Training Manual on Intensified TB/HIV package

For Para-medical Workers

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

It is estimated that 2.31 million people are infected with HIV in India and considering estimated 40% of the Indian population is infected with Mycobacterium tuberculosis, an estimated 0.9 million persons are co-infected with Mycobacterium tuberculosis & HIV. HIV is the strongest known risk factor for the progression of TB infection to TB disease. Active TB disease is the commonest opportunistic infection amongst HIV-infected individuals and is also the leading cause of death in PLHA (People living with HIV/AIDS).

TB can be easily cured through the DOTS strategy provided free through RNTCP and with ART being provided free through NACP, HIV is now a **chronic manageable illness**.

The basic purpose of HIV-TB collaborative activity is to ensure synergy between the two programmes for the prevention and control of both diseases. In order to further strengthen the collaborative activities training of staff is very crucial. To streamline training, both the programmes have come up with joint modules which address the training needs of various categories of staff. It is envisaged, that standardized modular training shall be imparted to all the Programme and general health staff in the country.

This module details the important components of the Intensified TB/HIV package – Routine offer of HIV Counselling and testing to all TB patients with unknown HIV status, provision of decentralized CPT to HIV-infected TB patients, Referral of HIV-infected TB patients to ART Centre for evaluation and initiation of ART & an expanded recording and reporting system to manage and monitor these interventions. We hope this module would be useful for further strengthening the TB/HIV collaborative activities in the country.

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INTRODUCTION

Active TB disease is the most common opportunistic infection amongst HIV-infected individuals. 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. The risk of TB in HIV-infected persons continues to increase as HIV disease progresses. While anti-retroviral treatment can substantially decrease the risk of TB, this risk always remains higher than that in HIV negative individuals. TB patients who are HIV positive have higher risk of dying during treatment than TB patients without HIV. Furthermore, among cured TB patients with HIV infection, the risk of recurrent TB is also quite 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 and can thus prevent the disease burden of HIV-TB co-infected cases. Among HIV-infected persons, early detection of TB, proper TB treatment, and linkage to HIV care and treatment also can reduce the harmful impact of TB on the patient's health and well-being.

The Revised National Tuberculosis Control Programme (RNTCP) and National AIDS Control Programme (NACP) have developed a policy of TB/HIV collaborative interventions, for implementation across the country. These include the establishment of coordination mechanisms at all levels, HIV testing of TB patients, linkage of HIV-infected TB patients to HIV care and treatment, early detection of TB in HIV-infected patients through Intensified TB Case Finding, involvement of NGOs in TB/HIV activities, and implementation of airborne infection control measures in HIV care settings.

An Intensified TB/HIV Package of Services has been established to provide additional services. These services include: Routine offer of HIV test to all TB patients, decentralized cotrimoxazole prophylaxis for HIV-infected TB patients, Referral of HIV-infected TB patients to ART Centre for evaluation and initiation of ART, and expanded recording and reporting on TB-HIV. This Intensified TB/HIV Package of services is being expanded in a phased manner nationwide.

OFFER VCT TO ALL TUBERCULOSIS PATIENTS

Rationale

HIV counselling and testing is now widely available under the National AIDS Control Programme. For persons who are HIV-infected, care and treatment services are also widely available, and access to treatment for HIV infection is rapidly expanding. Surveillance has shown that where HIV seroprevalence is high, HIV infection among TB patients is common. Because of this association, it is important that patients with tuberculosis have the opportunity to know their HIV status. This will allow appropriate prevention, care, and treatment for patients and their families.

HIV testing of TB patients

Central TB Division (CTD) & the National AIDS Control Organization (NACO) have adopted the policy of **routinely offering voluntary HIV counselling and testing to all TB patients** as part of an intensified TB/HIV package of services. This policy will facilitate early detection of HIV infection in TB patients, and lead to early access to HIV care and treatment. These interventions are expected to reduce death and disease among HIV-infected TB patients.

In settings implementing the Intensified TB/HIV Package, providers will routinely offer HIV testing to all TB patients, except those with an already known HIV status. **"Known" HIV status** means those patients with a history of positive HIV test from an NACO HIV testing centre, or those with a negative HIV test from an NACO HIV testing centre[1] within the past 6 months. HIV test results from NACO are preferred because HIV testing in these centres use quality-assured diagnostic kits, is conducted using a multiple-test algorithm to reduce false results, and is properly accompanied by counselling.

