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Ministry of Health and Family welfare
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Integrated Training Module for HIV/TB Collaborative Activities

2015

Central TB Division
Directorate General of Health services
Ministry of Health and Family welfare
Government of India, New Delhi

Basic services Division
National AIDS Control organization
Ministry of Health and Family Welfare
Government of India, New Delhi

Government of India
Ministry of Health and Family Welfare

PREFACE

Tuberculosis continues to be a public health challenge in India and it is commonest opportunistic infection (OI) in persons living with HIV (PLHIV) .TB is the foremost cause of death among people living with HIV. To mitigate the effect of dual burden of HIV and TB co-infection the ministry of Health and Family Welfare, Government of India through its National AIDS Control Organisation (NACO) and Central TB Division has been undertaking joint collaborative efforts as per the National Framework for HIV TB collaborative activities in India.

Training of staff under NACP and RNTCP is very crucial for strengthening of TB/HIV activities and imparting updated knowledge regarding HIV/TB to program staff. To streamline the training, both the programmes envisage, that uniform, standardized modular training be imparted to all the programme and general health staff throughout the country.

National Technical group on HIV/TB collaborative activities recommended to revise the training modules for HIV/TB considering the latest revisions in RNTCP, Programmatic management of Drug resistant TB, recording and reporting and newer initiatives like formation of NTCC at National level, TB notification, PITC among presumptive TB cases, Isonaizid preventive therapy and case based web based electronic recording and reporting system in RNTCP (NIKSHAY) and NACP (SIMS) etc. To train the staff of RNTCP and NACP at various level BASIC TB/HIV training module have been developed by NACO and Central TB Division with support from National institutes of RNTCP and NACP(NTI,NIRTD,NIRT,NARI,JALMA). This is product of hard work and dedication of Basic services Division, Central TB Division MOHFW and I appreciate the efforts made by this technical team and everyone who was involved in its initiative.

We hope this integrated module will be helpful to impart the desired knowledge regarding TB/HIV with the purpose to improve the effectiveness, efficiency, and sustainability of Government of India's response to TB/HIV.

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CONTENT

PART - A

CHAPTER1: INTRODUCTION:

National AIDS Control Programme (NACP)

India's National AIDS Control Programme has evolved a long way over the last two decades. The first phase launched in 1994 had a national level approach focusing primarily on setting up surveillance systems, awareness generation and blood safety. The second phase from 1999 to 2006 decentralized the programme to the state level with the establishment of State AIDS Control Societies and initiation of all the key interventions including Counseling, Testing & Treatment. NACP-III has been the critical phase when the programme was taken to massive scale improving the reach of all interventions and the focus shifted to district level, with strong evidence of impacts. The fourth phase of NACP (2012), envisages to consolidate the gains and address the emerging challenges.

NACP IV aims to Accelerate Reversal i.e. to reduce new infections by 50% (2007 Baseline of NACP III) and to Integrate Response i.e. to provide a Comprehensive care, support & treatment to all persons living with HIV/AIDS. The program has been consistently achieving its objectives with five-Pronged Strategies of Prevention, IEC & Behaviour Change, Treatment Services, Institutional Strengthening, and Strengthening of Strategic Information Management Systems. NACP-IV envisages **integration and scale-up** of service delivery to sub-district and community levels through existing health infrastructure in the public and private sectors.

Key priorities under NACP-IV:

- Preventing new infections.
- Prevention of parent to child transmission.
- Focusing on IEC strategies for behavior change in HRG, awareness among general population and demand generation for HIV services.
- Providing comprehensive care, support and treatment to eligible PLHIV.
- Integrating HIV services with health systems in a phased manner.

Revised National Tuberculosis Control Programme (RNTCP):

India has had a National Tuberculosis Programme (NTP) since 1962. However, a comprehensive review of the NTP in 1992 found that the NTP had not achieved its aims or targets. Based on the recommendations of the 1992 review, the Revised National Tuberculosis Control Programme (RNTCP), incorporating the components of the internationally recommended DOTS strategy for the control of TB, was developed. RNTCP has now been implemented in the country for more than a decade, and has been expanded geographically to achieve nation-wide coverage in March 2006. The spread of human immuno-deficiency virus (HIV) during the last two decades, emergence of various forms of drug resistant TB and vast and unregulated private sector pose additional challenges in effective TB control. All those who are infected do not necessarily develop TB disease. The lifetime risk of breaking down to disease among those infected with TB is 10–15%, which is increased to 10% per year amongst those co-infected with HIV.

Goal and objectives of RNTCP

The goal of RNTCP is to decrease the mortality and morbidity due to tuberculosis and cut down the chain of transmission of infection until TB ceases to be a public health problem.

The current focus is on ensuring universal access to quality assured TB diagnosis and treatment services under the programme.

HIV- TB burden in India:

It is estimated that there are 2.1 million people living with HIV in India with an estimated adult HIV prevalence of 0.27% (range: 0.2%–0.4%).TB accounts for 25% of deaths among People Living with HIV and AIDS (PLHIV) in India. Although only 5% of incident TB patients are HIV-infected, in absolute terms it means more than 100,000 cases annually, ranks second in the world and accounts for about 10% of the global burden of HIV-associated TB. However, HIV positivity among PLHIV varies from states /districts in the country, the proportion of HIV positive among TB patients over 10% in high HIV burden states to up to 40% in some high burden districts.

Active TB disease is the most common opportunistic infection amongst HIV-infected individuals. The primary impact of HIV on TB is that the risk of developing TB becomes higher in patients with HIV. Overall, HIV-infected persons have approximately an 8-times greater risk of TB than

persons without HIV infection. The risk of TB in HIV-infected persons continues to increase as HIV disease progresses and CD4 cell count decreases. While anti-retroviral treatment can substantially decrease the risk of TB, this risk always remains higher than that in HIV negative individuals. Furthermore, among cured TB survivors with HIV infection, the risk of recurrent TB is also quite high.

HIV positive patients who have TB have higher mortality than HIV positive patients without TB.

From the public health point of view, the best way to prevent TB is to identify all persons in the community with infectious TB as early as possible, provide prompt & effective treatment and cure them. This interrupts the chain of transmission and can thus prevent the disease burden of HIV-TB co-infected cases. Among HIV-infected persons, early detection of TB, proper TB treatment, and prompt linkage to HIV care and early initiation of treatment also can reduce the harmful impact of TB on the patient's health and well-being.

NACP and RNTCP Coordination in India:

To mitigate the effect of dual burden of HIV and TB co-infection, the ministry of Health and Family Welfare, Government of India through its NACO and Central TB Division (Department of Health and Family Welfare) has been undertaking joint collaborative efforts since 2001. While joint HIV/TB activities started with differential strategies based on underlying HIV burden initially, the programme evolved over the years and currently implements uniform HIV/TB collaborative activities across the country. The decade old collaboration between National AIDS Control Programme (NACP) and Revised National Tuberculosis Control Programme (RNTCP) in India is considered a global success. National AIDS Control Programme (NACP) and The Revised National Tuberculosis Control Programme (RNTCP) have developed a policy of HIV/TB collaborative interventions based on experience gained during programme implementation in initial years, important operational research (OR) studies instituted by NACP and RNTCP and the WHO HIV/TB interim policy, for implementation across the country. **Milestones of TB-HIV collaborative activities in India**: The year wise important milestones of evolution of TB HIV collaborative activities in India are as follows:

- 2001–Basic HIV/TB activities started in six high-HIV burden states.
- 2003: Pilot for HIV-TB cross-referral in four districts of Maharashtra.
    - Cross-referral started in six HIV high prevalence states.
- 2004– Cross referral of activities expanded to eight additional states.
- 2005–Joint training modules developed, joint surveillance initiated.

