TB/HIV Module

for ART Centre Staff

National AIDS Control Organization
And
Central TB Division
Ministry of Health & Family Welfare
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Foreword

The consequences of TB amongst HIV-infected patients are well documented but it continues to gain importance because of its significant impact on the National HIV and TB programmes. There is 3-8% annual breakdown of TB amongst patients on ART. HIV-infected TB suspects/patients may seek care in ART centers, exposing other HIV-infected persons to TB, thus demanding special attention to ensure early TB diagnosis and provision of anti-TB treatment with ART.

The "TB/HIV Module for ART Centre staff" establishes uniform activities at ART centers nationwide. The intensified TB case finding at HIV care settings will aid in the early diagnosis and provision of TB treatment alongside HIV care & support. The staffs at ART centres are in the best position to detect signs & symptoms of TB, fast track the TB suspects to the Medical Officer for evaluation and if diagnosed to be TB, be initiated on treatment. This will also reduce airborne transmission of TB in HIV care settings where large numbers of PLHIVs gather daily. The recommended changes in the recording and reporting at ART centres will help in tracking the HIV-infected TB patients on priority and ensure they receive timely care and support.

This module has been prepared by NACO & Central TB Division to act as a guidance tool for all programme managers for HIV and RNTCP to strengthen HIV-TB collaboration at HIV care settings. The overall purpose is to reduce the burden of HIV-infected TB patients in the country.

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Acknowledgement

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I. Introduction

The HIV/AIDS epidemic has increased the global tuberculosis (TB) burden, and has focused attention on the necessity to closely coordinate TB and HIV/AIDS control programme services. It is estimated that about 2.31 million adults are infected with HIV in India. The primary impact of HIV on TB is that the risk of developing TB becomes higher in patients with HIV. Overall, HIV-infected persons have approximately an 8-times greater risk of TB than persons without HIV infection. Throughout the course of HIV disease, there is an increasing risk of TB. This increased risk is detectable as early as HIV seroconversion, and the risk of TB almost doubles during the first year after HIV seroconversion. The risk of TB in HIV-infected persons continues to increase as HIV disease progresses and CD4 cell count decreases. While anti-retroviral treatment can substantially decrease the risk of TB, this risk always remains higher than that in HIV negative individuals. Furthermore, among cured TB survivors with HIV infection, the risk of recurrent TB is also quite high.

In India 55-60% of AIDS cases reported had TB, and TB is one of the leading causes of death in People living with HIV/AIDS (PLHA). TB patients who are HIV positive have higher risk of dying during treatment than TB patients without HIV. HIV positive patients who have TB have higher mortality than HIV positive patients without TB. Even if TB is successfully treated, TB may also accelerate HIV disease progression, increasing the risk of subsequent death or other opportunistic infections in TB survivors. Hence, long term post-TB mortality among PLHA is extremely high.

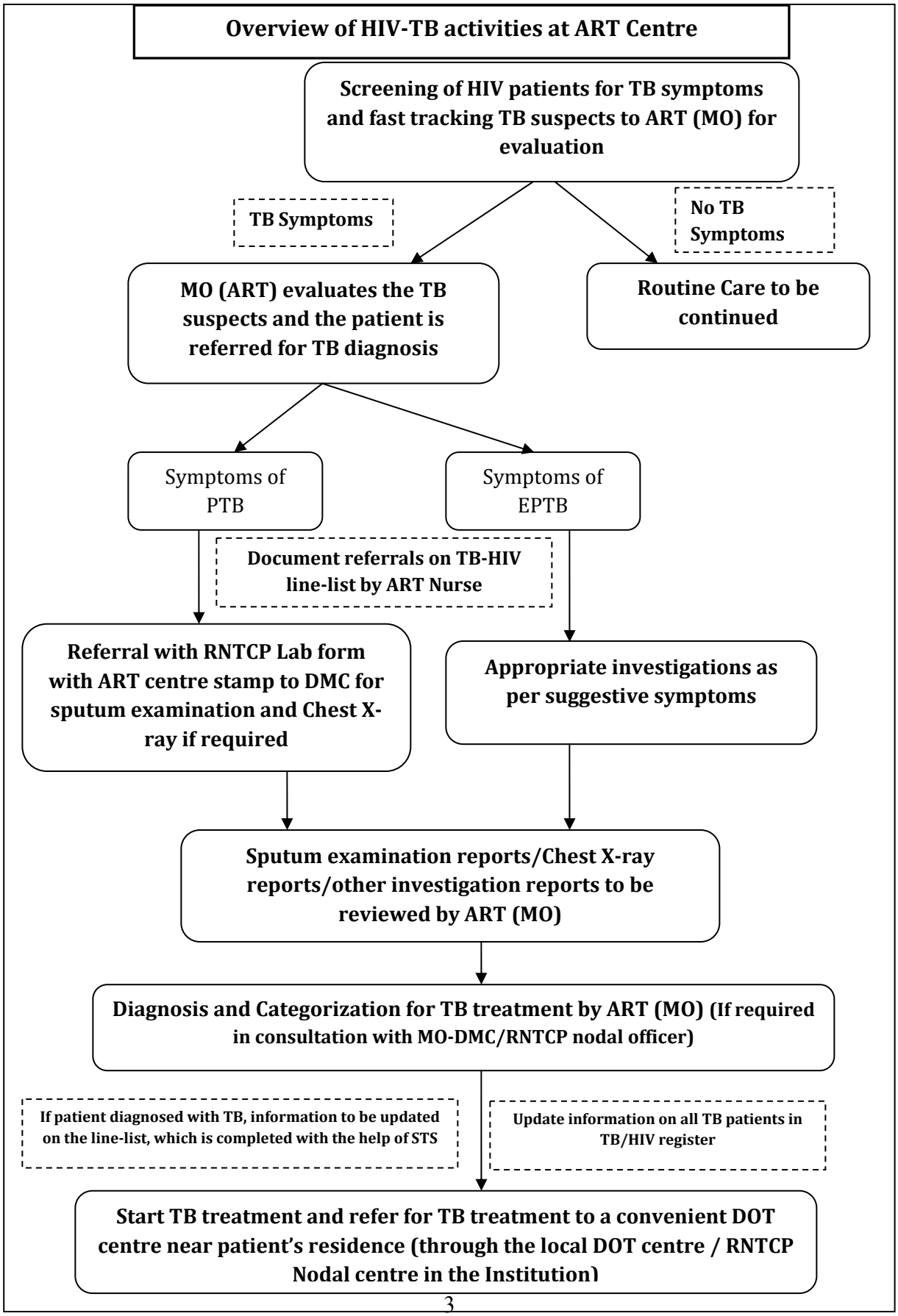
From the public health point of view, the best way to prevent TB is to identify all persons in the community with infectious TB as early as possible, provide prompt & effective treatment and cure them. This interrupts the chain of transmission including those with HIV-infection and can thus prevent the disease burden of HIV-TB co-infected cases. Beyond the implementation of high-quality basic TB services, the high burden of TB among PLHA demands special attention to early TB diagnosis and provision of anti-TB treatment. Special interventions include intensified TB case finding at places with large numbers of PLHA, like ART centers, Community Care Centers (CCCs), Link ART centers (LAC), ICTCs and NGO led Targeted Intervention sites (TIs). Intensified TB case finding should aid in the early diagnosis of TB and provision of TB treatment alongside HIV care & support. Early diagnosis and treatment of TB also means reduced transmission of TB in healthcare settings, which is particularly important in HIV care settings where large numbers of PLHA gather daily. Counselors and clinicians at HIV care settings provide daily care to the PLHA population, and thus are in the best position to detect signs or symptoms of TB and refer such patients to the nearest RNTCP services. Therefore, NACP ART centers and the Community Care Centers are crucial settings for implementation of TB/HIV collaborative activities.

2. Reasons for concern for TB in ART centers

HIV-infected persons attending the ART center for pre-ART registration or have a high burden of TB at baseline. After enrolment, the risk of TB remains extremely high, so the incidence of TB is very elevated compared to general outpatient facilities. ART alone somewhat reduces the risk of TB disease; however, even after ART is started, the risk of TB still remains many times higher than the general population, especially during the first few years of ART. Even among those who have already had TB in the past and been cured, they are still extremely susceptible to recurrent TB disease, usually caused after new exposure (re-infection) to TB in health care settings.

With so many opportunities to develop TB, HIV-infected clients with undiagnosed and untreated TB can be expected to seek care in ART centers posing the risk of exposing other HIV-infected persons to TB. The NACP ART guidelines describe that all patients coming to the ART center should be screened for opportunistic infections, especially TB. The process of screening patients for TB is known as "intensified TB case finding (ICF)". ICF is very important for early suspicion and diagnosis of TB; early diagnosis and treatment are crucial to control TB before it worsens and disseminates in HIV-infected persons, and can reduce the risk of death from TB. ICF is also important for preventing transmission of TB to other clients at the ART center, who should not be exposed to the risk of TB just because they are seeking care for their HIV. The ART centers staff (SMO/MO/Nurse/counselor/PLHA coordinator) should thus have a very high index of suspicion for TB and ensure that all patients with symptoms of TB should be provided prompt diagnosis and treatment in collaboration with local RNTCP services. TB should be high on the differential diagnosis in any HIV-infected patient with unexplained localized or constitutional symptoms.

Community care centers (CCC) and Link ART Centers (LAC) provide a range of services for HIV-infected persons in the community. Some of these centers have busy outpatient services, and create many of the same risks for TB as ART centres. Hence the activities described in these guidelines apply equally to CCC and LAC with outpatient services. The term ART centres, however, is used throughout the guidelines for simplicity.


Overview of HIV-TB activities at ART Centre
Screening of HIV patients for TB symptoms and fast tracking TB suspects to ART (MO) for evaluation
TB Symptoms
No TB Symptoms
MO (ART) evaluates the TB suspects and the patient is referred for TB diagnosis
Routine Care to be continued
Symptoms of PTB
Symptoms of EPTB
Document referrals on TB-HIV line-list by ART Nurse
Referral with RNTCP Lab form with ART centre stamp to DMC for sputum examination and Chest X-ray if required
Appropriate investigations as per suggestive symptoms
Sputum examination reports/Chest X-ray reports/other investigation reports to be reviewed by ART (MO)
Diagnosis and Categorization for TB treatment by ART (MO) (If required in consultation with MO-DMC/RNTCP nodal officer)
If patient diagnosed with TB, information to be updated on the line-list, which is completed with the help of STS
Update information on all TB patients in TB/HIV register
Start TB treatment and refer for TB treatment to a convenient DOT centre near patient's residence (through the local DOT centre / RNTCP Nodal centre in the Institution)

3. Intensified TB case finding at ART Centers

Screen all patients for the following signs and symptoms

Symptoms

- Cough (of any duration)
- Cough with blood in sputum
- Unexplained Fever
- Unexplained weight loss, excessive fatigue/night sweats/loss of appetite
- Pleuritic chest pain (increasing on cough/deep breathing)
- Swelling in the neck, arm pits, groin, abdomen, joints etc.

