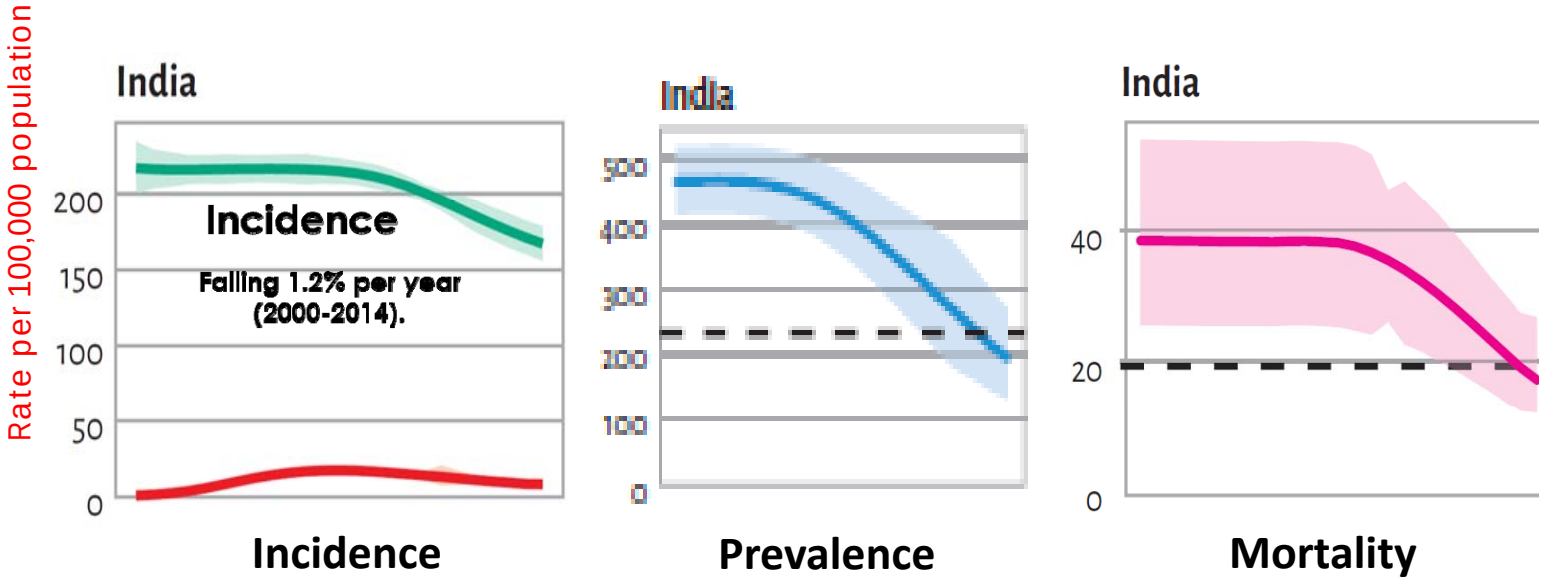


3.5 million additional lives saved since inception

TB EPIDEMIC REVERSED

50% DROP IN TB MORTALITY

50% DROP IN TB Prevalence

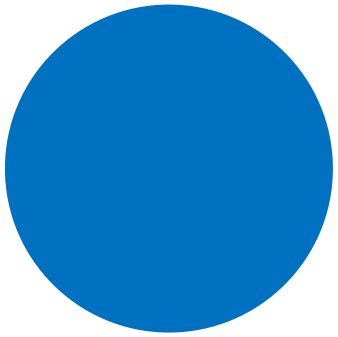


But huge burden of deaths & suffering remains in India. Estimated 22 lakh incident TB cases in 2014, with 2.2 lakh deaths

Current progress = Too Slow to reach 2035 target?

WHO Strategy Target For 2035

2014 Global TB incidence



It would take until 2180

target

10 / 100k

global

/ 100k

Global projections to 2035 compared with current trends

WHO

END TB

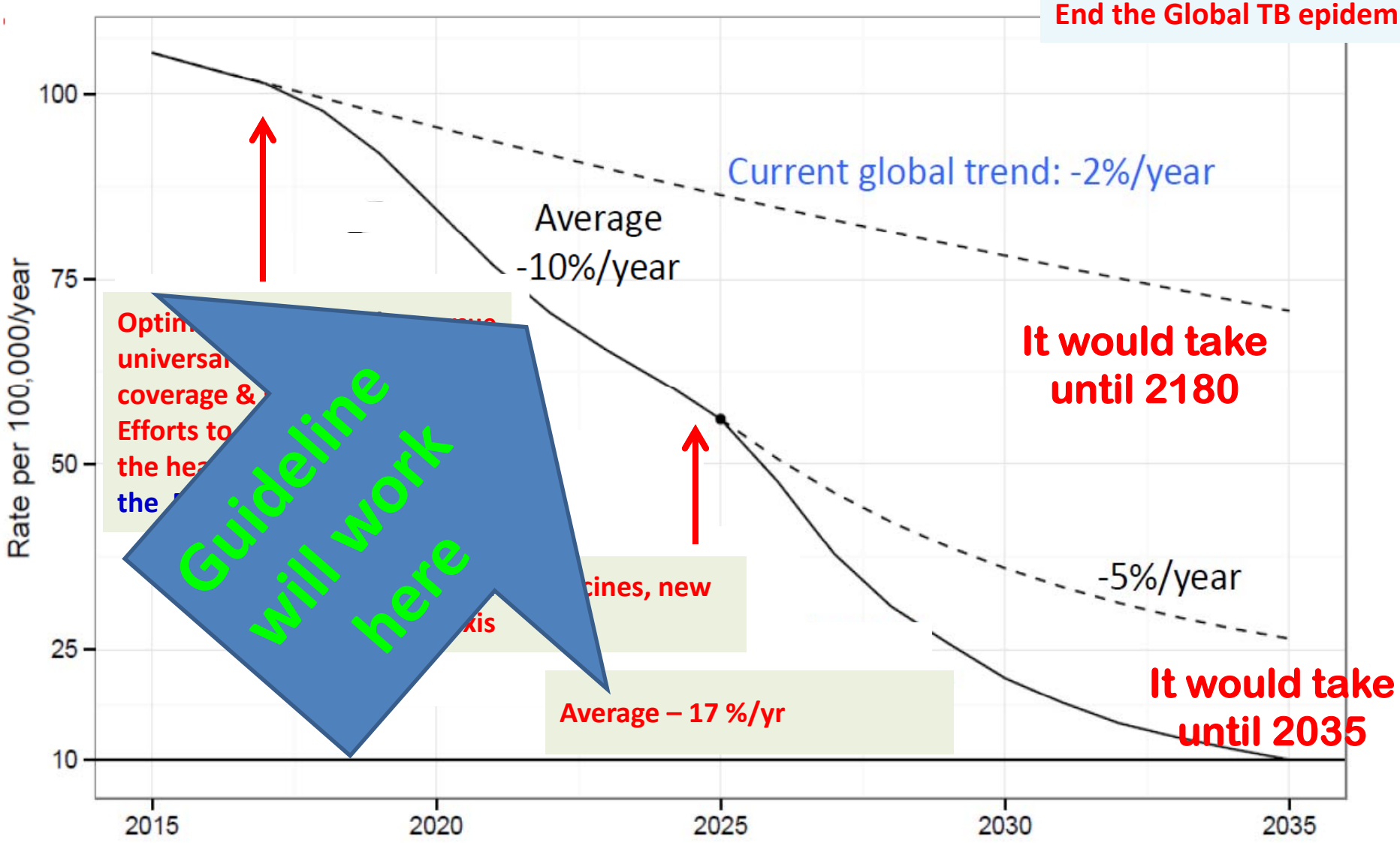
Vision:

A world free of TB

Zero TB deaths,
Zero TB disease, and Zero TB suffering

Goal:

End the Global TB epidemic



End TB Strategy

Vision, goal and targets

VISION:

- **A WORLD FREE OF TB**

  Zero deaths, disease and suffering due to TB

GOAL:

- **End the Global TB Epidemic**

MILESTONES FOR 2025:

- **75% reduction in TB deaths (compared with 2015)**
- **50% reduction in TB incidence rate (≤55/100,000 (compared with 2015)**
- **No affected families face catastrophic costs due to TB**

TARGETS FOR 2035:

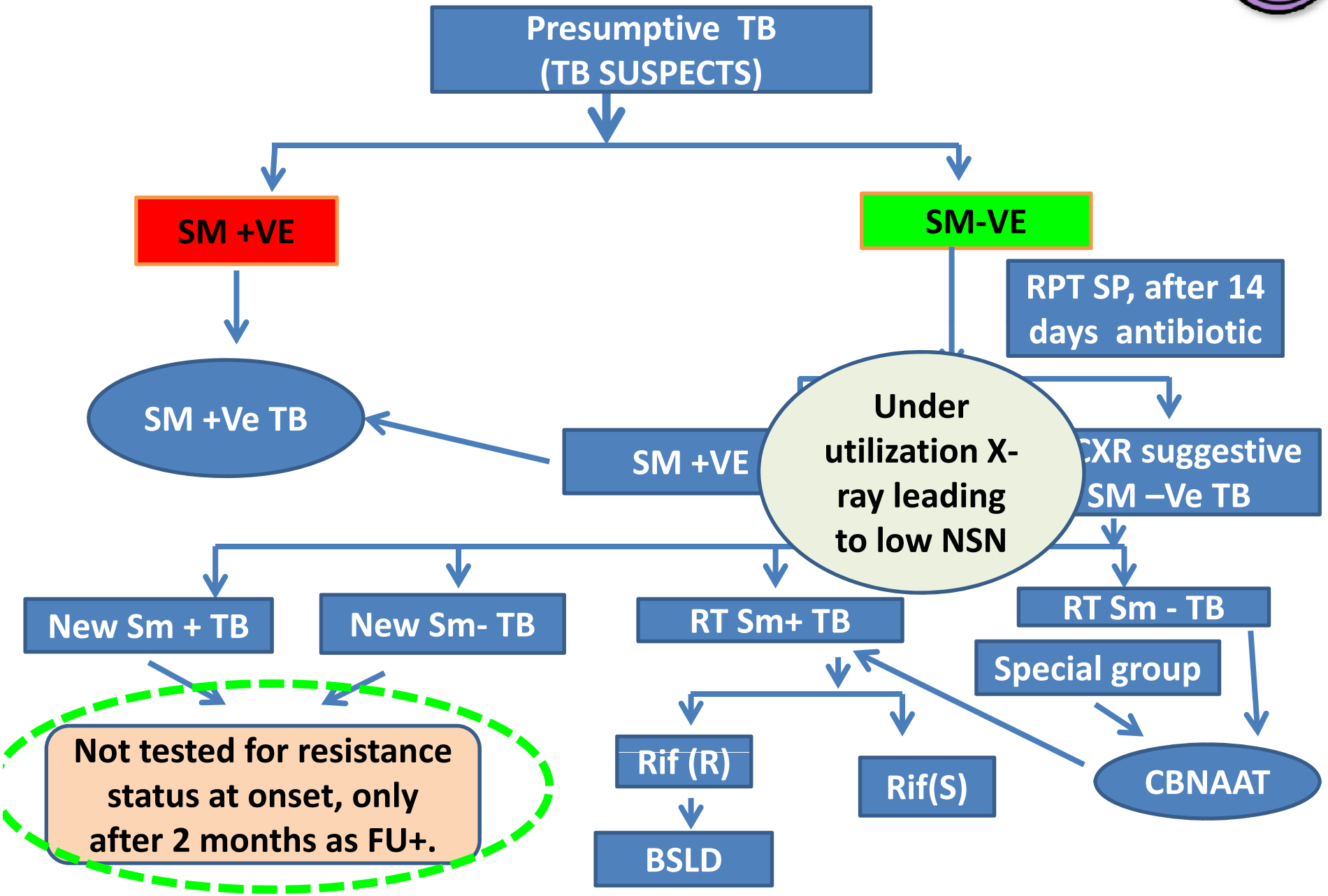
- **95% reduction in TB deaths (compared with 2015)**
- **90% reduction in TB incidence rate (≤10/100,000)**
- **No affected families face catastrophic costs due to TB**

End TB strategy

VISION	A WORLD FREE OF TB -Zero deaths, disease and sufferings due to TB			
GOAL	END THE GLOBAL TB EPIDEMIC			
INDICATORS	Milestones		Targets	
	2020	2025	SDG 2030	End TB 2035
Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20% (<85/100,000)	50% (<55/100,000)	80% (<20/100,000)	90% (<10/100,000)
TB-affected family facing catastrophic costs due to TB (%)	0	0	0	0

What new guideline contains ?

