







February 2021

Collaborative Framework for Management of Tuberculosis in Pregnant Women

February 2021

Ministry of Health and Family Welfare Government of India

Published by:
Ministry of Health and Family Welfare
Nirman Bhawan, Maulana Azad Road
New Delhi - 110011
www.mohfw.gov.in / www.mohfw.nic.in

Developed with Technical Support from: USAID - NISHTHA / Jhpiego

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FOREWORD

भारत सरकार स्वास्थ्य एवं परिवार कल्याण विभाग स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India
Department of Health & Family Welfare
Ministry of Health and Family Welfare

India has witnessed an exciting phase of development in healthcare delivery. Our success in eliminating Polio, Maternal and Neonatal Tetanus has spurred us to set ambitious targets for fulfilling our commitments towards a vision of Healthy India.

The ongoing efforts identify pregnant women as one of the groups needing special attention who can develop infections such as Tuberculosis (TB) shortly before or after delivery. The risk of activation of latent TB infection is much higher during pregnancy as a result of the immunological changes.

India accounts for a quarter of the global tuberculosis burden. In our fight against TB, the honorable Prime Minister has set a bold target of a TB-free India by 2025, five years ahead of the SDG targets of 2030. The Ministry of Health and Family Welfare has worked tirelessly to improve the quality of treatment and create comprehensive support systems for TB patients.

Early diagnosis and treatment of TB in pregnancy would not only reduce the adverse effects of maternal TB, but also reduce overall burden of childhood TB in India.

In this context it is important to build a response mechanism for early identification of maternal TB and integrate these services at the patient's first point-of-care to achieve "Health for All". I am glad to present this national framework for Management of Tuberculosis in Pregnant Women produced jointly by the Central TB Division (CTD) and Maternal Health (MH) Division of Government of India (Ministry of Health and Family Welfare).

I congratulate both the divisions in coming together and producing this important framework which will guide the country in its efforts to eliminate TB, especially among the pregnant women. Let us all work together to eliminate TB and ensure no mother dies due to this disease in our country.

Let's Unite to End TB!

Date: 03 February 2021

Place: New Delhi

(Rajesh Bhushan)



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January 22, 2021

MESSAGE

TB is the leading infectious killer in India that affects all irrespective of age or gender and every step taken towards the elimination of this disease is a step towards improving the lives of millions of families in the country. An important step in this direction is multi-sectoral collaboration to ensure a comprehensive approach to ending TB. India has been intensifying its efforts in accelerating the TB response, with the engagement of multiple stakeholders.

One such multi-sectoral collaboration is by the Central TB Division and Maternal Health Division of Government of India to address the emerging issue of pregnancy in TB. During pregnancy, tuberculosis is associated with poor outcomes, including increased mortality in both the neonate and the pregnant woman. In addition, social constraints and relationships can restrict women from freely accessing care in a timely manner and as such women remain a vulnerable group.

This framework developed jointly by the Central TB Division and Maternal Health Division of Government of India is a key collaborative step taken to address the issues of pregnant women across the country who may be impacted by this dangerous disease. It is important that we sustain our efforts in addressing the TB epidemic impacting the lives of not only pregnant women but also the neonates and in turn their families.

In order to sustain the efforts, we need to create systems that support and empower pregnant women to access care. This will help us to better address the impacts of the TB epidemic and pave the way for better healthcare for all women and improve case finding overall.

I call upon all the stakeholders to further strengthen this collaboration and drive sustained actions towards our efforts in eliminating TB especially among the pregnant women.

(Arti Ahuja)



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MESSAGE

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Women are strong pillars of any vibrant society. Evidence shows that women's health is a good indicator of economic development in a country. When women are healthy, economies tend to be healthy.

Motherhood is an event of joy and celebration for every family. However, high maternal mortality during pregnancy and childbirth is a matter of great concern worldwide. The causes of maternal death are now shifting. This includes non-obstetric causes-including HIV-related conditions, infectious diseases such as TB and other pre-existing medical conditions which account for nearly a third of maternal deaths and a host of maternal newborn health complications.

TB mainly affects women when they are economically and reproductively active, the impact of the disease is also strongly felt by their children and families. As tuberculosis mostly occurs in young women, many infected women are diagnosed having the disease during pregnancy, while others become pregnant during anti-tuberculosis medication; and more importantly, a significant proportion remain undiagnosed and suffer worse maternal and perinatal consequences.

A mother's well-being is intimately linked to that of her children. TB may spread from mother to child during pregnancy which in turn disrupts the whole family. In addition, the gendered vulnerabilities that women face further compound the problem which results in delay in seeking care.

The national framework on management of tuberculosis in pregnant women is a significant step taken towards addressing tuberculosis in pregnancy. I congratulate the Central TB Division and Maternal Health Division of Government of India (Directorate General of Health Services, Ministry of Health and Family Welfare) for their efforts in developing this framework which is the need of the hour.

I am confident that the implementation of this framework will ensure prompt, accurate diagnosis and timely treatment of TB among pregnant women which will go a long way in saving the lives of affected women and their children.

(Vandană Gurnani)





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MESSAGE

Tuberculosis remains a global health emergency and continues to present major public health challenges worldwide. Tuberculosis is also one of the principal causes of death in women of reproductive age and is a common non-obstetric cause of maternal mortality.

Women of reproductive age group (15-49 years) bear a significant burden of TB in India. When a mother has TB, it is dangerous not only for her but also for her baby. Women infected with TB are twice as likely to have a premature or underweight baby, and the baby can be born with congenital TB. Further the burden of tuberculosis disease specifically among pregnant women is largely not known and no systematic efforts have been made to detect TB among pregnant women, especially in high prevalent countries.

The National TB Elimination programme (NTEP) has undertaken many new initiatives and policy changes over the last few years. It is also working to ensure smooth and sustained coordination among different departments and ministries to ensure convergence of efforts. Once such endeavor is with the Maternal Health Division to develop this National Framework on Management of Tuberculosis in Pregnant Women

This is another major step towards the goal of Ending TB in India by 2025. The National Strategic Plan 2017-2025 envisages that early diagnosis and treatment of TB in pregnancy will not only reduce the adverse effects of maternal TB but will also reduce the overall burden of childhood TB in India

I would like to congratulate and thank all the partners who have been instrumental in bringing together this framework, and I am confident that together we can achieve elimination of TB from this country.

TB Harega, Desh Jeetega!

(Vikas Sheel) (Joint Secretary, NTEP)



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MESSAGE

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Tuberculosis is the leading infectious cause of death in women worldwide. It is one of the biggest non-obstetric causes of mortality in women of child-bearing age, and a major killer of the young. Tuberculosis remains a public health challenge in India, impacting the lives of numerous families every year.

For pregnant women in most countries with a high tuberculosis burden, the current standard practice of care for tuberculosis screening and diagnosis is the same as that used to detect the disease in the general population. This makes them more vulnerable to the disease. Thus, it is important to integrate TB with other health services such as family planning, maternal and child health etc. that can augment active TB case finding and ensure treatment adherence.

As a result, the Central TB Division and Maternal Health Division teamed up to collaborate on the development of this national framework, with an aim to integrate TB and Maternal Health services. This will go a long way to ensure that pregnant women are screened for TB as part of their regular antenatal checkup and mitigate barriers to accessing quality TB care.

The framework highlights integrations in service delivery, setting up of co-ordination mechanisms between the divisions, sensitizing the health service providers, information education and communication activities and monitoring mechanisms. I am grateful to all those who have provided valuable inputs to this document.

NTEP remains committed to pioneering paradigm shifts in the response to TB while building comprehensive preventive and curative services through a multi-sectoral and integrated approach to end the scourge of TB.

(Dr. K. S. Sachdeva)

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MESSAGE

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India has made significant progress in improving maternal health in recent years and has progressed towards achieving National and Global targets of Maternal Mortality Reduction. Tuberculosis is one of the non-obstetric causes which contribute to maternal mortality.

Women of reproductive age group (15-49 years) bear a significant burden of TB in India and globally. TB among pregnant women can adversely affect the health of the mother, fetus, neonate, and their children with a wide spectrum of short- and long-term implications.

Keeping these issues in mind, the national guideline has been developed jointly by the Central TB Division and Maternal Health Division of Government of India This is one of the major steps towards the goal of "Elimination of TB in India" by 2025, which envisages early diagnosis and treatment of TB in pregnancy would not only reduce the adverse effects of Maternal TB but also reduce the overall burden of childhood TB in India.

I am sure that this guideline will help the States and UTs, Mission Directors and programme officers to ensure early detection and timely management of TB cases in pregnant women in India.

(Dr Teja Ram)





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ACKNOWLEDGEMENT

Tuberculosis remains a global health emergency and is continues to be a major public health challenge worldwide. Govt of India has expressed its strong commitment to achieving the SDG Goal of ending TB by 2025, five year ahead of the global timelines.

The collaborative framework for the management of Tuberculosis in Pregnant Women have been developed with the intent to integrate Tuberculosis and Maternal Health services. Through this, we are ensuring the screening of all pregnant women for TB as a part of their regular antenatal checkup and mitigate barriers to accessing quality TB care.

I extend my heartfelt thanks to Shri Rajesh Bhushan, Secretary (Health & Family Welfare) for guiding us in framing the guidelines. I am also grateful to Ms Vandana Gurnani, AS & MD(NHM), Mr Vikas Sheel, Joint Secretary JS(P), Preeti Pant, JS(RCH) for their unflinching support.

I also wish to acknowledge my colleagues in TB division Dr Sanjay Mattoo, Joint Director CTD, Dr K S Sachdeva, DDG TB and their team comprising Dr Priyanka Agarwal and Dr Deepak Balasubramanium for this integration.

The efforts were undertaken by our colleagues Dr Tejaram (Joint Commissioner), Dr Padmini Kashyap (Assistant Commissioner), Dr Ashish Chakraborty (Assistant Commissioner) and the Maternal Health team comprising Dr Bhumika Talwar, Dr Santosh Ojha, Dr Tushar Purohit and Dr Surbhi Seth) is deeply appreciated.

I am confident that these guidelines will serve as an effective tool to guide States and UTs in this important initiative and ensure effective implementation of the programme.

(Dr. S.K Sikdar)

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Technical support, facilitation and layout

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Acknowledgements >>>

Considering India's commitment to ending TB, the National TB Elimination Program is adopting a comprehensive approach and collaborating with different departments and ministries to ensure convergence of efforts.

Women of reproductive age bear a significant burden of TB in India. The burden of TB in pregnant women is largely not known and no systematic efforts have been made to address the issue of TB in pregnant women. In view of this, Central TB Division in collaboration with Maternal Health Division constituted the National Technical Expert Committee on TB in Pregnant Women in 2018 to develop the collaborative framework for management of TB in pregnant women.

