सत्यमेव जयते

Guidelines on Prevention and Management of TB in PLHIV at ART Centres

December 2016

NACO

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संयुक्त सचिव

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Joint Secretary

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National AIDS Control Organisation
Ministry of Health & Family Welfare
Government of India

MESSAGE

India has a high burden of both tuberculosis (TB) and HIV, and faces a high burden of HIV-associated TB. TB continues to remain as the most common opportunistic infection among People living with HIV. Addressing this dual burden has been a key priority for the Ministry of Health and Family Welfare, Government of India. A major strategic thrust in this area has been on strengthening the collaboration between the National AIDS Control Programme (NACP) and the Revised National TB Control Programme (RNTCP) to ensure seamless care to HIV-TB co-infected patients. The joint initiative aims to provide single window services for management of HIV-TB co-infections at ART centres so as to improve access to HIV-TB care and ensure seamless services to PLHIV.

Government of India, NACO and Central TB Division, is scaling up Newer rapid diagnostics (CBNAAT), Single window treatment services including daily anti-TB treatment (ATT) and ART for TB HIV co-infected patients at ART centres and Isoniazid Preventive Therapy (IPT) as important components of the package of care delivered by HIV and TB service providers for people living with HIV. NACO has also initiated measures that include strengthening of intensified case finding (ICF) for TB and implementation of airborne infection control (AIC) practices at ART centres.

The "Guidelines for Prevention and Management of PLHIV at ART Centres" has been developed jointly by NACO and Central TB Division to guide the programme staff of NACP and RNTCP for implementation of IPT and daily ATT in the country. I appreciate efforts of all the stakeholders involved in developing these guidelines and hope that the concerns will find these guidelines useful in the planning and implementation of their activities within the framework of the national policy.

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PREFACE

The End TB Strategy aims to end the global Tuberculosis epidemic, by reducing the TB deaths by 95% and to cut new cases by 90 percentage between 2015 and 2035. It emphasises on early diagnosis, treatment and prevention for all TB patients including co-infected with HIV. TB is most common opportunistic infection and leading cause of death among people living with HIV.The "National Framework for HIV-TB collaborative activities (Nov-2013)" and the "Standards of Tuberculosis care in India" recommend Isoniazid preventive Therapy (IPT) as an important strategy for prevention of TB among PLHIV and daily Anti TB treatment for HIV TB co-infected patients.

NACO and Central TB Division launched the "Innovative intensified TB case finding and appropriate treatment at high burden Antiretroviral therapy (ART) centers in India"-(3Is Project) in 30 high burden ART centers in 5 States Andhra Pradesh, Telangana, Maharashtra, Tamil Nadu and Karnataka on World TB Day 2015.This included Single window service delivery for TB & HIV ,Intensified case finding using CBNAAT,daily anti-TB therapy drugs in Fixed Dose Combination (FDC), Innovative drug intake tracking mechanism using missed call at a toll free number on the FDCs strips, Airborne Infection control at HIV care settings.

The "Guidelines for Prevention and Management of PLHIV at ART Centres"are based on the experience gained in the pilot implementation and intended to build the capacity of programme staff at various level and provide operational guidance for implementation of IPTand daily Anti TB Treatment (ATT) in country. The use of this manual will assist programme staff to deliver daily ATT and IPT as single window since for TB HIV co-infected patients in effective manner.

Collaborative efforts of NACP, RNTCP and programme partners in bringing out this operational manual are highly appreciable.

(Dr K.S.Sachdeva)

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FOREWORD

Tuberculosis (TB) is one of the most common opportunistic infections leading to high morbidity and mortality among people living with HIV (PLHIV). India has the second highest burden of HIV-TB cases in the world. To mitigate the effect of the dual burden of HIV and TB co-infection, the National AIDS Control Programm1e (NACP) and the Revised National TB Control Programme (RNTCP) of the Govenm1ent of India have been, since 2001, undertaking joint collaborative efforts as per the National Framework for Joint HIV-TB Collaborative Activities. Both RNTCP and NACP aim to reduce the HIV-TB burden and the morbidity & mortality associated with dual infections. This can be achieved through conce1ied efforts towards prevention, early detection, and prompt management of HIV as well as TB.

As a strategic move in this direction, it is aimed to provide single window services for management of HIV-TB co-infections at ART centres so as to improve access to HIV-TB care and ensure seamless services to PLHIV. Recently, it has also been decided to provide daily anti-TB treatment (ATT) at ART centres across the country through ART Medical Officers. For prevention of TB transmission in PLHIV, NACO has also initiated measures that include strengthening of intensified case finding (ICF) for TB, implementation of airborne infection control (AIC) practices at ART centres and provision of Isoniazid preventive treatment (IPT).

In order to ensure that all the ART centres adhere to standard practices, the National AIDS Control Organisation (NACO) and the Central TB Division (CTD) have prepared comprehensive guidelines for prevention and management of TB at ART centres. The US Centers for Disease Control and Prevention (CDC) - Division of Global Health and TB (CDC-DGHT) India, SHARE India, and WHO India have provided technical supp01i in development of the guidelines. These guidelines describe the operational processes at ART centres in providing single window services to PLHIV and coordination mechanism between ART centres and RNTCP. This document has been designed with the intent to orient and equip ART centre staff on the guidelines and processes to identity TB in PLHIV, initiate early ART/ATT, and implement IPT and AIC activities to reduce the burden of TB. This document is also intended to provide guidance to the managerial staff of NACP and RNTCP for better coordination and smooth implementation of this initiative.

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Acknowledgement

The Guidelines on Prevention and Management of TB in PLHIV at ART Centres have been jointly prepared by the National AIDS Control Organisation and the Central TB Division, Ministry of Health and Family Welfare, Government of India. The document was developed under the overall guidance of Dr. R.S. Gupta, Deputy Director General, CST, NACO; Dr. Sunil Khaparde, Deputy Director General, TB, CTD; and Dr. K.S. Sachdeva, Deputy Director General, BSD, NACO.

The National AIDS Control Organisation wishes to acknowledge the contributions made by the following team members:

Dr. Raghuram Rao, DADG, TB; Dr. B.B. Rewari, NPO-ART, WHO; Dr. Rajasekaran, National Consultant, NACO; Dr. Rajesh Deshmukh, Programme Officer - HIV-TB, NACO; Dr. Amar Shah, Consultant - HIV-TB, CTD; Dr. Reshu Agarwal, Public Health Specialist, CDC; Dr. Sukarma Tanwar, Public Health Specialist, CDC; Dr. Ramesh Reddy Allam, Associate Project Director, SHARE India and Dr. Tarun Chengappa, Project Manager, SHARE India.

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Abbreviations

ACH	Air Change Per Hour
AIC	Airborne Infection Control
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ATT	Anti-tubercular Treatment
CBNAAT	Cartridge Based Nucleic Acid Amplification Test
CDC	Centers for Disease Control and Prevention (US)
CLHIV	Children Living with HIV
CPT	Cotrimoxazole Prophylaxis Therapy
CTD	Central TB Division
DMC	Designated Microscopy Centre
DOTS	Directly Observed Treatment Short Course
DST	Drug Susceptibility Testing
DTO	District TB Officer
FDC	Fixed Dose Combination
F-ICTC	Facility Integrated Counselling and Testing Centre
HICC	Hospital Infection Control Committee
HIV	Human Immunodeficiency Virus
HRG	High-Risk Group
IC	Infection Control
ICF	Intensified Case Finding
ICTC	Integrated Counselling and Testing Centre
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
LTBI	Latent TB Infection
MTB	Mycobacterium Tuberculosis
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NGO	Non-Governmental Organisation
OI	Opportunistic Infection
PHI	Peripheral Health Institution
PI	Protease Inhibitor
PITC	Provider-Initiated HIV Testing and Counselling
PLHIV	People Living with HIV
RIF	Rifampicin
RNTCP	Revised National Tuberculosis Control Programme
STLS	Senior Tuberculosis Laboratory Supervisor
STS	Senior Treatment Supervisor
TB	Tuberculosis
TBHV	TB Health Visitor
TI	Targeted Intervention
TU	Tuberculosis Unit
UVGI	Ultraviolet Germicidal Irradiation
WHO	World Health Organization

Scope of the Document

The guidelines contained in this document are intended to delineate the processes to be followed for prevention and management of TB in PLHIV at ART centres. These guidelines were finalized in September 2016 with inputs from technical experts from NACO, CTD, CDC, WHO, and SHARE India. These guidelines will continue to evolve in line with emerging evidence and the data available nationally as well as globally and will be updated regularly.

This guideline is part of a series of NACO guidelines and has been adapted from:

- National Technical Guidelines on ART, including PEP
- Operational Guidelines for ART Centres
- National Guidelines for Management of Opportunistic Infections (Ois)
- RNTCP: Technical and Operational Guidelines for Tuberculosis Control in India 2016
- Guidelines on Airborne Infection Control in Healthcare and Other Settings
- National Framework for Joint HIV/TB Collaborative Activities, November 2013
- Operational Manual for Isoniazid Preventive Therapy

These guidelines describe the operational processes at ART centres for provision of single window services to PLHIV. The services include TB screening with 4S complex, referral for diagnosis of TB to DMC/CBNAAT, provision of daily ATT, and initiation of IPT for TB prevention. The guidelines also describe the coordination required between NACP (ART centres) and RNTCP and provide direction to the managerial staff for smooth implementation of these initiatives. The guidelines serve as a ready reckoner on prevention and management of TB in PLHIV for healthcare providers at the ART centre.

Chapter 1

1. Introduction

About 1,10,000 people in India are estimated to be HIV-TB co-infected annually, with the national average for HIV prevalence among incident TB cases at 5%.[1] It is recognized that HIV and TB make for a fatal combination with extremely high death rates (15–18%) reported among HIV-infected TB cases notified under the Revised National Tuberculosis Control Programme (RNTCP). Further, even among cured TB cases with HIV infection, the risk of recurrent TB is quite high. Overall, TB is estimated to cause about 25% of all deaths among PLHIV in India.[2]

Early detection of TB, effective TB treatment, and prompt linkage to HIV care and early initiation of treatment can mitigate the impact of TB on the health and survival of PLHIV. As PLHIV have a higher risk of developing TB, efficient implementation of strategies for TB prevention is imperative to reduce the TB burden in PLHIV.

HIV-TB Collaborative Activities

The need for strong collaboration between HIV and TB prevention activities is well recognized by the Government of India. To effectively control the dual burden of HIV and TB co-infection, the National AIDS Control Programme (NACP) and RNTCP have been undertaking joint collaborative efforts since the year 2001. *The National Framework for Joint HIV/TB Collaborative Activities* articulates the national policy for collaboration between NACP and RNTCP for HIV-TB activities to ensure reduction of the HIV-TB burden in India.

Objectives of the National Framework

The key objectives of the national framework are to:

1. Maintain close coordination between NACP and RNTCP at national, state, and district levels
2. Decrease morbidity and mortality due to TB among people living with HIV/AIDS
3. Decrease the impact of HIV in TB patients and provide access to HIV-related care and support to HIV-infected TB patients
4. Significantly reduce morbidity and mortality due to HIV-TB through prevention, early detection, and prompt management of HIV and TB together

To achieve these objectives, a four-pronged strategy for strong HIV-TB collaboration has been adopted. The four-pronged strategy (summarized in Figure 1) is based on the foundation of strong collaboration between NACP and RNTCP.

Figure 1. Four-pronged strategy for HIV-TB coordination to reduce mortality

Prevention 1. Isoniazid preventive therapy (IPT) 2. Airborne infection control (AIC) 3. Awareness generation	Early Detection of HIV-TB 1. 100% coverage of provider-initiated HIV testing and counselling (PITC) in TB patients 2. PITC in presumptive TB cases 3. Rapid diagnostics for detecting TB and DR-TB in PLHIV 4. ICF activities at all HIV settings (ICTCs, ART centres, LACs, and TI settings)
Prompt Treatment of HIV-TB 1. Prompt initiation of TB treatment 2. Early initiation of ART	Management of Special HIV-TB Cases 1. TB-HIV patients on Protease Inhibitor (PI) based ART 2. HIV-TB in children 3. HIV-TB in pregnant women 4. Drug resistant HIV-TB

Chapter 2

2. Initiatives for Prevention and Management of TB in PLHIV at ART Centres

Both NACP and RNTCP are making concerted efforts to reduce the HIV-TB burden as well as to reduce the morbidity and mortality associated with dual infections. To achieve this objective, both programmes are focusing on prevention, early detection, and prompt management of both HIV and TB.

NACO and CTD have made the decision to provide single window services for management of HIV-TB co-infection at ART centres so as to improve access to HIV-TB care and ensure seamless services to PLHIV. Further, to reduce the risk of TB transmission, NACO has also initiated measures to strengthen TB infection control practices at ART centres. These measures include intensified case finding (ICF) for TB, Isoniazid preventive therapy (IPT) for all PLHIV, and robust airborne infection control (AIC) at ART centres. In this regard, NACO has, in collaboration with CTD, planned to strengthen 3Is (ICF, AIC, and IPT) strategy along with provision of daily anti-TB treatment (ATT) for PLHIV at all ART centres.

As part of the single window approach, the following initiatives have been identified for seamless implementation of 3Is and the provision of daily ATT: i) ICF for TB in HIV care setting, with 4-symptom (4S) screening for TB and fast-tracking of all PLHIV with presumptive TB; ii) prioritization of rapid molecular Cartridge Based Nucleic Acid Amplification Test (CBNAAT) for all PLHIV with presumptive TB to ensure early diagnosis of TB and to identify Rifampicin resistance; iii) provision of daily ATT with fixed dose combination; iv) provision of IPT for prevention of TB in PLHIV; and v) AIC activities at ART centres.

2.1 Intensified Case Finding for TB at ART Centres

Intensified case finding (ICF) involves systematic screening for active TB among high-risk populations at each visit to a health facility.[3] ICF is one of the critical interventions for increased TB case detection. ICF is not "passive screening", and shifts the onus for active TB screening to the health care worker. ICF for TB in PLHIV is an important step towards:

- Earlier diagnosis and treatment of TB to reduce mortality
- Prevention of ongoing TB transmission
- Initial step in ICF-IPT cascade for excluding the TB disease to initiate TB preventive therapy

The national ART guidelines clearly state that all the patients coming to ART centres should be actively screened for opportunistic infections (Ois), particularly TB. All PLHIV should be regularly

screened for four symptoms—current cough of any duration, fever of any duration, weight loss, or night sweats—during every contact with a health care provider in the ART centre. Similarly, children living with HIV (CLHIV) who have one or more of the following four symptoms—poor weight gain, fever of any duration, cough of any duration, or history of contact with a TB patient—should be evaluated for TB. Figures 2 and 3 present information on the efficacy of the 4S complex for TB screening in PLHIV and the algorithm for ICF at ART centres.

Figure 2. Four-symptom complex for TB screening among PLHIV

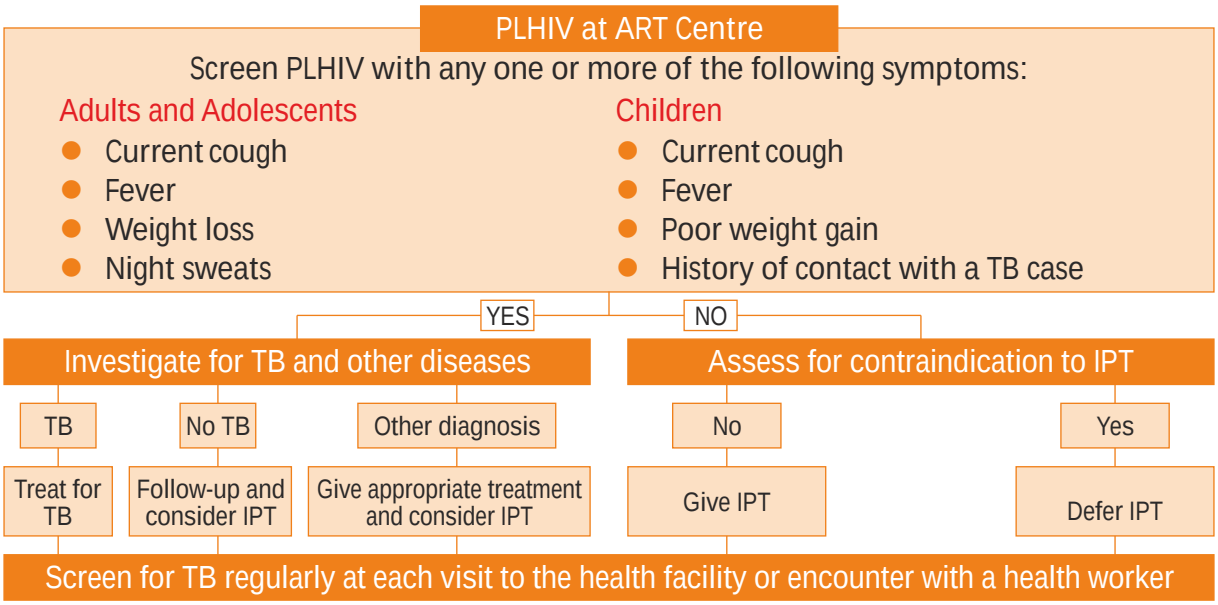
4 Symptom Complex for TB screening among PLHIV

Adults	Children
• Current cough • Fever • Weight loss • Night sweats	• Current cough • Fever • Poor weight gain • Contact with a TB case

Getahun H., et al. Development of a standardised screening rule for tuberculosis in people living with HIV in resource-constrained settings: individual participant data meta-analysis of observational studies. PLoS Medicine, 2011, 8(1): e1000391. doi:10.1371/journal.pmed.1000391.