- 2007– Pilot for Routine referral of TB patients for HIV testing and CPT.
    - National (policy) framework for TB/HIV developed.
- 2008–National Framework revised.
    - All-India implementation of HIV-TB activities.
    - Intensified Package (IP) rolled out in nine states.
- 2009- National Framework revised.
    - Intensified Package rolled out in eight more states.
    - Uniform activities at ART centers and ICTCs nationwide for intensified TB case finding and reporting, established.
- 2010 – Intensified package launched in 11 states.
- 2012 (June) - Nationwide coverage achieved.

2013(Nov)-National Framework for HIV/TB collaborative activities in India developed

National Framework for HIV/TB in India:

The first National Framework was published in November 2007, which endorsed *differential strategy* or implementation of HIV/TB activities in the country, reflecting the heterogeneity of HIV/TB epidemic in India. This strategy included "**essential**" HIV/TB interventions to be implemented nationwide and an "Intensified TB/HIV package of services" for states having high burden of HIV/TB.

The selection of states for implementation of intensified package was based on HIV prevalence, absolute HIV burden, availability of decentralized HIV testing and treatment services and programme management capacity. In 2008, it was started in nine states (Andhra Pradesh, Goa, Karnataka, Maharashtra, Manipur, Mizoram, Nagaland, Puducherry and Tamil Nadu). Review of this implementation demonstrated that it was a highly useful strategy for early detection of HIV in TB cases and prompt linkage to HIV care and support. The National Framework was therefore revised in 2009 with a decision to implement full spectrum of HIV/TB activities including scale-up of Intensified HIV/TB package uniformly across the country by 2012. This revision established uniform set of activities at all ART centres and ICTC including intensified TB case finding and reporting. It also strengthened joint monitoring and evaluation with specified national HIV/TB programme indicators and performance targets. Latest revision of National Framework Nov 2013 aimed to incorporate recent policy updates in NACP and RNTCP and align with respective national strategic plan for next 5 year along with recommendations in WHO HIV/TB policy guidelines 2011.

The overall purpose of **National Framework** is to articulate the National policy for TB/HIV collaborative activities between RNTCP and NACP to ensure reduction of TB and HIV burden in India.

Objectives:

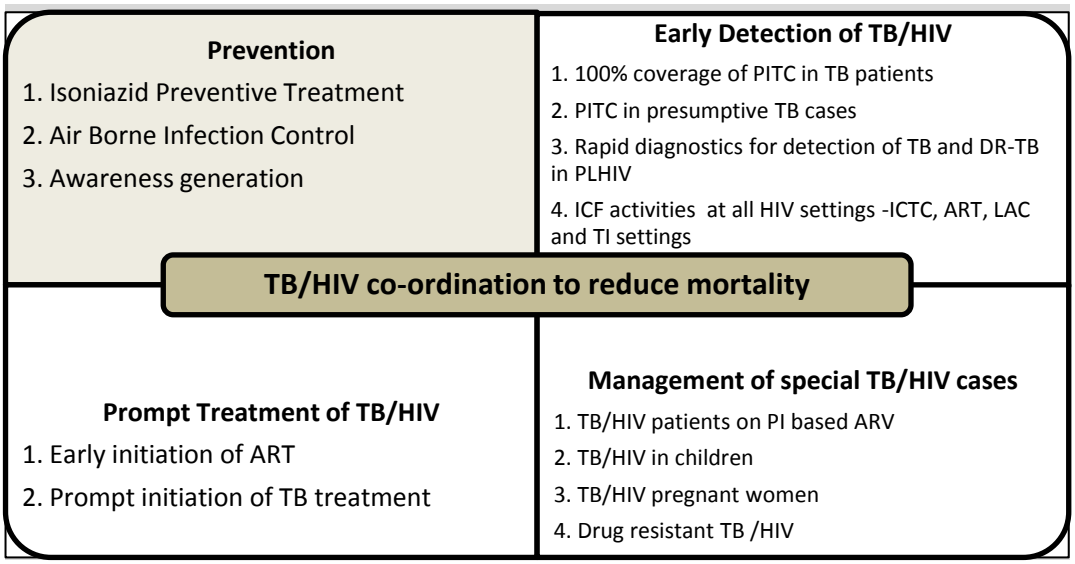
1. To maintain close coordination between RNTCP and NACP at National, State and District levels.

2. To decrease morbidity and mortality due to TB among persons living with HIV/AIDS.

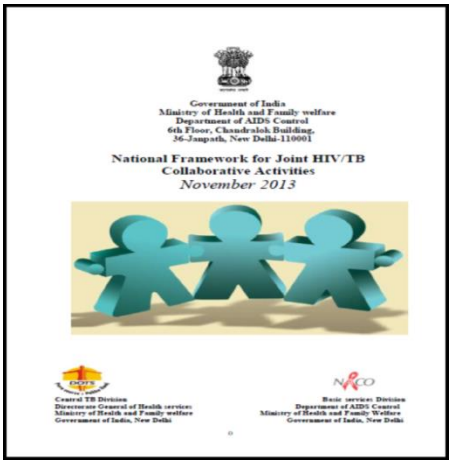
3. To decrease impact of HIV in TB patients and provide access to HIV related care and support to HIV-infected TB patients.

4. To significantly reduce morbidity and mortality due to HIV/TB through prevention, early detection and prompt management of HIV and TB together.

The four pronged strategy summarised below is based on the foundation of strong collaboration between NACP and RNTCP



National Framework for HIV TB Collaborative activities 2013:



1. Emphasis on **Integrated TB and HIV services** e.g. HIV screening at RNTCP DMC.
2. Focus on **early detection and early care**:
   a. **Early detection of TB in PLHIV**:
      i. Early suspicion of TB–symptoms of any duration among PLHIV
      ii. Use of an **<u>expanded clinical algorithm for TB screening</u>** that relies on presence of **<u>four clinical symptoms</u>** (current cough, weight loss, fever or night sweats) instead of only cough, to identify patients with presumptive TB
      iii. Strengthen ICF at ART, Link ART centre (LAC) and Targeted intervention projects (TI) for High Risk Group (HRG) specially Injection Drug Users (IDU)
   b. **Early detection HIV/TB:**
      i. Enhance HIV testing facilities in settings with lack of co-located HIV and TB testing facilities, by establishing HIV screening services using **whole blood finger prick test (WBT)**
      ii. Strengthen HIV testing of TB patients in high HIV prevalent settings by promoting establishment of **Facility Integrated Counselling and Testing Centre(F-ICTC)** where DMC exists
      iii. **PITC** among patients being evaluated by diagnostic smear microscopy presumptive TB cases in high HIV prevalent settings
   c. Early Care:
      i. Strengthened linkage of HIV/TB patients to ART centres through travel support by RNTCP as per NSP (2012-2017) etc.
      ii. ART for HIV infected TB cases irrespective of CD4 count
      iii. Prompt ART initiation- within first 8 weeks of commencing Anti-TB treatment.
      iv. Monitoring of timeliness of ART initiation through expanded ART reporting formats
3. **Early detection and care of HIV infected Drug Resistant TB patients (DR-TB/HIV)**:
   i. Strengthen HIV testing in presumptive DR-TB cases (Criteria C)
   ii. Ensure access to culture and drug susceptibility testing for HIV infected TB patients
   iii. Prompt linkage of HIV infected DR-TB cases to ART centres
   iv. Prompt initiation of ART in HIV infected DR-TB cases

