

# Training Manual on Intensified *TB/HIV Package*

for Pharmacists



**Central TB Division and National AIDS Control Organization**

Ministry of Health and Family Welfare

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# **Intensified TB/HIV package**

**Training Manual for Pharmacists**

## Index

1.	Preface	2
2.	Acknowledgements	3
3.	Introduction	4
4.	Routine offer of HIV testing to all TB patients	5
5.	Cotrimoxazole prophylaxis therapy (CPT)	6
5.	Summary: Role of Pharmacist / Institutional DOT Provider	10
6	Annexures	11

## Preface

It is estimated that 2.5 million people are infected with HIV in India and considering estimated 40% of the Indian population is infected with Mycobacterium tuberculosis, an estimated 1 million persons are co-infected with Mycobacterium tuberculosis & HIV. HIV is the most powerful 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). This is further substantiated by the fact that an HIV positive person has 50-60% lifetime risk of developing TB disease as compared to an HIV negative person who has a lifetime risk of 10% of developing the TB disease.

HIV survey amongst the TB patients jointly conducted by CTD & NACO has shown 1% to 13% HIV amongst TB patients. This diverse data shows us that different strategies need to be employed within the country to reach out to PLHAs and addresses their needs for early diagnosis, treatment and care & support. The need of the hour is to establish an intensified package of services for TB-HIV for high HIV prevalence areas and a basic package for the rest of the country.

TB can be easily cured through the DOTS strategy provided through RNTCP; there is still no cure for HIV. 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. National Framework for joint TB/HIV collaborative activities has been laid down by both the programmes and the collaborative activities have yielded very promising results over the last few years. 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.

The modules cover the relevant aspects of both the diseases comprehensively, and will be a valuable guide for the different category of health service provider towards discharging their duties optimally. 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. From the public health point of view, the best way to prevent TB is to provide prompt effective diagnosis & treatment to people with infectious TB. This interrupts the chain of transmission. For HIV-infected patients who have TB, they will benefit from HIV-related care and treatment. Basic TB/HIV collaborative interventions are necessary across the country. These include the establishment of coordination mechanisms at all levels, service delivery coordination and cross referrals, involvement of NGOs in TB/HIV activities, and implementation of airborne infection control measures in HIV care settings.

Surveillance has shown that where HIV seroprevalence is high, HIV infection among TB patients is also common. Because of this association, in areas where HIV seroprevalence is high and HIV testing services are widely available, it is important that patients with tuberculosis have the opportunity to know their HIV status. An Intensified TB/HIV Package of Services has been established for high HIV prevalence areas. This package would facilitate early detection of HIV infection in TB patients and promote early access to HIV care and treatment, and is expected to reduce death and disease among HIV-infected TB patients.

HIV counselling and testing and care and treatment services including management of OIs, Cotrimoxazole Prophylaxis and access to ART is rapidly expanding and widely available under the National AIDS Control Programme. Management of TB is provided through widely acclaimed DOTS strategy under RNTCP which now provides emphasis amongst HIV/TB patients for management of TB and early linkage to care & support services.

The expanded scope of a new approach to TB control in populations with high HIV prevalence comprises of up scaled interventions against TB and HIV. Interventions include intensified case finding at high HIV settings like ART centers, Community Care Centers (CCCs), NGO led Targeted Intervention sites (TIs). This would help in early diagnosis of HIV/TB patients and provision of care & support including DOTS treatment for TB, CPT prophylaxis and ART. Counsellors and clinicians at HIV care settings regularly interact with persons living with HIV and thus are in the key position to refer to the nearest RNTCP services when indicated. Therefore, the crucial service delivery sites of NACP i.e. ICTCs, ART centers, Community Care Centers, and Targeted Intervention sites should be effectively involved for implementation of the up scaled activities.

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## ROUTINE OFFER OF HIV TESTING TO ALL TB PATIENTS

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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.

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, initially for states with the highest HIV burden. 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 these states, providers will be asked to help TB patients know their HIV status. This will be done through the routine offer of voluntary counselling and testing for 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 a ICTC or those with a negative HIV test from ICTC within the past 6 months. HIV test results from ICTCs are preferred because their HIV testing uses reliable laboratory 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 ICTC. The referral may be made any time after TB diagnosis, during or after initiation on TB treatment (preferably at the earliest). Treating physicians and paramedical workers should explain the need and importance for patients to be confident 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 VCT, then the patient is referred to the nearest ICTC using the standard **“Integrated Counseling and Testing Centre referral form”** (Annex 1). As HIV testing should lead to access to HIV care, counsellors during the counselling session should spend adequate time with the TB patients to explain the importance of sharing their HIV test result with the treating physician, for better care.