Meta-analysis of 12 studies and 8,148 PLHIV with all forms of TB showed that the sensitivity of 4S complex (current cough, fever, weight loss, and night sweats) was 85%, i.e., if 100 persons are suffering from TB, at least 85 persons can be identified through 4S. The absence of current cough, fever, night sweats, and weight loss had a 98% negative predictive value (NPV) for cases of pulmonary TB among PLHIV (NPV 97.7% [95% CI 97.4–98.0]).

Figure 3. Algorithm for ICF at ART centres



2.2 Prioritization of Rapid Molecular Test - (CBNAAT) for all PLHIV with Presumptive TB

As per RNTCP guidelines, CBNAAT is the preferred diagnostic technique for TB testing in PLHIV when compared to smear microscopy. Sputum microscopy has poor sensitivity in detecting TB in PLHIV due to fewer organisms in sputum.[4] In addition to diagnosing TB, there is also the need to test for drug resistance so as to provide the most effective treatment to curb the progress of drug-resistance TB (DR-TB) in patients and also to reduce risk of transmission in the community. Although culture is currently the main tool for drug susceptibility testing (DST) and has a very high accuracy, it is highly specialized and has procedural (long duration) and operational (requires trained personnel and expensive laboratory equipment) difficulties.

CBNAAT is a molecular test that detects the DNA of the TB bacteria in PLHIV. It uses sputum or any other biological specimen (except blood and blood-contaminated specimens) and can give a result in less than two hours. It can also detect the genetic mutations associated with resistance to the drug Rifampicin. As per studies, the median sensitivity of smear microscopy was 52.8% (range 22.2–68.9), compared to 84.0% (58.3–91.7) with CBNAAT.[5] The sensitivity of CBNAAT relates to the severity of symptoms, which may in turn reflect mycobacterial load. As per RNTCP guidelines, CBNAAT testing is now the standard of care for TB diagnosis in PLHIV.

2.3 Provision of Daily Anti-TB Treatment with Fixed Dose Combination

The Standards for TB Care in India (STCI) recommend daily anti-TB treatment (ATT) instead of the current intermittent regimen. The daily regimen is preferred because the intermittent dosing schedules result in higher rates of treatment failure and relapse.[6,7,8,9] As per STCI, all new TB patients should receive standard treatment regimen, which consists of two months of the drugs Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E) in the initial phase (IP). The continuation phase should consist of the three drugs Isoniazid, Rifampicin, and Ethambutol given for at least four months. The patient should be given the daily regimen in dosages depending on body weight (weight bands). Fixed dose combinations (FDCs) are desirable as they simplify drug procurement and logistics. In previously treated TB patients, after multi-drug resistant TB (MDR-TB) is ruled out, the patient may receive the retreatment regimen containing first line drugs: 2HREZS/1HREZ/5HRE.

Based on the recent recommendations of the National Technical Working Group (NTWG) on HIV-TB, it has been decided that, in accordance with STCI, all patients with HIV associated TB will be initiated on daily ATT regimen instead of the current intermittent regimen.

2.4 Provision of Isoniazid Preventive Therapy (IPT) for PLHIV

Isoniazid preventive therapy entails administration of Isoniazid (INH) to individuals with latent TB infection so as to prevent progression to active TB disease. About 50% adults in the community have latent TB infection (LTBI). Isoniazid is one of the most effective bactericidal

anti-TB drugs that protect against progression of latent TB infection to active disease (against endogenous reactivation). It also prevents TB re-infection post exposure to an open case of TB (against exogenous re-infection/super infection/nosocomial transmission). Several studies have shown that IPT administration in PLHIV prevents incidence and relapse of TB and is, therefore, a key public health intervention for TB prevention in PLHIV. IPT has been recommended as part of a comprehensive HIV and AIDS care strategy by the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the *National Framework for Joint HIV/TB Collaborative Activities* (November 2013), and the Standards for TB Care in India (STCI). PLHIV who do not have active TB should receive six months of IPT as part of a comprehensive package of HIV care.

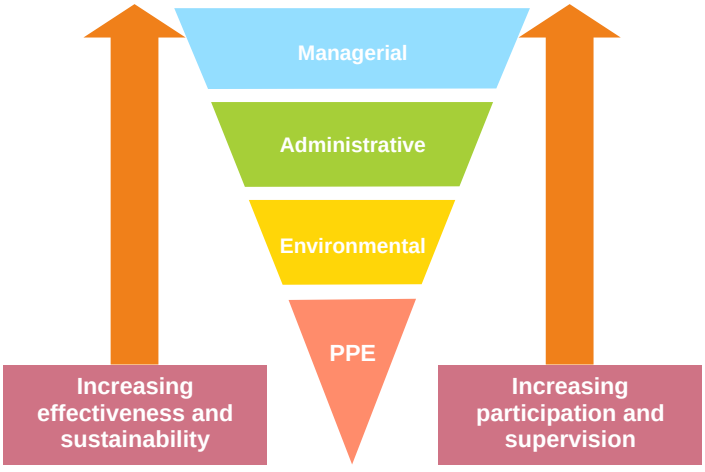
The effects of IPT augment the effects of ART on reducing the incidence of TB. With the concomitant administration of both ART and IPT, there is likelihood of restoration of TB-specific immunity by ART, and the beneficial effect of IPT may be prolonged. IPT does not promote Isoniazid resistance when used to treat latent TB infection. In latent TB, the *Mycobacterium tuberculosis* bacilli are fewer in number and are dividing slowly, resulting in an extremely low risk of selecting drug-resistant mutants. A study[10] conducted in 2010 reflected that prevalence of INH resistance among IPT-exposed persons was similar to the background population.

Adults and adolescents living with HIV should be screened for TB with a clinical algorithm, and those who do not report any one of the symptoms of current cough, fever, weight loss, or night sweats are unlikely to have active TB and should be offered IPT. Children living with HIV (more than 12 months of age) who do not report poor weight gain, fever, current cough, or history of contact with a TB case, are unlikely to have active TB and should be offered IPT. Additional investigations (chest X-ray and Tuberculin Skin Test) can help in ruling out active TB but are not mandatory.

2.5 Airborne Infection Control Activities at ART Centres

Presence of immuno-compromised patients in health care and congregate settings lacking effective infection control measures creates a favorable environment for TB transmission. The national *Guidelines on Airborne Infection Control in Healthcare and Other Settings*,[11] developed by the Ministry of Health and Family Welfare (MoHFW), Government of India, has identified ART centres as one of the high-risk settings for TB

Figure 4. Hierarchy of AIC measures



transmission. Presence of robust systems and policies is vital to control airborne transmission of TB infection in PLHIV at ART centres. Effective implementation of AIC measures involves four recognized controls in a hierarchy, as presented in Figure 4.

Managerial controls: Managerial controls relate to formulation of policy, establishment of AIC committees, and preparation and review of AIC plans. Measures at this level include the framework for implementing AIC at national, state, and district levels, like Hospital Infection Control Committee (HICC), AIC sub-committees, and human resources. The Nodal Officer of the ART centre should be member of the HICC in the institution where the ART centre is located, so as to effectively advocate for policy measures and facilitate preparation as well implementation of AIC plans for the ART centre. The HICC sub-committee on AIC should take up facility risk assessment and develop a facility plan for AIC, rethinking the use of available spaces and considering renovation and/or construction to optimize implementation of controls. The AIC sub-committee should designate focal points for facility-level activities, support training of frontline health care workers, as well as supervise and monitor infection control activities.

Administrative controls: Administrative controls seek to identify persons with respiratory symptoms, separate them into an appropriate environment, promote cough etiquette and cough hygiene, fast-track them through the health care facility to reduce exposure time to others, and diagnose/treat them with minimal delay. Hospitalization should be reduced or avoided to the greatest extent possible. At the facility level, administrative controls play a major role in reducing the risk of TB transmission and are essential for the implementation of other controls (i.e., environmental controls and personal protective equipment [PPE]).

Environmental controls: The choice of environmental controls is largely determined by local factors and resources. Ventilation should be prioritised to reduce the number of infectious particles in the air. Effective ventilation may be achieved through natural ventilation where possible or through mechanically aided ventilation systems (such as exhaust fans, air handling units, heating, ventilating, and air-conditioning system). In high-risk settings where optimal ventilation cannot be achieved through natural or mechanically-aided means, properly designed, placed, and maintained shielded ultraviolet germicidal irradiation (UVGI) devices should be considered as a complementary control.

Personal protective equipment: Personal protective equipment (for example, surgical mask to patients, particulate respirators certified as N95 or FFP2 in DR-TB wards) should be available as required in high-risk situations, especially DR-TB, and during high-risk aerosol-generating procedures such as bronchoscopy or sputum induction.

Chapter 3

Operational Steps

The operational steps for each of the HIV-TB initiatives introduced at ART centres are provided below.

3.1 Intensified Case Finding Using 4-Symptom Complex for TB Screening and Fast-Tracking

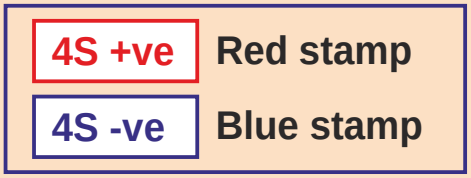
- ART centres must screen all the patients for TB using the 4-symptom (4S) complex screening tool—which includes cough of any duration (only for PLHIV), fever, weight loss, and night sweats among adults—at each and every visit to the ART centre. In children, the 4S complex includes current cough, fever, poor weight gain, and history of contact with a TB case. Table 1 presents the 4-symptom complex for screening TB in PLHIV and CLHIV.

Table 1. The 4-symptom (4S) complex for screening TB in PLHIV

Adults	Children
• Current cough • Fever • Weight loss • Night sweats	• Current cough • Fever • Poor weight gain • Contact with a TB case

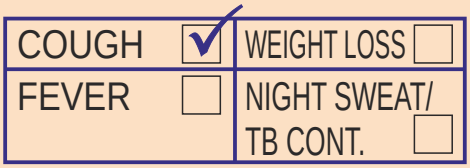
- All PLHIV (both ART and pre-ART patients) should be screened for TB using the 4-symptom complex by the Care Coordinator, Staff Nurse, Counsellor, and Senior Medical Officer/Medical Officer during every visit to the ART centre. Specific stamps have been provided for documenting TB screening by different ART staff, as seen in Annexure 1.
- TB screening will begin with the Care Coordinator at the ART centre, who is the first point of contact for the PLHIV. Patients with any one or more of the four symptom/s will be marked as 4S+ve (4S positive), and patients with no symptoms will be marked as 4S–ve (4S negative). The 4S status of the patent has to be recorded in the Patient Visit Register and Green Book of the patient using the 4S stamps (shown in Figure 5).
- The PLHIV marked as 4S+ve will then be referred by the Care Coordinator to the Staff Nurse, who will in turn do a further assessment to ascertain the patient's 4S status. The

Figure 5. Red and blue stamps for use by the Care Coordinator



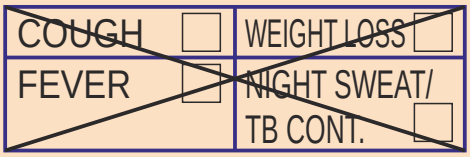
Staff Nurse will record the 4S screening status in the patient's Green Book using a detailed stamp (shown in Figure 6) by ticking the appropriate symptom/s that the PLHIV presents with. In paediatric cases, the Staff Nurse will strike out 'Night Sweat' and tick for 'TB Contact', if relevant for CLHIV.

Figure 6. Detailed 4S stamp for use by the Staff Nurse (with the relevant symptom/s ticked for 4S+ve patients)



- The Staff Nurse will send all the 4S+ve PLHIV to the Senior Medical Officer/Medical Officer who will finally ascertain the 4S status of the patient. The flow of patients for fast-tracking of 4S+ve patients at the ART centre is presented in Annexure 2.
- The patients marked as 4S–ve by the Care Coordinator will follow the routine patient flow at the ART centre, and will, therefore, be sent to the Counsellor.
- The Counsellor will screen all the 4S–ve patients (using the 4-symptom complex tool) and record the 4S status in the Green Book using the detailed stamp. If none of the 4S symptoms are present, the Counsellor will place a large cross over the stamp (as shown below in Figure 7).

Figure 7. Detailed 4S stamp crossed by the Counsellor for 4S–ve patients



- All the 4S–ve PLHIV will then be referred to the Senior Medical Officer/Medical Officer who will finally ascertain the 4S status.
- The Senior Medical Officer/Medical Officer will mark the patient's 4S status (4S+ve or 4S–ve) in Section 13 of the patient White Card, and will be responsible for appropriate management of the patient as described in subsequent sections of the guidelines.

3.2 Referral for TB Testing

- The Medical Officer will identify the PLHIV for referral to TB diagnosis and indicate the appropriate TB test (CBNAAT or other relevant investigations based on the symptoms of the patients to establish TB diagnosis) in the Green Book of the patient and send the patient to the Staff Nurse for referral and guidance.
- The Staff Nurse will prepare the TB Lab Referral Form (Annexure 3) with all the relevant information, including the e-mail ID of the ART centre. It should be ensured that complete and correct contact details (address and phone number) of the patient is provided in the Lab Referral Form.
- All the patients referred for TB diagnosis (CBNAAT/sputum smear/radio diagnosis or other relevant investigations) should be documented in the HIV-TB Line List (Annexure 4). The

Line List should be prepared by the Staff Nurse in hard copy initially. Later, the HIV-TB Line List must be recorded as soft copy in Excel format by the ART centre Data Manager on financial year basis.

- The Staff Nurse will facilitate/guide the patient to reach the Designated Microscopy Centre (DMC)/CBNAAT lab and instruct the patient to come back when reports are available.
- CBNAAT is the preferred diagnostic technique (compared to smear microscopy) for TB testing in PLHIV. For CBNAAT testing in PLHIV, only one sputum sample (spot sample) is required. However, in situations when CBNAAT testing is not available, smear microscopy can be performed for which two sputum samples (spot-spot sample) are sufficient.
- Biological specimen collection and transportation should be facilitated by the district RNTCP staff.
- The DMC/CBNAAT Lab Technician will perform the test, generate the patient's NIKSHAY ID, and share the result report to the ART centre on a daily basis. In case of CBNAAT testing, an electronic copy of the report should be shared with the ART centre through e-mail on the same day; this will help in initiating the patient on ATT early.
- In instances where the CBNAAT lab is not co-located in the same facility as the ART centre, the District TB Officer (DTO) will ensure sample collection and transportation mechanism to the nearest CBNAAT lab using RNTCP funds. Specimen collection for transportation will be done at the DMC of the health facility where the ART centre is located, and the patient will not be required to travel to the CBNAAT lab in such cases.

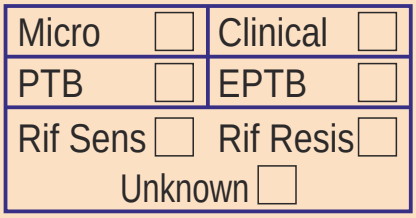
3.3 TB Categorization and Treatment

3.3.1 Initiation of TB Treatment

- Based on the lab reports/clinical investigations, the Medical Officer will establish the diagnosis of TB.
- All PLHIV diagnosed with TB should be initiated on daily ATT at the ART centre itself.
- Based on the clinical history and investigation reports, the ART Medical Officer will classify the TB case as:
  - Microbiologically or Clinically diagnosed TB case
  - Pulmonary or Extra Pulmonary TB case
  - Rifampicin sensitive or Rifampicin Resistant or Status not known
  - New case or Previously treated case

  (Definitions for classification of TB case and treatment status are provided in tables 2 and 3.)
- The Medical Officer will use the prescribed stamp, as shown in Figure 8, to classify the TB case. The relevant boxes must be ticked and the Rifampicin status should also be marked. The stamp should be placed in Section 7 of the patient White Card.
- The Medical Officer will also record the past history of TB treatment and other relevant details pertaining to treatment in the White Card.

Figure 8. Stamp for use by the Medical Officer for classifying TB case



- The Medical Officer will also record the past history of TB treatment and other relevant details pertaining to treatment in the White Card.