PRESESNT DIAGNOSTIC PROTOCOL



Changes in Diagnostic Protocol…1

Present opportunity to test

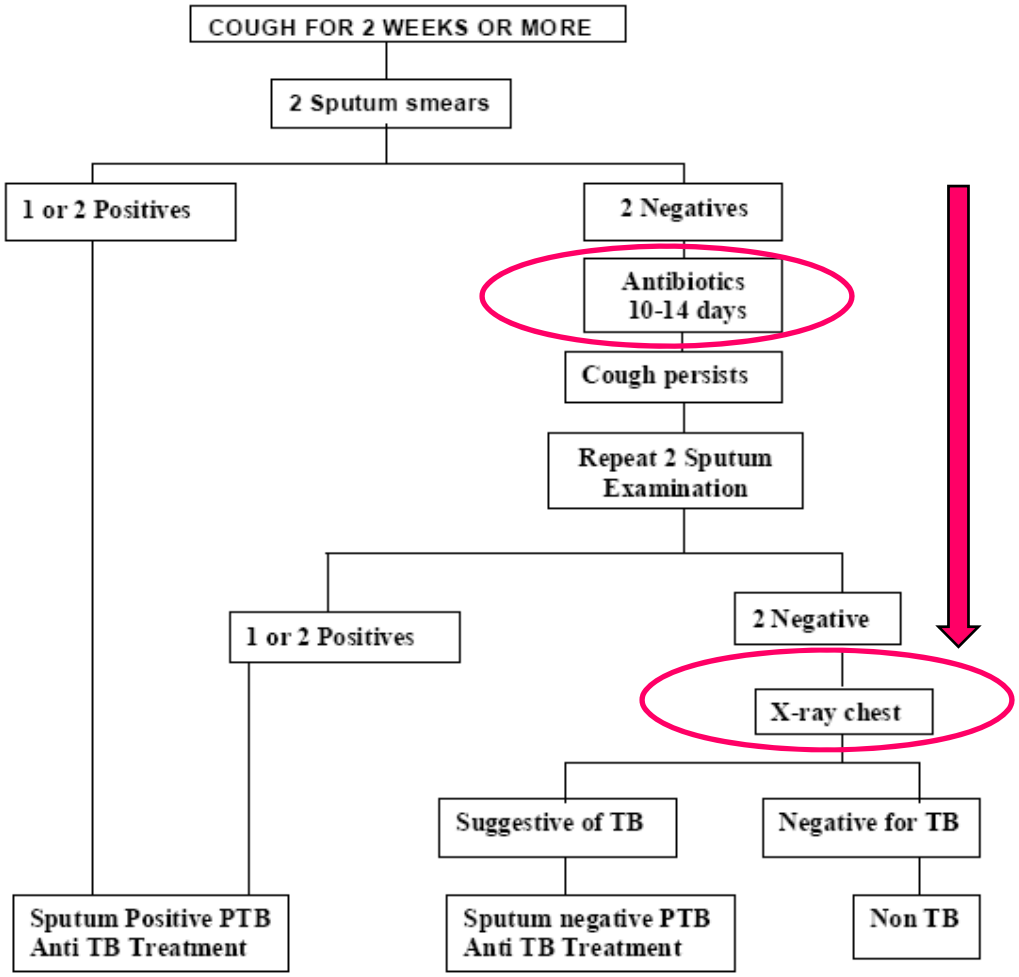
- Any FU +ve while TB patients on treatment
- Old cases as RT+ve & RT-ve at diagnosis,
- Contacts of DRTB who are TB symptomatic,
- PLHIV
- Paediatrics
- EP cases

Changes in new TOG, opportunity to test

- All types of smear negative (new or retreatment) are to be tested by CBNAAT, if X-ray is suggestive.
- All Rif resistant cases are to be tested for level of INH resistance by LPA or LC
- All Rif resistant cases are to be tested for base line 2nd line DST
- All Ofx and kanamycin resistant cases are to be tested for resistance to Clofazimine , Bedaquiline, PAS by extended by extended DST.