When to do the screen: **All visits, including:**

- Pre-ART registration & follow-up visits
- ART initiation
- Monthly visits to ART centre & ART medical follow up (6 monthly)
- Unscheduled follow-up visits
- At all patient encounters at the ART centre

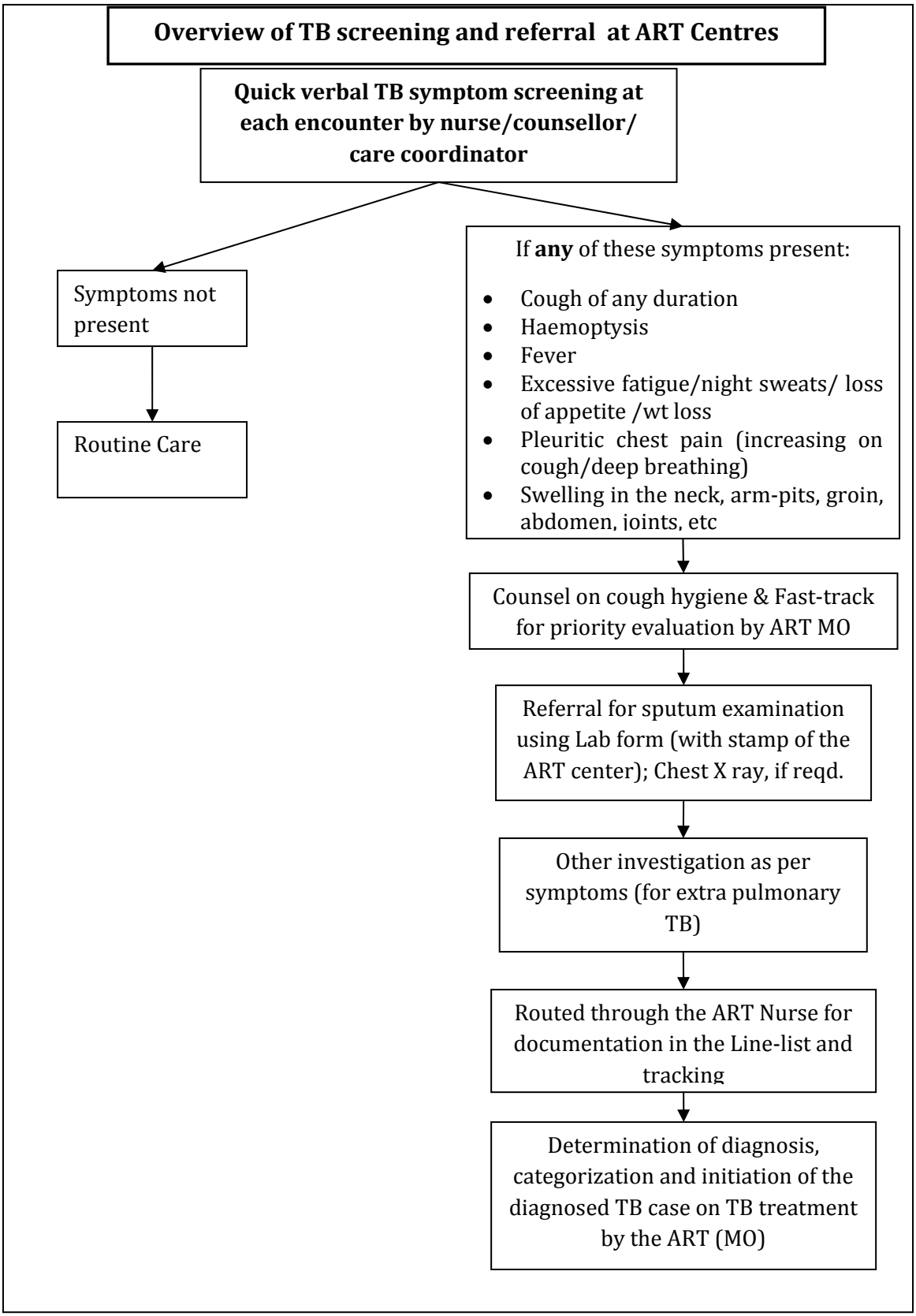
Fast tracking of chest symptomatics

Nurse, Counselors, medical officers, care coordinator, pharmacists and any other ART center staff is responsible to screen the patients for TB as per the above mentioned guidelines. The care coordinator, counselor and Nurse at the ART center would be made responsible for identification and fast tracking all the patients coughing in the OPD and waiting area to the medical officer. This would help in segregating the chest symptomatics from the others. The ART staffs get to spend the maximum amount of time with the patients, so are in the best position to do a quick screening of the patient for TB and if required, refer the patient to the ART MO for evaluation.

If symptoms suspicious for TB disease are present

- ART Centre health staff to refer patient to ART MO for clinical evaluation
- ART Centre medical officer to refer patient on the same day for:
    - Sputum microscopy to the institutional Designated Microscopy Centre using a RNTCP lab form with an ART center stamp for prioritization at the DMC (annex 4)
    - Chest X-Ray, if indicated as per NACO ART guidelines
    - Any additional investigations as clinically indicated like FNAC, Ultrasound, etc (refer to ART guidelines).

It is to be noted all the HIV positive patients need not be referred routinely for sputum microscopy; *only those with symptoms* (especially cough with expectoration) need to be referred for microscopy.


Overview of TB screening and referral at ART Centres
Quick verbal TB symptom screening at each encounter by nurse/counsellor/ care coordinator
Symptoms not present
Routine Care
If any of these symptoms present:
Cough of any duration
Haemoptysis
Fever
Excessive fatigue/night sweats/ loss of appetite /wt loss
Pleuritic chest pain (increasing on cough/deep breathing)
Swelling in the neck, arm-pits, groin, abdomen, joints, etc
Counsel on cough hygiene & Fast-track for priority evaluation by ART MO
Referral for sputum examination using Lab form (with stamp of the ART center); Chest X ray, if reqd.
Other investigation as per symptoms (for extra pulmonary TB)
Routed through the ART Nurse for documentation in the Line-list and tracking
Determination of diagnosis, categorization and initiation of the diagnosed TB case on TB treatment by the ART (MO)

Counselling of coughing patients on cough hygiene

It is of utmost importance for the nurse/counselors/care coordinators at the ART centers to reinforce again and again cough hygiene practices in patients with any chest symptoms. Cough hygiene is especially important for the undiagnosed patients, who would be the most infectious to others as treatment would have not yet started. All coughing patients should be advised to:

- ❖ Cover the nose and mouth when coughing/sneezing either by using tissue/handkerchief or putting nose/mouth in the hollow of their elbow.
- ❖ Use tissues to contain respiratory secretions and dispose of them in the nearest garbage bin after use.
- ❖ Wash hands with soap and water after having contact with respiratory secretions or contaminated objects.
- ❖ If space permits, try to sit at least 3 feet away from others in common waiting areas.

Referral to RNTCP, Designated Microscopy Center (DMC)

- The ART MO would refer the TB suspect directly to the Designated Microscopy Center for sputum examination without necessarily having to pass through the general OPD. This would help in preventing unnecessary delay in diagnosis of TB and would minimize the exposure of the HIV patient to other nosocomial infections. This referral process is facilitated by the Nurse who assists with the completion of a standard RNTCP Laboratory Referral for Sputum Microscopy form (next page). The source of referral should be named and indicated as "ART Centre" on the referral forms itself.
- The Nurse then documents the TB suspect referral in the "LINE-LIST OF PERSONS REFERRED FROM ART CENTRE TO RNTCP" (Table 2, discussed in detail later in the Reporting & Recording chapter of this module). The line list would then be shared between the nurse and the STS (of the TU where ART centre is located) during the monthly coordination meetings.
- The Lab. Technician at DMC would be instructed to collect the sputum sample of the patient referred from the ART centre on priority. The lab technician would be instructed to mention "ART centre" as the source of referral for such patients in the RNTCP lab register.

RNTCP Laboratory Form for Sputum Examination

Name of Referring Health Facility: _____ Date: _____

Name of patient: _____ Age: ____ Sex: M □ F □

Complete address: _____

_____

Contact Phone number / Mobile No.: _____

Type of suspect / disease: □ Pulmonary

□ Extra-pulmonary **Site**: _____

Reason for examination:

□ Diagnosis

□ Repeat Examination for Diagnosis

□ Follow-up examinations

- For new and previously treated cases - Month of follow-up …….
- For MDR-TB cases – Month of follow-up ……

Treatment Regimens (tick ✓ appropriate box):

□ New cases □ previously treated □ MDR-TB

Patient's TB No. _____

(Name and signature of referring person/ official)

If sputum samples are being transported:

Specimen identification No.: _____ Date of sputum collection: _____

Specimen Collector's name and signature _____

RESULTS (To be completed in the laboratory of DMC)

Name of DMC: _____

Lab. Serial No.: _____

Date of examination	Specimen	Visual appearance (M, B, S)*	Results (Neg or Pos)	Positive (grading)			
				3+	2+	1+	Scanty**
	a						
	b						

* M = Mucopurulent, B = Blood stained, S = Saliva

** Write actual count of AFB seen in 100 oil immersion fields

Signature of Lab. Technician

Date: _____ _____

The completed form (with results) should be sent to the referring PHI within a day of the examination.

Feedback on microscopy results to the ART center:

- The Lab technician would send the sputum report of the HIV positive patient directly to the ART MO, to enable diagnosis and categorization of the patient for TB treatment.
- The ART center (MO) on receiving a feedback from the DMC (or any other investigation suggested) for Extrapulmonary (EPTB) would proceed to diagnose the patient. The ART MO, like any MO in a peripheral health institute, is empowered to make those decisions. The ART MO may elect to take the support of other clinicians, of course, in establishing the diagnosis. The basic responsibility, however, to manage opportunistic infections in ART center clients is with the ART MO themselves.
- If TB of any type is diagnosed, the ART MO would then categorise the patient as per the RNTCP guidelines. He would then link him to the nearest DOT centre (preferably in the same facility) for starting TB treatment. For the patients who require DOT outside the facility, they would be linked to the most convenient DOT centre through the RNTCP Referral for treatment mechanism. The referral would be facilitated by the DTC/RNTCP unit at the health facility.
- In case the TB patient is admitted, treatment may be started using prolongation pouches for the duration of admission, registered in the local TU and then transferred out for the continuation of treatment to the nearest and most convenient DOT centre to the patient's place of residence as per RNTCP guidelines.
- The information on TB diagnosis would be recorded in the line-list by the ART Nurse and shared with the STS, who then would complete the line-list by entering treatment details. This information along with other details would then be entered in the "TB-HIV Register" (Table 1, discussed in detail later in the Reporting & Recording chapter of this module) which would be maintained by the nurse at the ART center. This register would be a dynamic register with information not just on the diagnosis of TB but also other treatment being provided (CPT and ART) along with the treatment outcome for TB.