Table 2. Classification of TB case

Microbiologically confirmed TB case	TB patient with biological specimen positive for acid fast bacilli (AFB), or positive for Mycobacterium tuberculosis (M. TB) on culture, or through quality assured rapid diagnostic molecular test
Clinically diagnosed TB case	TB patient who is not microbiologically confirmed but has been clinically diagnosed with active TB by a clinician on the basis of radiological abnormalities or clinical signs with a decision to treat the patient with a full course of ATT
Pulmonary TB	Any microbiologically confirmed or clinically diagnosed case of TB involving lung parenchyma or tracheo-bronchial tree
Extra-Pulmonary TB	Any microbiologically confirmed or clinically diagnosed case of TB involving organs other than lungs, such as pleura, lymph node, intestine, joints, bones, etc.

Table 3. Type of TB patient

a	New		A TB patient who has never had treatment for TB or has taken anti-TB drugs for less than one month
b	Previously treated		A TB patient who has received one month or more of anti-TB drugs in the past
	i	Recurrent	A TB patient declared as successfully treated (cured/treatment completed) and subsequently found to be microbiologically confirmed TB case
	ii	Treatment after failure	A TB patient who has previously been treated for TB and the treatment failed at the end of their most recent course of treatment
	iii	Treatment after Loss to Follow Up (LFU)	A TB patient previously treated for TB for one month or more and declared LFU in the end of their most recent course of treatment and subsequently found microbiologically positive
	iv	Other previously treated patients	TB patients who have been previously treated for TB but whose outcome after their most recent course of treatment is unknown or documented
c	Transferred in		A TB patient who is received for treatment in a TB unit after registering for TB treatment in another TB unit

- Based on the classification of the type of TB patient and weight band, the ART Medical Officer will initiate ATT as per RNTCP guidelines at the ART centre itself and document the same in the White Card. Tables 4 and 5 provide details of the daily treatment regimen for adults and Table 6 provides details for paediatric patients.
- For antiretroviral treatment, the existing national guidelines for ART initiation/ continuation/modification in HIV-TB co-infection should be followed. Refer to the ART operational guidelines and OMs.

Table 4. Anti-TB treatment schedule

Type of TB Case	Treatment Regimen
New: A TB patient who has never had treatment with anti-TB drugs or has taken it for less than one month	$2H_7R_7Z_7E_7 + 4H_7R_7E_7$
Previously Treated: A TB patient who has received one month or more of anti-TB drugs in the past	$2H_7R_7Z_7E_7S_7$ + $1H_7R_7Z_7E_7$ + $5H_7R_7E_7$
H: Isoniazid, R: Rifampicin, Z: Pyrazinamide, E: Ethambutol, S: Streptomycin	

Table 5. Daily dose schedule for adults (as per weight band)

Weight Band	Number of Tablets		**Inj. Streptomycin mg (Intensive Phase Only)**
	Intensive Phase (IP)	Continuation Phase (CP)	
	HRZE (4FDC)	HRE (3FDC)	
	75/150/400/275 mg	75/150/275 mg	
25–39 kg	2	2	**500mg**
40–54 kg	3	3	**750 mg**
55–69 kg	4	4	**1000 mg**
‡70 kg	5	5	**1000 mg**

Table 6. Daily dose schedule for paediatric patients (as per weight band)

Weight Band	Number of Tablets (Dispersible FDC)				Injection Streptomycin mg (Intensive Phase Only)
	Intensive Phase (IP)		Continuation Phase (CP)		
	HRZ 50/75/150 mg	E 100 mg	HR 50/75 mg	E 100 mg	
4–7 kg	1	1	1	1	100 mg
8–11 kg	2	2	2	2	150 mg
12–15 kg	3	3	3	3	200 mg
16–24 kg	4	4	4	4	300 mg
25–29 kg	3 +1A	3	3 +1A	3	400 mg
30–39 kg	2+2A	2	2+2A	2	500 mg
A= Adult 4FDC in IP and 3FDC in CP					

- The treatment dose will remain the same (for both adults and paediatric cases) even if the weight band changes during the course of TB treatment.
- In the case of previously treated patients, CAT II ATT, including Inj. Streptomycin along with daily FDCs, will be provided by ART centres on a monthly basis.
- Patients diagnosed with drug resistant/Rif resistant TB should be referred to the DR-TB centre for management. Patient's referral to the concerned DR-TB centre should be ensured by RNTCP (District DR-TB and HIV-TB Supervisor) and the updated information regarding DR-TB treatment initiation must be communicated to the ART Staff Nurse to complete the record in the HIV-TB Line List.
- TB Treatment Card for these patients will be prepared by the Staff Nurse in duplicate and will be duly signed by the Medical Officer. One copy of the TB Treatment Card will be handed over to the patient for documentation of adherence and follow-up in the field by the RNTCP staff.
  - The HIV details need not be written in the patient copy of the TB Treatment Card (only to maintain confidentiality of the patient).
  - Patients will be required to bring this card to the ART centre on every visit until the completion of ATT.
  - After the completion of treatment, one copy of the TB Treatment Card will be retained by the ART centre, while the copy of the card with the patient will be collected by the health care worker and will be retained at the Tuberculosis Unit (TU) under the custody of the Senior Treatment Supervisor (STS).

- Patient will also be given the TB ID Card prepared by the Staff Nurse.
- The ART Counsellor will ensure proper counseling of all the HIV-TB co-infected patients regarding adherence, usage of 99DOTS, and possible side effects of ATT.
- The ART Data Manager will take the patient details from the Staff Nurse and register the patient on the 99DOTS website (www.99dots.org). The Data Manager should make sure that he/she adds all the phone numbers of the patient, as that is essential for adherence monitoring through 99DOTS. He/she must also select the correct district for that patient to allow the RNTCP staff to access the patient details and monitor adherence on the website. A tutorial on how to do this can be found at http://99dots.org/.
- The Staff Nurse will share the details of all the patients initiated on ATT at the ART centre with the HIV-TB Coordinator on a daily basis. This will help the RNTCP to identify a treatment supporter in a timely manner.
- The HIV-TB Coordinator will ensure that a heath care provider/treatment supporter is identified for provision of Inj. Streptomycin.

3.3.2 Dispensing of ATT to Patients

- For PLHIV with drug-sensitive TB, the daily ATT drugs will be dispensed to the patients by the ART Pharmacist at the ART centre on a monthly basis. The ATT drug dispensing chart for adults is provided in Annexure 5.
- All the HIV-TB co-infected patients should be dispensed 28 days of ATT along with CPT by the ART Pharmacist at the ART centre.
- The patients should be dispensed the medication in the correct envelopes for their weight band.
- The due date or the next date of visit should be adjusted by the Counsellor/Medical Officer/Pharmacist based on the ATT schedule.
- At the completion of TB treatment, the leftover ART pills need to be adjusted while giving the next date of visit.

3.3.3 Registration and Coordination between RNTCP and ART Centres

- The DTO must assign the responsibility for coordinating the registration of PLHIV for TB treatment to the HIV-TB Coordinator. The District DR-TB & HIV-TB Coordinator is ultimately accountable for treatment support and adherence of all HIV-TB co-infected patients. The STS of the concerned TU is responsible for registering patients and for ongoing retrieval actions.
- After the patient has been initiated on ATT by the ART centre, he/she will be registered and allotted the TB number by the STS of the concerned TU (where the patient resides) as per RNTCP guidelines. HIV-TB Coordinator should coordinate registration for TB treatment by concerned STS/Tuberculosis Health Visitor (TBHV).
- If the patient belongs to a different district, the HIV-TB coordinator will coordinate

with his/her counterpart from the other district for registration and follow-up of patient and exchange of information.

- The HIV-TB Coordinator, in coordination with STS/TBHV, will also identify treatment supporter for all HIV-TB co-infected patients for Directly Observed Treatment Short Course (DOTS) provision and further follow-up. The ART centre needs to be informed of the same.
- Contact details of the STS/TBHV should be available with the ART Staff Nurse.
- The patient must be registered and allotted the TB number by the STS of the concerned TU as per RNTCP guidelines at the earliest (no later than within one month) and the HIV-TB Coordinator should be informed.
- The District DR-TB & HIV-TB Coordinator should coordinate with the ART centre on a weekly basis and update the NIKSHAY ID/TU number in the TB Treatment Card available at the ART centre and the HIV-TB Line List.

3.3.4 Adherence

- The ART Counsellor will ensure proper counselling of all the HIV-TB co-infected patients regarding adherence, usage of 99DOTS, and possible side effects of ATT.
- The initial counselling about adherence and possible side effects will be done at the ART centre by the Counsellor and in the field by the designated RNTCP staff.
- Any adverse drug reactions identified by the ART staff or the RNTCP staff should be informed immediately to the local Medical Officer at the Peripheral Health Institution (PHI) and the ART Medical Officer.
- Regular follow up of patients, testing for sputum as per RNTCP guidelines, and adherence to ART and ATT treatment must be ensured by the DOTS provider, STS, Senior TB Laboratory Supervisor (STLS), and the ART Medical Officer. The ART Counsellor should ensure proper counselling of all HIV-TB co-infected patients on adherence and possible side effects of ATT during every visit.
- Patients should be asked to bring back empty blisters to the ART centre.
- The District DR-TB & HIV-TB Coordinator is ultimately accountable for monitoring the adherence of all TB-HIV co-infected patients using 99DOTS.
    - The District DR-TB & HIV-TB Coordinator can login on the 99DOTS website using the district username and password (same as NIKSHAY username and password). He/she should ensure that all the staff details for the district (that is, his/her own name and phone number for the district, as well as field staff's contact details for each TU) are up-to-date.
    - As soon as the Data Manager of the ART centre adds the patient on the 99DOTS website (and selects the correct district), the District DR-TB & HIV-TB Coordinator will be able to see the patient on the 99DOTS website using the district username and password (same as NIKSHAY login and password). If the District DR-TB & HIV-TB Coordinator's contact details are updated on the website, an SMS (with patient details) will also be sent to him/her as soon as the Data Manager of the ART centre adds the patient.

- The District DR-TB & HIV-TB Coordinator will link the patient to the correct TU by going to the patient's individual page on the 99DOTS website. As soon as this is done, the field staff for that TU will start receiving SMS alerts for that patient's adherence on a daily basis. Doing this will also enable the TU staff to access that patient on the 99DOTS website using their TU login and password (same as NIKSHAY login and password).
- The District DR-TB and HIV-TB Coordinator has to make sure that patients are adherent. In case of any missed doses (as seen on the 99DOTS website), he/she should arrange a phone call to the patient and make sure that the concerned field staff is following up with the patient. All such follow-up actions should be updated on the 99DOTS website as patient notes. The 99DOTS website will also automatically flag patients as "HIGH attention" to make this easier.
- The District DR-TB and HIV-TB Coordinator can take the help of the Data Manager to make sure that all staff and patient details are up-to-date on the 99DOTS website.

3.3.5 TB Treatment Follow-up and Outcomes

- Regular follow-up of patients, testing for sputum as per RNTCP guidelines, and adherence to ATT and ART treatment must be ensured by the DOTS provider, STS, STLS, and the ART staff.
- Sputum follow-up testing by smear microscopy must be done at the end of intensive phase of ATT and end of ATT treatment. The follow-up sputum examination will be done by sputum microscopy at the DMC and not by CBNAAT.
- In case of non-conversion at the end of intensive phase/end of treatment, drug susceptibility testing (DST) has to be carried out at RNTCP sites on referral by the ART Medical Officer. It must be noted here that in the revised guidelines, the intensive phase will not be extended based on sputum microscopy results.
- In case of extra-pulmonary TB, patients should be evaluated clinically/or by other diagnostic tests that were used earlier for diagnosis by the ART Medical Officer.
- The treatment outcome will be assigned by the ART Medical Officer in the White Card and will be updated in the TB Treatment Card by the ART Staff Nurse and in the NIKSHAY software by concerned TU staff. Table 7 lists the possible outcomes that will be ascertained by the ART Medical Officer.
- In case a patient on ATT is transferred out to any other ART centre, the RNTCP Referral/Transfer Out Form needs to be completed with relevant information and sent along with the ART transfer out form. The HIV-TB Coordinator should be kept informed about transfer outs, and 99DOTS should also be updated by RNTCP. Transfer Out Form is shown in Annexure 6.
- Guidance on Treatment after LFU: As per RNTCP definition, a patient who interrupts treatment for one month continuously after taking at least one month of treatment is declared as lost to follow-up (LFU). If such patients are retrieved back to the system

and found microbiologically confirmed, then they are categorized as previously treated cases (CAT II) and termed as treatment after loss to follow-up.

- A treatment after LFU patient will go for DST as per the current MDR suspect criteria. If found drug sensitive, the patient will be put on CAT II. If found drug resistant, the patient will be put on the MDR-TB regimen at the DR-TB centre.
- If the LFU patient comes back to the system and is diagnosed as having TB on clinical grounds, the patient will be put on treatment under the category 'Retreatment Others'.

- Guidance for PLHIV who report to the ART centre as already diagnosed TB case: The treatment regimen for such cases must be determined as follows:
  - Diagnosed but not initiated on ATT: Must be started on daily ATT at the ART centre
  - Already initiated on intermittent ATT: Must be switched to daily ATT at the ART centre. Consider completed months of intermittent therapy as treatment taken, and any days above completed months of treatment should not be taken into account while switching to daily regimen (for example, if a patient of CAT I has completed one-and-a-half months of intermittent therapy, then he will get daily regimen for five months instead of four-and-a-half months). Patients in the last month of intermittent therapy should not be switched to daily regimen.
- All RNTCP and NACP facilities must be informed that all HIV-TB co-infected patients must be referred to ART centres for initiation of ATT as well as ART.

Table 7. TB treatment outcomes

Cured	A TB patient who was microbiologically confirmed for TB at the beginning of treatment but who is smear or culture negative at the end of complete treatment
Treatment completed	A TB patient who completed treatment without evidence of failure or clinical deterioration BUT with no record to show that the smear or culture results of biological specimen in the last month of treatment was negative, either because the test was not done or because the result is unavailable
Treatment success	TB patients either cured or treatment completed are accounted in treatment success
Failure	A TB patient whose biological specimen is positive by smear or culture at the end of treatment Failure to Respond: A case of paediatric TB who fails to have bacteriological conversion to negative status or fails to respond clinically/or deteriorates after 12 weeks of completion of intensive phase shall be deemed to have failed response, provided alternative diagnoses/reasons for non-response have been ruled out
Lost to follow up (LFU)	A TB patient whose treatment was interrupted for one consecutive month or more
Not evaluated	A TB patient for whom no treatment outcome is assigned; this includes former 'transfer-out' cases
Treatment regimen changed	A TB patient who is on first line regimen and has been diagnosed as having DR-TB and switched to drug resistant TB regimen prior to being declared as failed
Died	A patient who has died during the course of anti-TB treatment

3.3.6 ATT In Specific Situations

The table below provides information on the ATT regimen for some specific situations.

Table 8. TB treatment in specific situations

SCENARIO	ACTION
TB treatment in PLHIV on Protease Inhibitor (PI) based ART	Rifampicin suppresses bioavailability of boosted PIs (Atazanavir/ritonavir, Lopinavir/ritonavir, Darunavir/Ritonavir). However, Rifabutin, an effective anti-TB derivative of Rifamycin group, does not inhibit effectiveness of these drugs. Rifabutin is not available in FDC and hence should be provided as a loose drug. Substitute Rifampicin with Rifabutin (150 mg daily) for the entire duration of Anti-TB treatment in such cases Ensure the availability of Rifabutin substituted combination before initiating anti-TB treatment While Anti-TB treatment initiation should be done as soon as TB is diagnosed even in patients on PI based ART, it is important to recognise that Rifampicin containing FDC should not be given immediately and then try to replace Rifampicin with Rifabutin later, whenever the Rifabutin is available. This will make boosted PI based regimen ineffective and will quicken the emergence of drug resistance mutants and eventual treatment failure for ART
TB treatment in children living with HIV (CLHIV) on Protease Inhibitor (PI) based ART	Super boosting of Lopinavir (LPV) with Ritonavir is recommended in children in proportion of 1:1. If super boosting of LPV is contraindicated, triple NRTI is to be considered as next choice. Higher dose of Nevirapine (NVP) is to be considered as the last choice.
Pregnant women	Streptomycin is Ototoxic to the fetus and should not be used during pregnancy. Injection Streptomycin in pregnant women should not be used.
Use of Injection Streptomycin for active TB, in patients over 50 years of age and/or <50 kg of weight	Patients aged over 50 years may not tolerate the daily dose of Streptomycin more than 750 mg. Similarly, patients weighing less than 50 kg may not tolerate doses above 500-750 mg daily.
In special situations like bone and joint TB, spinal TB with neurological involvement, and neuro-tuberculosis.	Extend CP by 3 to 6 months.

3.4 Isoniazid Preventive Therapy

Isoniazid preventive therapy (IPT) entails the administration of Isoniazid (INH) to individuals with latent TB infection so as to prevent progression to active TB disease. Before the start of IPT, it is critical to rule out active TB in the patient.

