- TB treatment should never be delayed, but it should be stressed to the patient to attend the ART centre as soon as possible, without delay. Patients who are on ART from a source other than NACO should be referred to an NACO ART Centre if they are willing or to their existing ART providers with information on TB treatment initiation otherwise.

Process at ART Centre

1. In view of advanced clinical stage of HIV disease, HIV-infected TB patients are to be evaluated for ART on priority (Fast-tracked). HIV-infected TB patients should be prioritized for CD4 testing.

2. The ART Centre Staff Nurse are to record patients' TB notification number and name of referring unit in the pre-ART register (along with 'entry point code') and ART- register.

3. The ART Centre Staff Nurses are to record the patient in the "ART Centre TB-HIV Register", and include information on whether or not ART was initiated.

4. If the HIV-infected TB patient is initiated on ART, they would also continue their CPT from the ART Centre.

5. The ART Centre staffs are expected to provide feedback to the referring physician. In particular, the ART Centre staff should communicate when they have assumed responsibility for CPT provision, so that the PHI Medical Officer can know if CPT is to be discontinued from that source.

6. The daily anti-TB regimen will be dispensed from ART centre on monthly basis to the patient by ART centre pharmacist.

Provision of Co-trimoxazole Prophylaxis Therapy (CPT) to HIV-Infected TB patients:

- Co-trimoxazole is a fixed dose combination of sulfamethoxazole and trimethoprim; it is a broad spectrum antibiotic that targets a range of gram-positive and gram-negative organisms, fungi, and protozoa. Co-trimoxazoleis given routinely for the prevention of opportunistic infections in HIV-infected persons; this strategy is called **Cotrimoxazole prophylaxis therapy.** CPT reduces morbidity and mortality of HIV-infected patients in general and HIV-infected TB patients in particular.Additional points to remember include:

- Dose for prophylaxis for adults (> 14 years old) and > 30 kg body weight): 960 mg (800 mg sulfamethoxazole + 160 mg trimethoprim) daily.

- For children and very low-weight adults (<30 kg), CPT for these patients is managed by ART centres as per separate protocol.

- CPT is provided to patients in monthly pouches.

- CPT is self-administered by the patient on a daily basis, and not under direct observation.

- CPT can be taken alongside anti-tuberculosis treatment (ATT) and ART. Many patients who are eligible for ART would also have CPT continued at ART center.

- Pregnant patients are also eligible, regardless of foetus gestational age.

- Patients should have no history of a serious drug allergy to sulpha drugs or glucose-6 phosphate dehydrogenase (G6PD) deficiency.

Isoniazid Preventive Therapy (IPT) For PLHIVs

IPT is one of the 3 I's globally recommended for prevention of incident TB among HIV infected individuals. Isoniazid is the most effective bactericidal, anti-TB drug available at currently. While it protects against progression of latent TB infection to active disease i.e. reactivation, it also prevents TB reinfection post the exposure to an open case of TB. In 2011 the World Health Organization (WHO) issued specific recommendations regarding the use of IPT in its guidelines on "Intensified TB case finding and isoniazid preventive therapy for people living with HIV in resource constrained settings". The key recommendations included the following:

a) Adults and adolescents living with HIV should be screened for TB with a clinical algorithm and those who do not report any one of the symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered IPT. The guideline group strongly recommend use of Isoniazid 300 mg once daily for 6 months, in adult and adolescents,
b) Children living with HIV who do not have poor weight gain, fever or current cough are unlikely to have active TB
c) Children living with HIV who have any one of above symptoms may have TB and should be evaluated for TB and other conditions. If evaluation shows no TB, such children should be offered IPT regardless of their age.
d) Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening, and have no contact with a TB case should receive six months of IPT (10 mg/kg/ day) as part of a comprehensive package of HIV prevention and care services
e) All children living with HIV who have successfully completed treatment for TB disease should receive INH for an additional six months
f) Although IPT is more effective among Tuberculin Skin Test positive individuals (TST), it is not a requirement for initiating IPT intervention among the PLHIV considering difficulty in logistics and administration of the TST,
g) Providing IPT to people living with HIV does not increase risk of developing isoniazid (INH) resistant TB later. Therefore, concerns regarding development of INH resistance should not be a barrier to providing IPT

Steps in Provision of Isoniazid Preventive Therapy (IPT): The IPT provision involves following steps:

a) TB symptom screening at ART centre /Link ART-Plus and Link ART centres
b) Investigations for diagnosis of TB, if found symptomatic
c) If found Asymptomatic, assessment for the eligibility of Isoniazid Preventive therapy
d) If found eligible, initiation of IPT and Registration in IPT register maintained at the Nodal ART centre
e) Monthly collection of Isoniazid
f) Systematic recording and reporting
g) Continued TB symptom screening on each follow-up visits and reconsideration of IPT if symptoms develop