We thank all the members of the Expert Committee for their participation in the various meeting and their technical inputs towards the framework. The members of the Expert Committee include Dr. Anjali Tempe - Professor & Head, Dept. of Obs & Gyn., MAMC & L N hospital, New Delhi; Prof (Dr.) Narayan Jana - Professor & Head, Department of Obstetrics and Gynecology, CRSS College of Obstetrics, Gynecology and Child Health, Kolkata, India; Dr J B Sharma - Professor, Department of Obstetrics & Gynecology, AIIMS New Delhi; Dr Rohit Sarin - Principal Consultant (NITRD) & Technical Advisor (NTEP), Central TB Division, MoHFW; Dr Urvashi B Singh - Professor, Chief, Tuberculosis Section Department of Microbiology, AIIMS, New Delhi; Dr Beena Thomas - Social Scientist and Former Head of the Department of Social and Behavioral Research ICMR-NIRT, Chennai; Dr Jaikishan Karahyla - Professor & Head, MM Institute of Medical Sciences, Ambala, Haryana; Dr. Amardeep Tembhave - Associate Professor, Obs. &Gyn., MGIMS Wardha; Dr Suman Vishwakarma - Deputy CS (TB) Bhiwani, Haryana; Dr Lakshmi Murali - DDMS (TB), Tiruvallur, Tamil Nadu; Dr. Upasna Aggarwal -Specialist (SAG), NITRD, New Delhi; Ms Amrita Pitre - Lead Specialist, Gender Justice at Oxfam India; Ms Anupama - Assistant Director, REACH; Dr Sundari Mase-ex-Medical Officer (TB), WHO country Office, New Delhi; Dr Ashber G - Health Specialist, UNICEF; Dr Apurva Chaturvedi - Health Specialist, UNICEF; Dr Salima Bhatia - National Consultant, UNICEF; Dr Ajay Patle - Lead Health System Strengthening, NISHTHA/Jhpiego.

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We thank the NISHTHA/Jhpiego team for providing technical inputs for development of the document and also facilitating the layout and design of the document. Our sincere gratitude to the USAID for supporting the development of this document through NISHTHA/Jhpiego. We hope the framework will ensure the provision of integrated services for management of TB in pregnant women in both private and public sectors.

Abbreviations

ACSM Advocacy, Communication, and Social Mobilization

ANC Antenatal care

ANM Auxiliary Nurse Midwife
APO Assistant Program Officer

ASHA Accredited Social Health Activist

BCG Bacille Calmette Guerin

BMI Body Mass Index

BMO Block Medical Officer

CB NAAT Cartridge Based Nucleic Acid Amplification Test

CHC Community Health Centres
CHO Community Health Officer
CME Continuing Medical Education

CTD Central TB Division

DDG TB Deputy Director General TB

DCC District Coordination Committees

DEO Data Entry Operator

DMC Designated Microscopy Centre

DNO-MH District Nodal Officers – Maternal Health
DOTS Directly Observed Treatment, Short course

DR-TB Drug Resistant Tuberculosis
DTC District Tuberculosis Centre
DST Drug-Susceptibility Testing

HIV Human Immuno-deficiency Virus

HRP High-risk Pregnancy

HWC Health and Wellness Centres

ICT Information Communication Technology
IEC Information Education Communication

IFA Iron and Folic Acid
INC Intra-natal care

INH Isoniazid

IRL Intermediate Reference Laboratory
JSSK Janani Shishu Suraksha Karyakram

JSY Janani Suraksha Yojna

LED-Florescence Microscopy

LPA Line Probe Assay
LT Lab Technician

MH Maternal Health

MCPMother and Child ProtectionMDR-TBMultidrug resistant Tuberculosis

M&E Monitoring and Evaluation

MoHFW Ministry of Health and Family Welfare

MO Medical Officer

MO-I/C Medical Officer-Incharge
MO-TC Medical Officer - TB Control

MTP Medical Termination of Pregnancy

NHM National Health Mission NPY Nikshay Poshan Yojana

NRL National Reference Laboratory

NTEP National Tuberculosis Elimination Program

OPD Out-patient Department
PDS Public Distribution System
PHC Primary Health Centre

PHI Peripheral Health Institution

PMSMA Pradhan Mantri Surakshit Matritva Abhiyan

PNC Post Natal Care

RCH Reproductive and Child Health

RNTCP Revised National Tuberculosis Control Programme SCC State TB-Comorbidity Coordination Committee

SN Staff Nurse

SNCU Sick Newborn Care Unit SNO State Nodal Officer

STDC State Tuberculosis Training and Demonstration Centre

STO State Tuberculosis Officer

STLS Senior Tuberculosis Laboratory Supervisor

STS Senior Treatment Supervisor STWG State TB Working Group

TB Tuberculosis

TB HV Tuberculosis Health Visitor

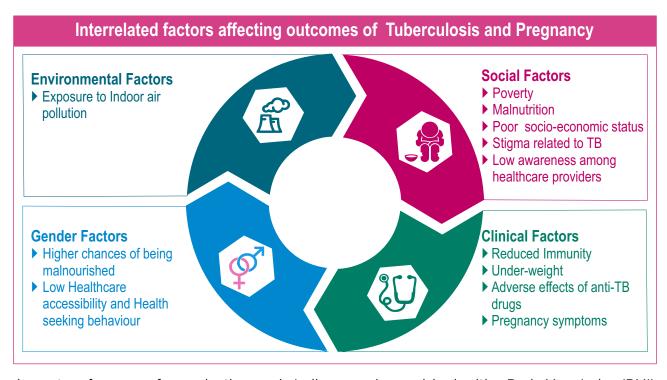
TU Tuberculosis Unit

VHSND Village Health Sanitation and Nutrition Day

WHO World Health Organization

Introduction

Tuberculosis (TB) remains a major public health challenge worldwide. Women of reproductive age group (15-49 years) bear a significant burden of TB in India and globally. TB among pregnant women can adversely affect health of the mother, fetus, neonate, and child with wide spectrum of short and long-term implications. TB in pregnancy can have serious and sequential effects: repeated reproductive failure, fetal ill-health, preterm delivery, and TB of the newborns and infants, leading to high maternal and perinatal morbidity and mortality. Although, these issues have been reported widely from several countries including India, no systematic efforts have been made to detect TB among pregnant women, especially in high prevalent countries, which bear a higher burden of maternal TB.



A quarter of women of reproductive age in India are undernourished, with a Body Mass Index (BMI) of less than 18.5 kg/m (Source: NFHS 4 2015-16). Undernutrition in patients with active TB is associated with a two-to four-fold increase in mortality, five-fold risk of drug-induced hepatotoxicity, and patients are unable to regain a normal weight, despite effective treatment, in the setting of poverty and food insecurity. Evidence suggests that nutritional interventions are associated with better outcomes in TB patients including reduced mortality, improved weight gain and body composition, earlier sputum conversion, improved pharmacokinetics of key drugs, improved functional status and adherence to therapy (Guidance document: Nutrition care and support for patients with Tuberculosis in India, MoHFW, 2017).

Keeping these issues in mind, this national guideline has been developed jointly by the Central TB Division and Maternal Health Division of Government of India after wide consultation with

stakeholders. This is one of the major steps towards the goal of 'Elimination of TB in India' by 2025, which envisages that early diagnosis and treatment of TB in pregnancy would not only reduce the adverse effects of maternal TB, but also reduce overall burden of childhood TB in India.

Burden of tuberculosis in India

According to WHO, nearly 26.9 lakh people fell ill with TB in India in 2018, which alone accounted for more than a quarter of the world's TB burden (1,2,3). In India, women of reproductive age (15 to 49 years) face a substantial burden contributing approximately 26% of all TB cases notified in 2019. Moreover, the risk of activation of latent TB infection is much higher during pregnancy as a result of the immunological changes (Bates M, Ahmed Y, Kapata N et al. Perspectives on tuberculosis in pregnancy. International Journal of Infectious Diseases 32 (2015) 124–127). Unfortunately, women are most profoundly affected by tuberculosis, which is the third leading cause of death among women of reproductive age. As tuberculosis mostly occurs in young women, many infected women are diagnosed having the disease during pregnancy, while others become pregnant during antituberculosis medication; and more importantly, a significant proportion remain undiagnosed and suffer worse maternal and perinatal consequences (4). Therefore, it is pertinent to address the issues of TB among pregnant women in India with a special focus.

TB in pregnancy

The prevalence of TB among pregnant women is largely unknown. The incidence of tuberculosis in pregnancy is not readily available in many countries due to a lot of confounding factors. However, it is expected that the incidence of tuberculosis among pregnant women would be as high as in the general population, with possibly higher incidence in developing countries (5). Two independent estimates suggest that the burden of active TB cases in pregnant women in India is substantial (4,6). In a recent epidemiological modelling study, Sugarman et al. estimated that there may have been 216,500 (95% uncertainty range 192,000- 247,000) active TB cases among pregnant women globally in 2011(6). For India alone, their estimated burden of active TB among pregnant women was 44,500 (95% uncertainty range 36,000-62,000), which contributes 20.6% of global burden of all active TB among pregnant woman (4). Considering the incidence of tuberculosis among women of reproductive age (around 100 cases per 100,000 populations) and a total of 26 million births annually, Jana et al. estimated that approximately 20,000 to 40,000 pregnant women are likely to suffer from active TB in India annually (4). Although congenital TB occurs rarely, there is a significant risk of transmission to infant in postpartum period as a result of inhalation of droplets coughed out by the mother (Repossi AC, Bothamley GH. Tuberculosis and pregnancy: an updated systematic review. Pulm Res Respir Med Open J. 2015; 2(1): 63-68.

Impact of Pregnancy on TB

Pregnancy masks the effects and symptoms of tuberculosis, while these effects are exacerbated in the immediate postpartum period. Early postpartum women are twice as likely to develop tuberculosis as non-pregnant women (MathadJS, Gupta A. Tuberculosis in Pregnant and Postpartum Women: Epidemiology, Management, and Research Gaps. Clin Infect Dis. 2012 Dec, 55(11):1532-49.

Impact of TB on Pregnancy

The presence of tuberculosis disease during pregnancy, delivery, and postpartum is known to result in unfavorable outcomes for both pregnant women and their infants, which is compounded by the late presentation, non-specific symptomatology delaying diagnosis and need for prolonged medication (4,7-16). These outcomes include a roughly two-fold increased risk of preterm birth, low birthweight, intrauterine growth restriction, and a six-fold increase in perinatal death (7). (Figure 1).