TB patients with unknown HIV status are to be referred to the **nearest and most-convenient place where NACO HIV counselling and testing is offered**. This may be an ICTC or any PHI where whole blood testing is offered for HIV screening. The referral should be made at the earliest after TB diagnosis, but may be made at any time during TB treatment if HIV status remains unknown. Treating physicians and paramedical workers should explain the need and importance for patients to be certain about their HIV status, and also that HIV testing is **'voluntary'** and **'not mandatory'**. This offer should be made at least once during the course of TB treatment.

If the patient accepts the advice for HIV testing, then the patient should be referred using the standard "**Integrated Counselling and Testing Centre referral form**" (**Annex 1)**. During the counselling session, the counselling provider should spend adequate time with the TB patient to

[1] In many settings, NACO has made available whole-blood HIV testing by the general health staff. Whole-blood HIV-testing involves limited pre-test counselling by general health staff, followed by the use of a single rapid test using a drop of whole blood to screen for HIV infection. Patients who are screened for HIV through NACO whole-blood testing and are found to be HIV-negative do not require further testing. If whole blood testing results are reactive/positive, then the patient should be referred on priority to an NACO ICTC for confirmatory testing and diagnosis.

explain the importance of sharing their HIV test result with the treating physician, regardless of whether the result is HIV-positive or HIV-negative. This will enable better care of the TB patient.

Communication of HIV test result to treating physician: 'Shared Confidentiality'

HIV test counselling may be conducted by ICTC counsellors or ANM/Staff Nurse/MO in a NACO approved HIV counselling and testing centre. Health care providers who are conducting HIV test counselling should also motivate patients to share their HIV result with the referring physician. In addition, unless patients object, these providers should directly and confidentially share HIV test results with the referring or treating physician, to ensure optimal care & case management.

This process of sharing confidential health information of a patient within the health care system for the benefit of the patient is termed as **'shared confidentiality'**. Knowledge of HIV status will enable providers to appropriately manage other illnesses and link to HIV care and support services.

The **mechanisms** for sharing the HIV status of referred TB patient, with the treating physician are as under:

1. **Through the client:** The counselling provider motivates the client to share the HIV test result, completes the feedback in the referral form, and sends the form via the client to the referring physician. If no referral form is available, patients should be asked to inform their providers and show their laboratory results.

2. **By the counselling provider**: When the physician referring the TB patient for HIV testing is physically located in the same premises or in very close proximity, the counselling provider can personally share or telephonically communicate the HIV result with the concerned Medical Officer.

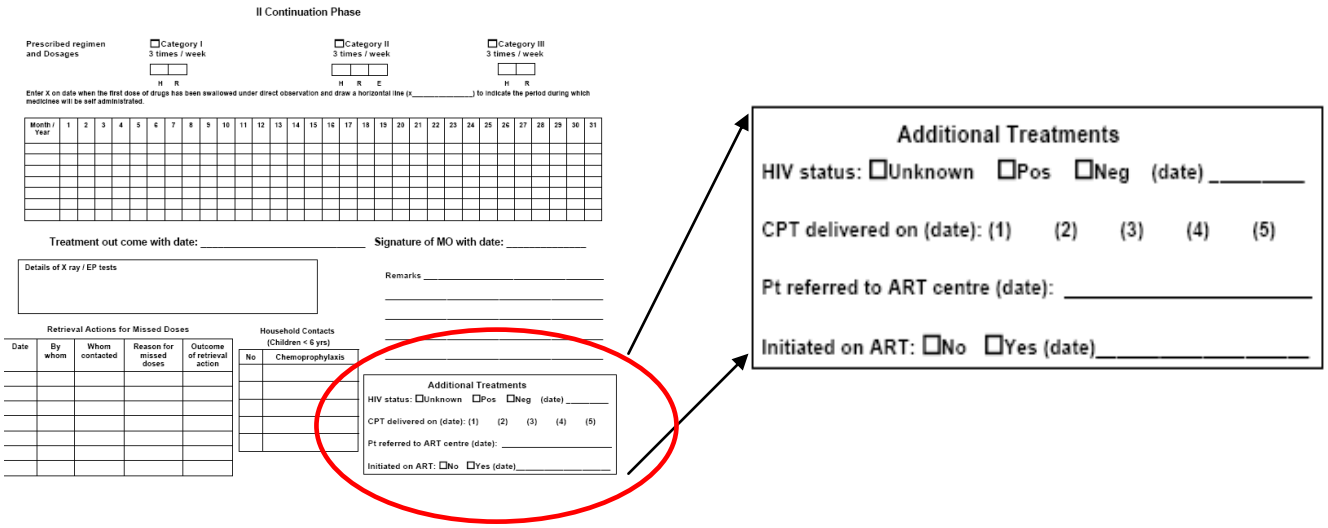
In case the TB patient raises his/her objection to the direct communication of the HIV test result to the medical officer, his objection should be honoured and the HIV test result should not be communicated directly to the referring physician.