4. **Prevention of TB among HIV infected adults and children:**

i. Implementation of IPT for all PLHIV (On ART + Pre-ART)

ii. Strengthen implementation of air borne infection control strategies.

5. Strengthen HIV/TB activities among children and pregnant women

6. Promotion of participation of private, NGO, CBO health facilities and affected communities working with NACP and RNTCP to strengthen HIV/TB collaborative activities.

NACP-RNTCP coordination mechanisms at various levels :

A. National Level:

1. National TB/HIV Coordination Committee(NTCC)

The National AIDS Control Organization, Government of India Vide letter no. T-11025/15/2013-NACO/BSD has constituted National TB/HIV Co-ordination Committee' (NTCC) under the chair of Secretary with the following terms of reference:

1. To strengthen co-ordination mechanisms between NACP and RNTCP at National, State and District level
2. To review and adopt policies for strengthening implementation of joint TB/HIV activities
3. To suggest strategies for roll out and scale up of activities aimed at minimizing mortality and morbidity associated with TB/HIV
4. To review implementation of joint TB/HIV activities and identify key areas for strengthening

The composition and terms of reference (TOR) of NTCC are annexed (**Annex 1**)

I. National Technical Working Group (NTWG)

At The Department of AIDS Control, Government of India Vide letter no. T-11020/77/05-NACO/BSD has constituted national level technical working group comprising of key officials from NACO and CTD, experts from WHO, National institutes and civil society members. The NTWG should meet quarterly and performs following key functions:

- Review NACP-RNTCP coordination activities at state and district level
- Review, optimize, and plan for future HIV/TB collaborative activities.
- Joint monitoring and review of HIV/TB activities

- Planning of supervision of HIV/TB activities, including joint field visits, joint national level review etc.
- Facilitate operational research to improve programme implementation and assess impact of joint HIV/TB activities
- Develop normative tools and training material for HIV/TB

The composition and key functions of NTWG are annexed (**Annex 2**)

II. State level coordination mechanisms:

A. State Coordination Committee (SCC): To ensure smooth implementation and regular review of HIV/TB collaborative activities, State Coordination Committee chaired by principal secretary health are established in all states. The SCC meeting should be organized at least bi-annually by the State AIDS Control Society (SACS). The composition and terms of reference (TOR) of SCC are annexed (**Annex 3**). Decisions of SCC meeting must be shared with BSD/NACO and Central TB Division.

B. State technical Working Group (SWG): The State technical Working Group (SWG) should meet once a quarter to review and streamline HIV/TB activities in the state. Composition of SWG meeting is annexed (**Annex 4**). Approved minutes of SWG meetings must be shared with Basic services Division/NACO and CTD by member secretary of SWG.

III. District level coordination mechanisms

A. District Coordination Committees (DCC): To ensure smooth implementation and regular review of HIV/TB activities, District Coordination Committee DCC) are established. The composition and TOR of DCC is annexed (**Annex 5A**). Minutes of DCC meetings should be sent to the State AIDS Control Society (SACS) and State TB Cell (STC). State HIV/TB coordinator or other officers from STC and SACS can attend these meetings to improve the coordination with the districts. **B. Monthly HIV/TB coordination meeting:** A monthly meeting of RNTCP and NACP staff should be held with participation of all key programme staff. Monthly meetings of RNTCP staff are routinely conducted at district level. During these meetings, one session should be dedicated to review of HIV/TB activities and all Key NACP staff including DAPCU officer or DNO, district ICTC supervisor, ICTC counsellors, ART centre SMO/MO and ART centre staff nurse should participate in this meeting. The issues identified in these meetings should also be discussed in monthly medical officer review meeting by CMHO at district level. Generic agenda

items for monthly HIV/TB coordination meeting is annexed **(Annex 5 B**) and quarterly report on HIV/TB Collaborative activities is annexed at **(Annex 6)**

IV. Annual review of HIV/TB collaborative activities at National and State level:

Joint review of HIV/TB activities is done with participation of state programme managers of both programmes. This meeting is held jointly by NACO and CTD.

Similar joint review meetings are held at state level by adding one additional day to one of the quarterly RNTCP review meetings, inviting all district nodal officers for HIV/AIDS or DAPCU officer and SACS officials. The joint review meetings should be organised in close coordination by SACS and STC.

CHAPTER 2: ORGANISATIONAL STRUCTURE OF NACP AT STATE LEVEL:

State AIDS Prevention and Control Societies (SACS)

National AIDS Control Organization provides leadership to HIV/AIDS Control Programme in India, implementing one National Plan within one monitoring system. State AIDS Prevention and Control Societies (SACS) implement NACO programme at state level, but have functional independence to upscale and innovate. Each State AIDS Prevention and Control Society has a governing body, its highest policy-making structure, headed by either the minister in-charge of health or the chief secretary. For better financial and operational efficiency, administrative and financial powers are vested in the Executive Committee and the Programme Director.

Category	NACP-III Definition
A	**> 1% ANC prevalence in any of the sites in the last 3 years**
B	**< 1% ANC prevalence in all the sites during last 3 years with > 5% prevalence in any HRG site (STD/FSW/MSM/IDU)**
C	**< 1% ANC prevalence in all sites during last 3 years with < 5% in all STD clinic attendees or any HRG, with known hot spots**
D	**< 1% ANC prevalence in all sites during last 3 years with < 5% in all STD clinic attendees or any HRG OR no or poor HIV data with no known hot spots**

District and Sub-District Level: The District AIDS Prevention Control Units (DAPCU) are established in A and B category districts across the country. DAPCUs are expected to play a pivotal role in monitoring and coordination of service delivery from the different facilities in the district. Their consistent efforts under the leadership of District Collectors will result in effective HIV awareness campaigns, strengthening of referral linkages, and provision of care and treatment to all HIV positive in the district. DAPCUs are also expected to play a key role in integration of NACP with NHM and work closely with other line departments in government setup to mainstream the HIV/AIDS Programs.

Based on the epidemiological and vulnerability criteria, districts in the country have been divided into four categories viz Category A-districts-High prevalence; Category B- Districts-concentrated epidemic; CategoryC-districts-increased presence of vulnerable population and Category D-districts-low/unknown vulnerability. Differential package of services have been planned for each category of districts.