3.4.1 Ruling Out Active TB

The absence of all the four symptoms of current cough, night sweats, fever, or weight loss (4S–ve) can identify a subset of adolescents and adults living with HIV who have a very low probability of having TB disease and who can be reliably initiated on IPT. This screening rule has a negative predictive value of 97.7% (95% CI [confidence interval] 97.4–98.0) at 5% TB prevalence in PLHIV. In children, the absence of poor weight gain, fever, and current cough can identify children who are unlikely to have TB.

3.4.2 Eligibility for IPT

- All adults and adolescents living with HIV should be screened for TB with a clinical algorithm. Those who do not report any one of the four symptoms of current cough, fever, weight loss, or night sweats are unlikely to have active TB and should, therefore, be assessed for IPT initiation.
- All children living with HIV (more than 12 months of age) who do not report poor weight gain, fever, current cough, or history of contact with a TB case, are unlikely to have active TB and should, therefore, be assessed for IPT initiation.
- Additional investigations (chest X-ray and Tuberculin Skin Test) can help in ruling out active TB but are not mandatory.
- It should be noted that IPT is not an emergency. If there is any doubt about the TB status of a patient, IPT should be delayed.

3.4.3 Contraindications to IPT

- IPT should not be provided to patients in the following conditions:
  - Active TB disease
  - Active hepatitis
  - Signs and symptoms of peripheral neuropathy
- Persistent tingling, numbness, and burning sensation in the limbs
  - Poor adherence to Cotrimoxazole preventive therapy (CPT)
  - Poor understanding of IPT by the guardian
  - Contact with MDR-TB case
  - PLHIV who have completed DR-TB treatment

3.4.4 IPT Work Up

- Ask the patient for signs of liver disease (yellowness of eyes) and neuropathy (persistent numbness and burning sensation in feet and hands).
- Examine the patient for jaundice and tenderness in the right upper quadrant of the abdomen.
- Where available, routine liver function tests/ALT should be offered, but lack of LFT/ALT results should not delay the initiation of IPT in asymptomatic patients.
- If the patient does not have any abnormality based on the assessment above, assess for adherence using the criteria on the backside of the ICF/IPT card.

3.4.5 IPT Regimen Plan

The regimen plan and dosing chart are provided below.

- **Adult and Adolescent:** Isoniazid 300mg + Pyridoxine 50mg (Vitamin B6) per day for 6 months
- **Children above 12 months:** Isoniazid 10mg/kg + Pyridoxine 25 mg (Vitamin B6) per day for 6 months

Table 9. Pediatric dosage chart for IPT

Weight Range (kg)	Number of 100 mg tablets of INH to be administered per dose (Total dose 10 mg/kg/day)	Dose (mg)
<5	½ tablet	50
5.1–9.9	1 tablet	100
10–13.9	1 ½ tablet	150
14–19.9	2 tablets	200
20–24.9	2 ½ tablets	250
‡25	3 tablets or one adult tablet	300

3.4.6 IPT Initiation and Follow-up

- The Counsellor at the ART centre will screen all the 4S–ve patients and record the status in the Green Book. The Medical Officer will finally ascertain the 4S–ve status and determine eligibility for IPT.
- The Medical Officer will initiate IPT if not contraindicated and document the same in the opportunistic infection (OI) prophylaxis column (Section 13) of the patient White Card.
- IPT drugs must be provided on a monthly basis to all eligible patients.
- 4S screening should be done for all the patients (ART and pre-ART) on IPT during every visit to exclude active TB.
- In case a patient becomes 4S+ve during the IPT course, the patient should be referred for TB diagnosis, and if found positive, IPT should be stopped and ATT should be initiated. The ART Medical Officer should record the IPT status of the patient in the White Card at every follow-up visit.
- IPT should be considered for both on-ART and pre-ART patients (if found 4S–ve).
- IPT drugs will be dispensed to the patient by the ART Pharmacist at the ART centre on a monthly basis.
- IPT will be provided only at ART centre and not in linked ART centre (LAC) or LAC Plus. All the patients at LAC/LAC Plus should be linked out to the nodal ART centre when it is due (for 6 monthly CD4 testing or occurrence of any major OI). Such patients will be

duly screened for any TB symptom at the ART centre using 4S complex screening tool. All the 4S –ve patients eligible for IPT will be initiated for IPT by the S/MO and linked back to the LAC/LAC Plus only after completion of full course of IPT.

3.4.7 IPT in Specific Situations

- IPT provision in special circumstances, such as patients who are previously treated for TB, patients with ART, pregnancy, and MDR-TB, is summarised in Table 10.

Table 10. IPT provision in specific situations

Scenario	Action
Patients previously treated for TB (Secondary prophylaxis)	▸ All CLHIV/PLHIV who had successfully completed treatment for TB disease earlier should receive INH for six months. ▸ All CLHIV/PLHIV who have just completed successful treatment for TB disease should receive INH for an additional six months.

IPT with ART
(Secondary prophylaxis)
	▸ Combined use of IPT with ART is recommended for all CLHIV/PLHIV irrespective of:
	  ▸ Degree of immune suppression
	  ▸ Previous treatment for TB
	  ▸ Pregnancy
	▸ ART should not be delayed while starting or completing a course of IPT.

IPT and pregnancy	▸ Pregnant woman living with HIV should not be excluded from symptom-based TB screening and receiving IPT ▸ Isoniazid is safe in pregnancy. Start IPT in all HIV positive pregnant women irrespective of their gestation period ▸ Advise women to complete IPT if a woman becomes pregnant while taking IPT ▸ Assure patient that IPT is safe while breastfeeding
IPT in children born to microbiologically confirmed TB mothers	▸ If a baby is born to a microbiologically confirmed TB mother, assess the newborn for active TB ▸ Non-specific features suggestive of neonatal TB include: Fever, low birth weight, hepato-splenomegaly, irritability, feeding intolerance ▸ If the child has none of the above, give IPT for 6 months
IPT and MDR-TB	▸ Contacts of MDR-TB and PLHIV who have completed DR-TB treatment are not eligible for IPT.
Patient on IPT develops TB during IPT treatment	▸ If a patient develops TB symptoms during IPT treatment, evaluate the patient for TB and conduct DST. Based on DST results, the appropriate treatment should be provided. ▸ If the patient is sensitive to all the drugs, then based on history of ATT and duration of IPT decide on the following: ▸ If the patient has not received anti-TB treatment in the past and has taken IPT for less than 1 month then provide the patient with treatment for new case (CAT I).

Scenario	Action
	◦ If the patient has received anti-TB treatment in the past OR if the patient has taken IPT for more than 1 month, then provide the patient with retreatment (CAT II) regimen. ▸ If the patient is found to have DR-TB, refer the patient to the DR-TB centre.
Patients develop TB after IPT treatment	▸ Treat the TB episode as new or previously treated case, based on previous TB treatment history and Rifampicin resistance pattern (whenever available). *IPT is not to be considered as past history of TB in such cases*
If a patient had taken IPT for less than one month in total and discontinued for any reason (like toxicity or loss to follow up)	▸ Conduct adherence counselling, address reasons for discontinuation, conduct ICF, and, if asymptomatic, restart INH afresh. ▸ Ensure they have completed a 6-month course.
After taking IPT for more than one month: If the patient had discontinued IPT for less than three months	▸ Conduct adherence counselling, conduct ICF, and, if asymptomatic, restart INH. ▸ Ensure they complete a 6-month course within a 9-month period.
After taking IPT for more than one month: If the patient discontinued for more than three months or had discontinued more than once	▸ Do not re-initiate IPT.

3.5 Inventory Management for ATT and IPT

- DTO, with the support of District HIV-TB and PMDT/DR-TB Coordinator, will ensure availability of drugs (in 99DOTS wrapped envelopes for all weight bands) for ATT and IPT and also of recording and reporting formats at ART centres.
- ATT and IPT drugs will be dispensed to the eligible patients by the ART Pharmacist on a monthly basis based on weight bands.
- The ART Pharmacist will maintain the inventory of stocks for ATT and IPT drugs at the ART centre.
- Drug reporting will be done on a monthly basis by the ART centre (Pharmacist) to the DTO in TB drug monthly reporting format given in Annexure 7.
- The District HIV-TB and PMDT coordinator should ensure uninterrupted availability of adequate stock of ATT and IPT drugs and logistics in coordination with the ART centre, the DTO, and the District Drug Store Pharmacist.

Note: *A summary of 4S screening, TB diagnosis, treatment, and IPT consideration is presented as a flow diagram in Annexure 8.*

Chapter 4

4. Recording and Reporting for HIV-TB Activities at ART Centres

Recording and reporting form an important integrated activity in HIV-TB management at ART centres. Recording and reporting of data ensures high-quality patient care through information-sharing with patients, transfer of information between health facilities, and helping the staff in providing adequate services to individual patients. Well-documented records and reports allow managers at different levels to monitor programme performance in a standardised format and provides the basis for programmatic and policy development. Recording and reporting of all patients should be done as per the revised HIV-TB tools in both NACP and RNTCP formats.

4.1 NACP Recording and Reporting Tools

The following formats and monitoring tools are presently being used by NACP for recording and reporting activities pertaining to HIV-TB co-infection at ART centres:

1) Patient Visit Register: It contains details of all the patients visiting the ART centre each day, with details about the patient's pre-ART/ART registration number, whether the patient is new or on a follow-up visit, and if the patient is on ART, and had come for a scheduled/ unscheduled visit.
   - The Care Coordinator maintains this register. The Care Coordinator will evaluate all the patients for the four symptoms and record the findings (4S+ve or 4S–ve) in the remarks column of the Patient Visit Register using the specified stamp (red stamp for 4S+ve and blue for 4S–ve patients).

Patient Visit Register

S No.	Name	HIV care (Pre-ART) registration No. (For Patient no on ART)		ART Registration No. (for patients on ART)		Patients referred for EID from ICTC/LAC (mother's PID No./HIV Care Registration No. to be entered)	Remarks
		New Patient	Followup	Schedule	Unscheduled		
1	Xxxxxxxxx Xxxxx			185			4S+
2	Xxxxxxxxx Xxxxx			533			4S-
3	Xxxxxxxxx Xxxxx			892			4S+
4	Xxxxxxxxx Xxxxx		236				4S+
5	Xxxxxxxxx Xxxxx			83			4S-
6	Xxxxxxxxx Xxxxx			1019			4S-
7	Xxxxxxxxx Xxxxx		321				4S+
8	Xxxxxxxxx Xxxxx		112				4S-
9	Xxxxxxxxx Xxxxx			499			4S+

2) Patient's Green Book: The Green Book is a document issued to the patient as an identity document, in which details of the patient along with basic history of visits and treatment details are documented.

- The Care Coordinator will mark the 4S+ve or 4S–ve status in the patient Green Book using the specified stamp (red stamp for 4S+ve and blue for 4S–ve patients).
- For all the 4S+ve patients referred by Care Coordinator, the Staff Nurse will record the 4S screening status in the patient's Green Book using a detailed stamp (shown in Figure 6) by ticking the appropriate symptom/s that the PLHIV presents with.
- For all the 4S–ve patients, the Counsellor will validate the 4S status and record the status in the patient Green Book using the detailed stamp indicating the four symptoms and mark the symptoms presented by the patient during the screening. In case no symptoms are found, the Counsellor will place a large cross on the detailed 4S stamp.

Counselling / Clinical Notes

Date of visit: **4S+**

Counselling notes:

Chief Complaints:

Clinical examination (major findings):

Weight:

WHO Clinical stage:

COUGH ☑	WEIGHT LOSS ☑
FEVER ☐	NIGHT SWEAT/ TB CONT. ☐

Investigations

Treatment

3) Patient's White Card (Patient Treatment Record): The White Card is one of the key records maintained at the ART centre, and contains patient-wise record of diagnostic tests, CD4 count, opportunistic infections diagnosed, treatment provided, etc.

The Medical Officer will document the following on the White Card:

- 4S screening status: 4S+ve or 4S-ve; (Section 13, Column 19 [Remarks])
- IPT status: The IPT status has to be recorded in Section 13, Column 9 [Others] indicating the options for IPT status given below:
  - Not applicable (NA)
  - Initiated on IPT during this visit (IPT I)
  - Contraindicated (Cont)
  - On IPT (IPT)
  - IPT stopped due to medical/other reasons (ST)
  - IPT full course completed (Comp)
  - TB treatment status: The TB treatment status has to be recorded in Section 13, Column 14, indicating the options for ATT treatment given below:
    - Not Applicable (NA)
    - Initiated on ATT during this visit (ATT-I)
    - On ATT (ATT)
    - ATT stopped due to medical/other reasons (ST)
    - ATT full course completed (COMP)

ART White Card (SMO / MO)

13 Follow up

S. No.	1 Date of visit	2 Date of next visit (due date)	3 Weight (kg)	4 Height (cm) of child	5 Functional Status WAB**	6 WHO Clinical State	7 Opportunistic Infections (code)*	8 Drugs prescribed for Opportunistic Infections/ Prophylaxis: CPT (Yes/No)	9 Drugs prescribed for Opportunistic Infections/ Prophylaxis: Others (with dose)	10 Anti retroviral drugs: Regimen	11 No. Pills remaining with the patient	12 Adherence to ART (%) ##	13 Any other mdicine	14 TB treatment Y/N	15 ART side effects code $	16 Concurrent condition e.g. STI	17 Pregnancy Y/N	18 Condoms given Y/N	19 Remarks / Referrals	20 Staff Signature
1									IPT-I					ATT-I					4S +ve	
2									Cont					ATT					4S -ve	
3									IPT											
4									ST											
5									IPt											
6									IPT											
7									Comp											

IPT status
Not applicab(NA)
Initiated on IPT during this visit (IPT-I)
Contraindicated (Cont)
on IPT (IPT)
IPT stopped due to medical/other reason (ST)
IPT full course completed (Comp)

TB Treatment status
Not applicable (NA)
Initiated on ATT during this visit (ATT-I)
On ATT (ATT)
ATT stopped due to medical / other reason (ST)
ATT full course completed (Comp)

ART White Card

12 Investigations

Test (date)		/ /	/ /	/ /	/ /	/ /	/ /
Hb							
TLC							
DLC							
ESR							
PLT							
MCV							
Type of Anaemia (GBP)							
Blood Urea							
S. Creatinine							
S. Billirubin							
SGOT (AST)							
SGPT (ALT)							
Alk. PO4							
S. Amylase							
Blood Sugar							
S. Cholesterol							
S. Triglycerides							
S. DHL							
S. LDL							
Serum Lipase							
Serum Lactate							
VDRL							
HBsAg							
Anti-HCV							
CD4 count / CD4 %							
Urine R&M							
Viral Load							
Pap smear							
Mantoux Test							
CXR (PA view)		Date & Finding:		Date & Finding:		Date & Finding:	
USG (ABD)		Date & Finding:		Date & Finding:		Date & Finding:	
Other (specify) Sputum AFB/CBNAAT							

- Investigation results: The results of the relevant investigations that were done for TB diagnosis should be recorded in Section 12. The results of CBNAAT/smear microscopy should be recorded under 'Others'.

- Classification of TB: The classification of the TB case should be recorded in Section 7, using the stamp. The relevant box should be ticked based on the type of TB given below:
  - Microbiologically or clinically diagnosed TB cases,
  - Pulmonary or extra pulmonary TB case,
  - Rifampicin sensitive or Rifampicin resistant or Status not known.

The Medical Officer should also record the past history of TB treatment and other relevant details pertaining to treatment in Section 7 of the White Card. Details about TB registration should be filled-up by the Staff Nurse.

ART White Card

7. Tuberculosis treatment (RNTCP) during HIV care

7 (a) Episode 1			7 (b) Episode 2
☐ **Disease class** ( ) ☐ **Pulmonary TB** ☐ Smear-positive ☐ Smear-negative ☐ Extra pulmonary **Site:** ..... ☐ **Past Hstory of TB** Micro ☑ Clinical ☐ PTB ☑ EPTB ☐ Rif Sens ☐ Rif Resis ☑ Unknown ☐	**TB Regimen (✓)** ☐ Category I ☐ Category II ☐ Other specify: ☐ Non DOTs ☐ Rx for MDR Date starts TB Rx: 04 / 06 / 2016 CAT II	**TB registration** District: DELHI TB Unit: DDU TB number: XXYY **Rx outcome for episode1:** ☑Cured ☐Rx completed ☐Rx failure ☐Died ☐Defaulted ☐Transferred out Date: ____/____/_____	**Type:** **Rx Category:** **Rx Outcome:**

4) HIV-TB Line List (revised): The revised HIV-TB Line List format contains 20 columns to enable recording of details of all the referrals made by the ART centre for TB diagnosis to DMC/CBNAAT or other facilities. The format of the revised HIV-TB Line List is presented in Annexure 4.