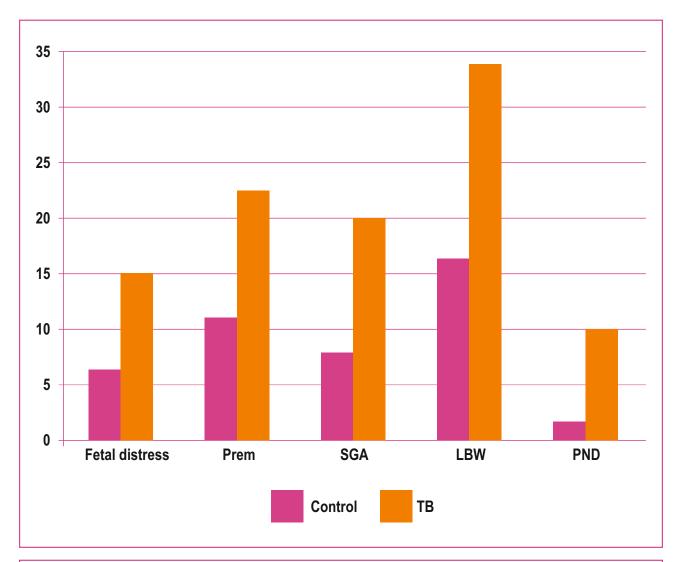


Figure 1: Perinatal outcome in pregnancies complicated by pulmonary tuberculosis (Data from Jana et al. 1994; reference 7. Prem. - Prematurity; SGA - Small for gestational age; LBW - Low birthweight; PND - Perinatal death. Data in Y-axis is expressed in percentage)

With the exception of tuberculous lymphadenitis, extrapulmonary tuberculosis – abdominal, vertebral, renal, and meningeal involvement – has adverse outcomes for pregnancy including increased antenatal hospitalization and perinatal complications (9,10). Recent systematic analysis which included studies from India (7,9) and other countries (15-17) clearly showed that "active TB in pregnancy is associated with adverse maternal and fetal outcomes." (8). Compared with pregnant

women without TB, pregnant women with active TB were associated with significantly increased risks of overall maternal morbidity [odds ratio (OR) 2.8], maternal anemia (OR 3.9), caesarean section (OR 2.1), preterm birth (OR 1.7), low birth weight neonates (OR 1.7), birth asphyxia (OR 4.6), and perinatal death (OR 4.2) (8). Recent Indian studies also re-affirmed these adverse effects of TB involving pulmonary and extrapulmonary sites on maternal and perinatal morbidity and mortality (10,14). A recent post-mortem analysis of maternal deaths highlights that infection, including TB, is an important contributor to maternal death in India (18). Furthermore, it has been emphasized that TB results in nearly 10 million cumulative orphans because of parental deaths, which include maternal mortality due to TB (19). Therefore, active tuberculosis poses grave maternal and perinatal risks, for which early diagnosis, and appropriate and adequate anti-tuberculosis treatment of the mothers are mainstay for successful pregnancy outcomes (4,20). Maternal care services could be used as a platform to improve case detection (19).

Recently, WHO recommended that "in settings where the tuberculosis prevalence in the general population is 100/100 000 population or higher, systematic screening for active TB should be considered for pregnant women as part of antenatal care "(21).

National Programmes for TB and Maternal Health

National Tuberculosis Elimination Programme

The Revised National Tuberculosis Control Programme (RNTCP), based on the internationally recommended Directly Observed Treatment Short course (DOTS) strategy, was launched in 1997 and expanded across the country in a phased manner with support from World Bank and other development partners. Complete nationwide coverage of RNTCP was achieved by March 2006. In terms of treatment of patients, RNTCP has been recognized as the largest and the fastest expanding TB control programme in the world. The RNTCP programme was renamed as National Tuberculosis Elimination Programme (NTEP) in January, 2020 with the aim to eliminate TB by 2025.

Programme Structure

The structure of NTEP comprises of five levels, as follows: (1) National (2) State (3) District (4) Subdistrict (5) Peripheral Health Institutions. A major organizational change is the creation of a subdistrict level – the Tuberculosis Unit (TU) for the systematic monitoring and supervision of diagnostic and treatment aspects of the programme.

National Level (Central TB Division)

The Central TB Division (CTD) is a part of Ministry of Health and Family Welfare (MoHFW), and is responsible for tuberculosis control in the whole country. A National Programme Manager – the Deputy Director General TB (DDG TB) heads this programme. The programme is being implemented under the umbrella of the National Health Mission (NHM).

State Level

At the State level, the State Tuberculosis Officers (STOs) are responsible for planning, training, supervising and monitoring the programmes in their respective states as per the guidelines of the state health societies and technically following the instructions of the CTD for programme implementation.

District Level

The district is the key level for the management of primary health-care services. The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district. The District TB Officer (DTO) at the DTC has the overall responsibility of physical and financial management of NTEP at the district level as per the guidelines of the District Health Society.

Sub-district Level -Tuberculosis Unit (TU)

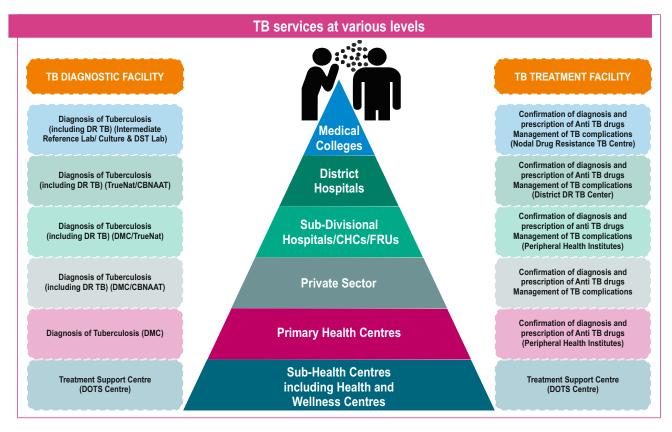
The TU is the nodal point for TB control activities in the sub-district. A team comprising a specifically designated Medical Officer–TB Control (MO–TC), Senior Treatment Supervisor (STS) and Senior Tuberculosis Laboratory Supervisor (STLS) at the TU have the overall responsibility of management of NTEP at the sub-district level. There are 6,264 TUs functioning in the programme. These TUs are aligned with the block level.

Peripheral Health Institutions (PHIs)

PHIs include dispensaries, Primary Health Centres (PHCs), Community Health Centres (CHCs), referral hospitals, major hospitals, specialty clinics/hospitals (including other health facilities) within the district. Some of these PHIs are also Designated Microscopy Centres (DMCs).

Facilities for TB Detection and Treatment

NTEP has a quality-assured laboratory network for bacteriological examination of sputum in a three-tier system of DMC, Intermediate Reference Laboratory (IRL), and National Reference Laboratory (NRL). DMC is the most peripheral laboratory under the NTEP, having been decentralized to the primary health care setting. There are 20,345 DMCs across the country. The programme provides free testing facilities for patients and those with presumptive TB, including Drug-Resistant TB (DR-TB), paediatric TB, HIV-TB and extrapulmonary TB.



In addition, the laboratory services include state-of-the-art testing facilities and rapid testing methods such as Cartridge Based Nucleic Acid Amplification Test (CBNAAT), TrueNat and Line Probe Assay (LPA) in addition to the range of conventional diagnostic modalities like direct smear microscopy, LED-Florescence Microscopy (LED-FM), solid and liquid culture. Under the current strategy, the programme is rapidly expanding the laboratory and newer technology platforms capacity to achieve universal access to quality and assured diagnosis. As of December 2019, there were 92 culture and Drug-Susceptibility Testing (DST) labs, 64 LPA labs, 350 TrueNat Labs and 1,195 CBNAAT labs functional in the country.

All TB patients registered under the programme are provided free quality-assured treatment

services through its network of providers. This includes the nearly four lakh community volunteers at the village level and more than 39,000 facilities in public sector and 1.6 lakh facilities in private sector, including maternal and child health hospitals. In addition, several NGOs are involved in providing services under the programme.

Maternal Health Programme

- Maternal Health (MH) Division provides quality services to pregnant women and their newborns through various interventions and programmes, building capacity of health personnel and routine health systems strengthening activities.
- Pregnant women should receive at least four antenatal check-ups during their entire pregnancy apart from one special checkup for high risk identification by specialist/medical officer under the Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA).
- The maternal health programme also aims to ensure early registration so that the first checkup is conducted within 12 weeks (first three months of pregnancy). Women would require additional check-ups in 2nd and 3rd trimester of pregnancy by MO/Obstetrician gynecologists depending on the clinical condition.

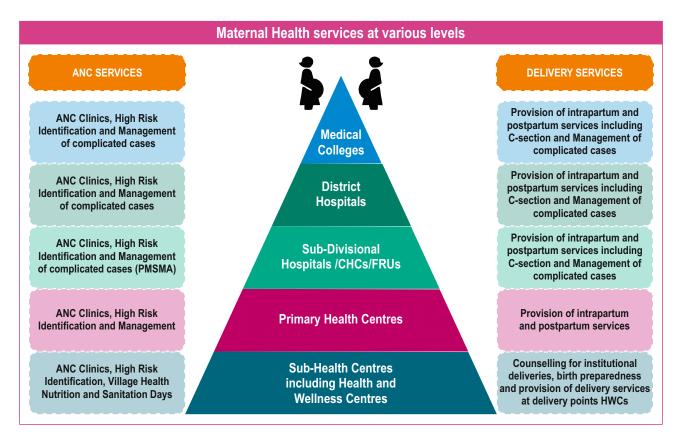
Programme Structure

National Level

- Government of India adopted the Reproductive, Maternal, Newborn, Child, and Adolescent Health (RMNCH+A) framework in 2013, It essentially aims to address the major causes of mortality and morbidity among women and children. This framework also helps to understand the delays in accessing and utilizing health care services
- Based on the framework, comprehensive care is provided to women and children through five pillars or thematic areas of RMNCH+A. The programmes and strategies developed by various divisions are guided by central tenets of equity, universal care, entitlement, and accountability to provide 'continuum of care' ensuring equal focus on various life stages.
- Following this strategy, the MH division strives to provide quality services to pregnant women and their newborns through various interventions and programmes, building capacity of health personnel and routine health systems strengthening activities.
- The National MH division is a part of MoHFW and is responsible for maternal health programme in the whole country. It is headed by Joint Commissioner, MH Division. The programme is being implemented under the umbrella of NHM.

State Level

At the state level, the State Programme Officers (SPOs) are responsible for planning, training, supervising, and monitoring of the maternal health programmes in their respective states as per the guidelines.