The DAPCU will ensure implementation and supervision of ongoing NACP-III activities related to care and treatment, and further facilitate civil society partnership at the district with NGOs, CBOs, Red Ribbon Clubs and PLHAs network, private sector organization and academic institutions working in the area of HIV/AIDS in the district. Simultaneously, it will attempt to create a wider knowledge base in the district for effective prevention, detection, referrals and treatment strategies through convergence with the ongoing interventions of NRHM, RCH, TB Control etc. and build a strong monitoring and evaluation system through the public health infrastructure in the district.

Role of DAPCUs:

- Implementation of NACP strategies;
- Convergence with NRHM activities; and
- Convergence with the other related Departments in the District.

Integrated Counseling and Testing Centers (ICTC)/F-ICTC:

An Integrated Counseling and Testing Centers (ICTC) is a place where a person is counseled and tested for HIV on his own free will or as advised by a medical provider. In India, ICTCs are often the first interface of citizens with the entire range of preventive, care and treatment services provided under the umbrella of the NACP. HIV counselling and testing services were started in India in 1997. The introduction of antiretroviral therapy (ART) services to people living with HIV/AIDS in 2004, gave a major boost to counseling and testing services in the country. The strategy over the past years for scaling up of service delivery has been through establishing more and more Facility Integrated Model ICTCs (through the existing general health system) and PPP Model ICTCs.

Functions:

- Provision of basic information on modes of transmission and prevention of HIV/AIDS so as to promote behavioural change and reduce vulnerability
- Pre and Post-test counselling services
- Early detection of HIV
- Link people with other HIV prevention, care and treatment services
- ICTC plays a crucial role in early detection of HIV as well as promoting behavioural change among the high risk population so as to prevent HIV infection

Target Population

- Populations more vulnerable to HIV or practice high risk behaviour are the target for counselling & testing at ICTC
- It is not the mandate of ICTC to test everybody in the general population

Categories of ICTCs:

1) **FICTC- Fixed** is established in a Govt. Hospital like PHC/24*7PHC/CHC/UHC etc.
2) **FICTC- Mobile** is established in a Mobile Van not owned by NACO. (e.g. – NRHM, Mobile Medical Unit (MMU), NGO funded Mobile Van etc.)
3) **PPP- Fixed** is established in a PVT. Hospital (e.g. PVT Maternity Homes, Hospitals, Nursing Home etc.)
4) **PPP- Mobile** is established in a Mobile Van funded by the PVT Sector Organization.
5) **Stand Alone-Fixed** ICTC is established under NACO in a Govt. Hospital where counselor and technician are appointed (It includes PPP Performing 3 Testes).
6) **Stand Alone-Mobile** ICTC established by NACO funds where counsellor and technician are appointed

Anti-Retroviral Therapy Centre (ARTC):

Anti-Retroviral Therapy Centre is a place where all HIV Positive clients are being referred for further counseling, testing and management. Anti-Retroviral Therapy (ART) includes drugs, which act at various stages of the HIV life cycle in the human body. These drugs act by interrupting the process of virus multiplication and hence reduce the number of CD4 cells that are destroyed. They delay the progression of HIV disease. ART started at the right time can delay disease progression and death

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Functions of ART Centre:

Functions of ART centre are categorised as medical, psychological, and social as indicated below:

Medical Functions

- To diagnose and treat Opportunistic Infections.
- To screen PLHIV for eligibility to initiate ART.
- To monitor patients on ART and manage side effects, if any.
- To provide in-patient care as and when required in linkage with other hospital departments.
- To facilitate linkages between other service providers.
- To facilitate easy access to specialist's care as necessary.

Psychological Functions

- To provide psychological support to PLHIV accessing the ART centre.
- To provide counselling for adherence to ARV drugs.
- To educate PLHIV on proper nutrition.
- To advise for risk reduction behavior including usage of condoms.
- To provide problem solving and other counselling services.

Social Functions

- To facilitate PLHIV to access available resources provided by government and NGO agencies.
- To facilitate linkages between other service providers and patients, like educational help for the children and Income generation programmes.

1) Link ART Centers: 1086 Link ART Centres primarily established for dispensing ARV drugs, monitoring side effects and treating minor OIs. It provide a range of services for HIV-infected persons in the community

2) LAC plus: Among the LACs some LACs have been upgraded as LAC plus centres to provide Pre ART services additionally. Counselors working at centres designated as LAC plus, have the additional task of Pre-ART Care. This includes ensuring CD4 checking every 6months which determines when a client needs to begin ART.

3) Care & Support Centres: Care and Support Centre is a national initiative to provide

expanded and holistic care and support services for PLHIV.CSC expands access to essential services, supports treatment adherence, reduce stigma and discrimination, and improves the quality of life of PLHIV across India. The overall goal of CSC is to improve the survival and quality of life of PLHIV.

Specific objectives of the programme include the following

- **Early linkages of PLHIV to care, support and treatment services:** The CSC will support PLHIV in early linkage to care, support and treatment services.
- **Improved treatment adherence and education for PLHIV:** Adherence education and support can help PLHIV sustain and manage their treatment regimes.
- **Expanded positive prevention activities:** Early testing and diagnosis will be encouraged through appropriate counselling and peer support. All who are tested will be supported to engage their sexual partners, family members and children to ward testing.
- **Improved social protection and well-being of PLHIV:** The CSC will facilitate linkage to the excising social welfare and protection scheme sunder different line departments, corporate sector, public sector undertakings, faith based organizations, and civil society organizations.
- **Strengthened community systems and reduced sigma and discrimination:** To ensure a robust system that supports the program goal and ensures reduced sigma and a discrimination free access to quality services.

2.2 Organizational structure and functions of RNTCP

The structure of RNTCP comprises of five levels: National level, State level, district level, sub-district level and peripheral health institution level.

National Level

Central TB Division (CTD) of Directorate General Health Services (DGHS) is the technical arm of the Ministry of Health and Family Welfare (MoHFW). CTD, under the guidance of DGHS, manages the National TB Control Programme for the entire country at the central level through a National Programme manager, Deputy Director General TB (DDG TB). The financial and administrative control of the programme is managed by the Joint Secretary from the

administrative arm of the MoHFW. The CTD is supported by 8 national institutes: National Institute for Research in Tuberculosis (NIRT), Chennai, National Tuberculosis Institute, Bangalore, National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi, National JALMA Institute, Agra, Regional Medical Research Centre, Bhubaneshwar and BMHRC, Bhopal, and by National Task Force of Medical Colleges and a National Expert Committee on diagnosis & management of TB (comprising of renowned TB experts of the country from all sectors). Central TB Division has different units to manage various programme activities. These units are headed by the Additional DDG (TB) and assisted by other technical and secretarial staff.