The joint national policy of CTD and NACO (February 2008) is to routinely offer voluntary counselling and testing to all TB patients to *‘know their HIV status’*:

- If they do not know their HIV status, counsel for HIV testing
- If they already know their HIV status i.e. Patients who had a positive HIV test result from an ICTC or a negative test from ICTC within the past 6 months; should then be counselled to ensure that they are registered and regularly followed by ART center (if HIV positive) or practice behaviors to ensure they remain HIV negative (if HIV negative).

**Early detection of HIV infection in TB patients will allow early access to care and treatment including ART. This will reduce death and disease among HIV-TB co-infected patients.**

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## COTRIMOXAZOLE PROPHYLAXIS THERAPY (CPT)

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Co-trimoxazole is a fixed dose combination of sulfamethoxazole and trimethoprim; it is a broad spectrum antibiotic that kills a range of gram-positive and gram-negative organisms, fungi, and protozoa. Co-trimoxazole can also be given routinely for the prevention of opportunistic infections in HIV-infected persons; this strategy is called **Cotrimoxazole prophylaxis therapy**.

### **Why provide CPT?**

- Reduces morbidity and mortality of HIV-infected patients
- All HIV-infected TB patients registered under RNTCP are eligible for CPT, irrespective of their CD4 counts.

### **Eligibility**

- All adults who are HIV-infected with tuberculosis disease on RNTCP treatment
- Pregnant patients are also eligible, regardless of foetus gestational age.
- No history of a serious drug allergy to sulpha drugs
- No history of glucose-6 phosphate dehydrogenase (G6PD) deficiency.

### **Prescribing CPT**

- CPT is provided to patients in monthly packets.
- CPT can be prescribed at any point during TB treatment, whenever HIV-infection is determined.
- No baseline laboratory investigations are required to initiate CPT
- Dose for prophylaxis (adults and adolescents): 960 mg (800 mg sulfamethoxazole + 160 mg trimethoprim) daily.
- CPT is self-administered by the patient on a daily basis, and not under direct observation.
- Taken alongside anti-tuberculosis treatment (ATT) and ART

CPT would be delivered to HIV-infected TB patients (on RNTCP treatment) at two levels, which are:

- At all PHIs in the districts with DOTS Centres, - to deliver CPT to HIV-infected TB patients, while they are on DOTS.
- At the ART Centres – to deliver CPT after completion of TB treatment OR on initiation of ART

### **Duration of treatment**

Co-trimoxazole is to be given for the entire duration of TB treatment. After TB treatment, CPT should be continued from the patients' ART centre.

### **Treatment interruptions**

Patients who do not take CPT do not get the prophylactic 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; the treatment is voluntary. Patients who have interrupted CPT may choose to re-start and continue later.

### **Children**

HIV-infected children are recommended to be provided lifelong CPT. Paediatric HIV patients are to

be immediately referred to the most convenient ART centre for CPT and ART evaluation and initiation.

### **Side effects**

- Severe side effects (rare): exfoliative dermatitis, erythema multiforme (Stevens Johnson Syndrome), severe anaemia, and pancytopenia.
- Minor side effects: Loss of appetite, joint pains, nausea and vomiting.
- 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.

### **Managing CPT interruptions of CPT**

- STS/ health worker should not undertake active patient retrieval in case of CPT interruption. There are no “CPT defaulters”, as CPT is for prevention of opportunistic infections only.
- Any TB treatment interruptions should be promptly addressed as per RNTCP guidelines. When continuing anti-TB treatment, continue with CPT as well, emphasizing adherence to all treatments.
- Patients should continue to be offered CPT throughout TB treatment, regardless of at what point during TB treatment CPT is initiated, and regardless of any CPT interruptions that may have occurred earlier.