Platforms for Antenatal Care (ANC)

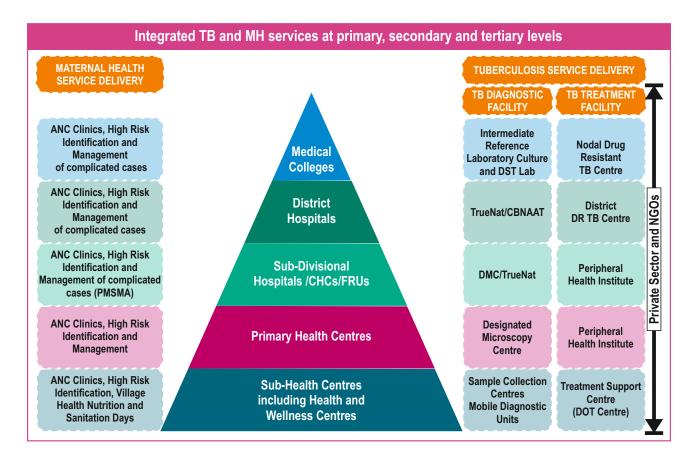
Antenatal services are provided at the following platforms:

- Village Health Sanitation and Nutrition Day (VHSND) at outreach sites The VHSND is to be organized once every month at the Anganwadi centre in the village depending on the population of village/hamlet etc. ANM, ASHA and Anganwadi workers conduct the VHSND sessions. Pregnant women get all ANC related services like ANC check-ups, drugs, vaccination etc. through this platform.
- ANC checkups are also organized at public health facilities such as Ayushman Bharat Health and Wellness Centres (AB-HWCs) Sub Centre level, AB-HWCs Primary Health Centre level, Community Health Centres and District Hospitals at the OPD level.
- Under PMSMA, assured, comprehensive and quality antenatal care is provided universally to all pregnant women on the 9th of every month. PMSMA is conducted by specialists/ doctors at designated public health facilities. Private sector providers are encouraged to provide free services at government health facilities under this programme.

Components of Quality ANC

- Ensuring that each and every pregnant woman received four ANC checkups apart from one PMSMA checkup.
- Ensuring physical examination, (weight, blood pressure); obstetric examination; laboratory tests for hemoglobin, blood sugar, blood grouping, HIV counselling and testing, syphilis, urine examination, ultra-sonography (at around 18-20 weeks of gestation), injection TT, folic acid supplementation in 1st trimester, iron and folic acid supplementation, calcium supplementation, tab albendazole (in 2nd or 3rd trimester); counseling etc.

- Ensuring Mother and Child Protection (MCP) cards and safe motherhood booklets are provided to all pregnant women and all checkups documented (RCH portal and HMIS).
- Advising and encouraging women to opt for institutional delivery and preparing a birth preparedness plan for every pregnant woman.
- Ensuring line listing of all High Risk Pregnancies (HRP) and follow up and delivery of HRPs at appropriate level of facility.
- Ensuring counseling on maternity benefits (JSSK, JSY, etc), nutrition counselling, consumption of IFA and calcium, personal cleanliness, physical activity, family planning, danger signs, etc.



National Framework for Joint TB and Maternal Health Collaborative Activities



Purpose

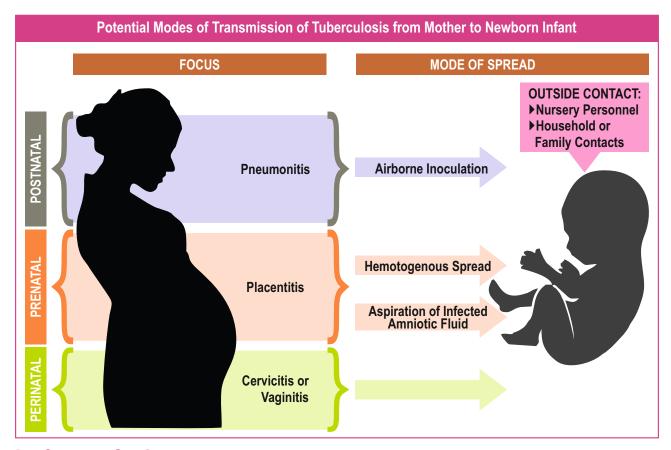
The overall purpose of the national framework for TB-Maternal Health is to articulate the collaborative activities between NTEP and MH Program to ensure early detection and timely management of TB cases in pregnant women in India.

Goal

To reduce morbidity and mortality due to TB in pregnant women and newborns through prevention, screening for early detection and prompt management of TB in pregnant women and achieve optimum maternal and perinatal outcomes.

Objectives

- 1. To develop collaborative mechanism between NTEP and MH for addressing TB among pregnant women
- 2. To ensure screening and detection of active TB cases among pregnant and postpartum women
- 3. To strengthen referral linkages between NTEP and MH program, including leveraging telemedicine options
- 4. To augment treatment of TB among pregnant women and screening for family members
- 5. To address TB and obstetric complications
- 6. To ensure screening for active TB, vaccination, and chemoprophylaxis/TB treatment to newborns of pregnant mothers affected by active TB
- 7. To provide supportive care on mental health and appropriate counseling to address lifestyle aspects, nutrition including linkages to nutritional and social support schemes
- 8. To establish surveillance, and Monitoring and Evaluation (M&E) mechanism for collaborative activities
- 9. To prepare joint annual budgeted plans for collaborative activities
- 10. To promote research and training in issues related to TB in pregnancy



Implementation Strategy

The following strategy is being proposed for collaboration between MH Program and NTEP:

- Establishing joint planning and review committees for collaboration at national, state and district levels
- Establishing service delivery protocols that address joint activities as follows:
 - Activities to improve diagnosis and management of TB among pregnant women
 - ▶ Intensified screening of TB among all pregnant women availing ANC services at community outreach activities and at health-care settings
 - ► Establishing functional Sample Collection Transportation (SCT) mechanism from community outreach activities and facility settings through appropriate mechanisms, including incentives available under the programme and partnership guidelines
 - ► Ensuring availability of functional referral linkages between the programmes for timely diagnosis and appropriate management of TB in pregnant women
 - ► Timely provision of drugs to TB patient at a convenient location through a healthcare worker or institutional treatment support centre (HWCs), including monitoring of adverse drug reactions.
 - ► Prevention of perinatal tuberculosis
 - ► Ensuring initiation of INH chemoprophylaxis to the newborn of active TB affected pregnant mother
 - Strengthening contact tracing protocol
 - ► Ensuring TB infection control measures in household, community outreach activities and health-care settings where pregnant women avail health services

- ► Section wise management: ANC, Intranatal Care (INC), and Postnatal Care (PNC) related to management of TB along with linkage to pediatric guidelines.
- Stakeholder engagement.
- ▶ Joint monitoring and evaluation with standardized reporting system shared between MH programme and NTEP.
- Joint training of key programme and field staff in TB-Maternal Health collaborative activities through incorporation of content related to TB in pregnancy in training resources of both programmes.
- Collaborative IEC development and planning awareness initiatives.
- Operational research to strengthen implementation of TB-Maternal Health collaborative activities.

Management of Pregnant Women diagnosed with Tuberculosis

Time Period Suggested Management for Drug Sensitive TB **Suggested Management for Drug Resistant TB** During ▶ Follow standard treatment regimen In pregnant women diagnosed with DR-**ANC Period** with monthly clinical follow up and TB, if the duration of pregnancy is <20 laboratory follow up at end of weeks, the patient should be advised to intensive and continuation phase opt for a Medical Termination of ▶ USG at 18-22 weeks of pregnancy to Pregnancy (MTP) in view of the potential diagnose congenital anomalies. severe risk to both mother and fetus Additional USGs maybe done for For patients who are unwilling for MTP or ruling out any complications as per have pregnancy of >20 weeks (making the treating physician them ineligible for MTP), the risk to Chest x-ray may be offered, if mother and fetus needs to be explained necessary, with adequate protection clearly and a modified all oral longer with lead aprons/abdominal shield regimen to be started with monthly Pregnant women require an additional clinical follow up and laboratory follow 350 kcal of energy and 23 g of protein up as per programme guidelines making their RDA: 2250 Kcal of ▶ USG at 18-22 weeks of pregnancy to energy and 78 g of protein diagnose congenital anomalies. Under Nikshay Poshan Yojana, Additional USGs maybe done for ruling Nutritional support through Direct out any complications as per the treating Benefit Transfer of 500 INR per month physician for all patients on TB treatment Chest x-ray may be offered, if necessary, throughout duration of treatment with adequate protection with lead aprons Ensure contact tracing. This is Pregnant women require an additional particularly important in order to 350 kcal of energy and 23 g of protein prevent transmission of TB to making their RDA: 2250 Kcal of energy newborn (after delivery) from other and 78 g of protein family members Under Nikshay Poshan Yojana, Nutritional It is advisable that pregnant women support through Direct Benefit Transfer with TB are referred to health facilities of 500 INR per month for all patients on where specialist facilities are available TB treatment throughout duration of or else to linked referral facility treatment

Time Period	Suggested Management for Drug Sensitive TB	Suggested Management for Drug Resistant TB
	Community level awareness on TB, JSSY, JSSK by ASHA in VHND	▶ Ensure contact tracing. This is particularly important in order to prevent transmission of TB to newborn (after delivery) from other family members. It is advisable that pregnant women with TB are referred to health facilities where specialist facilities are available or else to linked referral facility
At the time of Delivery	 Delivery at District Hospital/ facility with SNCU support to ensure management of fetal/neonatal complications Special focus on infection prevention protocols if pregnant woman is microbiologically confirmed case of pulmonary TB (especially open cases) Cesarean section in pregnant women with TB will be done only, if there is obstetric and fetal indication 	 Delivery at District Hospital level / facility with Sick Newborn Care Unit support to ensure management of fetal/neonatal complications Special focus on infection prevention protocols if pregnant woman is microbiologically confirmed case of pulmonary TB (especially open cases)
Post Delivery	 Both microbiological and histopathological examination of the placenta (using RKS funds) Rule out Neonatal TB (Refer to Updated Pediatric TB Guidelines) Ensure initiation of INH chemoprophylaxis to the newborn of active TB affected pregnant mother if Neonatal TB has been ruled out Continue treatment of mother during the breastfeeding period and breastfeeding should not be stopped Lactating women (0-6 months) require an additional 600 Kcal and 19 g protein making their RDA 2500 Kcal of energy and 74 g of protein. For a sedentary lactating woman suffering from TB, an addition of 10% calories increases the requirement to 2750 kcal, protein 74 gm, 300 mcg folic acid, 1200 mg calcium, 21 mg Iron and 950 mcg of Vitamin A Under Nikshay Poshan Yojana, Nutritional support through Direct Benefit Transfer of 500 INR per month for all patients on TB treatment throughout duration of treatment 	 Both microbiological and histopathological examination of the placenta (use RKS funds to conduct these investigations if not available in the hospital) Rule out Neonatal TB Chemoprophylaxis to the newborn of active TB affected pregnant mother if Neonatal TB has been ruled out Continue treatment of mother during the breastfeeding period and breastfeeding should not be stopped Lactating women (0-6 months) require an additional 600 Kcal and 19 g protein making their RDA 2500 Kcal of energy and 74 g of protein. For a sedentary lactating woman suffering from TB, an addition of 10% calories increases the requirement to 2750 kcal, protein 74 gm, 300 mcg folic acid, 1200 mg calcium, 21 mg Iron and 950 mcg of Vitamin A Under Nikshay Poshan Yojana, Nutritional support through Direct Benefit Transfer of 500 INR per month for all patients on TB treatment throughout duration of treatment

Coordination Mechanisms for collaboration between NTEP and MH

National Level

In order to ensure coordination between two health programmes in key policy decisions, representatives and experts from Maternal Health Division would be included in the existing National TB-Comorbidity Coordination Committee under the chairmanship of Secretary (HFW), which would meet on a biannual basis. The existing National Technical Expert Group on TB in women including Gender issues, with representatives from NTEP and Maternal Health Division, representatives from national institutes, professional bodies and development partners and civil society members would oversee overall implementation of the framework across all State/UTs.