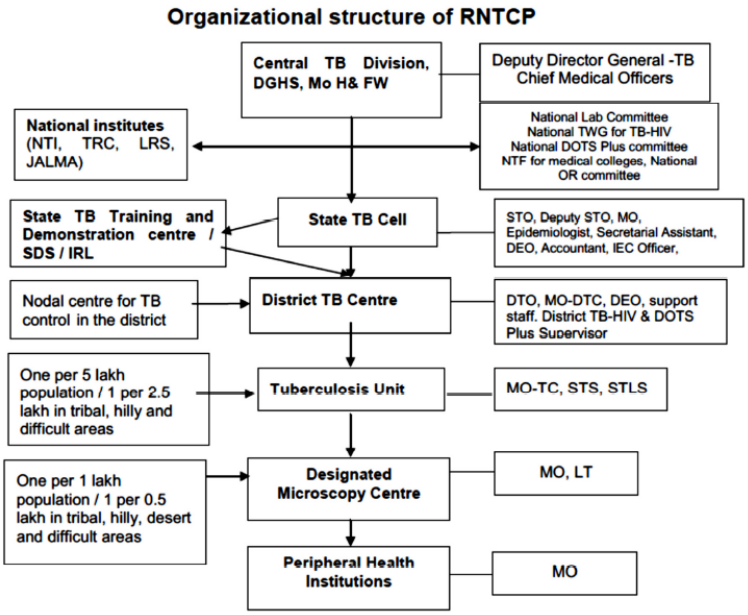
State Level

The States have total ownership and accountability for the TB control in their state. State Health Society or its equivalent under National Health Mission of the state manages the TB Control Programme. A full-time State Tuberculosis Officer (STO), trained at national level and based at the State TB Cell (STC), is responsible for planning, training, supervising and monitoring the programme in all the districts of their respective states. STO is administratively answerable to the State Government, technically follows the instructions of the CTD, and coordinates with CTD and the districts and is assisted by other technical & secretarial staff.

State TB cell is being supported by State TB Training and Demonstration Centre (STDC) in many states through its three units – a training unit, Supervision and monitoring unit and an Intermediate Reference Laboratory (IRL) supporting an effective Quality Assurance system of the Sputum smear microscopy network and C&DST work in the State.

Each state also has one (one for each 50 million population at least) fully operational State Drug Store (SDS). It is responsible for effective management of medicines and other logistics and ensuring uninterrupted supply of good quality 1st & 2nd line anti-TB medicines for adults and pediatric population.

The structure of RNTCP at State level, district level, and sub-district level is shown in flow chart below:



District Level

The key level for the management of primary health care services is the district. The Chief District Health Officer (CDHO) / Chief District Medical Officer (CDMO) / Civil Surgeon or an equivalent functionary in the district is responsible for all medical and public health activities including control of TB. The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district. A full-time District Tuberculosis Officer (DTO), trained at national level & based at the DTC, is responsible for planning, training, supervising and monitoring the programme in the district. DTO is assisted by other technical & secretarial staff. The primary role of the DTC is a managerial one.

Sub-District Level (Tuberculosis Unit Level)

Integrating the TB control programme with the health system increases effectiveness and efficiency of TB care and control. India's TB control programme has been mainstreamed efficiently with National Health Mission (NHM).

A major organizational change in RNTCP is the creation of a sub-district level (Tuberculosis Unit - TU). The TU is the nodal point for TB control activities in the sub-district. TUs are based mainly in NHM health blocks with the overall aim to align with NHM Block Programme Management Unit (BPMU) for optimum resource utilization and appropriate monitoring. In urban areas the TUs have been created based on a population of 1 per 200,000 (range 1.5 – 2.5 lakh). The Tuberculosis unit (TU) consists of a designated Medical Officer-Tuberculosis Control (MO-TC), as well as one full-time supervisory staff - Senior Treatment Laboratory Supervisor (STLS).1 Senior

Tuberculosis Treatment (STS) will continue to be in 5-lakh population. In Urban areas, TUs will be aligned with Urban CHC.

The Block Chief Medical Officer under NHM also functions as a MO-TC who is trained in RNTCP at a state level institution. MOTC has the overall responsibility of management of TB Control Programme at the TU and is expected to undertake supervisory visits for seven days in a month. The team of STS and STLS are under the administrative supervision of the MO-TC and the DTO. Ideally, the TU will have one Microscopy Centre for every 100,000 population (50,000 in tribal, desert, remote and hilly regions) referred to as the Designated Microscopy Centre (DMC). Microscopy Centres are also located in Medical Colleges, Corporate hospitals, ESI, Railways, NGOs, private hospitals, etc.

The TU is responsible for real-time case-based web-based online registration of TB patients under "NIKSHAY", who have been diagnosed and initiated on treatment. TU is also accountable for notification of TB cases under "NIKSHAY" that have been diagnosed/initiated on treatment in private sector. This surveillance system is used to analysis of programme performance, improve the management of cases, local monitoring of the programme and estimation of the disease burden. The functions of the TU team are given in the RNTCP Technical and Operational Guidelines.

As per the NTCC recommendation Medical Officer TB control will be in-charge of TB/HIV collaborative activities at the Sub district level to ensure implementation all TB/HIV collaborative activities at Sub district /Block level

There is one RNTCP **Designated Microscopy Centre** (DMC) for every 100,000 population under a TU (50,000 in tribal, desert, remote and hilly regions) to ensure lab services. DMCs are also established in Medical Colleges, Corporate hospitals, ESI and Railway health facilities, NGOs, private hospitals, etc., depending upon the requirement.

Peripheral Health Institutions (PHIs)

For the purpose of RNTCP, a PHI is a health facility, which is manned by at least a medical officer. At this level, there are dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics, or hospitals (including other health facilities), TB hospitals, and Medical colleges within the respective district. All health facilities in the private and NGO sectors participating in RNTCP are also considered as PHIs by the programme. Some of these PHIs also function as DMCs. Peripheral health institutions undertake tuberculosis case finding and treatment activities as a part of the general health services. In this regard, they are supervised by the TU contractual paramedical staff (STS and STLS). In situations where more than one MO is posted in any of the

peripheral health centres, one of them may be identified and entrusted with the responsibilities of the RNTCP. There are around 35000 PHI's under the programme. The categories of staff involved in TB control at PHI level and their principal responsibilities are given in the RNTCP Technical and Operational Guidelines.

Structure of RNTCP Laboratory network:

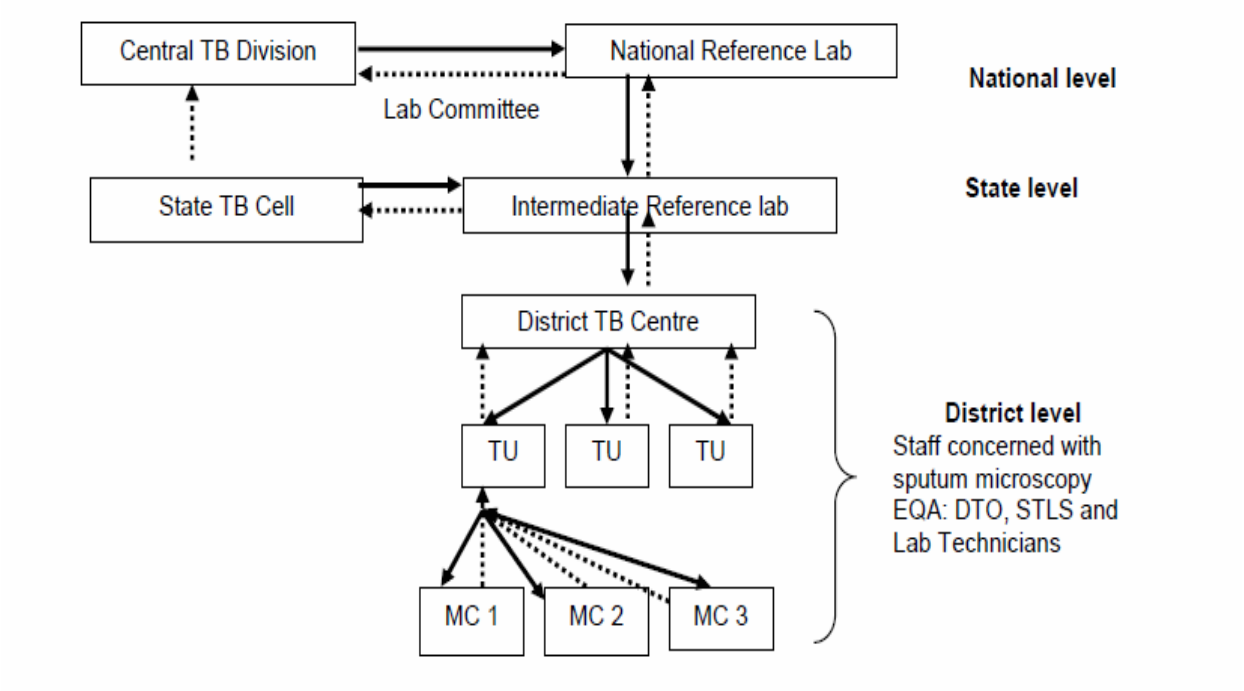


Figure 2.4 Different Levels of Laboratories under RNTCP

The services of the laboratory are utilized for diagnosing TB & DR-TB cases and for monitoring of treatment of these patients. The Laboratory network under RNTCP is a 3-tier system for provision of diagnostic services and maintaining its quality. The peripheral laboratories are situated in all health facilities within the district in the public sector like the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics / other sector hospitals / TB hospitals / Medical colleges and in the private/NGO sectors. Most of the health establishments have facilities of quality assured sputum microscopy (ZN method or LED FM), HIV testing, blood-sugar examination etc. For establishment of microscopy centre in a lab, it must have adequate physical infrastructure, Binocular microscope and a trained LT. Apart from it, many of these bigger hospitals and medical colleges will be having the facility of digital X-Ray, rapid molecular test (CBNAAT & LPA), FNAC, histo-pathology, and culture & DST for diagnosis of a TB patient.

Some of the labs may not be having facility for sputum microscopy and may function as a sputum collection centre, which may also be established in areas such as the tribal, hilly, desert and difficult to reach areas of the country for improving the access to diagnostic services. Sputum collection centres can also be established at sub-centres, private practitioners, private hospitals, anganwadis, schools, pharmacies and any other location as identified by the programme. Sputum samples collected at these centres are immediately transported to microscopy centres or labs with culture & DST facility.

At the state level a nodal laboratory is designated as (IRL) which is usually situated in the State TB Training and Demonstration Centre (STDC). If a state is not having a functional STDC then a Public Health Laboratory or Medical College Laboratory is identified and designated as IRL. All these IRLs have facilities for culture & DST for 1st& 2nd line anti-TB medicines using WHO endorsed, in-country validated Phenotypic (Solid – LJ & Liquid Culture – MGIT) and Genotypic technology (LPA & CBNAAT) platforms. The main functions of IRLs are monitoring of lab services across the state and maintenance of its quality through external quality assurance.

At the central level, there are six designated National Reference Laboratories (NRLs) namely National Institute for Research in Tuberculosis (NIRT), Chennai, National Tuberculosis Institute, Bangalore, National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi, National JALMA Institute, Agra, Regional Medical Research Centre, Bhubaneshwar and BMHRC, Bhopal. NIRT is also a Supra-Reference Lab (SRL) for World Health Organization (WHO) and NTI is a Centre of Excellence in SRL network. These NRLs are mainly responsible for External Quality Assurance of Lab network, drug resistance surveillance, training and research. NRLs, IRLs, Labs of Medical Colleges and bigger hospitals are also subjected for NABL certification. Quality assured laboratory services: RNTCP has established a nation-wide laboratory network of over DMCs, which are supervised by the IRLs at the state level and the NRLs and Central TB Division at the national level. The RNTCP aims to consolidate its laboratory network and organize a defined hierarchy for conducting sputum microscopy with external quality assessment (EQA).

Sputum collection Centres:

To improve access to diagnostic services in areas such as the tribal, hilly, difficult to reach are as of the country sputum collection centres may be established. Collection and transport of sputum samples should be as per the RNTCP guidelines .Each district shall identify such areas and plan for establishment of the sputum collection centres. Private practitioners in urban and rural areas can also collect sputum samples and send to the nearest DMC .

EXERCISES

1. List three levels of coordination mechanisms in RNTCP and NACP:
    i._____
    ii._____
    iii._____
2. The role of DAPCU is Three Fold
    i._____
    ii._____
    iii._____
3. List five major responsibilities of
    a. STO
        i._____
        ii._____
        iii._____
        iv._____
        v._____
    b. DTO
        i._____
        ii._____
        iii._____
        iv._____
        v._____
    c. MOTC /MO TB HIV at sub-district /Block level
        i._____
        ii._____
        iii._____
        iv._____
        v._____
4. List three levels of Laboratory Network in RNTCP concerned with EQA
    i._____
    ii._____
    iii._____

Chapter3: LABORATORY DIAGNOSIS OF HIV&TB AND QUALITY ASSURANCE

3.1: DIAGNOSIS OF HIV

HIV infection is diagnosed largely by the detection of antibodies against HIV in the blood of infected patients.

There are three main types of HIV antibody tests:

- Rapid HIV tests
- ELISA
- Western blot assay

Most tests have sensitivities and specificities of over 99% and 98%, respectively.