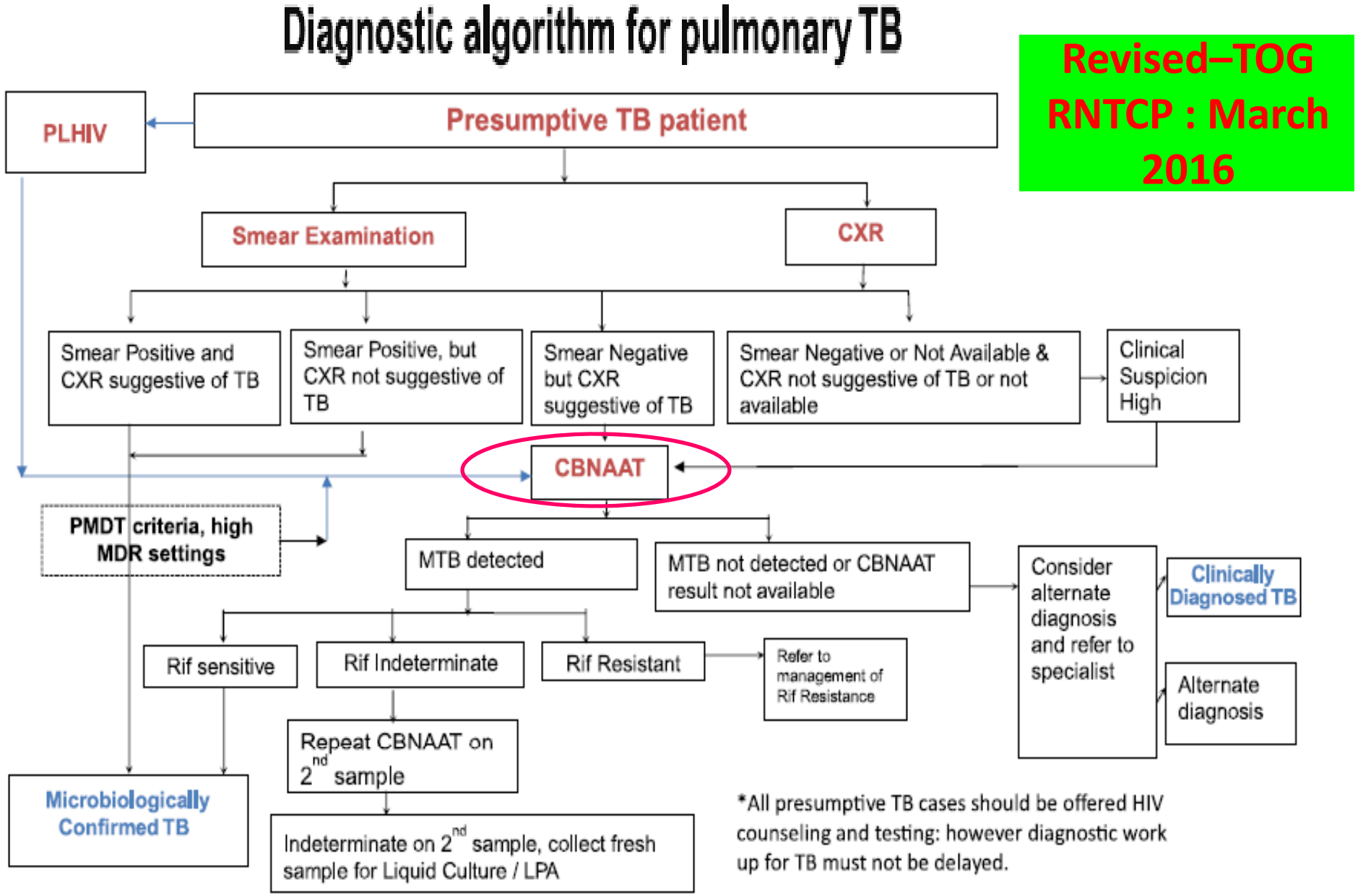
Changes in Diagnostic Protocol…1

Diagnostic algorithm

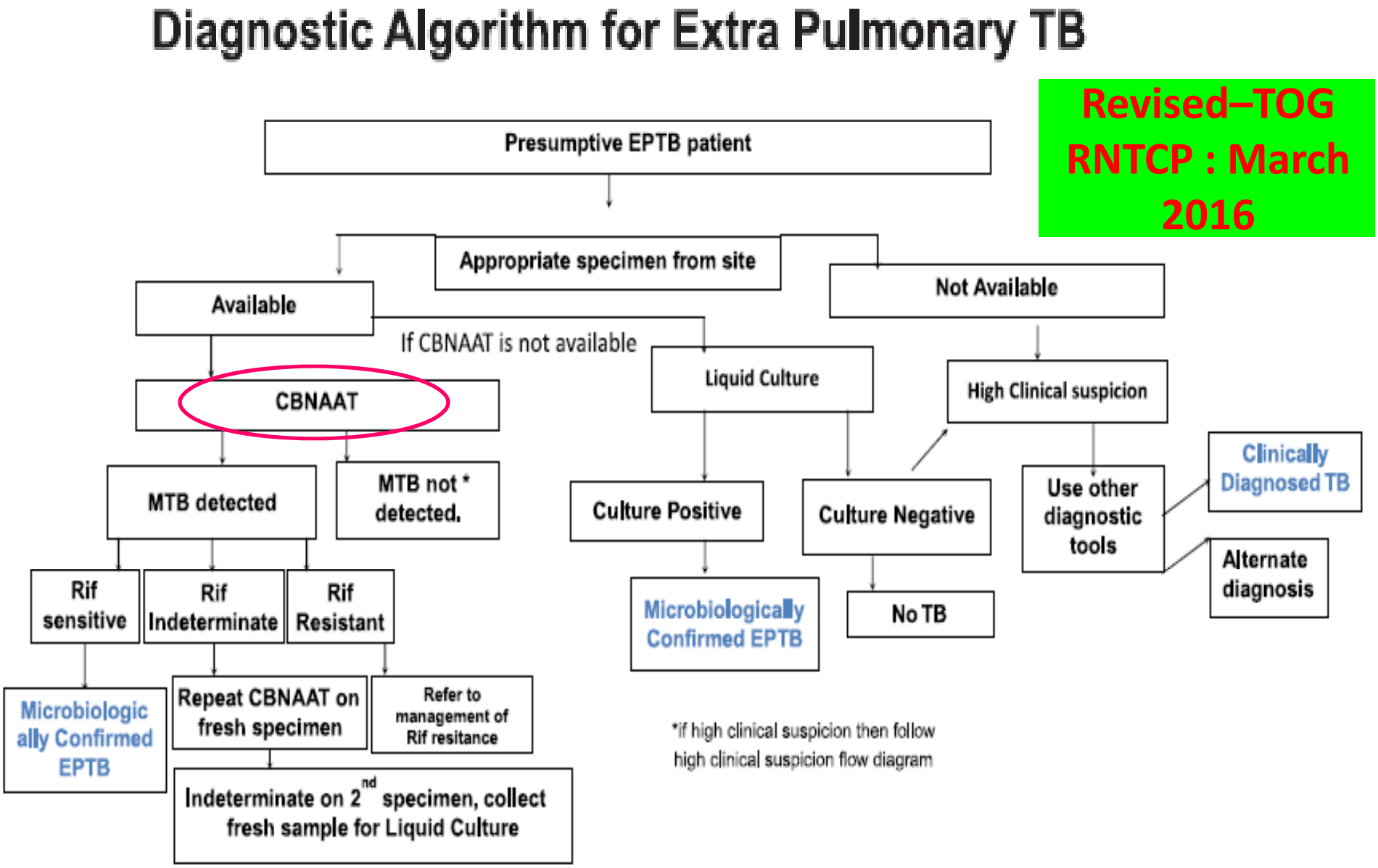


Revised–TOG RNTCP : March 2016

Changes in Diagnostic Protocol…1