State Level

To ensure smooth implementation and oversee implementation of NTEP and MH Program collaborative activities, the existing State TB-Comorbidity Coordination Committee (STCC), chaired by Principal Secretary (Health), would include representation from Maternal Health Program in all State/UTs. For periodic review of implementation of the framework, existing State TB-Comorbidity Working Group would include representation from Maternal Health Program. The STCC and State TB Working Group (STWG) would meet periodically to review and streamline TB-Maternal Health activities in the state. Based on deliberations and decisions, NTEP and MH Programs in the state would send feedback to all districts.

District Level

To ensure smooth implementation and regular review of TB-MH activities, existing District Coordination Committees (DCCs) and monthly TB-Comorbidity Review meeting would include representation of district official / program manager in charge of maternal health and include discussions on TB-Pregnancy framework implementation, including issues related to case management, adverse drug reactions.

Review of TB-Maternal Health Collaborative Activities

NTEP and MH Programme will conduct regular joint review meetings at national, state and district level. In the meetings, joint review of TB-Maternal Health collaborative activities will be done with participation of programme managers of both the programmes. The schedule of review meetings for NTEP will be communicated to MH Program and vice versa so that cross-participation is ensured.

TB and Maternal Health Service Delivery Integration

Procedure for Screening and Referral of Pregnant Women for TB

NTEP and MH programmes will work together to integrate screening for TB within existing services of MH programme with a special focus on screening of pregnant women during ANC sessions.

Screening and Diagnosis

All pregnant women would be screened for TB at every ANC visit. Following four symptoms complex screening in attendees of ANC clinics will be performed. Screening is expected to be carried out

every time the pregnant woman visits ANC clinic in all trimesters. Following questions to be asked after confirming that patient is not on active TB treatment.

- Four-symptom complex
 - Cough of duration > 2weeks
 - ► Fever of duration > 2weeks
 - Inadequate weight gain or Weight loss body weight in last 3 months)
 - Night Sweats
- Extra-pulmonary symptoms-localized swellings/lumps in the body (lymph node)

If any of above symptoms are positive, then the arrangements should be made for sputum collection /FNAC in case of localized enlarged lymph node and sample transportation from ANC clinic at all levels, preferably by sending to nearest TB molecular diagnostic center in coordination with DTO. All TB patients of reproductive age group would be screened for pregnancy.

Platforms for screening of pregnant women

Screening for TB will be made an essential component of ANC services wherein service providers will actively screen all the pregnant women for TB during each ANC visit. This will be applied to community outreach activities like VHSND and fixed day ANC service provision platforms like HWCs/PHCs and PMSMA. Both the programmes will also work together in undertaking intensified active case finding activities in this high priority population. The Prevention of Parent to Child Transmission (PPTCT) clinics under National AIDS Control Programme performing TB screening as part of the TB-HIV collaborative activities would also be leveraged.

Who will do the screening?

The ANC provider (ANM/Community Health Officer (CHO)/Staff Nurse/MO/OBGY specialist) will do the screening using four-symptom complex for pulmonary TB and localized enlarged lymph node for extrapulmonary TB. The presumptive TB cases will be referred to nearest DMC/PHI with referral slip if found positive on screening for any one or more of the symptoms or for symptoms of extra pulmonary TB. Staff Nurses, CHO/Counsellor and ANMs attending the pregnant women during ANC visits and community outreach activities will enquire about the TB symptom complex and refer the patient. The staff nurse and counselor would be trained by the MO-Incharge to screen the TB symptom complex at PHC.

Referral linkages for diagnosis and treatment

After screening, patients with one or more symptoms of TB symptom complex, the patient will be referred to the nearest TB Facility i.e DMC/PHI for diagnosis of TB. A referral and feedback mechanism will be developed to enable timely exchange of information. The MO/staff nurse/CHO/ANM will refer the patient with a NTEP Laboratory Request Form to the nearest TB molecular diagnostic center (sputum samples to be collected and transported preferably) for confirmation of TB disease. The TB clinic staff as per management guidelines stipulated in NTEP would manage the patients diagnosed with TB appropriately. The DMC will return the results of the TB test to the referring facility/service provider through the counterfoil of the Laboratory Request Form with the patient. The same will be presented to the MO/SN/CHO/ANM for recording the result.

Sample Collection and Transport

Sample for TB diagnosis may be collected and transported by ANM/ASHA/Community Volunteer/NGO/patient attendant/patient herself after training them properly in sample collection, to the nearest diagnostic center or the patient.

Incentive for Sputum Collection and Transport

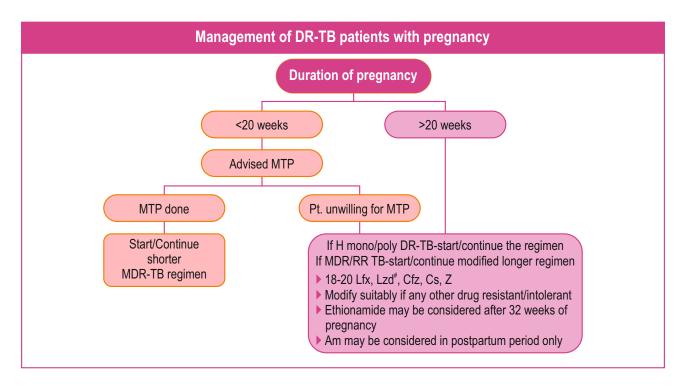
Non-salaried community volunteers including ASHAs/govt staff without provision of TA is incentivized for sample collection and transport based on state specific guidelines. In case any if a presumptive TB a patient for whom the sample was transported is diagnosed as positive then an additional amount of Rs 500/ patient is given as informant incentive through DBT.

Treatment and Adherence

WHO supports the use of the standard regimen in pregnant women: Use of standard regimen for six months of which four drugs (Rifampicin, isoniazid, Ethambutol, Pyrazinamide) to be given for first two months and three drugs for next four months (excluding pyrazinamide). Although the drugs used in the initial treatment regimen for TB cross the placenta, they do not have harmful effects on the fetus. In breast feeding women full course of anti-TB treatment is recommended. The dosage and the duration of anti-TB therapy is not modified due to pregnancy (4). Pyridoxine, 10 mg/day should be given with isoniazid during pregnancy because of increased requirement in pregnant women and to prevent potential neurotoxicity in the fetus.

Pregnancy is not a contraindication for treatment of active drug-resistant TB but poses a great risk to both the mother and fetus. There is lack of experience in treating pregnant women with DR-TB. In pregnant women diagnosed with DR-TB, if the duration of pregnancy is <20 weeks, the patient should be advised to opt for MTP in view of the potential severe risk to both mother and fetus. If the patient is willing, she should be referred to a gynecologist or obstetrician for MTP following which a shorter MDR-TB regimen can be initiated (if the patient has not started treatment) or continued (if the patient is already on treatment) by the DR-TBC Committee.

For patients who are unwilling for MTP with pregnancy of <20 weeks or have a pregnancy of >20weeks (making them ineligible for MTP), the risk to mother and fetus of continuing pregnancy needs to be explained clearly and a modified all oral longer MDR-TB regimen to be started or in case already on TB treatment, as detailed in the diagram.



Note: Please refer to PMDT Guidelines 2021 for management of DRTB in Pregnancy

Monitoring of adherence of anti-TB Treatment needs to be done as successful outcome of TB treatment will positively affect the pregnancy. Traditionally, treatment supervision methods were limited to Direct Observation of Therapy (DOT) by a trained person other than family members. In order to give priority to patient's needs and preferences, it is necessary to adopt a patient-centric approach in view of the better adherence standards. In some patients, a family member might be able to ensure better treatment supervision and adherence as compared to an external individual visiting the home. With the advent of Information Communication Technology (ICT), there are multiple options by which patients can reliably self-report drug consumption, be monitored and supported by various levels simultaneously. The newer guideline favors the principle of adherence monitoring which has to be applied logically and judicially. These also provide options, whereby, the most appropriate modality of adherence monitoring may be used as a collective decision for the patient, treatment supporter and the Medical Officer (MO). In addition, NTEP has a call-centre mechanism, NIKSHAY Sampark (1800-11-6666) in order to reach out to patients and counsel them on co-morbidities and adherence. Digital platform – Nikshay would be leveraged to ensure tracking of pregnant women with TB who migrate for cultural reasons.

ASHA, ANM and CHO will be the nodal persons for TB treatment adherence monitoring. During each ANC check-up the concerned health worker will check the treatment adherence status and counsel the patient regarding importance of complete treatment. In addition, the patient may be sensitized to contact the healthcare provider in case of any danger signs observed.

Incentive to providers

Private Provider Incentive: Under this scheme, 500 INR at notification and 500 INR on reporting treatment outcome is provided to the private provider who first notifies the case to the programme

Informant incentive: Under this scheme, incentive of 500 INR to informant for notification of patients in public sector.

Incentive for treatment support: Under this scheme, a treatment supporter for a new case of TB receives 1,000 INR at completion of treatment and for a Drug Resistant Case receives 2,000 INR at completion of intensive phase, 3,000 INR at completion of treatment.