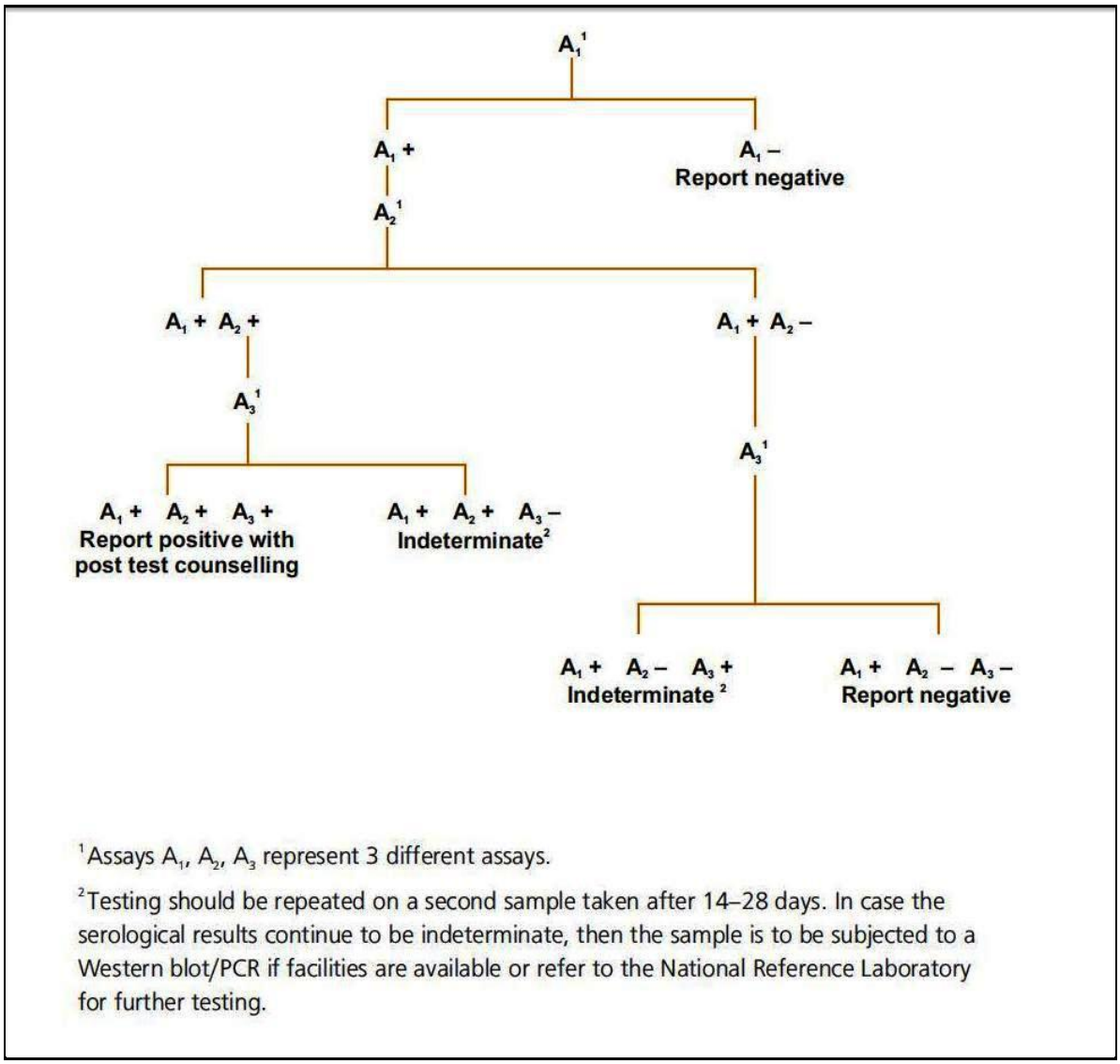
Advantages:

- Quicker to perform.
- Do not require batching.
- Do not require specialized equipment or trained personnel.
- Results delivered on the same day.

National Guidelines on HIV Testing

Currently, three-test policy to confirm the HIV status of the patient is being followed. The blood sample is collected at one time and tested with the HIV first test kit. If it is reactive then sample is retested sequentially with the second and third test kits. The inference of the result is interpreted as Positive, Negative or Indeterminate as per HIV testing algorithm.

HIV testing algorithm



[1]Assays A_1, A_2, A_3 represent 3 different assays.

[2]Testing should be repeated on a second sample taken after 14–28 days. In case the serological results continue to be indeterminate, then the sample is to be subjected to a Western blot/PCR if facilities are available or refer to the National Reference Laboratory for further testing.

Window Period:

The window period represents the period between initial infection with HIV and the time when HIV antibodies can be detected in the blood (6–12 weeks). A blood test performed during the window period may yield a negative test result for HIV antibodies. These cases may require further testing after 12 weeks.

.

Whole Blood Finger Prick Test (WBFPT): It is a type of HIV testing among patients who present with common opportunistic infections of HIV infection e.g. TB, pneumonia, persistent diarrhea etc. Patients presenting with conditions that may be associated with HIV like the sexually transmitted Infections (STI) or reproductive tract infections (RTI), pregnant women who register into antenatal care or present directly in labor & all Tuberculosis patients diagnosed or notified under RNTCP. HIV screening using whole blood finger prick test helps in early detection of HIV infected individual, thus helping early linkage to care and support.

Whole Blood finger prick test (WBFPT) should be used only for screening at health facilities and patients, who screened as positive, should be retested at Stand Alone ICTC for confirmatory test as per HIV testing algorithm.

Who can perform the Whole blood finger prick test for HIV (**WBFPT):** A trained medical officer (MO), laboratory technician or staff nurse can perform screening test for HIV at any health facility.

Screening Test Report:

- **If test result is HIV "non-reactive",** relevant sections of NACO HIV reporting format (**Annexure 8)** is filled by LT and hands over to MO to be shared with client / patient. The medical officer should provide the signed report to patient along with post-test counselling.

- **If test result is HIV, "reactive"** The LT **should NOT** fill test report. Instead, he shares result with MO confidentially and directs the patient to him for counselling and onward **referral to ICTC** for confirmation (**Annex 8**). Although WBFPT is highly sensitive, there is a miniscule probability of a false positive result. Therefore, "HIV-reactive" result on WBFPT is not confirmatory and HIV status can be confirmed only after three tests as per national guidelines for HIV testing. These are available only at NACO stand-alone ICTC's. On the contrary, if the test result is non-reactive it is accepted as negative result and no additional confirmation is required.

The institutional DOT provider should also provide post-test counselling to all clients. He should be educated on measures to stay negative and the concept of window period. If screening test is "HIV-

reactive", the health worker should reassure him and explain that WBFPT is only indicative and it is necessary for the client /patient to visit nearest ICTC for confirmation. At ICTC a trained counselor provides standard pre-test and post-test counseling, performs testing as per guidelines for HIV testing and provides report in a standard NACO reporting format**(Annex-9).**

Recording Test results: The test results must be documented in existing DMC laboratory register in a separate format at the end of register **(Annex-10)**

Confirmation of WBFPT test result: All clients / patients found reactive on screening test **must be referred to nearest ICTC** for confirmation of result. A referral form **(Annex-9)** should be filled in triplicate –one copy for record at referring PHI and 2 copies to be sent to ICTC with the client / patient. ICTC Counsellor will fill both copies and return one copy to client/patient and another copy to referring PHI MO**.** The MO DMC should use copies in record to check with ICTC counsellor whether referred clients are received at ICTC.

Shared Confidentiality: Similar to PITC among TB patients, a strategy of shared confidentiality is adopted for care of clients and patients screened with whole blood finger prick test. The MO and other health staff need to know HIV status to ensure linkage of infected person to appropriate care, support and treatment. Hence, the ICTC counsellor should provide feedback on the result of HIV test to referring doctor at the earliest. The feedback may be provided through either the referral form or directly (telephone call) after consultation with the client / patient.