4. Clinical features of TB in HIV-infected persons

Pulmonary TB (PTB) is most common form of TB disease. HIV positive and HIV negative patients with active pulmonary TB generally manifest similar clinical features, namely cough, fever, night sweats, haemoptysis and weight loss. The presentation may sometimes vary with the degree of immune suppression. In patients with mild immune suppression, the clinical picture often resembles usual adult post-primary pulmonary TB; that is, the sputum smear is frequently positive for acid-fast bacilli (AFB), and the chest X-ray (CXR) typically may show unilateral or bilateral upper lobe infiltrates, cavitations, pulmonary fibrotic changes, and/or volume loss.

In severely immune suppressed patients, the overall risk of TB is even higher, but it is more difficult to distinguish TB from other serious chest diseases. In persons with advanced HIV infection, disseminated and extrapulmonary TB (EPTB) are more common than in early HIV infection, and may be as common as pulmonary TB. The most common forms of EPTB seen are lymphadenitis, pleural effusion, pericarditis, miliary disease and meningitis. In PTB, the features of the disease are frequently atypical, resembling those of primary TB as historically seen in children. Smear-negative TB is as common as smear-positive TB. The chest x-ray pattern in advanced HIV infection shows may show any pattern. Hilar lymphadenopathy is frequently observed, and interstitial infiltrates tend to be common, especially in the lower zones; features such as cavitation or fibrosis are less common. Infiltrates may be unilateral or bilateral, and are seen more often in the lower lobes than in the upper lobes.

TB should be part of the differential diagnosis in any HIV-infected person with unexplained constitutional symptoms.

Process of diagnosis: (source NACO Opportunistic Infection Guidelines, and RNTCP guidelines)

The medical officer at the ART centre will undertake clinical evaluation of HIV-infected patients and if found to have symptoms suggestive of TB will refer patient on the same day for:

- Sputum microscopy to the institutional DMC
- Chest X-ray, if indicated
- Additional investigations as clinically indicated, depending on symptoms

Two sputum specimens are required for diagnosis of smear positive pulmonary TB, with one of them preferably being a morning sputum specimen. Using the RNTCP laboratory form for sputum examination, the medical officer / health staff of the health facility sends the TB suspects for sputum examination to the laboratory of RNTCP designated microscopy

centre (DMC). The two sputum specimens are collected over one, or two consecutive days. Of the two sputum specimens, one is collected on the spot and the other is preferably an early morning sample collected at home by the patient.

The diagnosis of TB made by an ART medical officer or any medical officer trained in RNTCP is adequate to warrant treatment under RNTCP. Though clinical consultation with the MO-DMC may be available to aid in decision making, the ART-MO are empowered to diagnose TB and initiate anti-TB treatment.

Tuberculosis case definitions and classifications

Tuberculosis is classified by the following criteria:

a) *disease site* (pulmonary or extrapulmonary)

b) *sputum smear-status* (smear-positive or smear-negative disease)

c) *registration type* of TB (based on prior anti-TB treatment) and

d) *treatment category* (I, II)

Disease site and sputum smear status

Pulmonary Tuberculosis: Smear-positive pulmonary TB

A patient with one or two smears being positive for AFB out of the two sputum specimens subjected for smear examination by direct microscopy is smear positive pulmonary TB

Pulmonary Tuberculosis: Smear-negative pulmonary TB

Patients with two smear negative on first occasion, persisting with symptoms following 10 – 14 days of broad spectrum antibiotics (other than those having anti tubercular activity) and repeat sputum examination being negative with radiological abnormalities suggestive of active TB is diagnosed as having smear negative pulmonary tuberculosis.

Extra-pulmonary TB

Tuberculosis of organs other than the lungs such as pleura, lymph nodes, intestine, genitor-urinary tract, joint and bones, meninges of the brain etc., is called as extra-pulmonary TB. Pleural tuberculosis is classified as extra pulmonary. The diagnosis should always be supported by investigations like histopathology, cytology, radiological and bio-chemical examinations. Wherever facilities for mycobacterial culture are available, this can be utilized for the diagnosis.

If a patient has both pulmonary TB and extra-pulmonary TB, the patient is classified as having pulmonary TB and the site of extra-pulmonary TB is recorded as well. In the ART register and White card the same patient would be recorded as a patient

with Extra Pulmonary manifestation. This is to initiate early ART and also shows an advanced immune compromised status.

Type of TB:

New

A TB patient who has never had treatment with anti-TB drugs or has taken it for less than one month.

Relapse

A TB patient reporting back after being declared cured or treatment completed by the treating physician and is found to be smear-positive.

Treatment after default

A patient, who was treated for TB for a month or more from any source and returns for treatment after having defaulted (i.e., not taken anti-TB drugs consecutively for two months or more) and is found to be smear-positive.

Failure

TB patient who is smear-positive at 5 months or more after starting treatment.

Others

A patient who does not fit into the any of the above categories mentioned above is considered as others. Reasons for labeling a patient under this type must be specified.

Transferred in

A TB patient who has been received for treatment in a different Tuberculosis Unit/District, after starting treatment in another unit/District where s/he has been registered is a case of transferred in.

Treatment Category

For purpose of treatment, TB patients are classified into two categories. The categorization of a TB patient depends primarily upon history of previous treatment. These categories must be strictly adhered to. The number of drugs and the duration of treatment are different in the two treatment categories of RNTCP

Category of treatment	Type of Patient	Regimen*
New - Category I	New sputum smear-positive	$2H_3R_3Z_3E_3+$
	New sputum smear-negative	$4H_3R_3$
	New extra-pulmonary	
Re-treatment- Category II	Sputum smear-positive Relapse	$2H_3R_3Z_3E_3S_3+$
	Sputum smear-positive Failure	$1H_3R_3Z_3E_3+$
	Sputum smear-positive Treatment After Default	$5H_3R_3E_3$
	Others**	

**The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. The dosage strengths are as follows: H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S:Streptomycin (750 mg). Patients who weigh 60 kg or more receive additional rifampicin 150 mg (total 600 mg). Patients who are more than 50 years old receive streptomycin 500 mg. Adult patients who weigh less than 30 kg, receive drugs as per body weight, available in RNTCP "Pediatric Patient Wise Boxes". Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.*

*** In unusual cases, previously-treated patients may be diagnosed with sputum smear-negative or extra-pulmonary disease. This diagnosis in all such cases should always be made by an MO and should be supported by culture, histological evidence, or very strong clinical evidence of current, active TB. In these cases, the patient should be categorized as 'Others' and given Category II treatment.*

In cases of TB meningitis, initial hospitalization is recommended. In TB meningitis, ethambutol should be replaced by streptomycin in the intensive phase and continuation phase of the treatment is for 6-7 months. Adjunctive steroids may be useful in pericardial and meningeal TB. Similarly CP may be extended for 6-7 months in case of Spinal TB with neurological complications.

It is very important to elicit history of previous anti-tuberculosis treatment to help define a case and to prescribe appropriate category of anti tubercular treatment.

5. Treatment of TB in HIV-infected persons

Treatment of TB in HIV-infected persons is essentially the same as treatment of TB in persons with out HIV infection, with a few additional considerations. First, all HIV-infected patients should be treated with a Category I or Category II regimen. Lastly, the risk of death during treatment is much greater, but can be greatly reduced if the patient is provided ART during TB treatment as early as possible, as per NACO guidelines.

DOT in TB-HIV

Direct observation of TB is even more important for HIV-infected patients with active TB disease and is strongly recommended. Directly Observed Treatment of quality-assured anti-TB drugs is the foundation of the internationally recommended DOTS strategy, which maximizes cure by providing effective medicines and confirming that they are taken. A health worker or a trained observer (DOT provider) encourages, supports, and supervises the patient to swallow the tablets. By direct observation, it is ensured that the TB patient receives the right drugs, in the right doses and at the right intervals. DOT is not just supervised swallowing; it is a mechanism to support the patient and help him/her complete the treatment.

In HIV-infected TB patients, direct administration of treatment has been associated with lower death and lower recurrent TB than in self-administration of treatment. Treatment interruptions could also lead to an increased risk of treatment failure or relapse of TB. Hence DOT which ensures adherence should be used for all HIV-positive TB patients.

Failure to use DOTS, with directly-observed treatment using quality-assured drugs, may lead to, higher risk of case-fatality and recurrent TB.

Provision of anti tubercular drugs under RNTCP

Under the RNTCP, anti tubercular drugs are supplied, free of cost, in colour coded patient-wise boxes (PWB) containing the full course of treatment, and packaged in blister packs. In each PWB, there are two pouches one for intensive phase (A) and one for continuous phase (B). For the intensive phase, each blister pack contains one day's medication. For the continuation phase, each blister pack contains one week's supply of medication. The drugs for extension of the intensive phase (prolongation pouches) are supplied separately. Under RNTCP, pediatric patients-wise boxes (PWB) are also available for children; these pediatric PWB are also to be used for adult patients with body weight <30 kgs.

For Outdoor patients and at ART centers:

- For outdoor (outpatient) patients drug supply is provided by the District Tuberculosis Centre (DTC) so that the patient can receive directly observed treatment from the most conveniently located DOT centre nearest to patient's area of residence.
- For patient diagnosed as TB at ART centres, the TB treatment may be initiated at the ART centers themselves, or at the facility DOTS center. Patients are to be provided a weeks drug's supply (ie three doses) to cover for the period prior to their referral for treatment and initiation of their patient-wise box of anti-TB drugs. Irrespective of where they get the first few doses of anti-TB treatment, these patients should then be linked to the hospital's DOT centre for further referral to their local area DOT centre for TB treatment.

For Indoor patients:

- All indoor patients are to be treated with RNTCP regimens using prolongation pouches. Prolongation pouches contain strips, each containing Rifampicin, INH, Ethambutol and Pyrazinamide. These prolongation pouches will be supplied by RNTCP for these patients.
- The DOT Centre of the respective hospital/ Medical College must be informed of the patient's admission at the earliest, to enable seamless transfer of the patient to the DOT Centre nearest to patient's area of residence on discharge.

- Patients who have commenced RNTCP treatment as indoor cases are to be provided with one week's drug supply (i.e. three doses) on discharge to cover intervening period prior to continuation of treatment at their respective DOT Centre, hence ensuring no interruption in treatment.

Management of TB in HIV-infected children

TB should be suspected among children presenting with fever and / or cough for more than 2 weeks, with or without weight loss or no weight gain; and history of contact with a suspected or diagnosed case of active TB disease within the last 2 years. Children showing neurological symptoms like irritability, refusal to feed, headache, vomiting or altered sensorium may be suspected to have TB meningitis. Diagnosis should be based on a combination of clinical presentation, sputum examination wherever possible, Chest X ray (PA view), Mantoux test (positive if induration >10mm after 48-72 hours), history of contact, and other clinical tests as appropriate. Diagnosis should be made by a Medical Officer and the existing RNTCP case definitions be used for all cases diagnosed. Where diagnostic difficulties are faced, the child should be referred to a pediatrician for further management.