Monthly collection of Isoniazid: All eligible patients are to be initiated on IPT. The regimen prescribed are as below:

a) Adult and Adolescent: Isoniazid 300mg +Pyridoxine 50mg (Vitamin B6) per day for 6 months
b) Children above 12 months: Isoniazid 10mg/kg +Pyridoxine25 mg (Vitamin B6) per day for 6 months

The strategy for monthly collection of Isoniazid + Pyridoxine is as follows:

a) Patients on ART monthly collection from the ART centre, LAC-Plus or LAC along with monthly collection of the ART

b) Patients in pre-ART care visit the ART centre only once in six months. These patients may collect the monthly Isoniazid/ Pyridoxine packet from the designated stand-alone ICTC.

Systematic recording and reporting

All events in the cascade of IPT implementation including symptom screening at all contacts, IPT eligibility assessment, investigations, and the compliance with regimen are to be systematically recorded and reported.

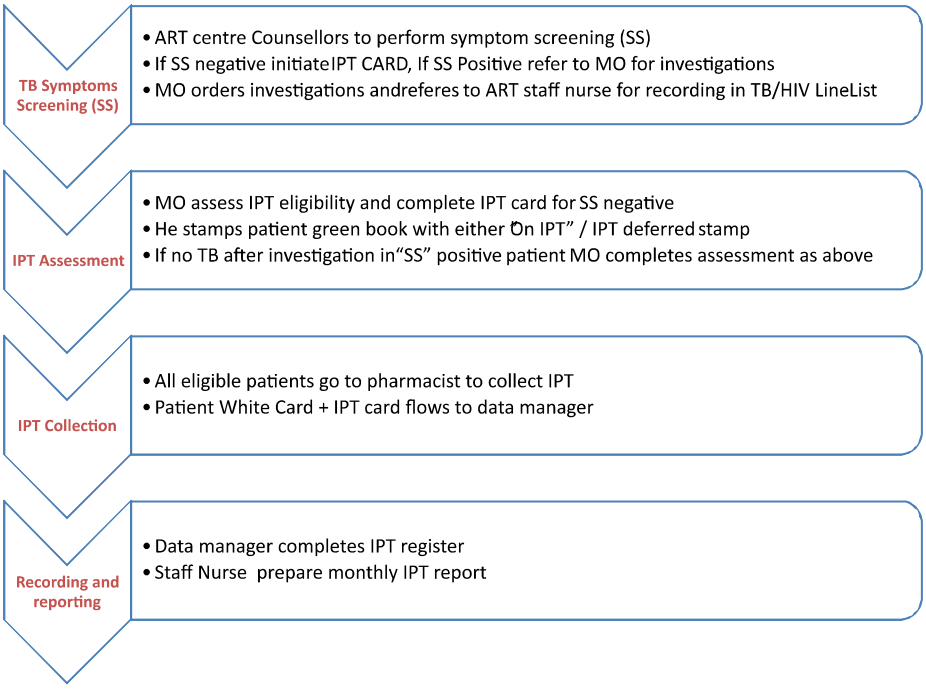
Mechanism of IPT implementation

The ART centre counsellor, staff nurse is to perform TB symptom screening (SS) among all the PLHIV attending the ART centre. If the SS is found negative, an IPT card is initiated, if the patient is found to be SS positive, s/he is referred to the ART centre Medical Officer for further opinion and investigations to rule out active TB disease. The MO prescribes the investigations and refers the patient to the ART centre staff nurse for inclusion in the TB/HIV Line-List

In rest of the patients, the MO undertakes assessment for eligibility of the patient for IPT and also completes the IPT card. He further stamps patient green book with either "On IPT" or IPT deferred stamp based on the situation. Also in patients found not suffering from TB after the investigations the MO undertakes the assessment as above.

All patients found to be eligible for IPT are referred to the pharmacist for collection of drugs. Concurrently the MO ensures that the Patients White Card and the IPT card are sent to the ART centre data manager so that the IPT register is updated. The data manager in turn updates the IPT register and Staff Nurse later prepares the monthly IPT report based on this register. This flow of patient and information is depicted pictorially in **Figure as follows.**

Figure: Mechanism of IPT implementation



TB and diabetes

As a consequence of urbanization as well as social and economic development, there has been a rapidly growing epidemic of Diabetes Mellitus (DM). India has second largest number of diabetic people in the world. As per recent estimates, there are around 66 million DM cases, with a further 77 million people having impaired glucose tolerance.