- All the patients referred for TB diagnosis (CBNAAT/sputum smear/radio diagnosis or other relevant investigations) should be documented in the HIV-TB Line List. The Line List should be prepared by the Staff Nurse in hard copy initially. Later, the HIV-TB Line List must be recorded as soft copy in the Excel format by the ART Data Manager on financial year basis, and information should be updated as and when available.
- The Staff Nurse will update columns 1 to 16 of the HIV-TB Line List. The Line List should be shared with the HIV-TB Coordinator on a weekly basis for updating NIKSHAY ID/TU number in column 17. However, details of the patients initiated on ATT at the ART centre should be shared with the HIV-TB Coordinator on a daily basis to facilitate identification of treatment supporter.
- In patients diagnosed with DR-TB, the information in column 18, 19, and 20 should be updated by the HIV-TB Coordinator.

HIV-TB Line List (Referred/Presumptive TB cases)

Recording Month and Year:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
S.No.	Date	HIV Care Registration Number (Pre-ART)	Name	Age	Sex (M/F/TG)	Contact Number	Address - Block, District, State	Status at the time of TB referral (Pre-ART/ART)	Type/Name of the facility where referred to (provide code and name of the facility)[1]	Type of test[2]	Is the patient diagnosed with TB (Yes/No)*	If Diagnosed with TB					If Diagnosed with Drug Resistance TB *(to be provided by HIV-TB coordinator)*		
												Drug Resistance status(Yes/No Unknown)	Type of TB diagnosed[3]	Date of TB diagnosis (DD/MM/YYYY)	Date of starting ATT (DD/MM/YYYY)	NIKSHAY ID *(to be provided by HIV-TB coordinator)*	Date of referral to DRTB center (DD/MM/YYYY)	Name of DRTB center referred for treatment **	Date of starting DRTB treatment *(to be provided by STS)*

Note:

1. (A) CBNAAT, (B) DMC, (C) Radiology, (D) Histopathology, (E) Others: Specify
2. (A) CBNAAT, (B) Smear, (C) Culture, (D) TST (for children under 5 years of age), (E) Others: Specify
3. Pick the relevent code: (A) Pulmonary TB (Microbiologically confirmed), (B) Pulmonary TB (Clinically diagnosed), Extra-Pulmonary TB (Microbiologically confirmed, (D) Extra Pulmonary TB (Clinically diagnosed)

* In case of indvalid/error/no-result/indeterminate result, wait for final diagnosis and update the status as and when the results become available

** Refer the patient to the DR TB center

5) HIV-TB Register (revised): The revised HIV-TB Register contains details of all confirmed TB cases in PLHIV and has 25 columns. In this register, the serial number should be continuous and not start afresh each month. The format of the revised HIV-TB Register is presented in Annexure 9.
   - The HIV-TB Register will be maintained by the ART Staff Nurse.
   - All the patients diagnosed by the ART centre as well as those reporting to the ART centre as a diagnosed case of TB should be included in the register.
   - The information pertaining to patient management and follow-ups/outcomes should be updated as and when available.

6) Master Line List (revised): The revised Master Line List (MLL) is maintained at the ART centre by the Data Manager. In addition to patient treatment details already being entered in the MLL, three columns pertaining to 4S screening, IPT status, and TB treatment status have been added to the existing MLL. The Data Manager should insert the columns in the existing MLL, with drop down menu for 4S screening, IPT status, and TB treatment status, as seen in Annexure 10. This information should be entered by the Data Manager every day from the relevant columns of the White Card.
   - The 4S status has to be updated from the remarks columns of the White Card.
   - IPT status has to be updated from Section 13, column 9 of the patient White Card.
   - ATT status has to be updated from Section 13, column 14 of the patient White Card.

7) HIV-TB Monthly Report (revised): The revised HIV-TB Monthly Report is part of the monthly report (MPR) sent by the ART centre to NACO. The HIV-TB Section of the MPR has three parts: i) intensified TB case finding and diagnosis, ii) treatment for TB and HIV in co-infected PLHIV, and iii) IPT status. It will contain details from the Patient Visit Register, the HIV-TB Line List, the HIV-TB Register, and the Master Line List. Apart from this, no separate HIV-TB report will be sent to SACS/NACO. The format of the revised HIV-TB Monthly Report is shown in Annexure 11.
   - TB Treatment Outcome Report: In addition to the HIV-TB monthly report prepared by ART centres, the DTC will generate a TB outcome report through NIKSHAY for patients initiated on daily ATT at ART centres. This report will be sent to ART centres by the DTO with support of the HIV-TB Coordinator. The ART centres are required to send this report along with the Monthly Progress Report (MPR). Information in Section 1 (4.c) of the report is for the reporting month, while information for Section 2 (4.d) is for the financial year and information for Section 3 (4.e) is for the reporting month. The draft format is available in Annexure 12.

HIV - TB Register (Confirmed TB Case)

Recording Month and 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
S. No.	Date	HIV Care Registration Number (Pre-ART)	Name	Age	Sex (M/F/TG)	Contact Number	Address-Block, District, State	Where was the patient diagnosed *(Pick appropriate code and provide name of the facility)*[1]	Drug resistance status (Yes/No/Unknown)	Type of TB diagnosed[2]	Date of TB diagnosis (DD/MM/YYYY)	NIKSHAY ID	Type of patient[3]	Date of starting ATT (DD/MM/YYYY)	If not initiated on ATT, reason for the same[4]	Type/Name of facility from where the patient is receiving TB treatment *(provide code and name of the facility)*[5]	Type of treatment (Category I/II/IV/V)	Date of treatment completion	Treatment outcome[6]	Is the patient on CPT? (Yes/No)	Date of ART initiation	ART Registration Number	If not initiated on ART, reason for the same[7]	Remarks

Note:

1. (A) Diagnosed for TB by ART centre, (B) Reported to ART centres as already diagnosed case of TB.
2. Pick the relevant code: (A) Pulmonary TB (Microbiologically confirmed), (B) Pulmonary TB (clinically diagnosed), (C) Extra-Pulmonary TB (Microbiologically confirmed, (D) Extra Pulmonary TB (Clinically diagnosed).
3. (A) New, (B) Recurrent, (C) Transfer in, (D) Treatment after Failure, (E) Treatment after LFU, (F) Others: Specify.
4. (A) Patient transferred-out to other ART Centre, (B) Patient not reporting for treatment/LFU, (C) Patient died before ATT initiation, (D) Patient taking treatment in the private sector, (E) Others: Specify.
5. (A) ART Centre, (B) RNTCP, (C) Private institution, (D) DRTB, (E) Others: Specify.
6. (A) Cured, (B) Treatment completed, (C) Died, (D) Treatment failure, (E) LFU, (F) Transfer out, (G) Switched over to MD TB Treatment, (H) Others: Specify.
7. (A) Patient transferred-out to other ART centre, (B) Patient not reporting for treatment / LFU, (C) Patient died before ART initiation, (D) Patient taking treatment in the private sector, (E) Others: Specify.

Master Linelist of Patients Enrolled in ART Centres

S. No.	Date of registraton in HIV care at ART Centre	Pre ART No	PID No	Name of Patient	Complete Address with Phone No.	Age	Sex	Baseline CD4 count	Latest CD4 count	Date of latest Cd4 count	Status in Pre-ART care	Date of ART eligibility	ART Registration No. (If initiated on ART)	Due date of visit at ART	Status in ART care	Due Date of Visit at ART	4 Symptom Screening	IPT status	TB treatment status
											Choose one from dorp down menu: Alive in Pre-ART, Initiated on ART, Eligible but not initiated on ART, Died, LFU, Opted out, Transfer Out				Choose one from drop down menu: Alive on ART, Died, LFU, Stopped, MIS, Transfer Out, Unknown		Choose one from drop down menu: 4S+ve, 4S-ve, Not done	Choose one from dorp down menu: Not applicable (NA), Initiated on IPT during this visit (IPT-I), Contraindicated (Cont), On IPT (IPT), IPT stopped due to medical / other reasons (ST), IPT full course completed (Comp)	Choose one from drop down menu: On ATT(ATT), initiated on ATT during this visit (ATT-I), ATT stopped due to medical/other reasons (ST), ATT full course completed (Comp), Not applicable (NA)
																	● 4S+ve ● 4S-ve ● Not done	● Not applicable (NA) ● Initiated on IPT during this visit (IPT-I) ● Contraindicated (Cont) ● On IPT (IPT) ● IPT stopped due to medical/other reasons (ST) ● IPT full course completed (Comp)	● On ATT(ATT) ● initiated on ATT during this visit (ATT-I) ● ATT stopped due to medical/other reasons (ST) ● ATT full course completed (Comp) ● Not applicable (NA)

4.c HIV - TB

4.c Intensified TB Case Finding and Diagnosis

For reporting month

		In Pre ART Care at the time of TB diagnosis					On ART at the time of TB diagnosis					Total	Source
		Adult			Children <15 Yrs		Adult			Children <15 Yrs			
		Male	Female	TS/TG	Male	Female	Male	Female	TS/TG	Male	Female		
4.c.1 Number of PLHIV attending ART Centre during the month (Pre ART and ART)													Patient Visit Register
4.c.2 Out of 4.c.1, number of PLHIV who underwent (4S) screening													Patient Visit
4.c.3 Out of 4.c.2, number of PLHIV with presumptive TB (those with one or more symptom(s) present)													Register/MLL
4.c.4 Out of 4.c.3, number of PLHIV with presumptive TB referred for TB diagnosis test													HIV-TB Line List, Column 1
4.c.5 Out of 4.c.4, number of PLHIV with presumptive TB, tested for TB													HIV-TB Line List, Column 11
4.c.6 Out of 4.c.5, number of PLHIV diagnosed as having TB:													
	(i) Pulmonary TB (Microbiologically confirmed)												HIV-TB Line List, Column 14
	(ii) Pulmonary TB (Clinically diagnosed)												
	(iii) Extra-Pulmonary TB (Microbiologically confirmed)												
	(iv) Extra Pulmonary (Clinically diagnosed)												
	TOTAL												
4.c.7 Out of 4.c.6, number of TB patients with Rif Resistance													HIV-TB Line List, Column 13

4d. Treatment For TB and HIV In Co-Infected PLHIV

Financial year (April - reporting month)

Indicator		Adults			Children(<15 Years)		Total	
		Male	Female	TS / TG	Male	Female		
4.d.1 Total number of Co-infected patients enrolled in HIV/TB register during the current finacial year (April till end of reporting month)	Diagnosed by ART Centre							HIV-TB Register, Column-9
	Reported to ART Centres as already diagnosed case of TB							
	Total							
4.d.2 Out of 4.d.1, number of Co-infected patients initiated on TB treatment	Government (ART / RNTCP)							HIV-TB Register Column-17
	Private							
	Total							
4.d.3 Out of 4.d.2, number of TB patients with DR TB (Drug Resistant TB) initiated on Cat IV treatment								HIV-TB Register Column-17
4.d.4 Out of 4.d.1, number of Co-infected patients initiated on CPT								HIV-TB Register Column-21
4.d.5 Out of 4.d.1, number of Co-infected patients initiated on ART								HIV-TB Register Column-22

4 e. IPT Status

For reporting month

4.e.1 Number of PLHIV newly initiated on IPT during the month							MLL
4.e.2 Number of PLHIV completed IPT during the month							

8) Drug Dispensing and Drug Stock Register: ART centres must use the same stock register that they maintain for ARV drugs. In the ARV drug dispensing register, dispensing of ATT drugs is to be recorded in the 'Others' column. The dispensing of IPT is to be recorded in the OI register. For daily ATT, the unit of measurement for ATT drugs is strips.

4.2 RNTCP Recording and Reporting Tools

Similar to NACP monitoring tools, the following RNTCP tools should be maintained at the ART centre:

1) Lab Referral Form: This form (Annexure 3) will be used by ART centres for requesting diagnosis of TB and DR-TB. The forms will be provided by RNTCP to all the ART centres.
   - The ART Staff Nurse will complete the Lab Referral Form for referring a patient for diagnosis; the form must carry the ART Medical Officer's signature. The ART Staff Nurse should complete all the details, including patient's information; details of the ART centre from where referral is being made; the reason for testing, that is, whether the test is for drug sensitive TB or DR-TB; and the type of test requested.
   - The Lab Technician at DMC/CBNAAT will perform the test and report the results along with the NIKSHAY ID to the ART centre on a daily basis.

2) TB Treatment Card: The TB Treatment Card must be prepared in duplicate for cases where daily ATT is initiated. One copy of the card should be retained at the ART centre, and the other copy should be provided to the patient. Patient's HIV-related information must not be mentioned in the patient's copy of the TB Treatment Card. The format of the TB Treatment Card is shown in Annexure 13.
   - The TB Treatment Card will be prepared in duplicate by the ART Staff Nurse, and it will be duly signed by the Medical Officer. The Staff Nurse should update the TB Treatment Card from the patient's copy at every visit. The update in the ART centre's copy of the TB Treatment Card must include details of ATT adherence and any other relevant information.
   - The details of TB treatment outcomes must be recorded in the White Card (ART Treatment Card) at the ART centre.

3) TB Identity Card: An identity (ID) card must be issued to all the patients initiated on ATT by the Staff Nurse. The format of the TB ID Card is shown in Annexure 14.
   - The Staff Nurse will issue the TB ID Card to the patients on ATT. This card must be stapled along with the ART ID Card (Green Book) issued to patients at the ART centre.

4) DR-TB Referral Form: This form is filled for referral of Rif-resistant TB cases to the DR-TB centre. The format of the RNTCP DR-TB Referral Form is shown in Annexure 15.
   - The ART Staff Nurse will complete this form for all the Rif-resistant TB cases referred to DR-TB centres in coordination with District DR-TB and HIV-TB Supervisor.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Treatment Card

HIV-TB No.1

TB Notification No. / NIKSHAY ID:

State: NEW DELHI City/District: DELHI TB Unit: 56 PHI:

Name: RAJKUMAR Sex: ☑M ☐F ☐TG Age: 25 Occupation: STUDENT Socioeconomic status: ☑APL ☐BPL

Complete address: House No. Road: Ward/Village: Town/City: Taluka/Mandal: District: WEST

State: DELHI Pin code: 110057 Important landmark: DISTRICT CENTRE Mobile: 9999999999 Aadhar No. Area: Slum/Tribal/Migrant/Refugee

Name and address of contact person: SITA DEVI Mobile No.: 8888888888

Initial home visit by: Date: Type of treatment adherence - DOT/ICT supported, specify: Other:

Disease classification
☑ Pulmonary
☐ Extra Pulmonary
Site

Type of Patient
☐New ☑Recurrent ☐Transfer in
☐Treatment After Failure ☐Treatment After LFU
☐Others, previously treated (Specify)
Basis of Diagnosis
☑Microbiologically confirmed ☐Clinical TB

Investigations (ZN / FM / CBNAAT / Liquid C / SolidC)	Lab	Lab No.	Test result	Sample sent to CDST (date)	DST result
Pre-treatment	DDU	123	MICRO PTB		
End of Intensive Phase			RIF SEN		
End of treatment					

H/O of previous ATT: 6 months of treatment 24 months since end of last episode

Source of treatment: ☑Public ☐Private Previous Regimen: CAT I

Other investigations (if any) with result

HIV related information

HIV Status: ☐Unknown ☑Reactive ☐NR Date PID
CPT delivered on: (1) (2) (3) (4) (5) (6)
Initiated on ART: ☐No ☑Yes Date & ART No. 185

Diabetes related information

Diabetes Status: ☑Unknown ☐Diabetic ☐Non-Diabetic
RBS: FBS:
Initiated on ADT: ☐No. ☐Yes Date: ADT No.:

Other co-morbidity

Details:

Signature of MO with date 4/6/16

	< 6 yrs	> 6 yrs
No of household contacts		
No screened		
No with symptoms		
No evaluated		
No diagnosed		
No put on treatment		

No of children less than 6 years given chemoprophylaxis:

Name	Wt (kg)	Dose (mg)	1	2	3	4	5	6

Addiction related information

Current Tobacco user: ☑Yes ☐No
If yes, ☑Smokking ☐Smokeless linked for cessation ☐Yes ☑No
If tobacco user, status of tobacco use at end of treatment ☐Quit ☐Not quit
H/o Alcohol intake: ☑Yes ☐No
If yes, linked for deaddiction ☐Yes ☑No

PC 2 D II
PC 5 D II

Regimen - New / Previously Treated **Date of initiation of intensive phase:** 4/6/16 **Date of initiation of continuation phase:**

Dosage frequency ☑Daily ☐Intermittent Drug formulations ☑FDC ☐Combipack ☐Loose drugs Drug packaging ☑PWB ☐Strips

Weight Band: Adult: ☐25-39 Kg, ☑40-54 Kg, ☐55-69 Kg ☐≥ 70 Kg Pediatric: ☐4-7Kg. ☐8-11Kg. ☐12-15Kg. ☐16-24Kg. ☐25-29 Kg. ☐30-39Kg.