Changes in Diagnostic Protocol…1



Changes in Diagnostic Protocol…1

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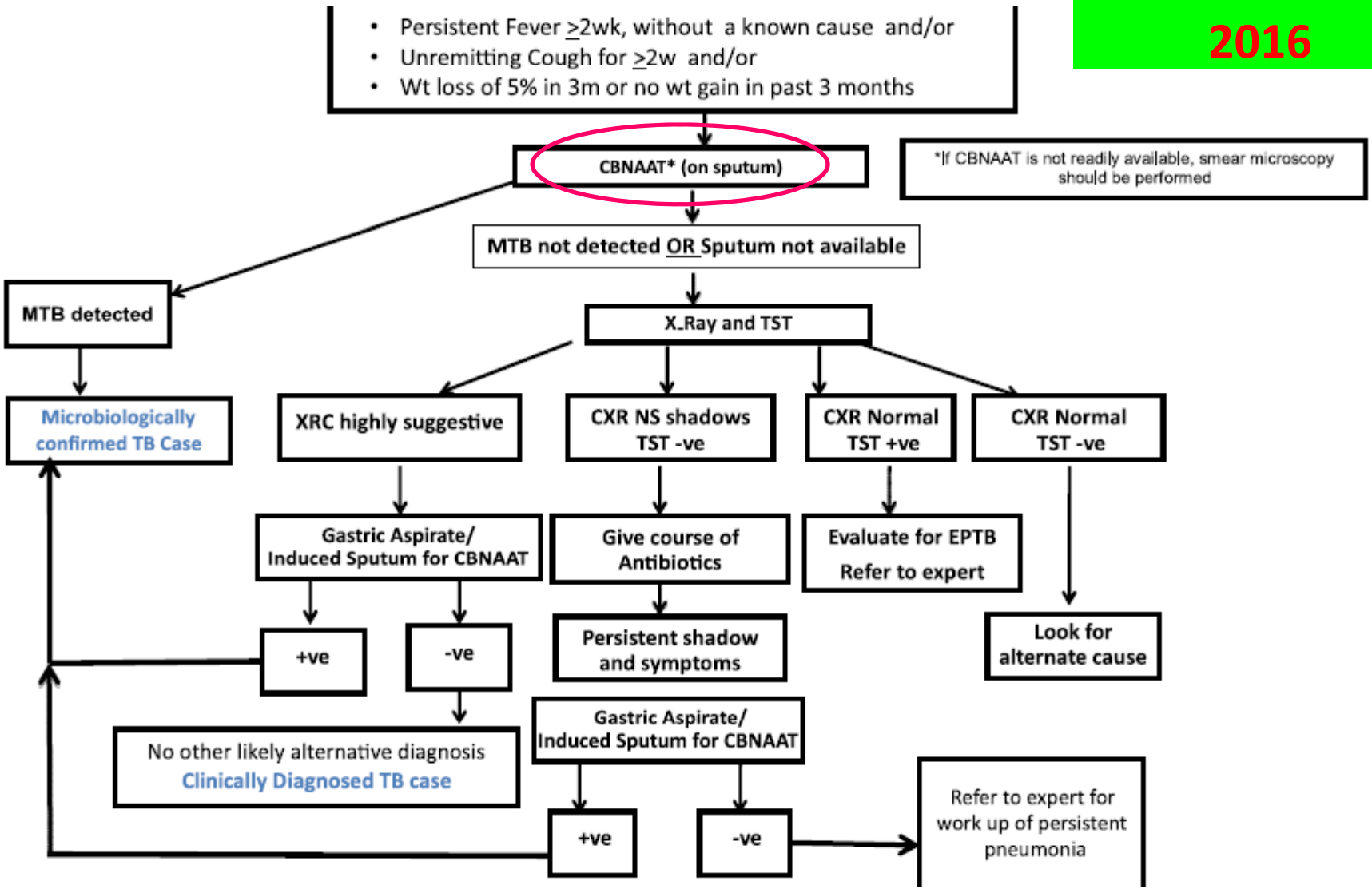
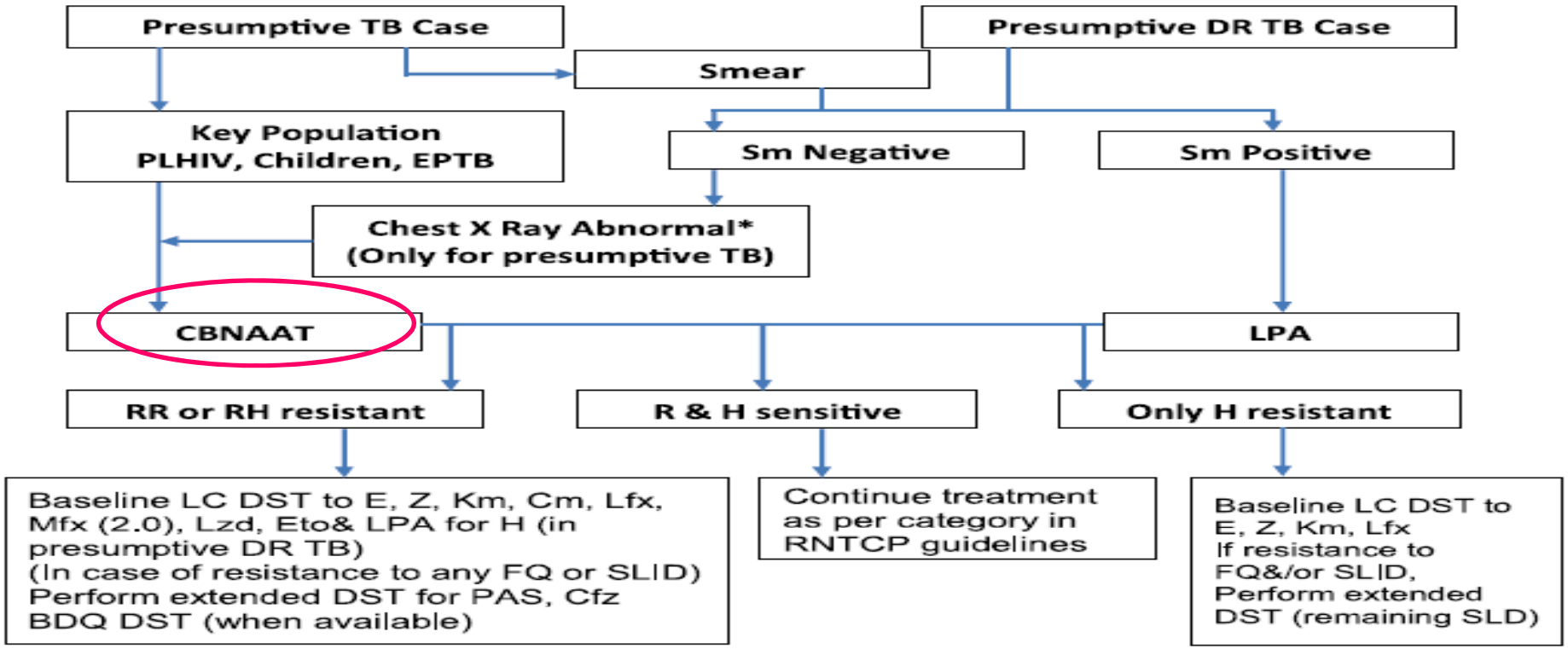