People with a weak immune system, as a result of chronic diseases such as diabetes, are at a higher risk of progressing from latent to active TB. Hence, people with diabetes have a 2-3 times higher risk of TB compared to people without diabetes.

- About 10% of TB cases globally are linked to diabetes.
- A large proportion of people with diabetes as well as TB is not diagnosed, or is diagnosed too late. Early detection can help improve care and control of both diseases.
- DM can lengthen the time to sputum culture conversion and theoretically this could lead to the development of drug resistance if a 4-drug regimen in the intensive phase of therapy is changed after 2 months to a 2-drug regimen in the presence of culture-positive TB.
- People with diabetes who are diagnosed with TB have a higher risk of death during TB treatment and a higher risk of TB relapse after completing treatment.
- DM is complicated by the presence of infectious diseases, including TB.
- It has been argued that good glycemic control in TB patients can improve treatment outcomes
- The precise biological mechanisms that result in this interaction between Diabetes and TB are still not clear. Epidemiological models have shown that DM accounts for 20% of smear-positive pulmonary TBand recent analyses have indicated that the increase in DM prevalence in India has been an important obstacle to reducing TB incidence in the country

National framework for joint TB- DM collaborative activities

The overall 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 strategy is proposed for collaboration between NPCDCS and RNTCP

1. Establishing joint planning and review committee for collaboration at National, State and District levels.
2. Establishment of service delivery protocols that address joint activities is as follows:

    a. Activities to improve diagnosis and management of Diabetes among TB patients:
    - Screening of all registered TB patients for DM
    - Ensuring DM management among TB patients

    b. Activities to improve diagnosis and management of TB among diabetic patients:
    - Intensified detection of active TB disease among DM patients
    - Ensuring TB infection control measures in health care settings where DM is managed
    - Ensuring TB treatment and management in comorbid patients

3. Joint monitoring and evaluation with standardized reporting shared between NPCDCS and RNTCP
4. Joint training of key programme and field staff in Diabetes/TB activities
5. Awareness and IEC activities
6. Operational research to strengthen implementation of DM/TB Collaborative Activities

Mechanisms for collaboration between RNTCP and NPCDCS

Mechanism for collaboration comprise at the National level, aNational TB-DM Co-ordination Committee (NCC) of key officials from NPCDCS and CTD, experts from WHO, national institutes and civil society; at the Stated level, State Coordination Committee on TB- DM, chaired by MD National Health Mission and at the district level, District Coordination Committee (DCC) under the chairmanship of District Collector. States may create Coordination committee on TB-Comorbidities and sub-committees (TB-DM, TB-Tobacco, TB-Alcohol) etc under the SCC for ease of functioning. Alternatively states may start with a separate committee till the systems are set and later on can be merged with the "one" body. These committees will ensure smooth coordination and oversight the collaborative activities.

Screening Intervention and Diagnosis of Diabetes among TB patients

- All TB patients who have been diagnosed and registered under RNTCP will be referred for screening for Diabetes. Referral of TB patients for screening for DM and its recording & reporting is responsibility of the Peripheral Health Institutions (PHI) where TB treatment is initiated.
- The screening for DM will follow the guidelines stipulated by NPCDCS in India. Those guidelines stipulate that fasting blood glucose (FBG) be carried out using a finger prick and glucometer with cut-off thresholds in line with those recommended by the NPCDCS.
- Screening TB patients for DM should be conducted as early as possible after diagnosis of TB; but can be done at any time during the course of TB treatment. Because of the difficulties in getting TB patients to first come to the clinic in a fasting state, TB patients will be initially screened with a random blood glucose (RBG) using a glucometer. If the RBG is less than 140 mg/dl, this is a normal result and no further tests need be carried out. If the RBG is at or greater than 140 mg/dl, this might indicate an abnormal glucose state and there is a possibility of DM. The patient will be asked to return in a fasting state, and a fasting blood glucose (FBG) will be carried out. FBG value at or greater than 126 mg/dl indicates DM.The criteria for diagnosing Diabetes will be as follows.

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

- Criteria for suspected Diabetes case is reading of 140 mg/dl for Random Blood Glucose by glucostrip. The suspected case needs to undergo Fasting Blood Glucose test and Post Prandial tests to confirm diabetes
- The blood glucose testing will be done by a person designated and trained for the purpose at every peripheral health institution (PHI). Though, this would vary from site to site the following general principles would apply. Wherever, NPCDCS is being implemented, the Auxiliary Nurse Midwife (ANM) has been trained to use glucometer and screen people for DM. In case this mechanism is not available, the laboratory technician working in the PHI will be trained to do the test. If a PHI does not have a laboratory technician, then either the staff Nurse or any other staff designated by the MO-PHI will be trained to do the test.