Dosages: FDC / Combipack 3 per day Height 175 (cm)

Loose drugs		H	R	Z	E	S
	Dose					
	Pills					

Mark ✓ when doses are taken under direct observation, (✓) when the doses was not observed, O when missed the dose

Record CP from the fresh line

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	Wt
4FDC-3V V D-S																																

Retrieval Actions for Missed Doses				
Date	By whom	Whom contacted	Reason for missed doses	Outcome of retrieval action

Details of Adverse event				
Date of adverse event	Details of symptoms	Action taken	Duration of management for adverse event	Outcome of adverse event

Post treatment follow up clinical & sputum				
Follow up	Clinical	Sputum	CXR	Impression
06 mths of Rx				
12 mths of Rx				
18 mths of Rx				
24 mths of Rx				

Remarks: _____

Nutrition support (if any, give details) .....

Treatment outcome with date: .....

Signature of the MO with date: Jibanjyoti 4/6/16

5) Monthly TB Drug Report: The ART Pharmacist will fill this report on a monthly basis to request ATT drugs from the RNTCP/DTO. The ATT related drug report should be sent to the DTO every month using the format shown in Annexure 7.

Note: *The roles and responsibilities of NACP and RNTCP staff for management of TB in PLHIV at ART centres are detailed in Annexure 16.*

For additional reading, a listing of other guidelines from NACO and CTD is provided in Annexure 17.

Annexures

STAMPS TO BE USED BY ART CENTRE STAFF

4S STAMP FOR CARE COORDINATOR

4S +ve

- This stamp is to be used by the Care Coordinator for all "**4S Positive**" cases and should be recorded in both the patient visit register and the green book.
- The **4S+ve** stamp should always be marked in **RED COLOUR**.

4S +ve

- This stamp is to be used by the Care Coordinator for all "**4S negative**" cases and should be recorded in both the patient visit register and the green book.
- **4S-ve** stamp should always be marked in **BLUE COLOUR**.

4S STAMP FOR STAFF NURSE & COUNSELLOR

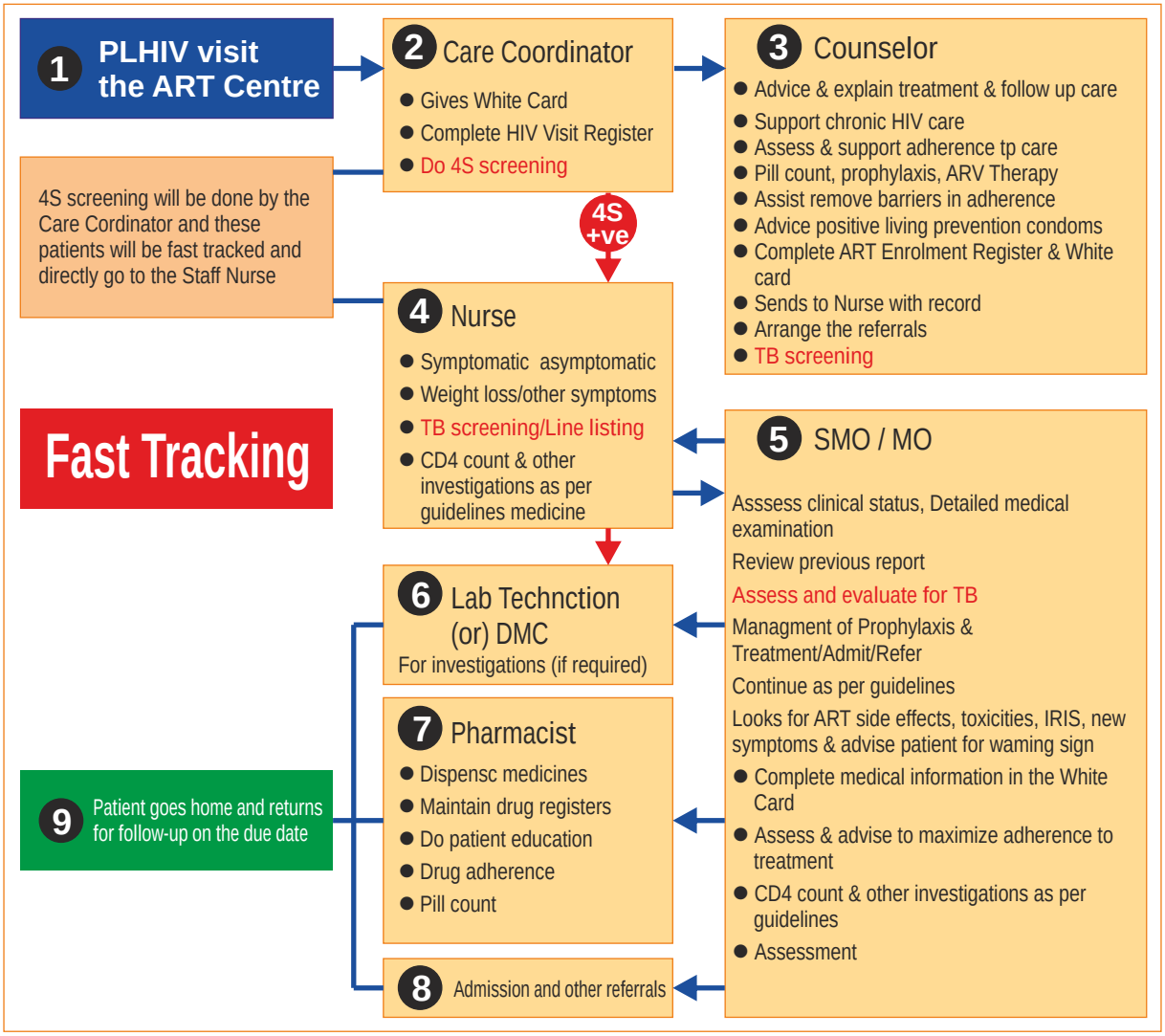
Cough ☐	Weight Loss ☐
Fever ☐	Night Sweat/ TB Cont. ☐

- This **BLUE COLOUR** stamp is to be used by the Staff Nurse and Counsellor for all patients visiting the ART center and should be recorded in the patient green book.
- The relevant sign/symptom should be **ticked** (✓) against all relevant symptoms.
- **For children** "Weigh Loss" should be replaced with **"Poor Weight Gain"** and "Nigh Sweat" should be replaced with any "**contact with TB patients (TB contacts)"** in the same stamp.

STAMP FOR SENIOR/MEDICAL OFFICER

Micro ☐	Clinical ☐
PTB ☐	EPTB ☐
Rif Sens ☐	Rif Resis ☐
Unknown ☐	

- This **BLUE COLOUR** stamp is to be use by all Medical Officers to categorise the patients based on the test and type of TB.
- The relevant boxes must be **ticked** (✓).
- The Rifampicin status should also be marked.


1 PLHIV visit the ART Centre
2 Care Coordinator
Gives White Card
Complete HIV Visit Register
Do 4S screening
3 Counselor
Advice & explain treatment & follow up care
Support chronic HIV care
Assess & support adherence tp care
Pill count, prophylaxis, ARV Therapy
Assist remove barriers in adherence
Advice positive living prevention condoms
Complete ART Enrolment Register & White card
Sends to Nurse with record
Arrange the referrals
TB screening
4S screening will be done by the Care Cordinator and these patients will be fast tracked and directly go to the Staff Nurse
4S +ve
4 Nurse
Symptomatic asymptomatic
Weight loss/other symptoms
TB screening/Line listing
CD4 count & other investigations as per guidelines medicine
Fast Tracking
5 SMO / MO
Asssess clinical status, Detailed medical examination
Review previous report
Assess and evaluate for TB
Managment of Prophylaxis & Treatment/Admit/Refer
Continue as per guidelines
Looks for ART side effects, toxicities, IRIS, new symptoms & advise patient for waming sign
Complete medical information in the White Card
Assess & advise to maximize adherence to treatment
CD4 count & other investigations as per guidelines
Assessment
6 Lab Technction (or) DMC
For investigations (if required)
7 Pharmacist
Dispensc medicines
Maintain drug registers
Do patient education
Drug adherence
Pill count
9 Patient goes home and returns for follow-up on the due date
8 Admission and other referrals

RNTCP Request Card for examination for biological specimen for TB

(Required for Diagnosis of TB, Drug Sensitivity Testing and follow up)

Patient Information			
Patient name		Age (in years):	Gender: ☐M ☐F ☐TG
Patient mobile no. or other contact no.		Specimen date of collection (DD/MM/YY):.....	☐ Sputum ☐ Other (specify)
Patient address with landmark		HIV Status: ☐Reactive ☐Non-Reactive ☐Unknown	
		Key populations: ☐Contact of known TB patient ☐Diabetes ☐Tobacco ☐Prison ☐Miner ☐Migrant ☐Refugee ☐Urban slum ☐Health care worker ☐Other (specify)	

Name referring facility (PHI/DMC/DR-TB Centre/Laboratory/Other): ..... Helath Establishment ID (NIKSHAY):	CLD NIKSHAY ID: _ _ - _ _ _ - _ - c - _ _ - _ _ _ _ _ RNTCP TB Reg No. ..... or ☐Not Applicable
State: ..... District: ..... Tuberculosis Unit (TU):	

Reason for Testing:

Diagnosis and follow up of TB		
Diagnosis (NIKSHAY ID: .....)		Follow up (Smear and culture)
H/O Anti TB Rx for > 1 month: ☐Yes ☐No.		RNTCP TB Reg. No. ..... NIKSHAY ID: ..... Regimen: ☐New ☐Previously Treated Reason: ☐End IP ☐End CP Post treatment: ☐6m ☐12m ☐18m ☐24m
☐Presumptive TB ☐Private referral ☐Presumptive NTM	Predominant symptom .... Duration ..... days	

Diagnosis and follow up Drug-resistnant TB		
Drug Susceptibility Testing (DST)		Follow up (Culture)
☐Presumptive MDR TB	☐New ☐Previously treated ☐At diagnosis ☐Contact of MDR/RR TB ☐Follow up Sm+ve ☐Private referral ☐Discordance resolution	PMDT TB No. ..... DR TB NIKSHAY ID: ..... Regimen: ☐Regimen for INH mono/poly resistant TB ☐Regimen for MDR/RR TB ☐Modified Regimen for MDR/RR TB + FQ/SLI resistance ☐Regimen for XDR TB ☐Modified Regimen for mixed pattern resistance ☐Regimenwith Bedaquiline for MDR-TB Regimen+FQ/SLI resistance ☐Regimenwith Bedaquiline for XDR TB ☐Regimen with Bedaquiline for failures of regimen for MDR TB ☐Regimen with Bedaquiline for failures of regimen for XDR TB ☐Other Treatment ☐month ☐week: .....
☐Presumptive H Mono/poly		
☐Presumptive XDR TB	☐MDR/RR TB at Diagnosis ☐> 4 months culture positive ☐3 monthly for persistent culture positives (treatment month .....) ☐Culture reversion ☐Failure of MDR/RR-TB regimen ☐Recurrent case of second line treatment ☐Discordance resolution	

Test requested:

☐Microscopy ☐TST ☐IGRA ☐Chest X-ray ☐Cytopathology ☐Histopathology ☐CBANNAT ☐Culture ☐DST
☐Line Probe Assay ☐Gene Sequencing ☐Other (Please Specify).....

Requestor Name, Designation and Signature: .....

Contact Number: ..... Email ID: .....

Results: CDL NIKSHAY ID Generated: _ _ - _ _ _ - _ - c - _ _ - _ _ _ _ _

Microscopy (☐ZN ☐Floresent)							
	Lab Sr. No.	Visual appearance	Result				
			Negative	Scanty	1+	2+	3+
Sample A							
Sample B							

Date tested: ..... Date reported: ..... Reported by: .....
(Name and signature)

Cartridge Based Nucleic Acid Amplification Test (CBNAAT)

Sample	☐A ☐B
M. Tuberculosis	☐Detected ☐Not Detected ☐N/A
Rif Resistance	☐Detected ☐Not Detected ☐Interminate ☐N/A
Test	☐Error (Please arrange for fresh sample)

Date tested: ..... Date reported: ..... Reported by: .....
(Name and signature)

Culture (☐LJ ☐LC)

Lab s. No.	Negative	Positive	NTM (write species)	Contamination

Date result: ..... Date reported: ..... Reported by: .....
(Name and signature)

Line Probe Assay (LPA)

☐Direct ☐Indirect Lab Serial .....

First Line LPA

RpoB:- local control:	present	absent						
Wt1:	present	absent	Wt2:	present	absent	Wt3:	present	absent
Wt4:	present	absent	Wt5:	present	absent	Wt6:	present	absent
Wt7:	present	absent	Wt8:	present	absent			
MUT1 (D516V):	present	absent	MUT2A (H526Y):	present	absent			
MUT2B (H526D):	present	absent	MUT3 (S531L):	present	absent			

KatG:locus control:	present	absent	InhA: - locus control:	present	absent			
Wt1 (315)	present	absent	WT1(15, -16):	present	absent	WT2(-8):	present	absent
MUT1 (S315T1):	present	absent	MUT1(C15T):	present	absent	MUT2(A16G):	present	absent
MUT2 (S315T2):	present	absent	MUT3A(T8C):	present	absent	MUT3(T8A):	present	absent

Second line LPA

gyrA:-			gyrB:-			rrs:-			eis:-		
locus control:	present	absent	locus control:	present	absent	locus control:	present	absent	locus control:	present	absent
WT1(85-90):	present	absent	WT1(536-541):	present	absent	WT1(1401-02):	present	absent	WT1(37):	present	absent
WT2(89-93):	present	absent				WT2(1484):	present	absent	WT2(14,12,10):	present	absent
WT3(92-97):	present	absent							WT3(2):	present	absent
MUT1(A90V):	present	absent	MUT1(N538D):	present	absent	MUT1(A1401G):	present	absent	MUT1(C-14T):	present	absent
MUT2(S91P):	present	absent	MUT2(E540V):	present	absent	MUT2(G1484T):	present	absent			
MUT3A(D94A):	present	absent									
MUT3B(D94N/Y):	present	absent									
MUT3C(D94G):	present	absent									
MUT3D(D94H):	present	absent									

Final LPA Interpretation:-

MTB result	MTB positive	MTB Negative				
RIF	Sensitive	Resistant	Indeterminate INH	Sensitive	Resistant	Indeterminate
Quinolone	Sensitive	Resistant	Indeterminate SLID	Sensitive	Resistant	Indeterminate

Date result: ..... Date reported: ..... Reported by: .....
R: Resistant; S: Susceptible; C: Contaminated; -- Not done
(Name and signature)

Drug Susceptibility Test (DST) result

Lab S. No.	1st line durg						SLI			FQ			Other										
	S	H1	H2	R	E	Z	Km	Cm	Am	Lfx	Mfx(0.5)	Mfx(2)	PAS	Lzd	Cfz	Eto	Cla	Azi					

Date result: ..... Date reported: ..... Reported by: .....
(Name and signature)

Other tests for TB diagnosis

Test (please specify): .....
Result: .....
.....
.....
Date reported: ..... Reported by: .....
(Name and signature)

HIV-TB Line List (Referred/Presumptive TB cases)

Recording Month and Year:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
												If Diagnosed with TB					If Diagnosed with Drug Resistance TB *(to be provided by HIV-TB coordinator)*		
S.No.	Date	HIV Care Registration Number (Pre-ART)	Name	Age	Sex (M/F/TG)	Contact Number	Address - Block, District, State	Status at the time of TB referral (Pre-ART/ART)	Type/Name of the facility where referred to (provide code and name of the facility)[1]	Type of test[2]	Is the patient diagnosed with TB (Yes/No)*	Drug Resistance status(Yes/No Unknown)	Type of TB diagnosed[3]	Date of TB diagnosis (DD/MM/YYYY)	Date of starting ATT (DD/MM/YYYY)	NIKSHAY ID *(to be provided by HIV-TB coordinator)*	Date of referral to DRTB center (DD/MM/YYYY)	Name of DRTB center referred for treatment **	Date of starting DRTB treatment *(to be provided by STS)*

Note:

1. (A) CBNAAT, (B) DMC, (C) Radiology, (D) Histopathology, (E) Others: Specify
2. (A) CBNAAT, (B) Smear, (C) Culture, (D) TST (for children under 5 years of age), (E) Others: Specify
3. Pick the relevent code: (A) Pulmonary TB (Microbiologically confirmed), (B) Pulmonary TB (Clinically diagnosed), Extra-Pulmonary TB (Microbiologically confirmed, (D) Extra Pulmonary TB (Clinically diagnosed)

* In case of indvalid/error/no-result/indeterminate result, wait for final diagnosis and update the status as and when the results become available

** Refer the patient to the DR TB center

Anti-TB Treatment (ATT) Drugs Dispensing Chart for ADULTS

Treatment Category	Weight Band	Unit	INTENSIVE PHASE (IP) HRZE (4FDC)				CONTINUATION PHASE (CP) HRE (3FDC)			
			Duration in months for IP	Total strips for IP	Strips/vials to be dispensed per month	Tab/Inj per day	Duration in months for CP	Total strips for CP	Strips to be dispensed per month	Tab per day
New Patients (Cat I)	25-39kg	Strips	2	4	2	2	4	8	2	2
	40-54kg	Strips	2	6	3	3	4	12	3	3
	55-69kg	Strips	2	8	4	4	4	16	4	4
	≥70 Kg	Strips	2	10	5	5	4	20	5	5
Previously treated cases (Cat II)	25-39kg	Strips	3	6	2	2	5	10	2	2
		Inj Streptomycin 500 mg Vials	2	56 vials	28 vials	1				
	40-54kg	Strips	3	9	3	3	5	15	3	3
		Inj Streptomycin 750 mg Vials	2	56 vials	28 vials	1				
	55-69kg	Strips	3	12	4	4	5	20	4	4
		Inj Streptomycin 1gm Vials	2	56 vials	28 vials	1				
	≥70 Kg	Strips	3	15	5	5	5	25	5	5
		Inj Streptomycin 1gm Vials	2	56 vials	28 vials	1				

For ATT "one month" is equal to 28 days, adjust the due date accordingly

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Referral form for treatment

To be filled in triplicate. One copy to be sent to the DTO receiving the patient, one copy to the health facility where the patient is referred to, and one copy to the patient

Serial Number

Name and address of referring health facility: .....