Contact Tracing, Vaccination and Chemoprophylaxis:

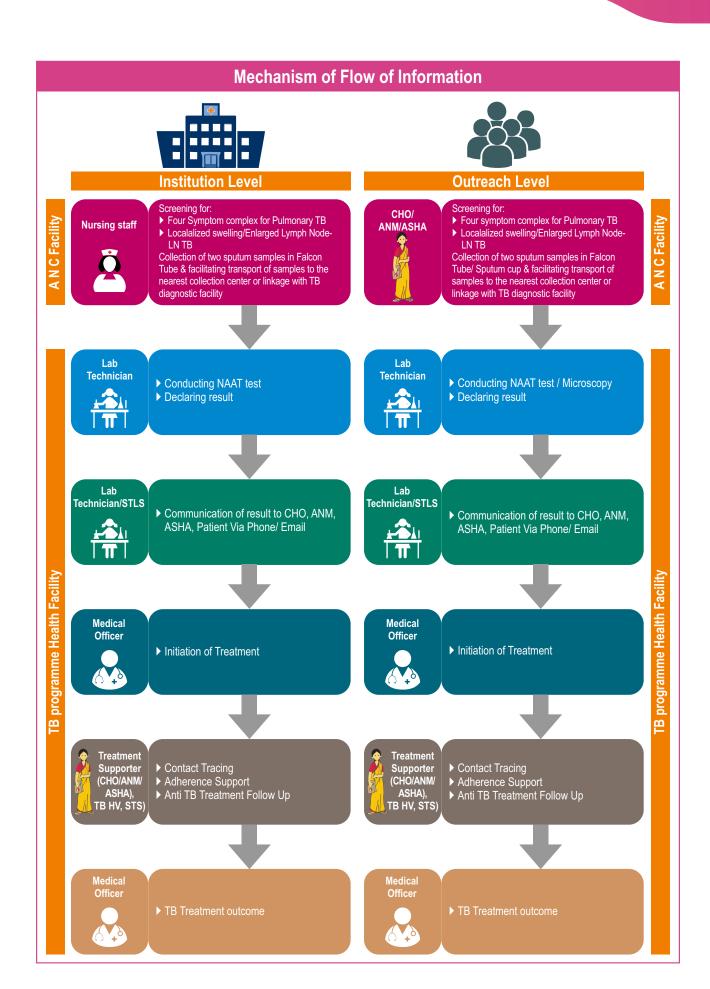
Preventive chemotherapy with isoniazid (H) is administered to all the children aged six years and below who are in contact with pulmonary TB cases. The number of such children residing in the household should be enquired during the initial home visit/ ANC clinic visit. The parents are advised to bring children to the health centre for screening for evidence of TB. They are examined and investigated to rule out TB disease. If the child is found to be suffering from disease, they should be treated appropriately. Children found eligible for chemoprophylaxis after ruling out TB are to be administered preventive chemotherapy with INH 10 mg/kg body weight daily for six months, irrespective of their BCG or nutritional status. It may be noted that the levels of TB drugs excreted in breast milk is minimal. Zero dose BCG may be given along with Isonized Preventive Therapy (IPT) for those children born to mothers with microbiologically confirmed TB. In HIV exposed infants, BCG may be provided along with exclusive breastfeeding. For details of neonatal care, current national guidelines on this issue should be followed. With regard to provision of TB preventive therapy, refer to the latest national guidelines.

Delivery of women in the secondary and tertiary centres is recommended because of higher maternal-perinatal complications, and to enable examination of placenta and newborn for TB.

Recording and reporting



- All details captured as part of the existing recording and reporting systems of both programs
- Pregnancy would be included as a 'key population' in the 'laboratory form for examination of biological specimen for TB" so that the same is captured for each patient while enrolling in Nikshay. The pregnancy details would be obtained through the software linkage with RCH portal.
- Linkages developed between Nikshay and RCH portal for sharing information.



Roles and Responsibilities

Roles and Responsibilities of NTEP

Position	Roles & Responsibilities
State level – STO, Director, State Tuberculosis Training and Demonstration Centre (STDC), Assistant Programme Officer (APO), Data Entry Operator (DEO)	 Coordinate and attend the SCC TB-maternal health meetings Review districts' components of TB- maternal health collaborative activities on a quarterly basis Establish coordination with the Medical colleges and MH clinics/hospitals in private sector Align the implementation of TB-maternal health collaborative activities Provide funds for relevant trainings pertaining to TB- maternal health collaborative activities Involve in the joint supervision of collaborative activities IEC activities regarding the collaborative activity
District level (DTO, District Programme Coordinator, MO-DTC, DEO)	 Coordinate and attend meetings of the DCC outlined for TB-Maternal Health collaborative activities Collaborate with ANC clinics for the implementation of TB-maternal health activities Establish coordination with the Medical colleges and MH clinics/hospitals in private sector Ensure submission of accurate and timely reporting of TB-maternal health formats to the state officials along with feedback about the progress of TB- maternal health collaborative activity Ensure other NTEP staff are appropriately involved in the collaborative activity Collaborate with relevant stakeholders to strengthen TB-maternal health activity in the district IEC activities regarding the collaborative activity
TB Unit level – MO TB Control (TC)/Block Medical Officer (BMO), Senior Treatment Supervisor (STS), senior treatment laboratory supervisor (STLS)	 The STS will capture information in TB notification register from treatment card. Maintaining TB Notification Register STS will do Nikshay entry
DMC/PHI level - MO, Laboratory Technician (LT), ANM, Staff Nurse, health worker	 Ensure the completeness of records The responsibility for collecting the information and updating the treatment card will rest with the institutional treatment supporter of the PHI/health worker

Roles and Responsibilities of MH Program

Position	Roles & Responsibilities
Role of State Level Officials (Director RCH, Project Director / Deputy Director Maternal Health)	 Review screening and management of tuberculosis in pregnant women across districts Plan budgeting for TB in pregnancy, which would be budgeted under NTEP, in coordination with NTEP counterparts
Role of Medical Officer	 Assist in training of ANC clinic staff and other staff on TB screening and referral mechanism Collaborate with district TU for the implementation of TB-maternal health activity Ensure screening of TB symptom complex at ANC clinic and its report sharing with district TB officer Ensure submission of accurate and timely reporting of TB-maternal health formats to the district along with feedback about the progress of TB- maternal health collaborative activity Collaborate with relevant stakeholders to strengthen TB-maternal health activity in the district Prepare action plan for implementation of framework
Role of Staff Nurse, CHO and ANM	 Conduct screening for TB symptom complex in ANC clients attending the ANC clinic and at outreach platforms Conduct counselling on diet and lifestyle Ensure completeness of the referral card filled for the presumptive TB patient under the guidance of MO and refer using NTEP Laboratory Request Form Ensure that the presumptive TB patient attends the TB clinic after confirmation of diagnosis and treatment initiation Ensure adherence to treatment Maintain the ANC clinic register and ensure data reporting

The roles and responsibilities are summarized in below table:

Activity	Outreach/ Health and Wellness Centre	Institutional
Screening for TB symptoms		
Collection of Sputum	ASHA, ANM and CHO	Staff Nurse and Medical Officer
Referral		Medical Officer
Development of Sputum transportation mechanism	MO PHI and MO-TC	I/C of institute and DTO
Testing of Sample	Lab Technician	
Communication of Results	LT, STLS, STS	
Treatment of Initiation	MO- PHI	
Counseling	ANM/CHO	Medical Officer/Staff Nurse/ Counselor
Supply of Medicine and formats	STS	
Supply of Falcon Tubes and logistics for packaging	STLS	
Issue of monthly anti TB Medicine to patient/ Treatment Supporter	Pharmacist/STS	Pharmacist/STS
Follow up	Treatment Supporter, ASHA, Al	NM and STS
Adherence monitoring	ASHA, ANM, CHO, STS	Staff Nurse, Medical Officer
Treatment Outcome	MO-PHI and STS	MO-PHI and STS
Maintenance of TB Treatment Card	Treatment Supporter	Treatment Supporter

Sensitization and Training

Sensitization and training of health staff for TB and maternal health collaborative activities

Sensitization workshop comprising of State Nodal Officers (SNO) will be done at the national level. Focal points of the states of both the programmes will conduct further sensitization training of focal points of districts. STOs, consultants and other NTEP staff will be trained on TB-Maternal Health collaborative activities during their ongoing training on NTEP Technical and Operational Guidelines. Programme officers of MH Program will attend the TB- Maternal Health portion of training at the state and district level as per the NTEP training plan and vice versa. Community preparedness would be ensured through effective ACSM campaign and incorporating messages in existing IEC materials.

	Trainings
State level training	 Training of State TB Officer, DTOs, District Nodal Officers - Maternal Health (DNOs) Continuing Medical Education (CME)/workshops for Medical college faculty
	Other sectors
District level	Training of DTO, Medical Officers, key contractual staff of both the programmes
Sub-district/CHC level	 Sensitization sessions for concern staffs at ANC clinics and TUs
	 Sensitization of stakeholders (administrators, partners) at state/local level is the responsibility of NTEP staff at state and district level

Information, Education and Communication

Information, Education and Communication (IEC) activity for awareness generation is an important in the implementation of framework. As IEC is an integral part of both NTEP and MH Programme, it is considered one of the important cross-cutting areas for the collaborative activity. The IEC strategy for TB-Maternal health will be included in both the programmes IEC and Advocacy, Communication and Social Mobilization (ACSM) plan.

Increased attention and focus will be given to primary health care workers who regularly interact with both TB patients and pregnant women. Awareness activities will be prioritized for the programme and hospital staff to make them aware about the purpose and mechanism of the collaboration. Relevant IEC and ACSM related materials will be developed and shared with the States for further adoption in the local languages. The States should prepare an IEC plan for the collaborative activity. Special emphasis will be given to generating awareness about the linkage in the marginalized and deprived communities. The plan for implementing IEC activities includes the following:

- Design content of IEC materials (posters, pamphlet, at-risk card, recipe book, banners, flyers, leaflets, AV materials) jointly by both programme divisions.
- Display of IEC materials at TUs, DMCs and ANC Clinics in local language to inform about the joint collaborative activity.
 - Display materials related to hygiene and TB awareness, diet and lifestyle related do's and don'ts at the ANC clinics;
 - Display IEC material about ANC at TUs and DMCs.
- Disseminate messages through various media electronic, multi-media and print media.
- Utilize every opportunity to increase awareness about TB and pregnancy.
- Conduct awareness activities to sensitize all stakeholders (partners, policy makers, administrators).
- ▶ Budget for IEC activities will be borne from IEC/ ACSM budget of respective programmes.

Implementation Plan

- Directives to state focal points to prepare action plan for implementation of collaborative activities.
- > Sensitization of stakeholders and capacity building of all cadres of relevant health care staff.
- Implementation of collaborative activities and reporting of performance.
- Joint visits by national and state level officials.