Linkage of TB patients with DM for Diabetes care and management –

All Diabetic TB patients should be linked for diabetic care. In the districts where NPCDCS is being implemented, TB patients with DM or with a FBG at or higher than 126 mg/dl will be referred to diabetes care using a referral form for definite diagnosis and management. A referral and feedback mechanism will be developed to enable timely exchange of information. Good cooperation and collaboration will need to be developed between the two sets of staff working in the different service areas.

- At districts where NPCDCS is not implemented, TB patients should be referred to the nearest healthcare facility for further diagnosis and management of TB-DM comorbidity.
- TB patients diagnosed with Diabetes should receive the same duration of TB treatment with daily regimen as non- Diabetic TB patients.

Screening and referral of Diabetic patients for TB

- Four-symptom complex screening for active TB in Diabetes patients is to be done. Screening is expected to be carried out every time the patient visits the DM clinic. Patients will be asked whether they are on TB treatment, and if not, they would be screened for four-symptom complex, i.e.Cough of any duration, Fever, Weight loss, Night sweat.
- The Screening results for Diabetes are to be recorded in the patient NPCDCS register
- NCD clinic will implement basic infection measures as stipulated in RNTCP guidelines

Linkage of Diabetic patients with TB for TB case management-

On screening, patients with one or more symptoms will be referred to nearest diagnostic facility for diagnosis of TB.A referral and feedback mechanism will be developed to enable timely exchange of information. The patients diagnosed for TB would be initiated on TB treatment as per management guidelines stipulated in RNTCP.

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. Still, there remains a question as to whether malnutrition predisposes to tuberculosis, or whether it is a consequence of the disease. There is as yet little evidence showing that additional nutrition support improves TB-specific outcomes, but low body mass index as well as lack of adequate weight gain during TB treatment are associated with an increased risk of TB relapse and death.

The basic recommendations to address nutritional needs of TB patients are discussed below:

1. Conducting an initial nutrition assessment of TB patients with further monitoring;
2. Providing ongoing counselling for patients on their nutritional status; Diet for TB patients starting treatment should include: cereals (maize, rice, sorghum, millets, etc.); pulses (peas, beans, lentils, etc.); oil; sugar, salt; animal products (canned fish, beef and cheese, dried fish); and dried skimmed milk.
3. Management of severe acute malnutrition should be treated according to national guidelines and WHO recommendations;
4. Management of moderate under nutrition for TB patients who fail to regain normal Body Mass Index (BMI) after two months of TB treatment or appear to lose weight during TB treatment should be evaluated for a proper treatment adherence and other comorbidities. If indicated, these patients should be provided with locally available nutrient- rich or fortified supplementary foods. Special categories of TB patients such as :
    - Children who are less than 5 years of age should be managed as any other children with moderate under nutrition. Pregnant women with active TB, patients with MDR TB should be provided with locally available nutrient- rich or fortified supplementary foods.

- Micronutrient supplementation for all pregnant women as well as lactating women with active TB. These women should be provided with iron and folic acid and other vitamin and minerals to complement their maternal micronutrient needs. In situations when calcium intake is low, calcium supplementation is recommended as part of antenatal care.

The Guidelines on Nutritional assessment and supplementation for the TB patients in India are being prepared so that the programme can adapt the basic principles of nutrition for better outcomes.

Under nutrition and underlying food insecurity are among the most important determinants of TB. Improving nutritional status at population level is important for TB prevention. This should be part of broader actions on social determinants. All efforts should be made to link TB patients for the nutritional support. It can be through the existing public distribution system, local self-government or NGO or donor agencies or through corporate sector under Corporate Social Responsibility (CSR).

Management of severe acute malnutrition: Children below 5 years, School-age children and adolescents (5 to 19 years), and adults, including pregnant and lactating women, with active TB and severe acute malnutrition should be managed for severe acute malnutrition.

TB and tobacco

India is the second largest consumer and the third largest producer of tobacco in the world(FAO, 2005). Nearly one million Indians die from tobacco use every year, which is much more than combined mortality resulting from HIV/AIDS, TB and Malaria. As per Global Adult Tobacco Survey, (GATS 2010, a household survey of persons 15 years of age and above) there are 275 million adult tobacco users in India. It is estimated that more than one- third (35%) of adults in India use tobacco in some form or the other. The prevalence of smokeless tobacco use (26%) is almost twice that of the prevalence of smoking tobacco (14%).