All pediatric TB cases diagnosed should be registered under the RNTCP and intermittent short course chemotherapy (SCC) be given under direct observation as per the RNTCP policy using pediatric PWBs.

Management of HIV-infected MDR-TB patients (source DOTS plus guidelines)

The presentation of MDR-TB in the HIV-infected patient does not differ from that of drug-sensitive tuberculosis in the HIV-infected patient. However the diagnosis of TB in HIV-positive persons can be more difficult and may be confused with other pulmonary or systemic infections. As the HIV disease progresses and the individual become more immunocompromised, the clinical presentation is proportionately more likely to be extrapulmonary or smear-negative than in HIV-uninfected TB patients. This can result in misdiagnosis or delays in diagnosis, and in turn, higher morbidity and mortality.

The anti-tubercular treatment of HIV-positive individuals with MDR-TB is the same as for MDR-TB in HIV negative patients.

Antiretroviral treatment in MDR TB also remains the same as in patients without MDR-TB, with Nevirapine-based regimens being the preferred first line ARV option. There are predicted drug interactions between ethionamide and NNRTI class drugs, though no formal guidelines are available.

Treatment of TB in HIV positive patients on second line ART/ alternate First Line with PI based regimen

The effectiveness of second-line antiretroviral therapy depends on the introduction of protease inhibitors (PIs) in the new regimen. However, there are significant drug

interactions with the PIs and rifampicin. Consequently, the treatment options are limited for TB patients who require PI-based therapy or develop TB while on PIs. PIs should not be used with rifampicin-containing regimens due to hepatic enzyme inducing capacity of rifampicin, which risks rendering PI levels sub-therapeutic.

Another rifamycin, Rifabutin is a less potent inducer of CYP 3A4 liver enzyme as compared to rifampicin, while being equally safe and effective for treatment of TB. It can be administered in the presence of PI-containing ART regimen without compromising the efficacy of ART or Anti TB treatment. In the presence of the boosting drug like Ritonavir (PI), rifabutin metabolism is also altered, and less rifabutin is needed than would be without ritonavir.

Therefore in patients taking lopinavir/ritonavir (LPV/r) based ART regimens, NACP and RNTCP have recommended the substitution of rifabutin for rifampicin for the duration of TB treatment. The dosage of rifabutin during the administration of second line ART regimen containing LPV/r shall be 150 mg Rifabutin, dosed thrice-weekly for all patients >30 kg weight. Rifabutin can cause neutropenia, leucopenia, liver enzyme elevation, rash and upper gastrointestinal complaints and more rarely uveitis. It is contraindicated in patients with WBCs below 1000/mm3 and platelet counts below 50,000/mm3. It is acknowledged that there is little experience or evidence regarding the safety of rifabutin use in patients taking LPV/r with thrice-weekly anti-TB treatment, hence these guidelines may evolve as further evidence becomes available.

Operationalization of Rifabutin procurement, distribution and use:

Procurement of Rifabutin is to be done by State TB Cell (STC) based on an initial assessment of the local requirement in consultation with the corresponding CoE (Centre of Excellence). It is to be stored in the State Drug Store (SDS) along with other Anti-TB drugs. An initial stock of Rifabutin may be supplied to CoE and refilled based on their reported consumption once in a quarter. STC may re-procure Rifabutin based on the need and re-assessment, once in 6 months.

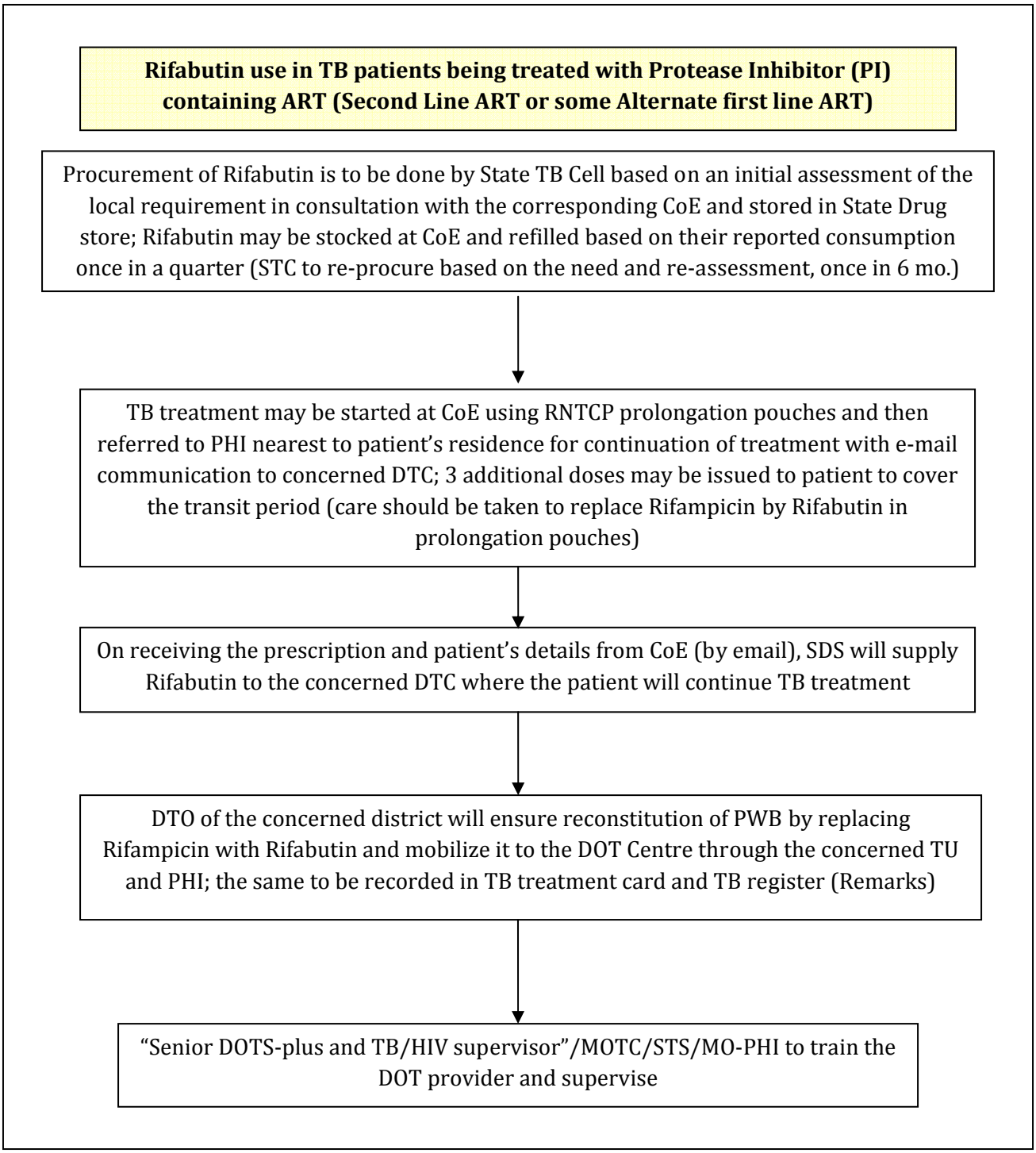
If a TB case is diagnosed in CoE, treatment may be started using RNTCP prolongation pouches (care should be taken to replace Rifampicin by Rifabutin in prolongation pouches). At the same time, a communication may be sent to STC, SACS and concerned DTC through email. At the time of discharge, the patient is referred to PHI nearest to his/her residence for continuation of TB treatment. Three additional doses (1 week medication) may be issued to patient to cover the transit period.

On receiving the prescription and patient's details from CoE (by email), SDS will supply Rifabutin to the concerned DTC where the patient will continue TB treatment. TB treatment categorization does not change with the use of rifabutin, which is a simple

substitution for rifampicin. The remainder of the TB treatment regimens, including dosing and duration, remain unchanged as per RNTCP guidelines. As with all anti-TB treatment, supervised treatment under DOTS is required. DTO of the concerned district will ensure reconstitution of PWB by replacing Rifampicin with Rifabutin and mobilize it to the DOT Centre through the concerned TU and PHI. "Senior DOTS-plus and TB/HIV supervisor"/MOTC/STS/MO-PHI should train the DOT provider regarding the substitution using rifabutin and supervise periodically.

The substitution of rifabutin for rifampicin should be noted on the TB treatment card, and in the TB register "Remarks" column.

The operational guidelines regarding the procurement and use of Rifabutin is summarized in the flowchart below


Rifabutin use in TB patients being treated with Protease Inhibitor (PI) containing ART (Second Line ART or some Alternate first line ART)
Procurement of Rifabutin is to be done by State TB Cell based on an initial assessment of the local requirement in consultation with the corresponding CoE and stored in State Drug store; Rifabutin may be stocked at CoE and refilled based on their reported consumption once in a quarter (STC to re-procure based on the need and re-assessment, once in 6 mo.)
TB treatment may be started at CoE using RNTCP prolongation pouches and then referred to PHI nearest to patient's residence for continuation of treatment with e-mail communication to concerned DTC; 3 additional doses may be issued to patient to cover the transit period (care should be taken to replace Rifampicin by Rifabutin in prolongation pouches)
On receiving the prescription and patient's details from CoE (by email), SDS will supply Rifabutin to the concerned DTC where the patient will continue TB treatment
DTO of the concerned district will ensure reconstitution of PWB by replacing Rifampicin with Rifabutin and mobilize it to the DOT Centre through the concerned TU and PHI; the same to be recorded in TB treatment card and TB register (Remarks)
"Senior DOTS-plus and TB/HIV supervisor"/MOTC/STS/MO-PHI to train the DOT provider and supervise

6. Treatment of HIV in HIV-infected TB patients

ARV drugs cannot cure HIV infection. The goals of therapy are as below:

Goals of ARV Therapy

- **Clinical Goals:** Prolongation of life and improvement in quality of life.
- **Virologic Goals:** Undetectable viral load for as long as possible.
- **Immunologic Goals:** Immune reconstitution i.e. rising CD4 count, to reduce risk of opportunistic infection.
- **Therapeutic Goals:** Achieve clinical, virologic and immunologic goals while maintaining future treatment options, limiting drug toxicity and facilitate adherence.
- **Public health goals:** Reduction of HIV transmission, i.e. reduction of HIV virus transmission from one individual to another when the viral load is suppressed.

In general, the clinical management of an HIV patient revolves around optimizing treatment regimen, reducing drug toxicity, reducing the pill burden and increasing adherence in the patient.