### **Discontinuing CPT**

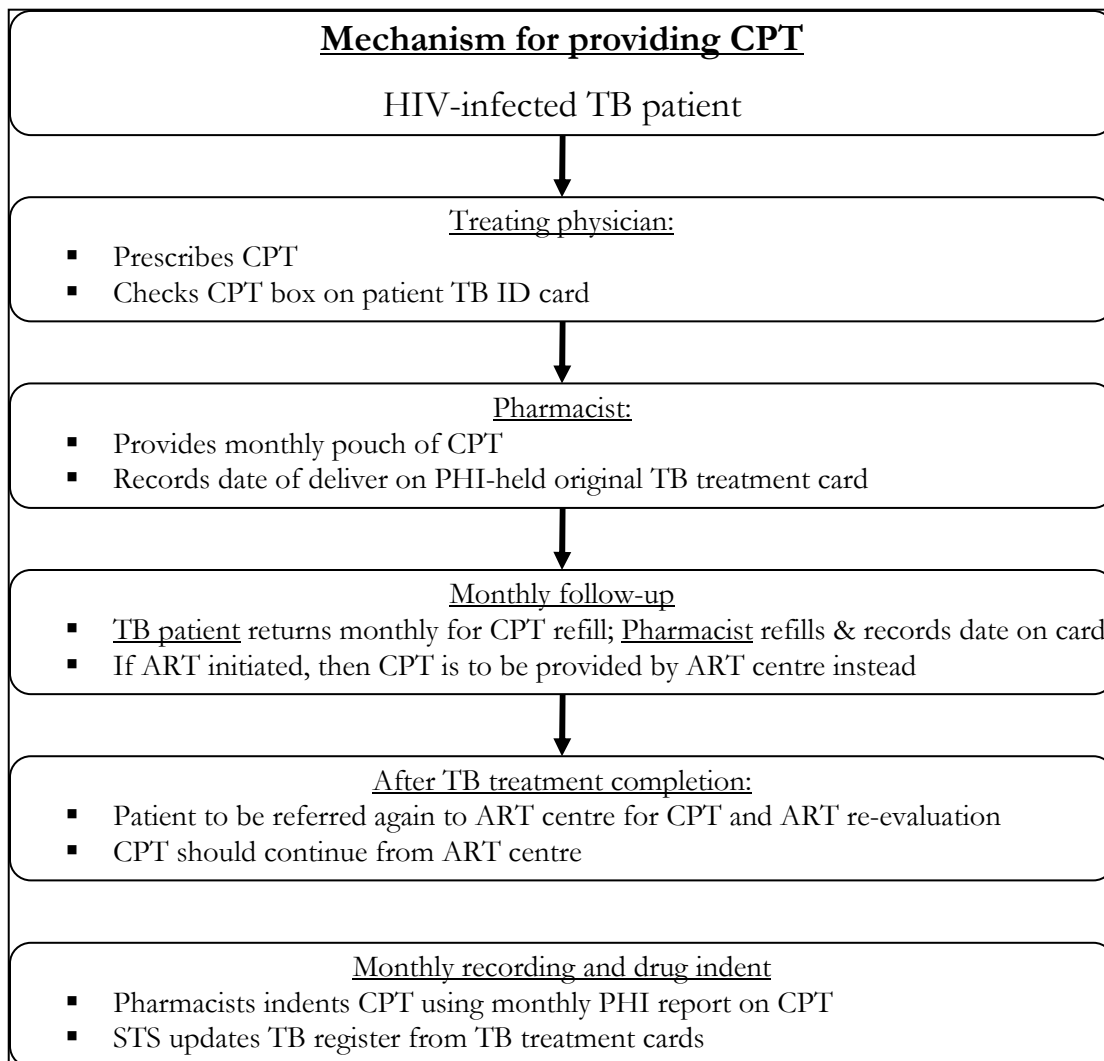
- Routine discontinuation is to be done by ART centre medical officers only, as per NACP guidelines.
- Serious side effects should lead to prompt discontinuation and referral to medical officer for appropriate action.

### **Mechanism for provision of CPT for HIV-infected TB patients**

- CPT will be prescribed by the MO, PHI, who initiates the TB patient on DOTS. MO-PHI prescribes CPT by ticking the relevant fields on TB identity card (Annex 2) and refers him to the DOT Centre in the PHI.
- At the DOT Centre of the PHI, the pharmacist / institutional DOT provider, on seeing the CPT prescription on TB identity card, provide a monthly supply of CPT.
- TB patient collects monthly supplies of CPT from PHI.
- The dispensing health care provider at the PHI (pharmacist or institutional DOT provider) records date of delivery of CPT on the TB treatment card (Annex 3). During these monthly visits to the PHI, the pharmacist/ health worker would encourage the patient to remain

adherent to CPT for prevention of opportunistic infections, and to meet the MO for clinical follow-up if any problems.