Changes in Diagnostic Protocol…1

Algorithm for detection of DRTB

Revised–TOG RNTCP : March 2016



- If RR by CBNAAT, in addition to other drugs, H resistance (by LPA) to be done and treatment modified accordingly.
- For samples reported by LPA – report must mention H- resistance by Kat G or INH A mutation.
- For new patients (those who do not fit in the definition of presumptive DR-TB case diagnosed as TB with RR by CBNAAT – a second CBNAAT test will be offered along with liquid culture DST

** Those who do not fit in the definition of presumptive DR-TB case*

Changes in Treatment Protocol…2

Present protocol.

- Schedule FU at IP/CP junction & end of treatment only.
- If IP/CP junctional sputum is positive, patients are given one month IP prolongation together with CDST for resistance status.
- Intermittent standardised regimes , i.e Cat I and II are used
- Drug resistant TB patients are being treated with Cat IV and Cat V

Changes in protocol.

1. **FDC is being introduced in country**
   - Fixed drug formulations with daily regimen is introduced
   - Prolongation of IP concept will go.
   - At present only PLHIV will get FDC and daily regime
2. **Extended FU of Cat I and II patients , beyond treatment outcome, up to 2 years.**

Post treatment follow up clinical & sputum

Follow up	Clinical	Sputum CXR	Impression
6 mths of Rx			
12 mths of Rx			
18 mths of Rx			
24 mths of Rx			

3. **Wherever DST pattern of extended panel of drugs would be available to guide the treatment like at six sites where Bedaquiline is introduced initially, the management protocol will follow essentially optimized regimen in case patients are diagnosed with drug resistance other than or in addition to MDR and XDR**

Changes in Treatment Protocol…2

Treatment Regimen for INH mono resistance

- **Mono Drug Resistant TB-**The treatment regimen is consisting of Injectable SLD + FQ Rifampicin + two out of the first line drugs (from H,E & Z) to which the patient is sensitive make a total of 5 effective drugs regimen given daily.

- In case of **reported baseline additional resistance to other FLDs**, the regimen is Inj SLD FQ + Rifampicin + any FLD to which patient is sensitive + one of the remaining Group 4 dru (Ethionamide, Cycloserine ,PAS).

In addition, High Dose INH is added to the regimen if LPA shows inhA mutation or culture repo show low level INH resistance.

The total duration of treatment will be 9 to 12 months. The Intensive Phase (IP) is for 3 mont with scope for extension to a maximum of 6 months. The Continuation phase (CP) is for a fix duration of 6 months. The patient is initiated on treatment at DR-TB Centre, and then sent ba for ambulatory treatment to the DTO for continuation of treatment regimen and regular follow-up

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
Rifampicin Sensitive INH Resistant[1] TB & DST of SEZ not known	(3-6) Km Lfx R E Z *(modify treatment based on baseline DST report to E,Z,KM, CM,Lfx, Mfx)*	(6) Lfx R E Z

Regimen for RR+ INH sensitive/unknown

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
Rifampicin resistant + Isoniazid sensitive or unknown[2]	(6-9) Km LfxEto Cs Z E H	(18)LfxEto Cs E H

Changes in Treatment Protocol…2

Addition of Different DST Guided Regimens

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
MDR or Rifampicin Resistant TB + Ethambutol resistance[1,2]	(6–9) Km Lfx Eto Cs Z	(18) Lfx Eto Cs
MDR or Rifampicin Resistant TB + Pyrazinamide resistance[1,2]	(6–9) Km Lfx Eto Cs E	(18) Lfx Eto Cs E
MDR or Rifampicin Resistant TB + Ethambutol + Pyrazinamide resistance[1,2]	(6–9) Km Lfx Eto Cs PAS	(18)Lfx Eto Cs PAS
MDR or Rifampicin Resistant TB + Levofloxacin	(6–9) Km Mfx Eto Cs Z E PAS Cfz	(18)Mfx Eto Cs E PAS Cfz
MDR or Rifampicin Resistant TB + Moxifloxacin	(6–9) Km Lfx Eto Cs Z E PAS Cfz	(18)Lfx Eto Cs E PAS Cfz
MDR or Rifampicin Resistant TB + Resistance to all Fluoroquinolones	(6–12) Km Eto Cs Z E PAS Cfz Lzd	(18) Eto Cs E PAS Cfz Lzd
MDR or Rifampicin Resistant TB + Resistance to Km only	(6–9) Cm Lfx Eto Cs Z E	(18)Lfx Eto Cs E
MDR or Rifampicin Resistant TB + Resistance to all SL Injectable	(6–12) Lfx Eto Cs Z E PAS Cfz Lzd	(18)Lvx Eto Cs E PAS Cfz Lzd

Change in Protocol on special attention to comorbid conditions…3

- Following comorbid conditions have been given special consideration in TOG
    - HIV and TB
    - TB and diabetics
    - TB and Nutrition
    - TB and Tobacco
    - TB and Silicosis
- Condition wise detailed protocol is mentioned in guidelines

Phase I - Summary details

Sr No	Activity	Status	What is required	Time line
2	• Initiation of treatment for Rif Sensitive and INH resistance cases	• No treatment is offered to this type of TB patients	• Treatment to be offered to this type of TB patients • Sputum samples of cat I , II patients at IP and CP junction to be religiouly sent to available LPA labs (Jaipur,Ajmer,Jodhpur)	Jan 2017
3	• Establish extended FU in basic regimen (Cat I / II) up to 2 years	• Patient are followed up till treatment duration only.	• Training and availabilities of printing materials	
4	• Introduction of Revised recoding/ reporting formats	• Old is in field	•	
5	• Implement activities for comorbid conditions 1. HIV and TB ; 2. TB and diabetics; 3. TB and Nutrition; 4. TB and Tobacco; 5. TB and Silicosis	• HIV-TB is happening	• As suggested in TOG , the activities to be implemented	
6	• Implement * Setting-specific screening strategy	• No Active search	• As suggested in TOG , the active case finding to be implemented	