Early Initiation of ART in HIV-infected TB patients

ART reduces both the TB case fatality rates, the incidence of TB, and the incidence of recurrent TB. Various international studies have been done on the effects of concurrent ART/TB treatment in HIV-TB co-infected patients. It has been widely observed that survival rates have drastically improved when ART has been started during TB treatment. At least one randomized controlled clinical trial has determined that initiating antiretroviral drug at the same time as TB treatment halved the death rate when compared with delaying HIV treatment until after TB treatment was completed. Operational research in India has suggested that delaying ART initiation may be associated with lower ART uptake. Therefore, NACO and Central TB Division recommend starting of ART in all patients who are eligible for ART.

Rationale for ART recommendation during TB treatment:

- HIV-infected patients with CD4 cell count < 350 cells/mm^3 and active tuberculosis are at greater risk for AIDS and death, in comparison to HIV-infected patients without TB with the same CD4 cell counts.
- In the absence of ART, TB therapy alone does not significantly increase CD4 cell counts, nor significantly decrease HIV viral load among HIV-infected TB patients.
- The use of HAART among patients with TB can lead to sustained reductions in HIV viral load, immunologic reconstitution, decrease in AIDS defining illness, and decreased mortality. This benefit is seen across all CD4 cell counts.

Who among HIV-infected TB patients are eligible for ART?

As TB is classified as defining WHO clinical stage III or IV, the great majority of HIV-infected TB patients will be eligible for ART. ART is recommended for:

Recommendations to initiate ART in HIV-infected TB patients (NACO, 2008)

Patient with any EPTB / disseminated TB, [with or without pulmonary TB]

- Start ART irrespective of CD4 count after 2 weeks of anti-TB treatment, when TB treatment is tolerated.

Patient with only Pulmonary TB

- CD4<350; start ART after 2 weeks of anti-TB treatment, as soon as TB treatment is tolerated
- CD4>350; defer ART; re-check CD4 at end of IP and end of treatment and re-consider ART.

Hence, only patients with isolated pulmonary TB and CD4 count >350 would not immediately be eligible for ART.

When to start first-line ART in patients with active TB?

For HIV patients with active TB, the first priority is to start TB treatment following the RNTCP guidelines. ART should be started as soon as possible to reduce the risk of death. Because of the need to establish a patient on ATT first, and because of concerns for high transmissibility of untreated TB, it is recommended that 2 weeks of anti-TB treatment be completed before the patient attends the ART centre.

Although clinicians should give due consideration to pill burden, counseling needs, drug interactions, toxicity and IRIS, they should give greater consideration to the risk of death if ART is unnecessarily delayed.

What ART regimen to start?

In HIV-infected patients with TB who are not currently on ART, and who are provided rifampicin-based anti-TB treatment, initiate ART directly with efavirenz. No lead in dose is required for EFV.

Recommended first-line ART for HIV-infected TB patients

- 1st choice: AZT + 3TC + (EFV) (for patients with Hb > 9 g/dl)
- 2nd choice: d4T + 3TC + (EFV)

Drug Interactions between first line ARVs and Anti TB drugs

Nevirapine should not be administered along with Rifampicin because of the enzyme inducing effect of Rifampicin which renders NVP levels subtherapeutic. EFV blood levels are also decreased in presence of Rifampicin, but remain at therapeutic levels. it is recommended to use the standard dose of EFV (usually 600 mg/day) in patients receiving EFV and Rifampicin.

The use of D4T in anti-TB treatment has been associated with a higher risk of side effects requiring ART regimen changes, compared to patients not taking anti-TB treatment. Peripheral neuropathy may be problematic in HIV-infected patients treated with both isoniazid and D4T. For this reason, AZT is preferred when possible.

Special considerations/ Alternate first-line regimen:

In cases where patients are intolerant to both AZT/D4T, alternate first-line regimen with Tenofovir (TDF) will be provided on a case-to-case basis, to be decided by an expert panel at SACS.

- ***TDF substitution for AZT/D4T: TDF + 3TC + (NVP/EFV)***: For special situations only when there is toxicity/other contraindications to AZT or d4T (and thus, is substituted with TDF as alternative first line):

Regimen III	Tenofovir+ Lamivudine + Nevirapine	For patients not tolerating ZDV or d4T on a NVP-based regimen	Refer to SACEP for decision. Dug supply mechanism to
Regimen III	Tenofovir +	For patients not tolerating ZDV	

(a)	Lamivudine + Efavirenz	or d4T on a EFV-based regimen	be decided.

- ***PI substitution***: In situations when there is toxicity to both Efavirenz and Nevirapine, NNRTI should be replaced by PI based regimen(Lpv/ r)

Regimen IV	Zidovudine + Lamivudine + Lopinavir/Ritonavir	For patients not tolerating both NVP and EFV, and Hb > 9 gm/dl	To be made available at Center of Excellence
Regimen IV (a)	Stavudine + Lamivudine + Lopinavir/Ritonavir	For patients not tolerating both NVP and EFV and Hb < 9 gm/dl	

Implication of TB diagnosed in *patients already receiving ART*:
The ART regimen should be adjusted for co-administration with rifamipicin-containing regimens. The following table shows the recommended ART regimen changes for such patients:

Recommended ART management action when a patient already receiving ART is diagnosed with TB		
First-line or Second-line ART regimen	**ART regimen at the time TB occurs**	**Management Options**
First-line	(AZT or D4T) + 3TC + EFV	Continue with two NRTIs + EFV
	(AZT or D4T)+ 3TC + NVP	Substitute to EFV [i, ii]
Second-line	Two NRTIs + PI	Continue LPV/r. Use rifabutin as substitution for rifampicin [iii]

[i]Substituting back to the original regimens once the rifampicin-containing regimen is completed should be done. When switching from EFV to NVP, no lead-in dose is required.
[ii]EFV should not be used in pregnant women during the first trimester; and in women of child-bearing potential, contraception use should be ascertained
[iii]Monitor closely for hepatotoxicity when PIs and rifamycins is used concurrently.

Implication of TB on referral for evaluation of ART treatment failure
The development of certain AIDS-defining illnesses in patients taking first-line ART may warrant further evaluation for ART treatment failure and consideration of second-line ART.

When patients already receiving ART develop TB, the table below describes the implication and recommended actions for referral for evaluation of ART treatment failure.

	Implication of TB diagnosis in patients already receiving ART on referral for evaluation of ART treatment failure
TB diagnosed < 6 months after ART initiation	**Should *not* be considered a clinical ART failure event**; irrespective of whether pulmonary or extra-pulmonary TB.
TB diagnosed > 6 months after ART initiation	***May* represent a clinical ART failure event** i. **Pulmonary TB** Consider referral after CD4 testing as per NACO guidelines. Should be considered as indicating ART failure only if supported by clinical and immunological evidence of HIV disease progression. ii. **Extra pulmonary TB** should be referred for evaluation of ART failure . Exception: simple lymph node TB or uncomplicated pleural disease may be less-significant forms of extra-pulmonary TB. In these cases, if there is good response to TB therapy the decision to refer for viral load testing can be deferred.

IRIS

HIV-infected TB patients already on ATT and who start on ART are at risk to develop Immune Reconstitution Inflammatory Syndrome. IRIS typically presents within 3 months of the initiation of ART but can occur as early as 5 days after ART initiation. TB-associated IRIS most commonly presents with fever and worsening of pre-existing lymphadenopathy or respiratory disease. The clinical manifestations of IRIS are similar to the paradoxical reactions sometimes seen in immune-competent patients on ATT. Most cases resolve without any intervention and ART can be safely continued. Rarely, serious reactions may occur, such as tracheal compression, caused by massive adenopathy or respiratory difficulty. Therapy for serious IRIS manifestations may require use of corticosteroids.

What to do after anti-TB treatment is finished

Patients on NVP regimen who have been shifted to EFV because of Rifampicin containing anti-TB treatment, should be shifted back to NVP after completion of TB treatment (unless other contraindications to NVP exist). The change from EFV to NVP should be made 2 weeks after completing anti-tuberculosis treatment. In this particular scenario, the lead-in dose/period is not recommended when EFV is changed to NVP (ie should start immediately on BID NVP dosage).

Initiation of 2nd line ART in patient already on anti-TB treatment

If a patient is already on anti-TB treatment, and needs to be initiated on second line ART, then substitute RIFABUTIN for rifampicin within the RNTCP regimen for 2 weeks prior to initiation of second-line ART. This is to allow hepatic metabolism (induced by rifampicin)

to normalize prior to initiation of PI containing regimens. While the patient is counseled and prepared for initiation of 2nd line regimen, the patient should still be taking the 1st line ART regimen. During this 2-week transition period when patients are taking their usual first-line ART regimen before starting second-line ART, no dose adjustments in EFV are required.

Pregnancy and TB:
In all women of child-bearing age provided EFV-based ART, counseling is indicated on the potential harmful effect of EFV on fetal development, and the importance of good contraception. The process and time of initiation and discontinuation of anti-TB treatment is the same in pregnant women as in other adults. For ART, Efavirenz is contraindicated for women in the first trimester, so routine monitoring for pregnancy is essential. The following table describes the recommended management in various combinations of pregnancy, ART, and TB.

Recommended management for HIV-infected TB patients in case of pregnancy		
Baseline condition	**New Event**	**Recommended action**
Taking ATT while pregnant	Detected HIV infection & eligible for ART	- First trimester – EFV contraindicated; delay ART or consider referral for 2nd-line ART. - Second or third trimester – EFV not contraindicated. Offer efavirenz-based regimen after detailed and well-documented counseling to patients.
Pregnant, taking NVP-based ART	Develops TB	- Initiate ATT with standard rifampicin-based regimen, promptly refer to ART center - First trimester – EFV contraindicated; refer for 2nd-line ART on basis of NVP and EFV contraindication. - Second or third trimester – EFV not contraindicated. Offer efavirenz-based regimen after detailed and well-documented counseling to patients.
Taking ATT and EFV-based ART	Becomes pregnant	- Discuss the potential complications for the newborn and offer MTP. - If patient opts to continue pregnancy after detailed and well-documented counseling, refer for second-line ART on basis of NVP and EFV contraindication.

7. Cotrimoxazole prophylaxis (CPT)

Routine prophylaxis with cotrimoxazole is provided by the national programme. CPT is efficacious against several organisms including Toxoplasma, Cryptococcus, PCP and several organisms causing diarrhea in HIV-infected persons. Recent evidence has shown that cotrimoxazole prophylaxis has a beneficial effect in preventing morbidity and mortality in adults with both early and advanced HIV disease.

Under the National Framework for TB-HIV collaborative Activities, CPT is to be provided to all HIV-infected TB patients, irrespective of their CD4 count, for the duration of treatment. For HIV-infected TB patients, CPT would be provided either the local PHI (in States implementing the RNTCP 'Intensified TB-HIV Package') or from the ART centre itself (in all settings). For the duration of TB treatment, the patient is considered symptomatic, and would continue CPT. Discontinuation of CPT would be as per NACO guidelines.