Recording of HIV status on PHI-held TB treatment Cards

- HIV status of the TB patient shall be recorded on the **"original" TB treatment card** in the provided space, along with date of testing and PID (Person Identification Digit) Number if available (**Figure 1**). The "original" TB Treatment Card is the card held at the PHI, which is present regardless of whether the patient is getting DOT from the PHI or from a local community DOT provider.

- **The HIV status should not be recorded on the duplicate treatment card, held by community DOT provider.**

Figure 1: Back of TB treatment card, and space for recording HIV status and additional treatment



- **If HIV status of the patient is known**, tick the appropriate box ('Pos' or 'Neg') and record the date of test & PID No. **(If PID is available).** If the HIV status is not known, don't tick any box initially.
- **If the HIV status is ascertained during the course of TB treatment**, the latest information should be updated on the card.
- **If HIV status of the patient remains unknown at the end of the treatment**, tick the appropriate box ('unknown'), at the time of declaring treatment outcome for the patient.
- Patients should **not** be required to show proof of HIV test results for recording on treatment cards. However it should be noted that NACO ART centres will require documentation of positive HIV test results from a NACO HIV testing centre whenever any patient seeks HIV care and treatment.

COTRIMOXAZOLE PROPHYLAXIS THERAPY

Co-trimoxazole is a fixed dose combination of sulfamethoxazole and trimethoprim; it is a broad spectrum antibiotic that targets many infectious agents. Co-trimoxazole is given routinely for the prevention of opportunistic infections in HIV-infected persons; this strategy is called **Cotrimoxazole prophylaxis therapy**.

This section describes the mechanism of decentralized delivery of CPT for HIV-infected TB patients. 'Decentralized' in this context means from all PHIs (Peripheral Health Institutes) having a Medical officer and an institutional DOT centre.

Why provide CPT?

CPT reduces morbidity and mortality of HIV-infected patients in general and HIV-infected TB patients in particular. Hence it is important to ensure that all HIV-infected TB patients are provided CPT from PHI along with TB treatment.

Eligibility for CPT

All adult HIV-infected TB patients on RNTCP treatment, not already being provided CPT from any other source should be initiated on CPT. Additional points to remember include:

- Pregnant patients are also eligible.
- **For children and very low-weight adults (<30 kg),** because alternate formulations of CPT are not provided under this decentralized mechanism, CPT for these patients is to be provided by ART centres.

How is CPT to be provided?

- 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**.

Duration of CPT provision from PHI

Co-trimoxazole is to be provided by the PHI up till the end of TB treatment, or till the ART centre assumes responsibility for CPT provision – whichever is earlier. If ART Medical Officer decides to discontinue CPT in an individual patient based on NACO guidelines, that clinical judgement should be honoured by all providers and CPT stopped at PHI.

Treatment interruptions

Patients who do not take CPT do not get the preventive benefits. If patients are noted to have interrupted CPT, counselling by the health staff (including medical officer) is recommended to promote adherence at the next available opportunity.

There is no "Default" in CPT; please note that it is 'prophylaxis' and not 'treatment'. Patients who have interrupted CPT may choose to re-start and continue later.

Side effects

- Severe side effects are **rare**. Minor side effects like loss of appetite, joint pains, nausea and vomiting are also **uncommon** and usually occur within first 2 weeks of starting treatment.
- In case patients report these side effects, they should be referred to MO-PHI for further evaluation.
- Patients with serious side effects should discontinue CPT immediately and be promptly referred to a higher level centre, for evaluation and treatment.