Supervision, Monitoring and Evaluation

Indicators for Monitoring and Evaluation

- 1. Proportion of pregnant women screened for TB among total ANC registered
- 2. Proportion of presumptive TB symptomatic identified among pregnant women screened for TB
- 3. Proportion of presumptive TB symptomatic pregnant women referred among screened for TB
- 4. Proportion of women tested for TB among pregnant women referred from ANC
- 5. Proportion of pregnant women diagnosed with TB among referred pregnant women who were tested for TB
- 6. Proportion of pregnant women with TB assessed for nutritional status
- 7. Proportion of pregnant women who were diagnosed as drug sensitive TB and were initiated on drug-sensitive TB treatment
- 8. Proportion of pregnant women who were diagnosed as drug resistant TB and were Initiated on drug-resistant TB treatment(excluding those who have availed MTP)
- 9. Proportion of pregnant TB patients who were started on Drug sensitive TB and who successfully completed Drug Sensitive TB treatment
- 10. Proportion of pregnant TB patients who were started on Drug Resistant TB and who successfully completed Drug resistant TB treatment

	Indicator	Numerator	Denominator	Division responsible
1.	Proportion of pregnant women screened for TB among total ANC registered.	Total pregnant Women Screened for TB	Total Pregnant Women registered in ANC	МН
2.	Proportion of Presumptive TB symptomatic identified among pregnant women screened for TB.	Presumptive TB pregnant women identified	Total pregnant Women Screened for TB	МН
3.	Proportion of Presumptive TB symptomatic pregnant women referred for TB diagnosis among screened for TB	Presumptive TB Symptomatic referred for TB diagnosis	Presumptive TB pregnant women identified	МН
4.	Proportion of women tested for TB among pregnant women referred from ANC	Pregnant women tested for TB	Presumptive TB Symptomatic referred for TB diagnosis	NTEP
5.	Proportion of pregnant women diagnosed with TB among those who were tested for TB	Pregnant Women diagnosed with TB	Pregnant women tested for TB	NTEP

Indicator	Numerator	Denominator	Division responsible
6. Proportion of pregnant women with TB assessed for nutritional status	Pregnant Women with TB assessed for nutritional status	Pregnant Women diagnosed with TB	NTEP
7. Proportion of Pregnant women who were diagnosed as drug sensitive TB and were initiated on drug-sensitive TB treatment	Pregnant women initiated on Drug sensitive TB Treatment	Pregnant Women diagnosed with Drug Sensitive TB (excluding those who had MTP)	NTEP
8. Proportion of Pregnant women who were diagnosed as drug resistant TB and were Initiated on drug-resistant TB treatment (excluding those who have availed MTP)	Pregnant women initiated on Drug Resistant TB Treatment	Pregnant Women diagnosed with Drug Resistant TB (excluding those who had MTP)	NTEP
9. Success Rate of Drug Sensitive Pregnant Women	Pregnant women cured+ completed DS treatment	Total Pregnant women initiated on DS Treatment	NTEP
10. Success Rate of Drug Resistant Pregnant Women	Pregnant women cured+ completed DR treatment	Total Pregnant women initiated on DR Treatment	NTEP

Proposed Research Areas

- Epidemiology of TB in pregnancy
- Prevalence of TB in pregnancy
- Barriers to diagnosis and compliance to treatment, including issues related to gender and TBrelated stigma
- Adverse Drug Reactions (ADR) in pregnancy
- Obstetric and perinatal outcomes
- Outcomes of TB in pregnancy including co-morbidities
- Community based research for seeking feedback from pregnant women on availability of services and beneficiary satisfaction

All research should also be disaggregated by women's age, parity, and sex of existing children (in case of women with parity greater than one).

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FAQs for Doctors

- Q1: What is impact of TB on pregnancy?
- Ans: Maternal tuberculosis has been associated with an increased risk of spontaneous abortion, perinatal mortality, small for gestational age and low birth weight babies in some studies.
- Q. 2 In which period (antenatal, intranatal, postpartum) TB transmission occurs commonly.
- Ans: TB transmission commonly occurs in postpartum period (air borne). However, vertical transmission can also occur through placenta in intranatal period resulting in congenital TB
- Q.3 Is X-ray safe for diagnosis of TB in pregnancy?
- Ans: There are many sensitive and accurate diagnostic methods available in TB programme freely like CBNAAT. If it is not possible to utilize these lab services (Microscopy/Molecular tests) available in TB programme, x-ray can be done by providing adequate cover for abdominal protection to avoid fetal exposure.
- Q 4: What is the value of serodiagnosis tests for diagnosis of TB?
- Ans: Sero-diagnostic tests i.e. tests based on reaction to the blood serum of a patient, have not been found to be useful in diagnosis of any form of TB. Therefore, WHO has recommended banning their use.
- Q.5 Are the TB drugs safe in pregnancy? What are the second line drugs which can be given to patient if she refuses to terminate pregnancy?
- Ans: Make sure you tell your doctor or nurse if you are pregnant or breastfeeding, so they can check the medicine being used is safe. Standard TB medicines (Rifampicin, Ethambutol, Isoniazid and Pyrazinamide) have not been associated with harmful fetal effects. Other medicines, such as Streptomycin, Capreomycin, Kanamycin, Prothionamide and Ethionamide are not recommended for pregnant or breastfeeding women.
- Q.6 Is the treatment duration for TB different in pregnant and non pregnant women?
- Ans: No. The dosage and the duration of anti-TB therapy are not modified due to pregnancy. Additionally, Pyridoxine, 10 mg/day should be given with isoniazid during pregnancy because of increased requirement in pregnant women and to prevent potential neurotoxicity in the fetus.
- Q. 7 What should be the treatment approach for drug resistance TB during pregnancy?
- Ans: Pregnancy is not a contraindication for treatment of active drug-resistant TB but poses great risk to both the mother and fetus. There is lack of experience in treating pregnant women with DR-TB. In pregnant women diagnosed with DR-TB, if the duration of pregnancy is <20 weeks, the patient should be advised to opt for MTP in view of the potential severe risk to both mother

and fetus. If the patient is willing, she should be referred to a gynecologist or obstetrician for MTP following which a shorter MDR-TB regimen can be initiated (if the patient has not started treatment) or continued (if the patient is already on treatment) by the DR-TBC Committee.

For patients who are unwilling for MTP or have a pregnancy of >20 weeks (making them ineligible for MTP), the risk to mother and fetus needs to be explained clearly and a modified conventional MDR-TB regimen started or continued. Please refer to the flow diagram on page 19

- Q.8 Why is it important to take TB medicines regularly for the entire duration of the prescribed course?
- Ans It is important to take TB medicines regularly for cure from the illness, better quality of life, prevention of Drug resistant TB and prevent TB transmission to the child as well as others.
- Q.9 Should pregnant women living with HIV take TB preventive treatment?
- Ans Pregnant women living with HIV are at risk for TB so after ruling out of active TB they should be provided TB Preventive Therapy (TPT) i.e. INH 300 mg+ Pyridoxine 50 mg daily for six months.
- Q.10 What are Nutritional requirements in pregnant and lactating women with TB?
- Ans Pregnant and lactating women have additional requirements of energy, proteins, folic acid, calcium, and iron, in addition to the enhanced requirements related to active disease and nutritional recovery. Pregnant women need an additional 300 cal, 15 g protein, 400 micrograms of folic acid, 1000 mg of calcium and 38 mg of iron per day. Lactating women require about 400-550 extra calories per day, 18-25 g additional protein, additional amounts of vitamin A.
- Q.11 Can a lactating mother receiving anti-TB treatment breastfeed her baby?
- Ans Breastfeeding should not be discouraged for women being treated with the first-line anti-TB drugs because the concentrations of these drugs in breast milk are too small to produce toxicity in the nursing newborn. For the same reason, drugs in breast milk are not an effective treatment for TB disease or latent TB infection in a nursing infant. So IPT should be given to newborn after ruling out active TB among them. BCG vaccine also should be given.
- Q.12 Please update about referral linkages for diagnosis and treatment in government sector?
- Ans Following the screening for TB in pregnant women by Medical officer/ANM, she should be referred to the nearest DMC/PHI for diagnosis of TB. The MO/private sector care provider/Staff Nurse/ANM will refer the patient with a NTEP Laboratory Request Form to the nearest DMC for confirmation of TB disease. The DMC will return the results of the TB test to the patient. The same will be presented to the MO/SN/ANM for recording the result. The TB clinic staff as per management guidelines stipulated in NTEP would manage the patients diagnosed with TB appropriately.

Joint Reporting Format for Collaborative Framework for Management of TB in Pregnant Women											
S No.	Activities	During the quarter	Up to the quarter in the Financial Year								
1	No. of meetings of the State Coordination Committee Meeting with dates										
2	No. of meetings of the State Technical Working Group with dates										
3	Whether State Level Advocacy Workshops held										
4	No. of participants in the Advocacy Workshops										
5	Training of Trainers programmes held										
6	Trainings on Collaborative Framework on Management of TB in Pregnancy for Health care providers										
7	No. of Participants in the Trainings on Collaborative Framework on Management of TB in Pregnancy										
8	Types of IEC materials adapted /developed (e.g. posters/stickers/handouts/wall paintings/hoardings etc.)										
9	Examples of different IEC materials disseminated										
10	Districts where District Level Comorbidity Committees have been set up										
11	Districts where meetings of the District Comorbidity Committees have taken place										
12	Total Meetings of the District Comorbidity Committees										

Financial Support Available under NHM for TB Related Activities

A. Incentives

Individual incentives are available under NTEP as follows:

S No.	Particulars	Amount	Eligibility				
	Ince	entives available under	NTEP				
1	Informant incentive for referring presumptive TB patients to public facility	Rs. 500 per patient detected with TB on referral to a government health facility by said informant	Available for confirmed TB patient				
2	Private Provider Incentive	Rs. 500 per TB patient notified and Rs. 500 on reporting treatment outcome per patient	Private Providers (Private Practitioner, Hospital, Laboratory, and Chemist) who notify/inform (refer) TB patients to NTEP on Nikshay and declare the outcome.				
3	Treatment supporter incentive	Rs. 1000 per DSTB patient & Patients on H-Monopoly and Rs. 5000 per DRTB patient for 'Treatment Supporter' on completion of treatment	On the update of Outcome for Drug sensitive TB patients INR 2,000 on completion of Intensive phase (IP) and INR 3,000 on completion of continuation phase (CP) of treatment for Drug- Resistant TB patients				
4	Transportation support for patients from tribal area	Rs 750 as one- time support	Upon notification for TB patient notified from notified Tribal areas				
5	Transportation support for DRTB patients	As per rates defined by State Government	All DR-TB patients				
6	Injection prick charges for DRTB patients	Rs. 25 per injection	For persons who are not supported by government for providing injection to DRTB patient				
7	Nikshay Poshan Yojana - To provide nutritional support to TB patients at the time of notification and subsequently during the course of treatment	Rs 500 for a treatment month paid in installments of up to Rs 1000 as an advance	All unique TB patients notified on or after 1st April 2018 (including all existing TB patients under treatment for at least one month from this date)				

B. Other financial support available for TB related activities

Support under NTEP is available for the following activities:

- Screening, referral linkages and follow-up under Latent TB Infection Management
- Incentives for Active TB Case Finding
- Community meetings
- Patient provider meetings
- School/college-based activities
- ▶ Sensitization of private providers, NGOs, PRIs
- ▶ IEC activities such as folk, mela, street plays, signages, wall paintings, wall writings, Hoardings, banners, miking

Funding for the above will be as per the rates and plan approved by respective State/UT Governments under NHM.