	Cotrimoxazole Prophylaxis Recommendations
When to commence primary cotrimoxazole prophylaxis	• Any WHO clinical stage and CD4 < 250 cells/mm3 or • Any WHO clinical stage, CD4< 350 cells/mm3 and patient is symptomatic
Doses of cotrimoxazole in adults & adolescents	• One double strength tablet or two single strength tablets once daily • Total daily dose is 960 mg (800 mg SMZ + 160 mg TMP)
Cotrimoxazole in TB patients	• Given to all HIV-infected TB patients irrespective of their CD4 count. • In all settings, CPT should be provided at ART centre. • In settings implementing "Intensified TB/HIV package", it will be initiated at PHI for HIV-infected TB patients. Once the patient is initiated on ART, CPT will be continued at ART centre. • If the patient is not initiated on ART during TB treatment, CPT will be continued at PHI till completion of TB treatment. After completion, the patient is referred back to ART centre for re-evaluation and continuation of CPT
Patients allergic to sulpha-based medications	• Dapsone 100 mg per day, if available. (Cotrimoxazole desensitization may be attempted but not in patients with a previous severe reaction to CTX or other sulpha-containing drugs.)
Monitoring	• No baseline laboratory investigations or laboratory monitoring of CPT is required. • Although Cotrimoxazole can induce haemolytic anaemia in patients with G6PD, routine testing for G6PD deficiency is not indicated. • Clinical monitoring should be carried out regularly, at least once every three months. During clinical monitoring visits, adherence

	should be encouraged.
When to stop prophylaxis (cotrimoxazole or dapsone) in patients on ART	Patients initiated on CPT with CD4 < 250: Stop CPT when two consecutive CD4 count > 250 ***and*** Patients initiated on CPT >250: Stop CPT when two consecutive CD4 count >350 or Patient on ART for at least 6 months, asymptomatic and well [TB patients would be considered symptomatic for duration of treatment] .

Side-effects due to CPT

- Drug-related side effects to Cotrimoxazole are uncommon and usually occur within first 2 weeks of starting treatment.
- Minor side effects: Loss of appetite, joint pains, nausea and vomiting..
- Severe side effects (rare): exfoliative dermatitis, erythema multiforme (Stevens Johnson Syndrome), severe anemia, and pancytopenia.
- Because patients are usually taking other medications with similar side effects (e.g. isoniazid, pyrazinamide, efavirenz), care must be taken during clinical evaluation.
- Patients with serious side effects should discontinue CPT immediately and be promptly referred to a higher level centre, for evaluation and treatment. Desensitization is possible by experienced physicians.

8. Infection control

Importance of TB infection control in ART centres

ART centers are frequented by large numbers of HIV-infected persons, who commonly develop TB. In many ART centres, between 2 – 6% of ART clients develop TB per annum. With such a high burden of TB patients in close proximity to large numbers of vulnerable patients, often very frequently visiting the ART centre, the opportunities for transmission are very common. Furthermore, environmental factors common in ART centres may add to the risk of transmission, particularly if crowding is created, natural ventilation is inadequate, or re-circulating air-conditioners are in use.

ART centres are required to initiate the following simple administrative and environmental measures aimed at reducing exposure of HIV-infected patients to M. Tuberculosis:

1. Infection control activities for facility management and ART nodal officers

   - All the team members of ART Centre shall be trained in Universal Workplace Precaution, Waste segregation and disposal and Airborne Infection Control Practices, with special reference to tuberculosis.
   - Conduct TB risk assessment, in collaboration with RNTCP and NACO
   - Developing a written TB infection control plan by Hospital infection control committee and ART nodal officer. This may be incorporated into facility infection control plan.
   - Assigning responsibility for TB infection control at ART centres– Hospital infection control committee and ART nodal officer
   - Display proper IEC material on cough and hand hygiene practices in the hospital, hospital waiting area, ART centre, and particularly the waiting area of the ART center.
   - Make surgical masks, tissues, and appropriate no-touch disposal receptacles available.

2. Location and design of ART centres

   - Located separately from Chest clinics, Direct Microscopy Centres, or DOT Centres, with no shared waiting areas.
   - Have a well ventilated waiting & seating area. Open outdoor roofed additional waiting areas are encouraged.
   - Have a separate, well-ventilated waiting area for respiratory symptomatic wherever possible (particularly busier ART Centres).
   - Adherence to ventilation standards for airborne infection control (>15 air exchanges per hour [ACH] throughout) should be ensured. Where natural ventilation is of concern, augmented ventilation through the well-planned use of supply and/or exhaust fans may be considered, if installations are properly designed and maintained, and electrical power is consistently available.

- As far as possible, use of re-circulating (split) air conditioners should be avoided as these invariably are implemented in a way that prevents adequate fresh air entry and exit. Any cooling/heating systems should be implemented in a way that does adheres to ventilation standards (>15 ACH).

3. Screening of clients for respiratory symptoms

    - Care coordinators or nurses should screen all clients arriving at ART centre as early as possible for respiratory symptoms. Patients with respiratory symptoms should be educated on cough hygiene, kept in a separate well-ventilated waiting area if possible, and fast-tracked through their visit.

4. Education on cough Hygiene for persons with respiratory symptoms

    - Educate HCWs, patients, family members, and visitors on the importance of covering their cough to help prevent the transmission of airborne infections (both TB and viruses)
    - Instruct patients about covering their mouth and nose with a tissue when coughing and dispose of used tissue in waste containers;
    - Provide a disposable surgical mask to coughing patients if possible.

5. Fast Tracking of known pulmonary TB patients and persons with respiratory symptoms

    - Fast-tracking of patients with respiratory symptoms is critical to reduce the time the patient is in the facility, so to reduce possible contamination of air and spread of disease
    - Community care coordinator or nurse of the ART Centre shall facilitate the fast-tracking of patients with respiratory symptoms.
    - They will be helped by the nurse to get them counseled by the counselors, examined by the doctors and provided with the drugs quickly, without making them waiting in the regular queue.
    - TB suspects shall be referred to the DMC / DOTS centre for their sputum smear examination as a part of Intensified Case finding. This will facilitate early recognition and identification of possible pulmonary TB patients.
    - Signboard display of the fast-tracking policy within the ART centre should be visible to dispel any confusion among waiting patients.

9. Recording and reporting

It has been observed that the documentation regarding TB diagnosis, treatment and treatment outcome has often been of sub optimal quality at the ART centers. This was attributable to weak linkages between ART centers and RNTCP service delivery centers. To address this concern, a series of reporting and recording formats have been introduced.

For ART centres and the HIV programme, these recording and reporting mechanisms would be expected to enable monitoring of intensive TB case finding activities, coordination with RNTCP to know the TB diagnostic and treatment status of ART clients referred for TB evaluation, and improve the ability to know the burden of TB in their own ART clients locally and nationally.

For the TB programme, proper implementation of these recording and reporting mechanisms may yield additional TB cases through intensified TB case finding, better linkages for referral for treatment, enable feedback on TB suspects received from ART centres, and improve the ability to determine if HIV-infected TB patients received CPT and ART.

There are 3 key records and 2 key reports at ART centres:

Records:

- Patient ART treatment card (white card)
- "Line List of Persons Referred from ART Centre to RNTCP"
- "TB-HIV Register"

Reports:

- "Monthly Report on TB-HIV"
- Routine ART Centre Monthly report, indicators 9.7a and 9.7b

Patient ART Treatment Card (White Card)

Current Recording on TB details of the HIV-infected patient in the ART White Card (Page 1 of the ART Center White Card) is shown below in this excerpt from the White Card. ART Centre staff are responsible for completing this section at any point during treatment.

TB related section of ART Centre White Card

<table>
<tr><th colspan="3">Tuberculosis treatment (RNTCP) during HIV care</th></tr>
<tr>
<td>Disease class (tick)
☐ Pulmonary TB
☐ Smear-positive
☐ Smear-negative
☐ Extrapulmonary TB
☐ Past history of TB
site: _____</td>
<td>TB Regimen (tick)
☐ Category I
☐ Category II
☐ Category III (if applicable)
☐ Other specify:
☐ NonDOTS
☐ Rx for MDR
Date of start TB Rx:
___/___ / _____</td>
<td>TB registration
District:
TB Unit:
Health Centre:
TB number:

Treatment outcome:
☐ Cure
☐ Rx completed
☐ Rx failure
☐ Died
☐ Default
☐ Transfer out

Date: ___/___/____</td>
</tr>
</table>

LINE-LIST OF TB PATIENTS REFERRED FROM ART TO RNTCP

A mechanism of line list (Table 1) is being introduced at the ART centre for better follow up of the HIV patients referred for diagnosis and treatment of TB. It is the responsibility of the Nurse at the ART centre to fill the line-list in coordination with the STS. The monthly line list will be shared between the two programmes during the monthly co ordination meetings. The information on the completed line list will then be used to generate the monthly TB/HIV report (Table 3) and update the ART center TB-HIV register.(Table 2)

The Line-List is prepared for each ART Centre of the district separately. On the Line-List, the name of the ART Centre, the district and the reporting month/year is to be filled in by the ART Centre Nurse. The Line List has two parts. Part A, i.e. columns 1 to 10 contains information on the persons referred by ART center to RNTCP for diagnosis and follow up for TB treatment. Part A is to be completed by the ART Centre Nurse and signed by her and the In-charge MO of ART Centre. Below the signature, date of completion of Part 'A' is to be mentioned. Note that both TB suspects and TB patients diagnosed at the ART centers are included in this line list.

Part A of LINE-LIST

COLUMN NO.	COLUMN TITLE	WHAT SHOULD BE WRITTEN
1	Sr. No.	This is the serial number that you will write as you are making the line-list
2	Pre-ART/ART No.	If a person is registered in ART Centre and not yet started on ART, the pre-ART No. may be mentioned. If the patient is on ART, the ART registration number is to be mentioned
3	Complete Name and Complete Address	It is important to have the complete name and address of the person, otherwise it is difficult to trace out whether these persons have reached RNTCP Unit, whether they have been investigated and put on treatment. Therefore the ART Centre Nurse should write the complete name of the person. The address is to be mentioned in detail with landmarks especially if the patient is from outside the district. Please note the phone number of the patient if available.
4	Age	Age of the person should be mentioned
5	Sex	Male, Female or Transgender (Eunuch) should be mentioned
6	Date of Referral	The date when the client is referred to the RNTCP Unit for investigation is to be mentioned. Some PLHIV would be diagnosed of TB with investigations other than sputum examination and referred to RNTCP for treatment, in such cases the column needs to include the date of investigation which resulted in the diagnosis of TB
7	Name of RNTCP Unit referred to	RNTCP Unit includes any health facility where the facility for sputum investigation for TB under RNTCP is available. For sputum examination, the ART Staff Nurse should identify the Microscopy Centre that is convenient for the patient. The ART Nurse should record the name of the centre the person has been referred to. In case the patient is referred to a doctor/OPD for investigation of Extra-pulmonary TB, the name of the OPD/doctor should be mentioned. The patient is to be followed up by the Staff Nurse

		in co-ordination with the RNTCP unit (STS/TBHV/DMC LT) of the institution to find out the result of the investigation
8	Is patient diagnosed as TB – Yes or No	If the patient is diagnosed as TB mention 'YES' and if non-TB mention 'NO'. For getting this information, the Staff Nurse will need to co-ordinate real-time with the local RNTCP Unit. The feedback of DMC LT on the RNTCP Laboratory form helps to identify if the patient has sputum positive TB.
9	If diagnosed as TB, specify whether patient is sputum positive TB, sputum negative TB or Extrapulmonary TB	If the patient is diagnosed as TB, the Staff Nurse should mention whether the patient is sputum positive TB, sputum negative TB or extrapulmonary TB. This information should be confirmed in discussion with ART-MO and documented correctly. Please note that the cases whose sputum smear result is negative need not be "Sputum negative TB"
10	Date of referral to RNTCP for treatment	Once the patient is diagnosed as TB or initiated on TB treatment at the ART center (through the prolongation pouch), refer the patient to the RNTCP unit for futher treatment. The date when the patient was referred is to be mentioned here. Depending on the convenience of the patient, the patient is either continued on treatment at the local DOT centre or referred to the DOT centre nearest to the patient's residence.