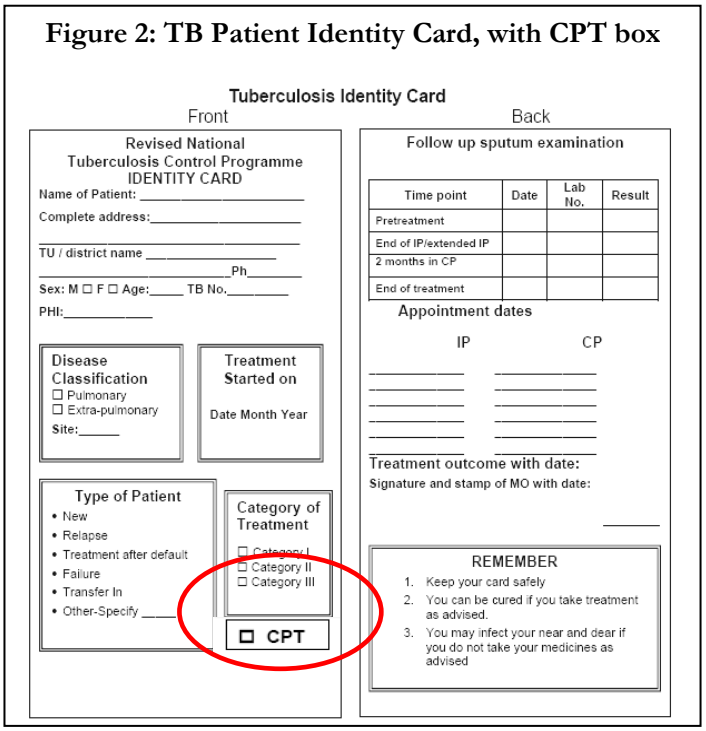
Mechanisms for CPT delivery to HIV-infected TB patients

CPT delivery sites:

a. At all the ART Centres and Link-ART Centres, and

b. At all PHIs in the districts having a Medical officer and an institutional DOT centre, supervised by RNTCP in coordination with NACP.

Figure 2: TB Patient Identity Card, with CPT box



The treating physician should:

a. The treating physician prescribes CPT by ticking the relevant cell on the TB patient identity card (**Figure 2**).

b. Records the prescription of CPT on the PHI-held, original TB treatment card (**Figure 1**).

c. Asks these clients to report to the PHI in case of any adverse drug reaction

d. Counsels the patient on the importance of regular follow-up examination and advice the client to come for monthly examination to monitor the progress of treatment.

At the PHI, institutional DOT provider (pharmacist/ health worker) should:

a. Provide a monthly supply of CPT on seeing the TB identity card.

b. Record the date of delivery of CPT on the space provided on TB treatment card

c. Ask the client to come on a monthly basis to collect the monthly supply of CPT.

d. Encourage the patient to meet the MO for clinical evaluation, at time of these monthly visits to the PHI.

HIV-infected TB patients getting TB treatment from community DOT provider would get his monthly CPT supply from institutional DOT centre and continue getting TB treatment from community DOT provider. Records of HIV status, CPT delivery and ART are not be updated on the duplicate TB treatment card kept with the community DOT provider.

Discontinuing Cotrimoxazole prophylaxis

Serious side effects should lead to prompt discontinuation and referral for care. Otherwise, discontinuation of CPT would be decided upon by the ART centre, as per NACO guidelines.

Transition of CPT for HIV-infected TB patients

- In case the HIV-infected TB patient is already on CPT before the initiation of TB treatment, CPT can be continued from that source.

- If not already on CPT, it should be initiated for the HIV-infected TB patient at the PHI.