- HIV-infected TB patients are also to be referred to the ART centres for ART evaluation as soon as possible. In case any HIV-infected TB patient is initiated on ART, they would continue their CPT from the ART Centre. Referral to ART centre would also be recorded on the TB treatment card.
- After completion of TB treatment patients should again be referred to the ART centre for follow up, adjustment or initiation of ART regimen, and for continuation of CPT.



## **Transition of CPT for HIV-infected TB patients**

- *During TB treatment* – CPT should be made available to the patient at the PHI for the duration of TB treatment, or till the time the patient takes CPT from the ART centre. 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. In case the HIV-infected TB patient is already on CPT before the initiation of TB treatment, CPT can be continued from that source.
- *After TB treatment* – After the completion of TB treatment the HIV-infected client is to continue CPT from ART Centre.

## **Drug management**

- Because of irregular duration of treatment that patients may have on CPT, the supply of CPT monthly pouches is based on consumption (similar to RNTCP prolongation pouches.)
- 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.
- At the beginning of the activity, all PHIs and TUs will be provided a buffer supply of CPT.
- Based on consumption, the PHI should indent additional CPT supply with the TU on a monthly basis using the monthly CPT request (Annex 4), to be sent to the TU along with the RNTCP PHI monthly report. The pharmacist compiles the request on the 2nd of each month.
- CPT monthly pouches would be provided by the TU to the PHI routinely. The District will maintain a supply at the TUs.
- In addition, emergency indent can also be made in case of urgent requirements.
- CPT monthly pouches at the PHI are to be used only for prophylaxis in HIV-infected persons for the duration of TB treatment.

## **Shared Confidentiality**

- HIV disease has stigma attached to it. Hence information related to the HIV infection of individual are accorded high confidentiality. However, in the interest of the patient, for better care & case management, information necessary to provide care and treatment of an individual can be shared with the health care system. This process of sharing confidential patient information, in his or her interest, within the health care system is termed as shared confidentiality.
- Shared confidentiality enables better health care to the patient and better management of HIV disease by the treating physician.
- The health care system, including the para-medical workers, are duty bound in maintaining the client's privacy by restricting access to personal information and keeping client's information confidential, especially HIV test results.
- The client's information is to be kept confidential and this information is not furnished under any circumstances to any other person, except those providing health services to him, without the individual's explicit consent.
- The Pharmacist / health care worker should deal with the TB treatment card in a confidential manner & not disclose any health information, including HIV status, on the individuals to any one outside the health care system.

## **Summary: Role of Pharmacist / Institutional DOT Provider**

- 1. Check the TB identity card for CPT prescription**
- 2. Provide monthly supply of CPT to the HIV-infected TB patients, who have been prescribed CPT by the attending MO and record the date of delivering on the TB treatment card.**
- 3. Encourage the HIV-infected TB patients, during their monthly visit to PHI for collecting CPT, to meet the Medical Officer for routine examination**
- 4. Ensure confidentiality of HIV status of the TB patients remains confidential with in the health system**
- 5. Monthly basis indent (from MO-TC) and maintain stock of Cotrimoxazole for the HIV-infected TB patients prescribed CPT for the entire duration of their TB treatment**

## 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 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

### 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 3

### Back of TB treatment card, and space for recording HIV status and additional treatment

II Continuation Phase

Prescribed regimen and Dosages:  Category I (3 times / week)  Category II (3 times / week)  Category III (3 times / week)

Enter X on date when the first dose of drugs has been swallowed under direct observation and draw a horizontal line (x) to indicate the period during which medicines will be self administered.

Month / Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	

Treatment out come with date: \_\_\_\_\_ Signature of MO with date: \_\_\_\_\_

Details of X ray / EP tests: \_\_\_\_\_ Remarks: \_\_\_\_\_

Retrieval Actions for Missed Doses				Household Contacts (Children < 6 yrs)		
Date	By whom	Whom contacted	Reasons for missed doses	Outcome of retrieval action	No	Chemoprophylaxis

**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) \_\_\_\_\_

## Annex 4

### Monthly PHI report on CPT for HIV-infected TB patients

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)
Cotrimoxazole monthly pouch (960 mg Double Strength tablets)	Monthly pouch (30 tablets)					