Part B of LINE-LIST

COLUMN NO.	COLUMN TITLE	WHAT SHOULD BE WRITTEN
11	Date of Starting Treatment	Once diagnosed, the patient should be started on treatment. From the RNTCP Records (Laboratory register/TB register/referral for treatment register), find out whether the patient is receiving RNTCP DOTS. The date of starting treatment as mentioned in the TB register should be recorded in the Line-List. Details of only those patients who are residing within the district should be mentioned here. If the TB patient is registered in the local TU and

		transferred out, then it should be considered as 'started on treatment' and date of starting treatment mentioned even if the patient is from outside district/state.
12	TB Number with TU Name	From the TB register, write the TB number and the name of the TU in which the patient is registered
13	Is the patient referred outside district (Yes/No)	If the patient has been referred outside the district for treatment, mention "Yes" and the name of the district. If the patient is taking treatment within the district, mention "No"
14	Is the patient initiated on Non-RNTCP treatment (Yes/No)	Mention Yes if patient is being treated under Non-RNTCP regimen and No if under RNTCP regimen
15	Remarks	The following may be entered here If patient is from the district and has not been started on treatment, mention the reason. If the patient is referred outside the district, efforts should be made to obtain the feedback from the concerned staff and mentioned here Name of the DOT centre to which Patient has been referred to If patient has died, date when expired Reason for placing the patient on Non-RNTCP regimen Any other

The Staff Nurse will meet the STS (of the TU where ART Centre is situated) with the line list on the 1st of the next month, i.e. the Line List for patients referred for diagnosis in the month of January (Columns 1-10) will handed over by the Staff Nurse to the STS by the 1st/2nd of February.

It is acknowledged that where ART staff are not involved in diagnosing TB as recommended here, Columns 8,9,10 may in some instances have to be completed by RNTCP staff. In case the information on diagnosis is not available in some cases, the STS/STLS will scan through the TB laboratory register to find out whether these patients have undergone the sputum microscopic examination. If the patient is sputum positive, then the TB number as mentioned in TB laboratory register will tell whether the patient has been started on DOTS and the treatment category. If the patient is sputum negative, then look for the patient in the TB register of the concerned Tuberculosis Unit. If patient was a case of Extrapulmonary TB, referring to the TB register would be helpful. For diagnosed TB patients referred out for DOTS treatment to another TU, the STS of the corresponding TU should be consulted, and for referrals for treatment outside the District the 'referral for treatment' register at the DMC should be scrutinized. It is important to co-ordinate with the RNTCP staff of other TUs/districts to obtain complete information.

Once the Line-List is completed (Columns 11-15), the STS will sign the list and write the date of completion of Line-List. The STS will then take the signature of the concerned DTO/CTO or MO-TC. This Line List is handed over to the ART Staff Nurse by the third of the month.

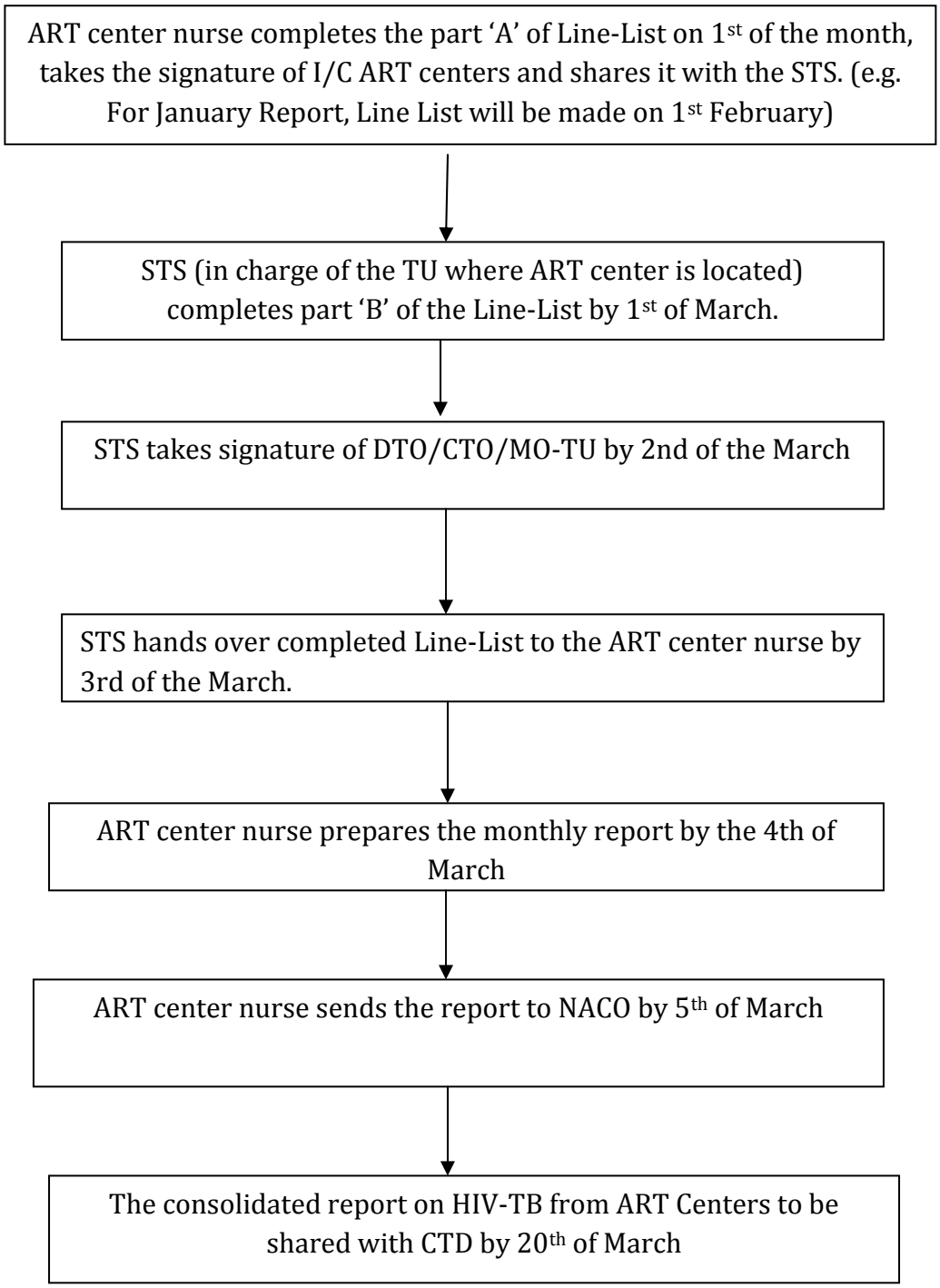
ART Centre TB/HIV Register (Table2)

This register is to be maintained by the ART Centre Staff Nurse. It contains details of all the TB cases visiting the ART centre. All the TB patients diagnosed as part of Intensified Case finding at ARTC should be entered into the register (from the Line-list and Report as mentioned above). In addition TB patients diagnosed elsewhere who are found to be HIV-infected may be referred to ARTC for evaluation and initiation of ART. The information of such patients also should be entered in this register. They are usually referred using a referral form (Annex 2). This form may be of help in identifying such cases and entering their details in the register. The information in this register should be shared with the RNTCP staff during their visits to ARTC and in the monthly co-ordination meetings for updating the RNTCP records.

This is to be the source document to calculate the ART centre monthly report indicators 9.7a (Out of 9.6, the number of patients on ART initiated on DOTS this month) and 9.7b (The number of patients on ART initiated on non-DOTS anti-tuberculosis treatment this month). This replaces whatever source was used previously to complete this report.

Monthly Report on TB-HIV

ARTC-RNTCP co-ordination is monitored with the help of the monthly report on TB/HIV activities. In order to prepare the monthly report, the first step will be to make the Line-List. Preparing the Line–List will be the joint responsibility of the ARTC and RNTCP. The Line List for patients referred for diagnosis in the month of January, will be completed by the 3rd of March by the Staff Nurse and STS. Once the Line-List is completed, the monthly report will be prepared by the ART Staff Nurse. The completed Line List and the Monthly Report will be compiled and submitted by the ARTC NACO and CTD by the 5th of the month.



The time taken for diagnosis and initiation of TB treatment may take up to 7 days and registering the patient in the TB register may take another few days and a maximum up to 1 month. Therefore, there will be a delay of one month in reporting of TB/HIV cross-referral. This time is also useful to obtain feedback of the referred out patients for treatment. It means that the report of January will be submitted in March, that of February

in April and so on. This is very important and "reporting month" should be mentioned accordingly in the report; patients listed in the reporting month should have been referred to RNTCP during that month only. For example, the report for patients referred to RNTCP during the month of January is submitted in March; for those patients the "reporting month" should be mentioned as January, even though the ART centre would not submit that report till March.