Tobacco smoke contains toxic chemicals which cause disturbances in the bronchial surface of the lung. It also weakens the immunity of the patient to fight with the TB bacteria.
The following evidence emerges from several studies conducted to look at the association of TB and tobacco in India:

- Almost 38% of TB deaths are associated with the use of tobacco.
- Prevalence of TB is 3 times as high among ever-smokers as compared to that of among never-smokers.
- Mortality from TB is 3 to 4 times as high among ever-smokers as compared to that among never-smokers.
- Smoking contributes to half the male deaths in 25-69 age groups from TB in India.

Exposure to tobacco smoke has also been found to affect TB in the following ways :

- Increase the risk of tuberculous infection and the risk of developing TB
- Affect clinical manifestations and increase risk of relapse among TB patients
- Affect microbiological conversion (sputum smear or culture) and outcome of treatment in TB patients
- Increase tuberculosis mortality and drug resistance to anti–tubercular drugs

Integrating Brief Advice for Tobacco Cessation

- When a patient gets registered as a tuberculosis case, the status of tobacco use is enquired.
- The information will be recorded in the TB treatment card in front portion using stamp
- If the TB patient is a smoker or tobacco user, he/she is offered 'Brief Advice' to quit tobacco used based on 5As and 5 Rs model
- The patient is assessed at every visit for follow up for TB and the status of tobacco use or quitting. At the end of treatment, his/her status of tobacco use is recorded in treatment card.
- If the patient has not quit tobacco use, he/she will be referred to the nearest Tobacco Cessation Clinic (TCC) or Quit line or m- cessation initiative.
- The information recorded in treatment card will be sent through the existing HMIS under RNTCP

Brief advice for quitting tobacco use consists of 5 'A's

1. **Ask** the patient if he/she is a tobacco user, during the course of every visit.
2. Briefly **Advise**against continuing tobacco use and link the current condition/ailment to continued tobacco use, where possible. Eg, “Quitting smoking/tobacco use would improve your health and will aid in early recovery from illness.”
3. Then **Assess** readiness to quit by asking the patient whether he or she is ready to quit tobacco use at this time. Eg, “How recently have you thought about quitting tobacco?” If the patient appears ready to change (quit), next steps are:
4. **Assist** the tobacco user in making a quit plan.
5. **Arrange** for follow-up by setting the next contact date.

If the tobacco user is not yet thinking about quitting tobacco use, the doctor/counsellor/treatment supporter will promote greater awareness of the **Relevance** to the patient of the advice to quit, the **Risks** of tobacco use and the **Rewards** (benefits) of quitting. Many tobacco users are largely unaware of the potential harm that continued tobacco use can do to them. If the patient is not ready to quit, the doctor/ counsellor/treatment supporter must not push the patient. People usually need time to change the mindset. If the patient is at least thinking about quitting, the doctor/ counsellor/treatment supporter can find out the patients' **Roadblocks** to quitting and help the patient see ways to overcome these. This process will assist the patient to get ready for quitting the tobacco use, without being forceful.

The 5 R's are :

- **Relevance** of quitting
- **Risks** of continuing
- **Rewards** of quitting
- **Roadblocks** to quitting
- **Repeat** at each visit

Awareness and IEC

- All the DOTS centre /Clinics will be made tobacco free
- IEC material will be displayed at TUs, DMCs and Tobacco Cessation Clinics.
- DMCs and TUs will display IEC material about the hazards of tobacco use, along with the brief advice.
- Tobacco Cessation Clinics will display hygiene and TB awareness related materials.
- Awareness building efforts will be done at both units for patients and staff.
- Sensitisation of all stakeholders (partners, policy-makers and administrators) will be done on regularly basis.
- Every effort will be made by both the programme divisions to sensitise the community about the ill effects of TB and tobacco use

Recording & reporting- Information on tobacco usage and its status is captured in treatment card.

Involvement of National Tobacco Control Programme in tuberculosis control

For enhancing active screening of TB patients through NTCP, the following process is indicated:

- Screening of four symptoms of active TB among tobacco users registered at the District TCC clinic and NCD Clinic at CHC- cough, fever, night sweat and weight loss
- Quit line established for tobacco cessation advice to conduct follow up of comorbid patients (TB patients with tobacco use) registered as TB cured, to identify TB relapse cases
- m-cessation initiatives to include TB-screening symptoms in cessation modules to identify active TB cases in people registered for tobacco cessation
- Ensure implementation of infection control guidelines in TCC Clinics
- Tobacco training modules prepared for teachers to include TB symptoms for increasing awareness among children and young adults

TB & 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.