Contact Number and e-mail address of referring health facility: .....

Name of health facility to which patient is referred: .....

Name of patient: ..... Age: ..... Sex: ☐M ☐F ☐TG

Complete address: .....

.....Contact No.....

Patient Details

Site of Disease	Diagnosis Details
☐Pulmonary ☐Extra Pulmonary, Site.....	Date of diagnosis: ...../...../.....
Type of Patient	Name of laboratory: .....
☐ New ☐Recurrent ☐Transfer-in	Type of test: ZN / FM / CBNAAT / Culture
☐Treatment After Failure ☐Treatment after LFU	Result:
☐Others, previously treated (Specify).....	TB Notification number: .....
Case Definition	HIV Status: ☐R ☐NR ☐Unkoown
☐Microbiologically confirmed ☐Clinical TB	DST Status: ☐Rif Sensitive ☐Rif Resistant ☐Unknown ☐Known
H/O of ATT	Sample sent for DST to..... Date ...../...../.....
..... Months of treatment	Treatment Details: .....
..... Months since end of last episode	Treatment Regimen: ☐New ☐Previously Treated
	Date of treatment initiation ...../...../.....
	Number of doses: .....

Referred for :

☐Initiation of treatment .....

☐Adverse durg reaction (give details) .....

☐Transfer out (give details) .....

☐Switch-over to daily RNTCP regimen (first-line) .....

☐Any other (give details) .....

Name and designation of the referring doctor .....

Date referred ...../...../.....

For use by the health facility where the patient has been referred

Serial Number

Name of receiving health facility .....

Name of patient .....

Age ..... Sex ☐M ☐F ☐TG

Date of initiation of treatment ...../...../.....

Result of End IP specimen examination .....

Treatment outcome .....

Signature: .....

Date: ...../...../.....

Name of TB Unit and District .....

TB No. (if available) .....

Date of receipt of patient ...../...../.....

Treatment regimen .....

Date of end IP specimen examination ...../...../.....

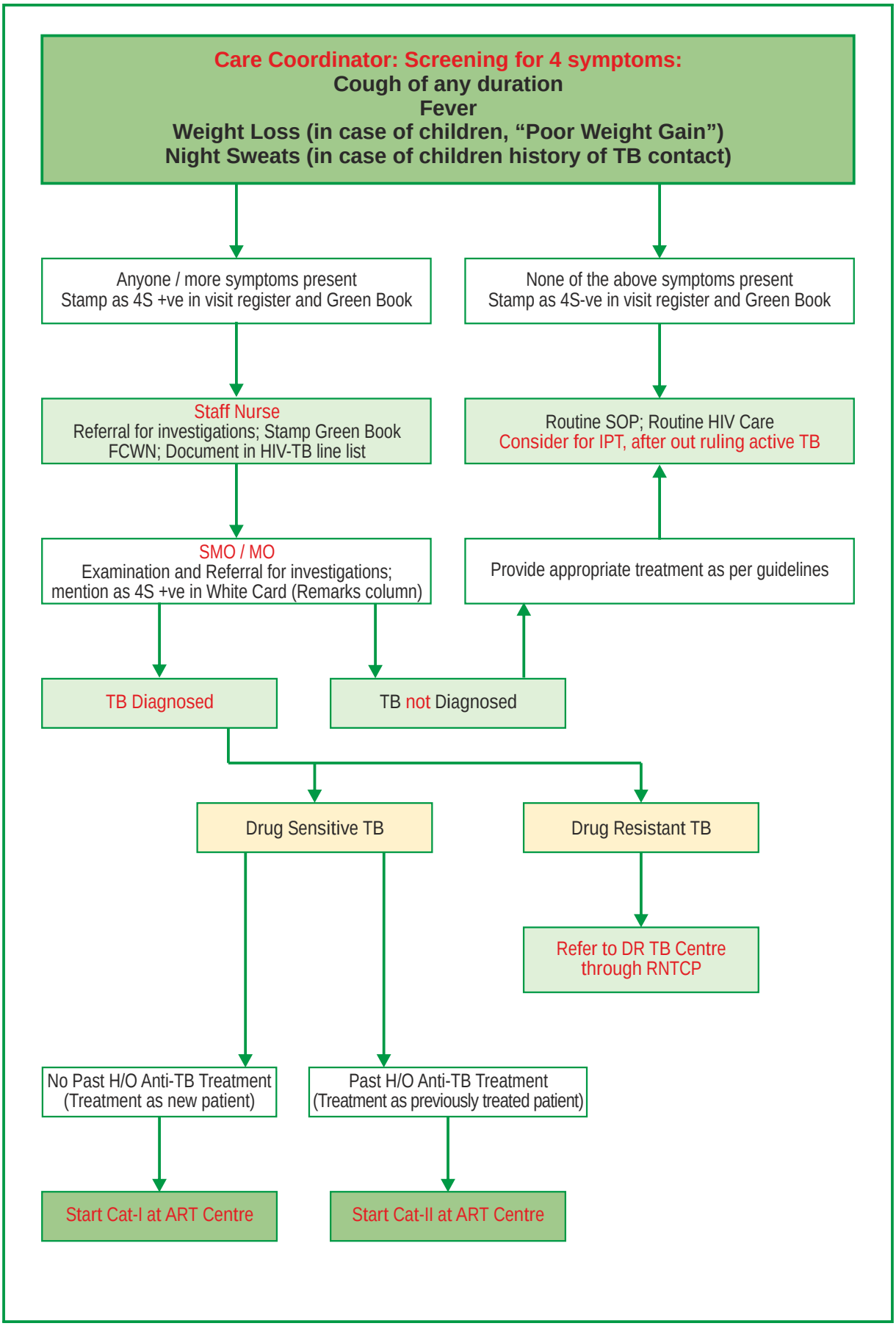
Date of treatment outcome ...../...../.....

Designation: .....

This portion of the forms has to be sent back to the referring unit as soon as the patient has been initiated on RNTCP treatment

Monthly Report on Programme Management and Logistics at ART centre: Medications

Product Code	Item	Unit of Measurement (UOM)	Stock on first day of month	Stock received during month	Patients initiated on treatment	Transferred back to district (if required)	Stock on last day of month	Quantity Requested
(a)	**(b)**		**(c)**	**(d)**	**(e)**	**(f)**	g= (c+d)-(e+f)	h= (e X 2) - g
4FDC-A	4 FDCs (adult)	Pack of 28 Tablets						
3FDC-A	3 FDCs (adult)	Pack of 28 Tablets						
3FDC-P	3FDC (paediatric)	Pack of 28 Tablets						
2FDC-P	2FDC (paediatric)	Pack of 28 Tablets						
PC-5	Inj. Streptomycin- 0.75 G	Vials						
PC-5 D I	Inj. Streptomycin- 1 G	Vials						
PC-11	Isoniazid-300 mg	Tabs						
PC-6	Rifampicin-150 mg	Caps						
PC-12	Rifampicin-300 mg	Caps						
PC-46	Pyrazinamide-400 mg	Tabs						
PC-48	Ethambutol-100 mg	Pack of 28 Tablets						
PC-7	Isoniazid-100 mg	Tabs						
PC-8	Pyrazinamide-500 mg	Tabs						
PC-23	Pyrazinamide-750 mg	Tabs						
PC-33	Rifabutin-150 mg	Caps						
PC-57	Pyridoxine-25 mg	Tabs						
PC-31	Pyridoxine- 50 mg	Tabs						


Care Coordinator: Screening for 4 symptoms:
Cough of any duration
Fever
Weight Loss (in case of children, "Poor Weight Gain")
Night Sweats (in case of children history of TB contact)
Anyone / more symptoms present
Stamp as 4S +ve in visit register and Green Book
None of the above symptoms present
Stamp as 4S-ve in visit register and Green Book
Staff Nurse
Referral for investigations; Stamp Green Book
FCWN; Document in HIV-TB line list
Routine SOP; Routine HIV Care
Consider for IPT, after out ruling active TB
SMO / MO
Examination and Referral for investigations;
mention as 4S +ve in White Card (Remarks column)
Provide appropriate treatment as per guidelines
TB Diagnosed
TB not Diagnosed
Drug Sensitive TB
Drug Resistant TB
Refer to DR TB Centre
through RNTCP
No Past H/O Anti-TB Treatment
(Treatment as new patient)
Past H/O Anti-TB Treatment
(Treatment as previously treated patient)
Start Cat-I at ART Centre
Start Cat-II at ART Centre

HIV - TB Register (Confirmed TB Case)

Recording Month and 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
S. No.	Date	HIV Care Registration Number (Pre-ART)	Name	Age	Sex (M/F/TG)	Contact Number	Address-Block, District, State	Where was the patient diagnosed *(Pick appropriate code and provide name of the facility)*[1]	Drug resistance status (Yes/No/Unknown)	Type of TB diagnosed[2]	Date of TB diagnosis (DD/MM/YYYY)	NIKSHAY ID	Type of patient[3]	Date of starting ATT (DD/MM/YYYY)	If not initiated on ATT, reason for the same[4]	Type/Name of facility from where the patient is receiving TB treatment *(provide code and name of the facility)*[5]	Type of treatment (Category I/II/IV/V)	Date of treatment completion	Treatment outcome[6]	Is the patient on CPT? (Yes/No)	Date of ART initiation	ART Registration Number	If not initiated on ART, reason for the same[7]	Remarks

Note:

1. (A) Diagnosed for TB by ART centre, (B) Reported to ART centres as already diagnosed case of TB.
2. Pick the relevant code: (A) Pulmonary TB (Microbiologically confirmed), (B) Pulmonary TB (clinically diagnosed), (C) Extra-Pulmonary TB (Microbiologically confirmed, (D) Extra Pulmonary TB (Clinically diagnosed).
3. (A) New, (B) Recurrent, (C) Transfer in, (D) Treatment after Failure, (E) Treatment after LFU, (F) Others: Specify.
4. (A) Patient transferred-out to other ART Center, (B) Patient not reporting for treatment/LFU, (C) Patient died before ATT initiation, (D) Patient taking treatment in the private sector, (E) Others: Specify.
5. (A) ART Center, (B) RNTCP, (C) Private institution, (D) DRTB, (E) Others: Specify.
6. (A) Cured, (B) Treatment completed, (C) Died, (D) Treatment failure, (E) LFU, (F) Transfer out, (G) Switched over to MD TB Treatment, (H) Others: Specify.
7. (A) Patient transferred-out to other ART center, (B) Patient not reporting for treatment / LFU, (C) Patient died before ART initiation, (D) Patient taking treatment in the private sector, (E) Others: Specify.

Master Linelist of Patients Enrolled in ART Centres

S. No.	Date of registraton in HIV care at ART Centre	Pre ART No	PID No	Name of Patient	Complete Address with Phone No.	Age	Sex	Baseline CD4 count	Latest CD4 count	Date of latest Cd4 count	Status in Pre-ART care	Date of ART eligibility	ART Registration No. (If initiated on ART)	Due date of visit at ART	Status in ART care	Due Date of Visit at ART	4 Symptom Screening	IPT status	TB treatment status
											Choose one from dorp down menu: Alive in Pre-ART, Initiated on ART, Eligible but not initiated on ART, Died, LFU, Opted out, Transfer Out				Choose one from drop down menu: Alive on ART, Died, LFU, Stopped, MIS, Transfer Out, Unknown		Choose one from drop down menu: 4S+ve, 4S-ve, Not done	Choose one from dorp down menu: Not applicable (NA), Initiated on IPT during this visit (IPT-I), Contraindicated (Cont), On IPT (IPT), IPT stopped due to medical / other reasons (ST), IPT full course completed (Comp)	Choose one from drop down menu: On ATT(ATT), initiated on ATT during this visit (ATT-I), ATT stopped due to medical/other reasons (ST), ATT full course completed (Comp), Not applicable (NA)
																	• 4S+ve • 4S-ve • Not done	• Not applicable (NA) • Initiated on IPT during this visit (IPT-I) • Contraindicated (Cont) • On IPT (IPT) • IPT stopped due to medical/other reasons (ST) • IPT full course completed (Comp)	• On ATT(ATT) • initiated on ATT during this visit (ATT-I) • ATT stopped due to medical/other reasons (ST) • ATT full course completed (Comp) • Not applicable (NA)

4.c HIV - TB

4.c Intensified TB Case Finding and Diagnosis

For reporting month

													Source
4.c.1 Number of PLHIV attending ART Centre during the month (Pre ART and ART)													Patient Visit Register
4.c.2 Out of 4.c.1, number of PLHIV who underwent (4S) screening													Patient Visit
4.c.3 Out of 4.c.2, number of PLHIV with presumptive TB (those with one or more symptom(s) present)													Register/MLL
4.c.4 Out of 4.c.3, number of PLHIV with presumptive TB referred for TB diagnosis test													HIV-TB Line List, Column 1
4.c.5 Out of 4.c.4, number of PLHIV with presumptive TB, tested for TB													HIV-TB Line List, Column 11
4.c.6 Out of 4.c.5, number of PLHIV diagnosed as having TB:	In Pre ART Care at the time of TB diagnosis					On ART at the time of TB diagnosis					Total		
	Adult			Children <15 Yrs		Adult			Children <15 Yrs				
	Male	Female	TS/TG	Male	Female	Male	Female	TS/TG	Male	Female			
(i) Pulmonary TB (Microbiologically confirmed)													HIV-TB Line List, Column 14
(ii) Pulmonary TB (Clinically diagnosed)													
(iii) Extra-Pulmonary TB (Microbiologically confirmed)													
(iv) Extra Pulmonary (Clinically diagnosed)													
TOTAL													
4.c.7 Out of 4.c.6, number of TB patients with Rif Resistance													HIV-TB Line List, Column 13

4d. Treatment For TB and HIV In Co-Infected PLHIV

Financial year (April - reporting month)

Indicator		Adults			Children(<15 Years)		Total	
		Male	Female	TS / TG	Male	Female		
4.d.1 Total number of Co-infected patients enrolled in HIV/TB register during the current finacial year (April till end of reporting month)	Diagnosed by ART Centre							HIV-TB Register, Column-9
	Reported to ART Centres as already diagnosed case of TB							
	Total							
4.d.2 Out of 4.d.1, number of Co-infected patients initiated on TB treatment	Government (ART / RNTCP)							HIV-TB Register Column-17
	Private							
	Total							
4.d.3 Out of 4.d.2, number of TB patients with DR TB (Drug Resistant TB) initiated on Cat IV treatment								HIV-TB Register Column-17
4.d.4 Out of 4.d.1, number of Co-infected patients initiated on CPT								HIV-TB Register Column-21
4.d.5 Out of 4.d.1, number of Co-infected patients initiated on ART								HIV-TB Register Column-22

4 e. IPT Status

For reporting month

4.e.1 Number of PLHIV newly initiated on IPT during the month							MLL
4.e.2 Number of PLHIV completed IPT during the month							

Block 2 TB Treatment Outcomes of HIV Positive TB Patients

Type of Patients	Total HIV positive patients registered during the period	Gender	Treatment Outcome							Not evaluated	Total number evaluated
			Cured	Treatment completed	Died	Treatment Failure	Defaulted	Transferred Out	Switched over to MDR-TB treatment		
HIV Positive New		MALE									
		FEMALE									
		TRANSGENDER									
		TOTAL									
HIV Previously treated		MALE									
		FEMALE									
		TRANSGENDER									
		TOTAL									

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Treatment Card

TB Notification No. / NIKSHAY ID

State: ..... City/District: ..... TB Unit: ..... PHI: .....

Name: ..... Sex: ☐M ☐F ☐TG Age: ..... Occupation: ..... Socioeconomic status: ☐APL ☐BPL

Complete address: House No. ..... Road: ..... Ward/Village: ..... Town/City: ..... Taluka/Mandal: ..... District: .....