EXPLANATION OF ART CENTRE MONTHLY TB/HIV REPORT

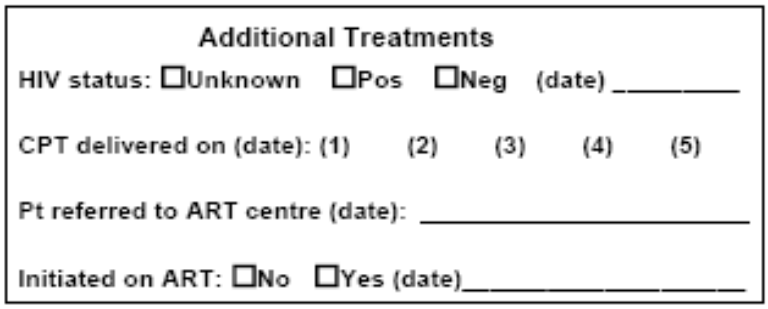
INDICATOR	WHAT SHOULD BE WRITTEN
a) Number of HIV positive patients attending ART centre during the month(Pre-ART and ART)	Refer to the ART and Pre-ART register and count the number of clients who visited ARTC in the month. The reporting period is from day one of the month to the last day of the month. Please note that this data should be of the "reporting month"
b) No. of TB Suspects referred from ART to RNTCP	From the Line-List count the total number of persons suspected to have TB who were referred to RNTCP Unit for diagnosis.
c) of the referred TB suspects, No. diagnosed as having: (i) Sputum Positive TB(ii) Sputum Negative TB(iii) Extra-Pulmonary TB	The information on whether the person is diagnosed as sputum positive TB/ sputum negative TB/ Extrapulmonary TB is available from column no. 9 of the Line-List.
d) Total diagnosed TB patients	This is the sum of the above three cells
e) Out of above (d), diagnosed TB patients, number receiving RNTCP treatment within the district	Include only those persons who are being treated with RNTCP regimen within the district. Referring to column no. 11 of the Line-List will give this information.

f) Out of (d), number of TB patients referred outside district for RNTCP treatment	Refer to column number 13 of the line-list to obtain this information
g) Out of (f), number of patients started on RNTCP treatment	The information on feedback of the referred out patients should be mentioned in the remarks column of the line-list; this should be used to compile this data
h) Out of (d), number of TB patients receiving Non-RNTCP treatment	Refer to column number 14 of the line-list to obtain this information

Note – In many cases TB may be diagnosed after excluding all other causes at the ARTC. All such cases should be reported in the line-list and the monthly report and updated in the TB/HIV register

Recording on TB-HIV in RNTCP records:

The following is routinely recorded on the TB treatment card that is kept for every patient. As can be observed, ART referral, initiation, and CPT information is present. Without good feedback from the ART centre to the MO-PHI on ART/CPT initiation, the MO-PHI will not have the necessary information to manage the patient in the field.


Additional Treatments

HIV status: ☐Unknown ☐Pos ☐Neg (date) _____

CPT delivered on (date): (1) (2) (3) (4) (5)

Pt referred to ART centre (date): _____

Initiated on ART: ☐No ☐Yes (date)_____

Table 1: Line List of Persons Referred from ART Centre to RNTCP

MONTH/YEAR NAME OF ART CENTRE: NAME OF DISTRICT:

To be completed by ART/CCC Nurse										To be completed by STS				
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*
Sr. No.	***Pre-ART/ART Number***	***Complete Name & Complete Address***	***Age***	***Sex***	***Date of referral to RNTCP for investigation***	***Name of facility referred to***	***Is patient diagnosed as TB – Yes or No***	***If diagnosed as TB, specify whether patient is sputum positive TB, sputum negative TB or Extra pulmonary TB***	***Date of referral to RNTCP for treatment***	***Date of Starting TB Treatment***	***TB Number with TU Name***	***Is the patient referred outside district (Yes/No)***	***Is the patient initiated on Non-RNTCP treatment (Yes/No)***	***Remarks***
Sign of ART Nurse Sign of SMO/MO-ART Date of completion										Sign of STS (TU where ART centre is situated) Sign of DTO Date of completion				

Table 2: ART Centre TB-HIV Register

MONTH/YEAR

1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*
Sr. No.	***Date***	***Complete Name & Address***	***Age***	***Sex***	***Type of TB - specify whether patient is Pulmonary TB or Extrapulmonary TB***	***Is patient initiated on RNTCP treatment (Yes/No)***	***Date of Starting Treatment***	***TB Number with TU and District Name***	***Pre-ART Number***	***Latest CD4 Count***	***Date of ART Initiation***	***ART Registration Number***	***Is the patient on CPT (Yes/No)***	***TB treatment Outcome***

Table 3: ART Centre Monthly TB-HIV Report

ART CENTRE MONTHLY TB-HIV REPORT

REPORTING MONTH: _____ YEAR _____

NAME OF ART CENTRE:_____ DISTRICT:_____

a) Number of HIV positive patients attending ART centre during the month(Pre-ART and ART)	
b) No. of TB Suspects referred from ART to RNTCP	
c) Out of the above persons, number diagnosed as having TB :	
(i) Sputum Positive TB	
(ii) Sputum Negative TB	
(iii) Extra-Pulmonary TB	
d) Total Diagnosed TB Patients	
e) Out of (d), number of TB patients receiving RNTCP treatment within the district	
f) Out of (d), number of TB patients referred outside district for RNTCP treatment	
g) Out of (f), number started on treatment	
h) Out of (d), number of TB patients receiving Non-RNTCP treatment	

Signature of Medical Officer / In-charge of ART Centre:

Name of Medical Officer / In-charge of ART Centre:

10. Roles and responsibilities:

Role of ART centre:

1. To screen all the HIV positive patients visiting the ART center for signs and symptoms of TB at every visit of the PLHA to the ART center
2. To evaluate suspects of TB for ART on priority. Prioritization also to be done for CD4 testing and collection of drugs.
3. Maintenance of HIV-TB register at the ART center by the staff nurse
4. Record patients' TB number and name of referring unit in the pre-ART register (in the column 'entry point code', along with the appropriate code for RNTCP) and the ART-register.
5. Provide CPT if the HIV-infected TB patient is initiated on ART
6. Provide feedback on CPT continuation and ART initiation to the referring physician, using the same ART centre referral form if received and available.

The ART center should provide counseling for:

1. Adherence on TB & ART;
2. Family and social support;
3. Risk reduction behavior particularly use of condoms;

Patients Focused Guidelines on:

1. Substance abuse;
2. Proper dietary intake;
3. Positive healthy living; and
4. Accessing appropriate health care services, when required

Role of the ART counselor/Nurse/ Care coordinator in care and treatment of HIV-infected TB patients:

1. Instigating practices of good cough hygiene for all patients, with any symptom of cough, at all ART centers for airborne infection control.
2. Ensure that any TB suspect at the ART center should be attended by the MO (ART) on priority and should also be prioritized for CD4 testing/lab investigations.
3. The ART Nurse/Counselor should keep a track, if the patient diagnosed with TB at their center, has been started on TB treatment
4. Emphasizing to all sputum positive TB patients the importance of getting their contacts screened.
5. Importance of adherence to Anti Tuberculosis Treatment and Anti Retroviral Treatment being taken simultaneously and separately.
6. Sharing the monthly report of all the patients referred and diagnosed as having TB with the STS during the monthly meeting

Role of nurses (w.r.t HIV-TB issues at the ART center):

1. Do a regular screening of the patients for symptoms of pulmonary/extra pulmonary TB.
2. The lab form given to the TB suspect should be stamped by the nurse with the ART center stamp to facilitate fast tracking of the patient for sputum testing.
3. Reinforce cough and hand hygiene practices among the suspects/diagnosed pulmonary TB cases
4. Keep a record of the patients referred from ART center to Designated Microscopy Center for the diagnosis of TB with the help of line list. Co-ordinate with STS to ensure completion of the line-list.
5. Attend the monthly RNTCP meeting along with the completed line list for the month to be shared with the concerned STS.
6. Prepare and submit the monthly TB/HIV report.
7. Maintain the TB/HIV register at the ARTC ensuring timeliness, accuracy and completeness.
8. Perform baseline assessment of the patient.
9. Assess the physical, social and psychological needs of the patient.
10. Provide need based nursing care and support to the patients.
11. To provide reports to the doctor and other members of the ART centre multidisciplinary team.
12. Ensure implementation of the UWP and proper waste disposal at the centre.
13. To monitor and ensure the implementation of the various infection control measures that has been developed.
14. Coordinating and tracking the referrals made within and outside the hospital.

Annex 1

Tuberculosis Identity Card

Front

Revised National
Tuberculosis Control Programme
IDENTITY CARD

Name of Patient: _____

Complete address:_____

_____

TU / district name _____

_____Ph_____

Sex: M ☐ F ☐ Age:_____ TB No._____

PHI:_____

Disease Classification
☐ Pulmonary
☐ Extra-pulmonary
Site:_____

Treatment Started on
Date Month Year

Type of Patient
- New
- Relapse
- Treatment after default
- Failure
- Transfer In
- Other-Specify _____

Category of Treatment
☐ Category I
☐ Category II
☐ Category III

☐ CPT

Back

Follow up sputum examination

Time point	Date	Lab No.	Result
Pretreatment			
End of IP/extended IP			
2 months in CP			
End of treatment			

Appointment dates

IP	CP
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Treatment outcome with date:

Signature and stamp of MO with date:

_____

REMEMBER
1. Keep your card safely
2. You can be cured if you take treatment as advised.
3. You may infect your near and dear if you do not take your medicines as advised

Annex 2

COMMUNICATION WITH PATIENTS

Use good communication principles when counselling all patients. However, some of them might be too depressed to understand the importance of good adherence to treatment for both HIV and TB.

- Patients may choose to ignore their persistent cough and may refuse to get tested for TB;
- If the patient refuses to share his HIV test result with the physician treating tuberculosis;
- If the patient lose adherence on ART or ATT, since he is on both the treatments simultaneously and separately;
- Importance of infection control practices to prevent the spread of infection to other household members and other patients at the ART center/CCC.

For each reason, you may use the tips below to counsel the patients for HIV testing:

***If the patient ignores the persistent cough**:*

-Explain to the patient about the chance of getting opportunistic infections esp. TB and how it may deteriorate the health of the patient in spite of taking ART regularly.
-Availability of free testing and treatment under RNTCP at all the health care facilities
- Convince the patient that TB is totally curable, provided complete treatment is taken as per the directions of the treating physician.

If the patient refuses to share his HIV test result with the physician treating tuberculosis:

Explain to the patient how sharing of the HIV status would help the treating physician in:

-providing correct anti TB treatment

-provision of Cotrimoxazole Preventive Therapy (CPT) to co-infected patients

- linking to better care, support and treatment services

If the patient do not adhere to ART or ATT, since he is on both the treatments simultaneously and separately:

-Explain how the TB treatment helps in treating the infection of TB and how ART helps in reducing the viral load and improves the immune system of the patient.

-Explain to the patients about the emergence of drug resistance which might develop, if the patient does not take the drugs as directed, which would make it further difficult to treat tuberculosis and HIV.

Importance of actions to be taken to prevent transmission of infection to household members or other HIV patients at the ART center:

-Cover the nose and mouth when coughing/sneezing either by using tissue/handkerchief or putting nose/mouth in the hollow of their elbow.

-Use tissues to contain respiratory secretions and dispose of them in the nearest garbage bin after use

-Advise the patient to wash hands with soap and water after having contact with respiratory secretions or contaminated

When space and chair availability permit, encourage coughing persons to sit at least 3 feet away from others in common waiting areas.

-Use a face mask when moving from one