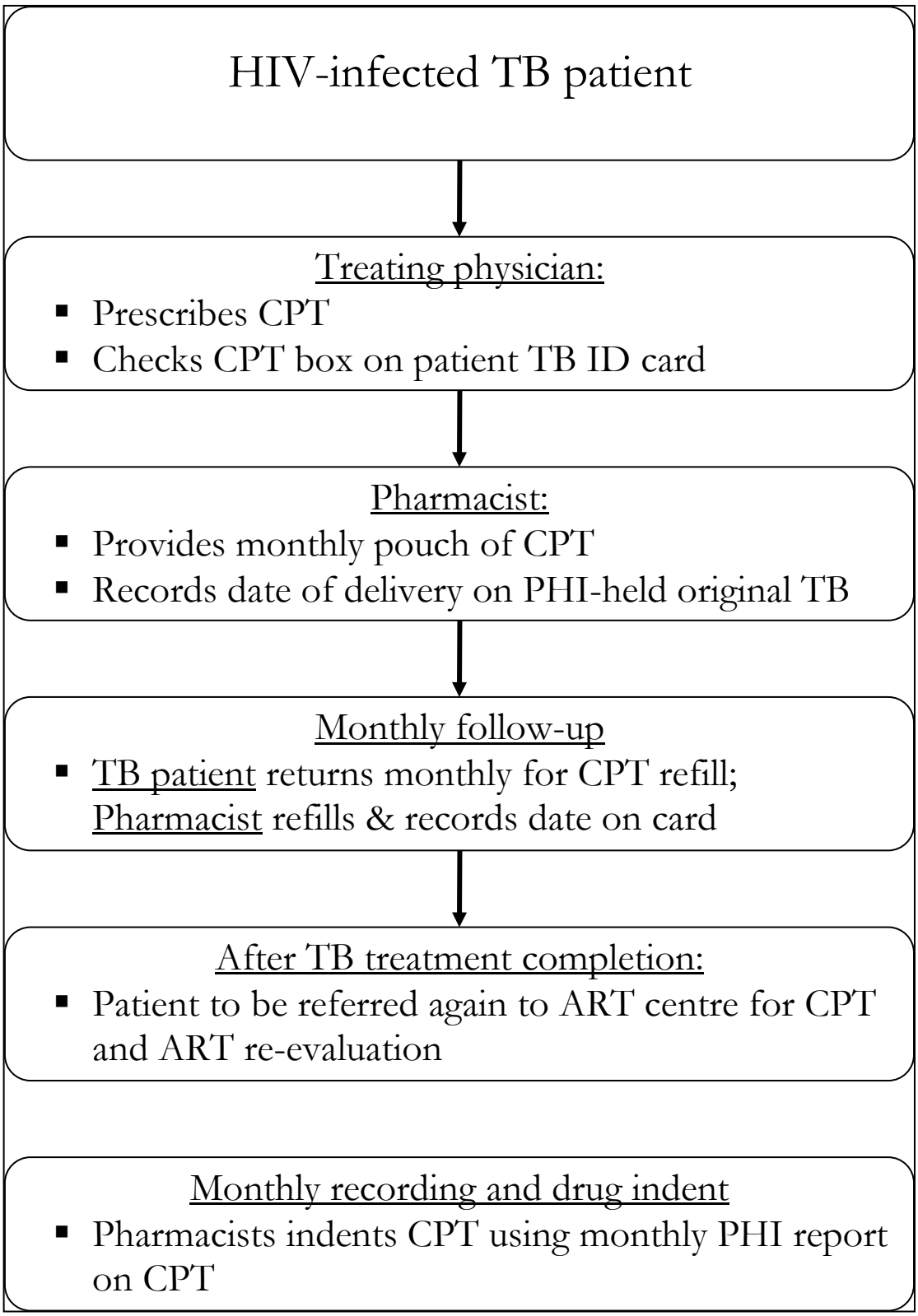
- If the HIV-infected TB patient is initiated on ART during TB treatment, he is to continue CPT along with ART from the ART Centre. **Feedback from the ART centre regarding initiation of CPT is essential to ensure a smooth transition**. If HIV-infected TB patient is not initiated on ART during TB treatment, CPT will be continued at PHI. After the completion of TB treatment the HIV-infected client should again be referred to the ART centre for ART re-evaluation and CPT continuation.

- Care should be taken that the patient is not receiving CPT from multiple sources.

Drug supply management

- The CPT is stored in the Pharmacy of the PHI and the Pharmacist is asked to maintain a record of stock in the PHI Stock Register.
- Consumption of CPT pouches during the month is to be reported by the PHI in the monthly PHI CPT report to the TU head quarters **(Annex 3)**.
- TU will supply CPT pouches basis on the reported consumption and request in the PHI report (monthly CPT PHI report).
- In addition, emergency indent can also be made in case of urgent requirements.