* Setting- specific screening strategy

- Urban Slums
- Household and Close Contacts of TB
- Health Care Workers
- Malnourished Children
- Antenatal Clinics/MCH clinics
- Prison inmates
- Patients with Co morbidities
- Patients with past history of TB
- Occupational high risk group
- Congregate Settings
- Hard to Reach Areas
- Missed cases in health system

(1) TB and HIV

The salient features

- **Emphasis on Integrated TB and HIV services** e.g. HIV screening at RNTCP DMC
- **Focus on early detection** and early care
  - Early detection of TB in PLHIV
    - four clinical symptoms (current cough, weight loss, fever or night sweats) in all settings
  - Enhance HIV testing facilities in settings with lack of co-located HIV and TB testing facilities, by establishing HIV screening services using whole blood finger prick test (WBT)
- **Focus on early** detection and **early care**
  - Promotion of 'single window delivery services' where in all HIV/TB patients get their
  - TB medications from the ART centres along with ART drugs.
- **Early detection & care of HIV infected Drug Resistant TB patients (DR-TB/HIV)**
- **Prevention of TB among HIV infected adults and children:**
  - Implementation of IPT for all PLHIV (On ART+ Pre-ART)
- **Strengthen HIV/TB activities among children and pregnant women**
- **Promotion of participation of private**, NGO, CBO health facilities and affected communities working with NACP and RNTCP to strengthen HIV/TB collaborative activities
- **Airborne Infection control activities at all the institutions**

(2) TB and Diabetes

- The Epidemic of DM is rapidly growing because of urbanization, social/economic development
- India has largest no. of diabetic case in the world (66 million)
- Diabetic has 2-3 time chance of getting TB because of imunologicaocal disturbances
- About 10 % of TB cases globally are linked with DM
- The purpose is to articulate the national strategy for TB Diabetes Mellitus Collaborative Activities between RNTCP and NPCDCS so as to ensure reduction of TB and diabetes in India. Following are the strategy points
  - Establish joint planning and review committee for collaboration at National, State and dist level
  - Establishment of service delivery protocol that address the joint activities
    - Screening of all diabetic patients for TB- four symptom screening
      - Cough any duration, Fever, Wt loss, Night Sweat
      - Results are recorded on NPCDCS register
      - NCD clinic will implement basic infection control measures
  - Establishments of linkages
  - Joint monitoring and supervision with standardized reporting protocol
  - Joint training of health staff
  - Awareness / IEC activities
  - Operational research
- Mechanism for collaboration between RNTCP and NPCDCS
  - National TBDM Coordination Committee
  - State TBDM Coordination Committee under the chairmen ship of MDNHM
    - State may create sub –committees for TB-DM, TB-Tobacco, TB Alcohol (state even can start with separate committee for this activity)
  - Dist TBDM Coordination Committee, under the chairmanship of DM

Diagnosis	Fasting Glucose (mg/dl)	2-hour Post-Load Glucose (mg/dl)
Diabetes Mellitus	>=126	>=200
Impaired Glucose Tolerance	<110	>140 to <200
Impaired Fasting Glucose	>=110 to <126	

(3) TB and Nutrition

- Under nutrition is considered as one of the risk factors in the development of TB since under nutrition is known to adversely affect the immune system. The document recommends that
  - Conducting initial assessment of TB patients with further monitoring
  - Provide ongoing counselling on nutrition status
  - Management of sever acute malnutrition
  - Management of moderate under nutrition
  - Micronutrient supplementation.
- It can done through existing PDS, local self government or NGO or donor agencies , CSR

(4) TB and Tobacco

- India is 2 nd largest consumer and 3 rd largest producer of tobacco in the world(FAO 2005)
- One million Indians die from tobacco use every year which is much more combined mortality of HIV-AIDS; TB and Malaria
- As per Global Adult Tobacco Survey (GATS 2010, a house hole survey , persons more than 15 yrs) 275 million adult tobacco users in India
- It is estimated more than one third (35 %) of adults in India uses the tobacco in some other form
- The prevalence of smokeless tobacco use (26 %) is almost double than smoking tobacco (14 %)
- Almost 38 % of deaths are associated with tobacco users
- Prevalence of TB is 3 times as high among ever smoker /never smokers

Involvement of National Tobacco Control program in TB Control

For enhancing active screening of TB patients through RNTCP, the following process is indicated-

Screening of four symptoms of active TB among tobacco users in NCD clinics etc

Conduct follow up of comorbid patients registered as TB for TB relapse cases

Active screening for TB among those enrolled in Tobacco cessation program

Tobacco training modules should contain information on TB symptoms

(5) TB and Silicosis

Occupational high-risk group: Although reliable statistics are not available in India, it is known that thousands of workers and local residents are exposed to hazardous silica levels during stone crushing operations. Studies have shown increased morbidity and mortality rates among stone crushing mill workers from silicosis, lung cancer, and other lung diseases. Several other occupations also increase risk for tuberculosis including coal and other mining, tobacco (bidi rolling) and carpet weaving. Vulnerable and socially marginalised groups including tribal communities, children and migrant population are often used in these industries and do not have access to routine health services.

The RNTCP is in process of engaging with the Ministry of Labour and Mining to identify high priority districts with stone crushing units / mining industry. The specific guidelines will be developed to support persons with an occupational risk for TB and provide access, diagnosis and treatment services from the programme.

Preparation of district wise action plan on Setting-specific screening strategy

(1) Setting- specific screening strategy

- **Urban Slums**
  - House to house, periodic symptom screening of all the mapped urban slums to actively screen for presumptive TB cases.
  - Liaising with NUHM, NPSP and other departments delivering health care services in urban slums for mapping and line listing of providers
  - Utilization of Urban slum schemes as in the revised NGO-PP partnership guidelines.
- **Household and Close Contacts of TB**
  - Household contact
  - Close contact:-
- **Health Care Workers**
  - Pre -placement screening & routine annual screening with Chest radiography of all the health care workers is strongly recommended.
  - If Health care worker surveillance is an existing policy in the health institution, facility or department then chest X-ray screening may be added on to the protocol.
  - Healthcare workers presenting with symptoms of TB should be evaluated.
- **Malnourished Children**
  - Active screening for TB symptoms with chest X-ray as the screening tool (or symptom screening if X- ray is not available) should be undertaken among children with malnourishment that attend any health facility
  - Engage and collaborate with Nutritional Rehabilitation Centres for routine screening of TB in malnourished children attending these centres.
  - Regular symptomatic screening of malnourished children attending the Anganwadi centres
- **Antenatal Clinics/MCH clinics**
  - TB Symptoms screening must be undertaken for all mothers attending the antenatal clinics at every visit and those who are symptom screen positive must be immediately linked to the nearest laboratory for early TB diagnosis and decision on TB treatment initiation.
- **Prison inmates**
  - Symptom screening at **Entry;** when prisoners enter the prisons.
  - **Periodic mass screening** with chest X-ray. If chest x-ray is not available then symptom screening should be done.