NTEP Request Form for examination of biological specimen for TB

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REFERRAL SLIP (Lab Copy)	Date:Lab referred to:	Patient's / Contact person's Mobile number :	Kindly tick Coughdays Feverdays Loss of weightdays Night sweatdays	Test ID:	Contact of TB / MDR TB Episode IDStamp of HF Referred by (Name & Sign)
REFERRAL SLIP [Patient copy]	Date:Lab referred to:	Patient's / Contact person's Mobile number :	Kindly tick Coughdays Feverdays Loss of weightdays Night sweatdays	Test ID:	Contact of TB / MDR TB Episode ID
REFERRAL SLIP (Referring health facility copy)	Date:Lab referred to:	Patient's / Contact person's Mobile number :	Kindly tick Coughdays Feverdays Loss of weightdays Night sweatdays	Test ID:	Contact of TB / MDR TB Episode ID

Infection Control Measures Guidelines

1. Location and design

- a. Ante Natal Clinics should have a well- ventilated waiting and seating area. Separate, well-ventilated waiting area for respiratory symptomatic should be made available wherever possible (larger ART Centres).
- b. Adherence to ventilation standards for airborne infection control (>12-15 ACH throughout during all hours of operation, in all seasons) should be ensured.
- c. ANC should be preferably located far away from Designated Microscopy Centre/DOT Centres.
- d. Open outdoor roofed additional waiting areas are encouraged, as are token systems to decompress crowded areas.
- e. As far as possible, use of re-circulating air conditioners in the waiting area should be avoided as these have been found to be leading to no air exchange.

2. General Hygiene:

- a. Hand washing facility (Universal Precaution) shall be in place for doctors, health care workers and patients.
- b. Running water, soap and alcohol hand rub solution shall be provided.
- c. Frequent wet mopping of the patient waiting area shall be undertaken.
- d. Lavatory shall be kept clean.
- e. An appropriate waste segregation and disposal system shall be in place.

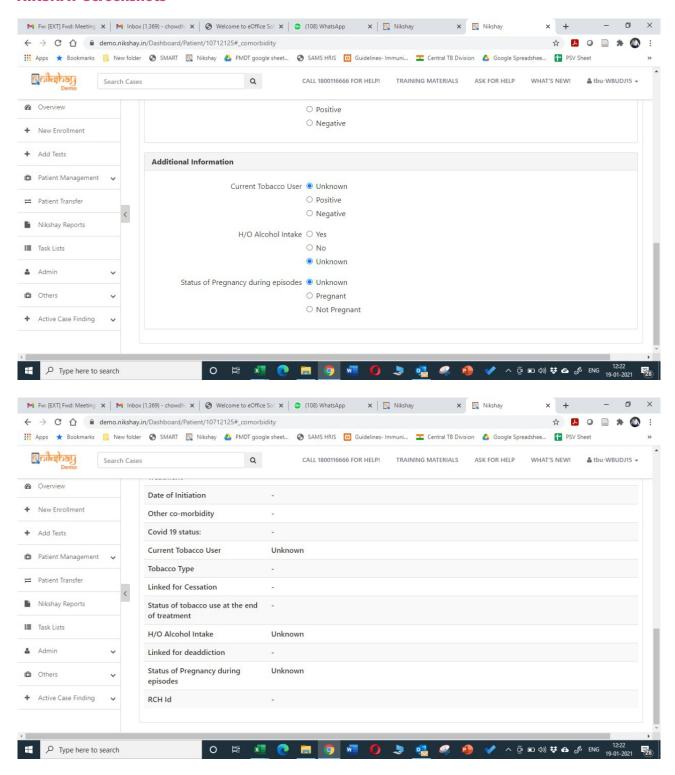
3. Cough Hygiene for persons with respiratory infection:

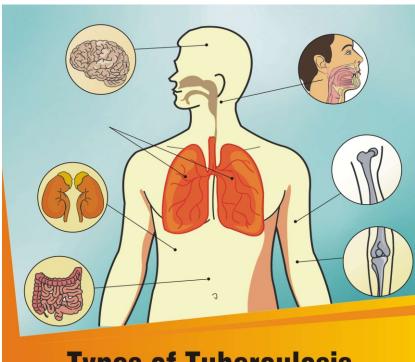
- a. Cover the mouth and nose with a tissue/ handkerchief when coughing and dispose of used tissue in waste containers.
- b. Use a mask if coughing. Surgical mask may be issued to coughing patients.
- c. Perform hand hygiene (use an alcohol-based hand rub or wash hands with soap and water) after contact with respiratory secretions.
- d. Display sign boards requesting patients and family members with acute febrile respiratory illness to use respiratory hygiene/cough etiquette.
- e. Educate HCWs, patients, family members, and visitors on the importance of containing respiratory aerosols and secretions to help prevent the transmission of influenza and other respiratory infections.

4. Training of hospital staff:

a. All the hospital staff shall be trained in Universal Workplace Precaution, Waste segregation and disposal and Air borne Infection Control Practices, with special reference to tuberculosis prevention.

NIKSHAY Screenshots

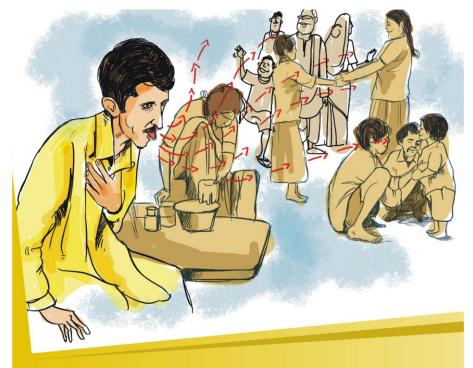




Types of Tuberculosis

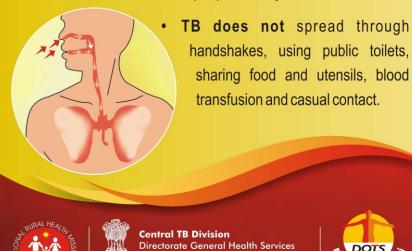
- Tuberculosis is of two types: Pulmonary TB and Extra-pulmonary TB.
- Tuberculosis of the lungs is called Pulmonary Tuberculosis and accounts for 80 % of all TB cases.
- TB affecting any other organs of the body like brain, lymph nodes, bones, joints, kidneys, larynx, intestines or eyes is called Extrapulmonary TB.
- About 50% of the patients suffering from Pulmonary TB are sputumpositive, which means TB germ can be seen in the sputum of those patients under microscope.
- The other half in which the TB germ cannot be seen in the sputum are categorized as sputum-negative TB.
- Sputum-positive pulmonary TB patients are most infectious.





How does one get TB?

- Sputum-positive pulmonary TB patients are main source of infection. When such a patient coughs, sneezes, shouts loudly or spits, he/she throws the TB germs in the atmosphere in the form of small droplets. When a healthy person inhales these droplets, TB germs get into his/her lungs.
- The disease may not occur immediately but may develop later in life, when the body resistance is weak. An infectious TB case, if untreated, can infect 10 to 15 people in one year.



Ministry of Health and Family Welfare







TB Harega, Desh Jeetega!



Recover quickly, Eat healthy, Rejoin life!



The Government of India provides each TB patient ₹ 500 per month for nutrition support during treatment through Nikshay Poshan Yojana.

Contact your District TB Officer (DTO) or call the Nikshay Sampark Helpline for TB at 1800-11-6666 for information.







TB Harega, Desh Jeetega!



Use your DBT payments to eat rice, roti, dal, eggs, milk and vegetables!

Taking tablets regularly is important, but you must eat a healthy diet to recover!



Counsellor



Take your family's support during treatment.



Eat healthy and take your tablets even when you feel better! You will have more energy!



The Government of India provides each TB patient ₹ 500 per month for nutrition support during treatment through Nikshay Poshan Yojana.

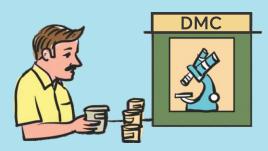
Contact your District TB Officer (DTO) or call the Nikshay Sampark Helpline for TB at 1800-11-6666 for information.







TB Harega, Desh Jeetega!



If you are diagnosed with TB, don't worry! Treatment adherence and nutrition will help you get cured.

Under Nikshay Poshan Yojana, you are eligible for nutrition support of ₹500 per month until your treatment is complete.

One, Two, Three...get DBT!



- Submit your bank account details to your treatment supervisor.
- You can open a zerobalance bank account under the Jan Dhan Yojana to receive payments or register with a relative's bank account.



 Check your registered mobile number for notifications of the deposit.





- Withdraw the money from the bank or ATM, and use it to supplement your diet.
- Contact your treatment supervisor if you do not receive payments.

Contact your District TB Officer (DTO) or call the Nikshay Sampark Helpline for TB at 1800-11-6666 for information.



TB is infectious, yet the easiest to prevent

TB spreads through air; one must cover his/her mouth while coughing/sneezing and do not spit here and there.

The TB patients should:

- Cover his/her mouth while coughing/sneezing, talking and should not spit here and there.
- Dispose off sputum in a piece of paper and burn it, or dispose it off in a pot filled with ash or lime and bury the sputum.
- Keep the windows of their room open for ventilation. TB germs don't survive for a long time in the sun-lit, well-ventilated atmosphere.
- Not miss a single dose of their DOTS.



Heard fictions about TB? Now, hear some facts

Myth: Tuberculosis is hereditary.

Fact: Tuberculosis is not hereditary. It spreads through the air. When a TB patient coughs, sneezes or speaks, he throws the germs into the air, which is inhaled by those around.

Myth: Smoking causes tuberculosis.

Fact: The cause of the infection is the mycobacterium tuberculosis. However, smokers are at an increased risk of getting TB disease.

Myth: BCG vaccination protects against developing TB.

Fact: While the vaccine prevents the severe forms of TB in childhood, it does not protect adults from developing the adult forms of pulmonary TB.

Myth: Tuberculosis affects only the lungs.

Fact: Tuberculosis primarily affects the lungs (80 percent), but can affect any part of the body except nail and hair.

Myth: An individual who has been infected with the mycobacterium tuberculosis will develop tuberculosis.

Fact: The tuberculosis infection does not always develop into tuberculosis

disease. It is estimated that only about 10 percent of the infected people develop tuberculosis sometime in their lives.

Myth: A positive tuberculosis test means that an individual has tuberculosis.

Fact: The A positive Mantoux/PPD TB skin test is only a confirmation of the exposure to TB. It is not a confirmation that the disease is present.

Myth: Individuals suffering from tuberculosis should be hospitalized.

Fact: Most patients suffering from tuberculosis can be treated at home and they can continue to work.

Myth: TB germs spread through handshakes, sitting on toilet seats, or sharing dishes and utensils with someone who has TB.

Fact: TB spreads only through the air.

Myth: TB can be diagnosed through blood tests.

Fact: It has been shown that blood tests for TB are unreliable, show large false positive and false negative results and should not be relied upon.





Central TB Division
Directorate General Health Services
Ministry of Health and Family Welfare
Government of India



Published by: Ministry of Health and Family Welfare Nirman Bhawan, Maulana Azad Road New Delhi - 110011 www.mohfw.gov.in / www.mohfw.nic.in

Developed with Technical Support from: USAID - NISHTHA/Jhpiego