Summary of mechanism for providing CPT for HIV-infected TB patients


HIV-infected TB patient
Treating physician:
Prescribes CPT
Checks CPT box on patient TB ID card
Pharmacist:
Provides monthly pouch of CPT
Records date of delivery on PHI-held original TB
Monthly follow-up
TB patient returns monthly for CPT refill;
Pharmacist refills & records date on card
After TB treatment completion:
Patient to be referred again to ART centre for CPT and ART re-evaluation
Monthly recording and drug indent
Pharmacists indents CPT using monthly PHI report on CPT

REFER ALL HIV-INFECTED TB PATIENTS TO ART CENTRE

Anti-retroviral drugs act by blocking the replication and functioning of HIV. Anti-retroviral therapy (ART) results in reductions in morbidity and mortality in HIV-infected people. For ART to remain effective, extremely good adherence is required. Intensive counselling, support, and monitoring are required to achieve good adherence.

ART eligibility

- **Most HIV-infected TB patients will be eligible for ART**.

- The ART Centre Medical Officer will decide if the patient is eligible for ART as per NACO ART guidelines.

Linking HIV-infected TB patient with ART Centres

HIV-infected TB patients not already on ART should be referred as soon as possible to an ART centre for pre-ART registration and free CD4 testing, using the standard **"ART Centre referral form"** (**Annex 2**).

The referral to ART centre should also be recorded on the TB treatment card. TB treatment is the priority, and should not be interrupted by ART referral. However, prompt referral and evaluation for ART are also very important.

While referring the HIV-infected TB patient to ART centre, the client must be counselled by the treating/referring physician and the ICTC counsellor on:

- The **importance and free availability of ART**
- The **locations** of ART centres
- The need to take the **NACO HIV test report** for confirmation of HIV status
- Procedure of pre-ART evaluation including CD4 testing
- The **days on which the CD4 testing is available** at the respective ART centre.
- The importance of **cough hygiene**, and patients should be asked to wear a mask or carry a cloth to cover their cough, especially important when visiting ART centre.

Timing of referral to ART Centre

- Patients who are <u>not yet on ART</u> should be provided with a referral to the ART centre immediately on identification as an HIV-infected TB patient. However, these patients (especially smear positive pulmonary TB) should be counselled to attend the ART centre after at-least 2 weeks of anti-TB treatment have been completed, so that the risk of TB transmission to others is lessened.

- Patients who are <u>already on ART</u> should be referred to the ART centre as soon as possible, as it is critical for the patient to have their ART regimen adjusted appropriately, to prevent adverse drug interactions and the consequent lowering of the efficacy of ART.

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. HIV-infected TB patients should be prioritized for CD4 testing.

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

3. The ART Centre staffs are to record the patient in the **"ART Centre TB-HIV Register" (Annex 4)**, 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.

Mechanism for feedback from ART centres to the referring physician:

1. Feedback is to be provided by the ART centre MO on the referral form sent from the physician treating TB.

2. The patient is to be counselled by the ART centre staff to share the ART patient booklet and treatment history with the TB treating physician

3. The ART centre staff Nurse is to update the TB/HIV register placed at ART Centre on a regular basis and share the same with the DTC staff during the monthly coordination meetings. This information can be directly updated onto TB registers.

Recording on the Treatment card

1. All known HIV-infected TB patients are to be referred for ART to the nearest ART Centre. For referred clients record the date of referral.
2. If patient initiated on ART, tick the "yes" box, and the date of initiation of ART and ART Registration Number should be recorded on the treatment card.
3. In case the TB patient is already on ART before the initiation of TB treatment, tick yes, and record approximate date of initiation.

SUMMARY

KEY POINTS

- All TB patients should have the chance to know their HIV status.
- Quality-assured HIV counselling and testing is available widely at NACO testing centres.
- All TB patients should be routinely offered voluntary HIV counselling and testing.
- All HIV-infected TB patients should be provided CPT and promptly referred for ART.
- PHI medical officer should ensure that patients complete their ART evaluation, and that HIV status, CPT, and ART initiation are properly documented on the TB treatment card.

What should providers and paramedical staff do?