(2) Setting- specific screening strategy

- **Patients with Co morbidities**
  - malignancy, on dialysis, on immune-suppressants, long term steroids have higher risk of tuberculosis - Symptom screening for TB should be done on all patient visits to the health facilities for follow up examinations
- **Patients with past history of TB**
  - Active symptom screening by health staff may be undertaken by visiting the homes of those patients at prescribed intervals
  - House to house visits may be undertaken of all patients notified and treated by private sector to screen for TB symptoms at prescribed intervals.
- **Occupational high risk group**
  - Screening should be done by X-ray and in case X-ray is not available then symptom screening should be done by holding periodic health camps
- **Congregate Settings**
  - transit camps, night shelter, old age home, orphanages and de addiction centres
- **Hard to Reach Areas**
  - Symptomatic screening may be done by holding periodic health camps or even by house to house survey
  - Mobile medical units equipped with microscopes and digital X-ray machines available under NHM can be used.
  - Sputum collection centres must be planned & established in strategic locations with the help of local NGOs
- **Missed cases in health system**
  - Establish sputum collection centres in all the primary health centres which do not have DMC
  - Enhancing the skills of MOs by providing special training package on interpretation of X-ray.
  - Wherever X-ray &histo-pathological/FNAC services are not available then outsourcing these services should be done

Establishment of Partnerships..1

Considered Under 4 thematic areas

1. **ACSM**
2. **Diagnosis and treatment**
3. **TB & Co – Morbidities**
4. **Programme management**

- Activities proposed
  1. **Engagement of professional associations** like IMA, IAP, INA, IPHA etc in knowledge sharing (RNTCP/STCI)
  2. **Pharmacist/chemists involvement**
     - RNTCP has signed MOU with IPA (Indian Pharmaceutical Association, AIOCD (All India Organization of Chemists & Druggists), PCI (Pharmacy Council of India , SEARPharm Forum representing WHO, FIP (International Pharmaceutical Federation Forum of National Associations In South East Asia for engaging pharmacist in RNTCP.
     - Pharmacist should be involved for early identification and referral of presumptive TB case for diagnosis/treatment supporter/increasing community Awareness on TB/MDRTB/patients education and counselling/promoting rational use of Anti TB drugs contributing to DRTB

Establishment of Partnerships..2

3. Laboratory involvement

- To reach all TB patients , India need to include dominant private sectors and pvt laboratories
- Pvt laboratories are engage through parternes options under national guidelines of partnerships
- One such mechanism is IPAQT (Initiative for Promoting Affordable , Quality TB Test) by which WHO and GOI approved lab test cane used in affordable price- this need to be promoted.
  - Under this mechanism there many labs have agreed for upper ceiling of prices, notifying cases to govt, and participating in EQA

4. Involvement of medical colleges

- Being higher institute, the involvement of medical college in RNTCP is of paramount importance.
- It is involved under the mechanism of task force and core committee in each medical college.
  - NTF – National Task Force; NTF review the performance of ZTF yearly
  - ZTF- Zonal Task Force (zone wise); ZTF reviews performance of STF every
  - STF- State Tsak Force (each state), STF reviews performance of each medical from the state
  - CC in each college reviews the activities in medical college every quarterly
- The activities in the medical need to be accelerated as RNTCP provides MO, LT and TBHV
- Colleges need to be promoted to come forward to support by establishing C & DST labs; DRTB centers, promote OR / thesis etc

Patients support…1

- **Adherence to regular and complete treatment** is the key to relapse free cure from TB.
- **To assess and foster adherence**, a patient-centred approach based on the patient's needs and mutual respect between the patient and the provider, should be developed for all patients
- **Treatment can be provided by**
  - DOT by Health worker in institutional situations
  - peripheral health worker in the public health system
  - a family member (sick and bed ridden patients, children, long-day workers ,PLHIV,etc.)
  - Information Communication Technologies (ICT) enabled adherence systems can be developed
    - frequent calls, SMS reminders, IVRS etc
    - For Frequent on-job travelers, truck drivers, sailors
- **Mobility support –**
  - if s/he prefers observation of treatment outside his residence.
  - Counselling may be required to quit substance abuse.
  - Nutritional assessment & support, ancillary drugs, co-morbidity management, compensation for lost wages etc. are some other requirements.
  - Healthcare providers should endeavor to derive synergies between various social welfare support systems like
    - RSBY / TB pension schemes / national rural employment guarantee scheme/ corporate social responsibility (CSR) initiatives/ Counselling centers etc.to mitigate out of pocket expenses such as transport and wage loss incurred by people affected by TB.

Patients support…2

- **All individuals** with active TB should receive
  - an assessment of their nutritional status and
  - appropriate counselling based on their nutritional status at diagnosis and throughout their treatment.
  - If malnutrition is identified, it should be managed according to WHO recommendations. Linkages for extra nutritional support for TB patients or of his/her contacts on IPT may be explored with existing Govt. schemes like public distribution system (PDS) or Food security act.
  - Under the programme, compensation is provided for transport costs incurred by DR TB patient for sending specimen for follow up or for travel to DR-TB centre.

- **Compensation** is provided for transport
  - Costs incurred by DR TB patient for sending specimen for follow up or for travel to DR-TB centre.
  - In addition, TB patients in tribal and difficult areas get Rs. 750.
  - Treatment supporters are also provided incentive to ensure completion of treatment

Nikshay

- Nikshay should be the utmost priority
- All the DTCs/IRL-STDC /CBNAAT site to complete previous pending entry and
- Continue to keep ongoing data entry regular

Notification

- Public sec at PHI level in NIKSHAY
- Private sec NIKSHAY self/DTO

Drug Manegment

- Stock at PHI one month

Thank You