State: ..... Pin code: ..... Important landmark: ..... Mobile: ..... Aadhar No. ..... Area: Slum/Tribal/Migrant/Refugee

Name and address of contact person: ..... Mobile No.: .....

Initial home visit by: ..... Date: ..... Type of treatment adherence - DOT/ICT supported, specify: ..... Other: .....

Disease classification

☐ Pulmonary

☐ Extra Pulmonary

Site .....

Type of Patient

☐New ☐Recurrent ☐Transfer in

☐Treatment After Failure ☐Treatment After LFU

☐Others, previously treated (Specify .....)

Basis of Diagnosis

☐Microbiologically confirmed ☐Clinical TB

Investigations (ZN / FM / CBNAAT / Liquid C / SolidC)	Lab	Lab No.	Test result	Sample sent to CDST (date)	DST result
Pre-treatment					
End of Intensive Phase					
End of treatment					

H/O of previous ATT: ..... months of treatment ..... months since end of last episode

Source of treatment: ☐Public ☐Private Previous Regimen: .....

Other investigations (if any) with result

HIV related information

HIV Status: ☐Unknown ☐Reactive ☐NR Date..... PID .....

CPT delivered on: (1) (2) (3) (4) (5) (6)

Initiated on ART: ☐No ☐Yes Date & ART No.....

Diabetes related information

Diabetes Status: ☐Unknown ☐Diabetic ☐Non-Diabetic

RBS: ..... FBS: .....

Initiated on ADT: ☐No. ☐Yes Date: ..... ADT No.: .....

Other co-morbidity

Details: .....

Signature of MO with date .....

	< 6 yrs	> 6 yrs
No of household contacts		
No screened		
No with symptoms		
No evaluated		
No diagnosed		
No put on treatment		

No of children less than 6 years given chemoprophylaxis:.....

Name	Wt (kg)	Dose (mg)	1	2	3	4	5	6

Addiction related information

Current Tobacco user: ☐Yes ☐No

If yes, ☐Smokking ☐Smokeless linked for cessation ☐Yes ☐No

If tobacco user, status of tobacco use at end of treatment ☐Quit ☐Not quit

H/o Alcohol intake: ☐Yes ☐No

If yes, linked for deaddiction ☐Yes ☐No

Regimen - New / Previously Treated Date of initiation of intensive phase: ..... Date of initiation of continuation phase:.....

Dosage frequency ☐Daily ☐Intermittent Drug formulations ☐FDC ☐Combipack ☐Loose drugs Drug packaging ☐PWB ☐Strips

Weight Band: Adult: ☐25-39 Kg, ☐40-54 Kg, ☐55-69 Kg ☐≥ 70 Kg Pediatric: ☐4-7Kg. ☐8-11Kg. ☐12-15Kg. ☐16-24Kg. ☐25-29 Kg. ☐30-39Kg.

Dosages: FDC / Combipack ..... per day Height ..... (cm)

Loose drugs						
	Dose					
	Pills					
		H	R	Z	E	S

Mark ✓ when doses are taken under direct observation, (✓) when the doses was not observed, O when missed the dose

Record CP from the fresh line

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	Wt

Retrieval Actions for Missed Doses				
Date	By whom	Whom contacted	Reason for missed doses	Outcome of retrieval action

Details of Adverse event				
Date of adverse event	Details of symptoms	Action taken	Duration of management for adverse event	Outcome of adverse event

Post treatment follow up clinical & sputum				
Follow up	Clinical	Sputum	CXR	Impression
06 mths of Rx				
12 mths of Rx				
18 mths of Rx				
24 mths of Rx				

Remarks: _____

Nutrition support (if any, give details) .....

Treatment outcome with date: .....

Signature of the MO with date: .....

RNTCP TB Identity Card

Name: .....

Sex: ☐M ☐F ☐TG Age: .....

Address: .....

.....

Contact No.: ..... Adhar ID: .....

PHI: ..... TU: ..... District: .....

NIKSHAY ID: .....

Name and designation of treatment supporter: .....

.....

.....

☐CPT ☐ART ☐Diabetic

☐Smoker

Date of starting treatment (DD/MM/YYYY): ...../...../.....

Type of Patient

☐New

☐Recurrent

☐Treatment after Lost to Follo up

☐Treatment after Failure

☐Other Previously treated

☐Transferred in

☐Site of Disease ☐Plumonarty ☐Extra pulmonary	☐Case Definition ☐Microbiologically Confirmed ☐Clinically diagnosed	Treatment regimen: ☐New ☐Previously treated

Weight Band:

Adult: ☐25-39 Kg, ☐40-54 Kg, ☐55-69 Kg ☐≥70 Kg

Pediatric: ☐4-7Kg. ☐8-11Kg. ☐12-15Kg. ☐16-24Kg. ☐25-29 Kg. ☐30-39Kg.

Sputum results				
	Smear Date	Smear Result	Culture Date	Culture Result
Diagnosis				
End IP				
End RX				
6 months				
12 months				
18 months				
24 months				

Appointment dates

.....

.....

.....

.....

In case of side effects or queries please contact

Name and contract Number: .....

.....

Treatment outcome:..... Date: ...../...../.....

RNTCP PMDT Referral for Treatment Form

(Fill in duplicate, send one copy to the concerned facility receiving the patient, and file the duplicate)

Name and Address of referring unit (District TB Centre/DR TB Centre): .....

Email address of referring unit: .....

Name of the facility where patient is referred: .....

Name of patient: ..... Age: ..... Gender: .....

Complete address: .....

.....

Patient Details

Disease classification:
☐Pulmonary ☐Extra Pulmonary (Site.....)
Type: ☐New ☐Recurrent ☐TA LFU ☐Failure ☐Others
Reason for testing:
☐New ☐Previously Treated
☐Presumptive TB
☐Private referral
☐Presumptive NTM
☐Presumptive MDR-TB
- ☐At diagnosis
- ☐Contacat of MDR/RR TB
- ☐Follo up Sm +ve
- ☐Private referral

☐Preseumptive H mono/poly
☐Presumptive XDR-TB
- ☐MDR/RR TB at diagnosis
- ☐‡ 4 months culture positive
- ☐3-montly for persistent culture positives (treatment month....)
- ☐Culture reversion
- ☐Failure of MDR/RR-TB regimen
- ☐Recurrent case of second line treatment

Latest TB No: .....

Latest regimen:
☐Regimen for INH mono/poly resistant TB
☐Regimen for MDR/RR TB
☐Shorter regimen*
☐Regimen for MDR/RR-TB + FQ/SLI resistance
☐Regimen for XDR TB
☐Modified regimen for mixed pattern resistance
☐Regimen with New Drug for MDR-TB Regimen + FQ/SLI resistance
☐Revimen with New Drug for XDR-TB
☐Regimen with New Drug for failures of regimen for MDR TB
☐Regimen with New Drug for failures of regimen for XDR-TB
☐Regimen with New Drug for mixed pattern resistance

**whenever available*

Sputum, Culture and DST Details

Date of culture result: ...../...../.....
Date of DST/LPA/CBNAAT result: ...../...../.....
DST/LPA/CBNAAT result*: .....
☐S ☐H1 ☐H2 ☐R ☐E ☐Z
☐Km ☐Am ☐Cm
☐Lfx ☐Mfx(0.5) ☐Mfx(2.0)
☐Eto ☐PAS ☐LZD ☐CFZ ☐..... ☐..... ☐.....
(* Tick the drugs to which resistance is demonstrated)

DR TB Treatment Details

PMDT NIKSHAY ID: .....
DR TB Centre: .....
Date of DR TB regimen initiation: ...../...../.....
Number of doses: .....

Date of regimen changes and details of change: .....
Past exposure to second-line anti TB drug: Drugs (duration) .....
HIV Status: ☐Pos ☐Neg ☐Not known, Date of CPT initiation: ...../...../..... Dat of ART initiation: ...../...../.....
Date of referal to DR-TB Centre / DTC: Day..... Month..... Year.....

Referred for:
Initiation of treatment: .....
Adverse drug reaction (give details) .....
Transfer out (give details) .....
Ambulatory treatment (if the patient is referred to DTC) .....
Any other (give details) .....
Name and designation of the referring doctor .....

Reminder for the health facility when the patient has been referred

Please send an e-mail to the referring unit, informing the referring doctor of the date that the above named patient reported at the receiving health facility

Nodal Person	Responsibility
NACP (SACS, DAPCU and ART Centres)	
JD-CST/ In charge and Regional Coordinator	• ART Staff training on Daily ATT and 3Is strategy • Filling-up of all key vacancies at ART centre • Provision of printed ART M & E tools, records and reporting formats to the ART centres • Provision of revised HIV-TB tools to the ART centres • Instruction to ART centres to ensuring availability of stamps (CC, Staff Nurse, Counsellor and SMO/MO) • Monitoring of activities through regular field visits and review meetings.
DAPCU	• Facilitating pre-rollout meetings with all key stakeholders at the district level to ensure effective coordination and planning. • Facilitating monthly HIV-TB coordination meetings at the district and ensuring key implementation challenges are discussed and addressesed. • Monitoring of activities through regular field visits and review meetings. • Coordinating with the district RNTCP team to ensure regular supply of drugs, 99DOTS pouches, consumables and recording and reporting formats. • Ensure smooth roll out of the new HIV-TB initiatives in the district.
Nodal Officer ART centres	• Monitor and mentor all the staff on HIV-TB related services. • Overall in charge to ensure smooth implementing of HIV-TB services at the ART centre. • Provide guidance to ART Centre staff in case of complicated cases and ADRs
Senior / Medical Officer	• Screening of all patients visiting the ART centre at every visit using the 4 symptom complex screening tool [Cough, Fever, Weight Loss / Poor Weight Gain (in children) and Night Sweats / History of TB Contact (in children)]. • Ascertaining the final 4S status of all patients • Determining the final eligibility of patients for IPT • Recording the 4S status of the patient in the patient White Card • Referring all the 4S +ve patients for TB diagnosis through the Staff Nurse • Interpreting the TB results and recording the same in the patient white card using the stamp. • Initiating the patient on relevant treatment • Assessing any side effects for ATT and IPT at every visit • Screening the 4S status of all patients on IPT at every visit and recording the same in the patient White Card • Determine the outcome of ATT treatment and record the same in the patient White Card as well as the TB Treatment Card • Ensure correct and timely reporting • Attend regular HIV-TB coordination meetings to discuss progress, gaps and challenges in implementing HIV-TB services at the ART centre.

Nodal Person	Responsibility
NACP (SACS, DAPCU and ART Centres)	
Staff Nurse	• Screening all the 4S +ve cases referred by the Care Coordinator for TB using 4 symptom complex screening tool [Cough, Fever, Weight Loss / Poor Weight Gain (in children) and Night Sweats / history of TB Contact (in children)]. • Recording the TB symptom of the patient using the detailed stamp in the patient Green Book. • Filling TB referral form, facilitation TB referral and updating TB results status • Recording and updating HIV-TB line list and register • Preparing, updating and maintaining TB Treatment Card • Preparing and issuing TB ID Card • Coordinate regularly with the HIV-TB coordinator / STS/STLS to ensure effective coordination between ART and RNTCP for smooth functioning and uninterrupted service delivery. • Share the details of all patients initiated on ATT at the ART centre with the HIV-TB coordinator on a daily bases.
HIV-TB Coordinator *(Provisional)*	• Conducting periodic visits to the ART centres to ensure effective coordination between RNTCP and ART centres for smooth functioning and service delivery. • Coordinating patient registration, generating TB number and NIKSHAY ID generation by local STS/TB. • In case the patient belongs to other District, Coordinate with concerned HIV-TB coordinator of that district for registration and follow ups • Ensuring identification of treatment supporter, patient follow-up and LFU tracking. • Ensuring DR TB patient's referral to the concerned DR-TB centre and treatment initiation & providing information to ART staff nurse to complete the line list • Coordinating with ART centre on weekly basis and updating the NIKSHAY ID/TU number in the treatment card available at ART centre and HIV-TB Line list • Ensuring registration of patients in 99 DOTS. Monitoring patients on 99DOTS website to trigger follow-up action (by calling patients himself and delegating to field staff). Linking patient to correct TU and maintaining TU staff contact details to ensure that they receive SMS alerts.
Counsellor	• Screening all the 4S –ve cases referred by Care Coordinator for TB using the 4 symptom complex screening tool [Cough, Fever, Weight Loss / Poor Weight Gain (in children) and Night Sweats / History of TB Contact (in children)]. • Recording the TB symptom of the patient using the detailed stamp in the patient Green Book. • Counselling on ATT drug adherence, usage of 99DOTS and possible side effects. • Counselling on IPT adherence, possible side effects and follow-up. • ATT/IPT pill counting, provision of due date or next date of visit based on the ATT schedule.

Nodal Person	Responsibility
NACP (SACS, DAPCU and ART Centres)	
Care Coordinator	• Act as first point of contact for all patients visiting the ART centre. • Screening of all patients visiting the ART centre at every visit using the 4 symptom complex screening tool [Cough, Fever, Weight Loss / poor weight gain (in children) and Night Sweats / history of TB Contact (in children)]. • Recording of 4S status in the Patient Visit Register and the patient Green Book.
Pharmacist	• Dispensing Daily ATT and IPT drugs and IPT drugs at the ART centre. • Maintaining inventory and preparation of ATT and IPT stock reports. • Identifying drug requirements and indenting for drugs
Data Manager	• Recording the HIV-TB line list and master line list in soft copy • Timely and correct reporting in the revised formats. • Registration in 99 DOTS
RNTCP (STC and DTC)	
STO and DTO	• Monitoring of activities through field visits and review meetings • Developing a linkage plan to ensure all ART centres are linked to CBNAAT testing facility. • Ensuring availability of drugs and other consumables (including 99DOTS envelopes).
State TB HIV Coordinator	• To assist the State TB officer in programme management activities related to TBHIV collaborative activities like planning, budgeting, implementing, monitoring, supervising evaluating and reporting. • To link State TB Cell with State AIDS Control society. • To assist State TB Officer in gathering political and administrative commitment required for TBHIV collaborative activities. • To assist State TB Officer in establishing intersectoral and interdepartmental coordination required for TBHIV collaboration. • To conduct exclusive and joined supervisory visits to the districts with SACS officials and report to State TB Officer; also participate as a member of State IE team • Coordinate with SACS for regular TB-HIV Coordination meetings and STWG meetings • To maintain updated databases of HIV and TBHIV related services and service providers. • To train the district programme managers and stakeholders on TBHIV collaboration. • To compile and analyse district/ART centre/ICTC wise TBHIV reports and provide feedback to them. To ensure quality of reports by data validation and data verification at source.

Nodal Person	Responsibility
RNTCP (STC and DTC)	
State TB HIV Coordinator	• To assist State TB Officer in supply chain management of drugs for CPT and IPT and modified TB regimen for PLHA with TB on second line ART. • To ensure ICF activities at ART/ICTCs and linkages • To facilitate trainings related to TB-HIV coordination at State level and monitor these trainings at District level
DTO	• Assign the responsibility to coordinate with ART Centres for smooth implementation of HIV-TB activities • Ensuring registration of PLHIV for TB treatment through HIV-TB Coordinator • Ensuring sample collection and transportation mechanisms in the district for CBNAAT testing. • Conducting monthly HIV-TB coordination meetings to review the progress and monitoring of activities. • Ensuring regular uninterrupted supply of lab referral forms, TB Treatment Card and TB ID Cards to the ART centres. • Ensuring regular uninterrupted supply of Daily ATT (in 99DOTS wrapped envelopes) and IPT drugs.
STS/TBHV	• The STS of the concerned TU is responsible for registering patients, generating NIKSHAY number, adherence and for ongoing retrieval actions. • Identifying trained treatment supporter for all TB-HIV co-infected patients for DOT provision. • Identifying health care worker for provision of Injection Streptomycin. • Ensuring patient adherence and follow ups.

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6 A study conducted in the Tiruvallur district of south India found a relapse rate of 12.3% among new smear positive patients treated under DOTS in RNTCP. (Thomas, A. et al. International Journal of Tuberculosis and Lung Diseases 2005; 9[5]:556-561).

7 "Relapse rate is high (almost 10%) in almost all the studies from India. It is higher than those found in international studies…The outcome of relapse cases put on treatment is positive…but clearly less effective than the results of DOTS for new TB cases never treated before…DOTS Category 2 treatment may not be adequate for re-treatment patients." (Azhar, G. S. et al. Lung India. 2012 Apr; 29[2]:147-53.)

8 Odds of relapse relative to daily regimens was 2.8 (1.4–5.7) for thrice-weekly intermittent regimen. (Chang, K.C. et al. Am J Respir Crit Care Med. 2006 Nov 15;174[10]:1153-8.

9 HIV-positive patients with pulmonary TB are at higher risk of acquired Rifampicin resistance, when failing a three times weekly short-course intermittent regimen irrespective of the length of treatment – 6 month or 9 month duration treatment. (Swaminathan, S. et al. AJRCCM, 2010, Vol 181).

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