- Refer all TB patients to nearest NACO HIV counselling and testing centre.
- Who need NOT be referred for HIV-testing?
    - Patients who report being HIV-positive, with results from an NACO counselling and testing centre.
    - Patients with prior HIV test result negative within the last 6 months from an NACO HIV counselling and testing centre.
- Use the referral form to facilitate feedback.
- Promptly record HIV status on original (PHI-held) TB treatment card.
- A verbal patient history regarding HIV testing and HIV test results is adequate to record HIV status for the purpose of recording.
- Prescribe CPT and ensure prompt referral to ART centre.
- Follow up with patient to ensure CPT and ART being taken.
- Document CPT and ART on original TB treatment cards only

ROLE OF INSTITUTIONAL DOT PROVIDER/PHARMACIST

1. **Offer of VCT to all TB patients (with unknown HIV status)**
    - Use referral form; ICTC gives feedback on test result
    - Record HIV status on 'original' treatment card

2. **Provide CPT to all HIV infected TB patients**
    - Check the TB identity card for CPT prescription
    - Provide monthly course of CPT; record date of delivery on 'original' treatment card

3. **Indent from MO-TC and maintain stock** of Cotrimoxazole to ensure uninterrupted supply of CPT for the HIV-infected TB patients.

4. Encourage the HIV-infected TB patients, during their monthly visit to PHI for collecting CPT, to meet the Medical Officer for routine examination

5. **Refer to ART Centre for ART evaluation**
    - Record referral on TB treatment card
    - Use referral form; Feedback from ART centre provided on same form

6. **Follow up with patient to ensure optimal care and support for HIV and TB**
    - **If patient initiated on ART**
        - Record ART initiation on TB Feedback recorded on TB treatment card
        - Continues CPT at ART Centre
        - Support patient for both ART and anti-TB treatment.

    - **If patient not initiated on ART**
        - Continue CPT from DOT centre
        - After TB treatment completion, refer patient again to ART Centre for ART re-evaluation & continuation of CPT

7. **Ensure confidentiality** of HIV status of the TB patients with in the health system.

Annex 1.

Integrated Counselling and Testing Centre referral form

Referral to Integrated Counselling and Testing Centre

Dear Counsellor,
The patient with the following details is being referred for VCT to your centre:

Name _____*age/sex*
TB Number (if available) _____
Kindly do the needful and provide me feedback on the same, in a confidential manner.

Referring Provider

Name: **Contact Phone #:**

Date of referral:

Name and address of the PHI:

Feedback by the Counsellor to referring provider

(To be filled in duplicate by the counsellor. One copy for patient, the other for referring MO)

TEST RESULT FROM ICTC

HIV positive ☐ **HIV negative** ☐
Indeterminate ☐ **Opted out** ☐

PID Number

Date of conducting test

Additional communication to the referring physician

Signature of MO ICTC/counsellor

ANNEX 2.

ART CENTER REFERRAL FORM

(To be filled in duplicate by PHI MO. One copy for patient, one for record)

ART Centre (location, address):

Dear Doctor,

I am referring _____ Age, _____ Sex,_____who is a diagnosed HIV-infected TB patient to your ART centre for further evaluation.

(If applicable: Type of TB Case & TB number……)

Referring Doctor: ***Contact Phone #:***

Name & signature: ***Date: _____***

Name & address of the PHI*:** ***District:

TU Name:

Details regarding ART

(to be filled by the ART medical officer and sent to the referring PHI through the patient)

Pre-ART Registration Number:_____

CD4 Count: _____

Patient Started On ART -If Yes ART Reg. Number_____

If No, reason:

Patient started on CPT - Yes / No

If No, reason:

Additional information:

Name & signature of the ART MO ***Date***

Annex 3 Monthly PHI report on CPT for HIV-infected TB patients (To be added as a line to the monthly PHI report)

ITEM	**Unit of Measurement**	**Stock on first day of month (a)**	**Stock received during the month (b)**	**Consumption during the month (c)**	**Closing stock on last day of the month (d) d=(a+b-c)**	**Quantity Requested (e)=c*2 -d**
Cotrimoxazole	Monthly pouch (30 tablets)					

Annex 4

ART CENTRE TB-HIV REGISTER

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***	***Is the patient on ART (Yes/No)***	***ART Registration Number***	***Is the patient on CPT (Yes/No)***	***TB treatment Outcome***