3.1.1. Recording and Reporting

Record of test result: Existing laboratory register at DMC should be used for documentation of test results. The key information to be recorded is

a. Date of screening
b. Whether the patient's found "reactive" on WBFPT are referred to ICTC for confirmation– Yes/No
c. Result of HIV test at stand- alone ICTC (as per feedback from ICTC):

3.1.2. Procedure at the HIV testing centre (ICTC/F-ICTC/Whole Blood HIV Screening Test Centre):

HIV Screening facility at DMC and F-ICTC:

1. TB suspects coming to the ICTCs will be offered counselling and testing as per the norms and standard operating procedures of the National AIDS Control Programme (NACP).
2. All referrals will be recorded in the ICTC counselling register as referrals from RNTCP (Column no. 4;Code4)
3. For patients with HIV positive results, the counselor will link the patient to the nearest ART centre available in the district/state .This will be done by giving a referral form and explaining the patient on how to access the centre. The patient will be given the contact details of the district programme managers for any assistance needed. It has been observed that nearly 75% of the H IV positive patients will have low CD4 counts and will be eligible for ART as per current national guidelines.

The counsellor will document the HIV status, date of HIV testing and PID number in the RNTCP laboratory form as a feedback to LT of DMC. The counselor will also assist the DMC LT to update the laboratory register with information on HIV status.

3.1.3. Confidential and anonymous testing-

Voluntary—the client must give informed consent for the HIV test to be performed after pre-test counselling and in the absence of coercion.

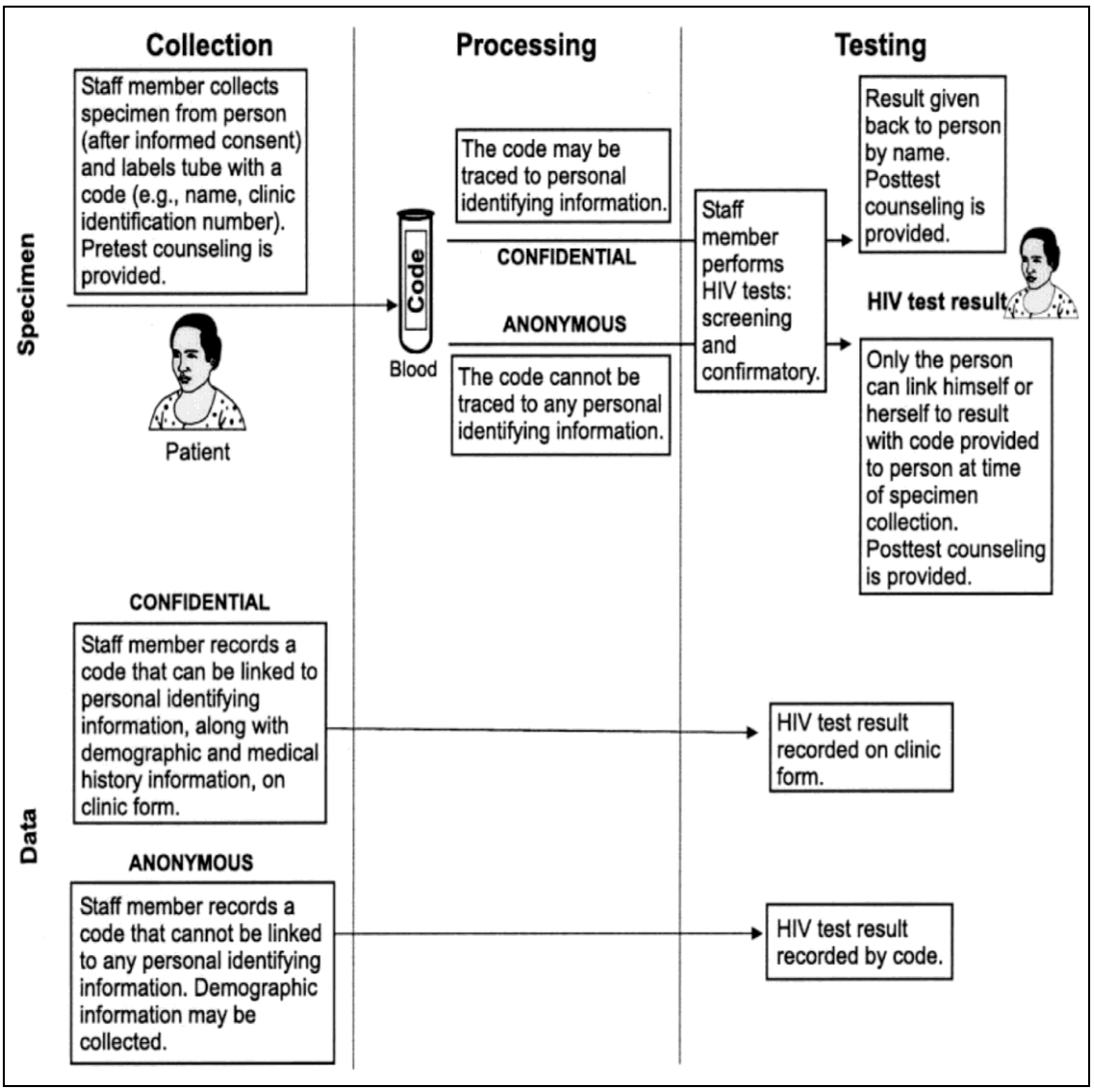


Figure 4.3: Linked confidential and anonymous HIV testing

Quality Assurance Programme:

- It is important that all ICTC programmes develop a quality assurance programme relating to HIV testing.
- This must involve an external reference laboratory, every quarter some sample load is sent to the reference laboratory for confirmation.

Assays for staging HIV disease and monitoring efficacy of ART-

- CD4 testing.
- Viral load testing.

3.2: DIAGNOSIS OF TUBERCULOSIS

3.2.1 TB in HIV positive patients

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

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

Features of PTB	Stages of HIV Infection	
	Early	**Late**
Clinical Picture	Often resembles post-primary TB	Often resembles primary TB
Sputum Smear Result	Often Positive	Often negative
Chest X-RAY Appearance	Often Cavities	Often infiltrates with no cavities

Smear positive pulmonary tuberculosis (PTB) is the most common and infectious form of tuberculosis and forms the major source of infection in the community. Every untreated case has the potential to spread infection to 10 – 15 persons annually. From the public health point of view, it is of utmost importance to detect and treat such cases as early as possible to cut the chain of transmission of disease in the community. Diagnostic services for other forms of tuberculosis

such as smear negative Pulmonary TB, extra pulmonary tuberculosis, Pediatric TB, TB in HIV and Drug resistant TB are also available under programme.

Symptoms of tuberculosis

The most common symptom of PTB is a persistent cough of two weeks or more, with or without expectoration.
It may be accompanied by one or more of the following symptoms

- Fever, night sweats, weight loss
- Chest pain, hemoptysis, shortness of breath, tiredness and loss of appetite

Extra pulmonary tuberculosis

Extra Pulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs such as pleura, lymph nodes, intestine, genitourinary tract, joint and bones, meninges of the brain etc., is called as extra-pulmonary TB**.**
A person with extra-pulmonary TB may have symptoms related to the organs affected along with constitutional symptoms stated above.

- Enlarged cervical lymph nodes with or without discharging sinuses (TB Lymphadenitis)
- Chest pain with or without dyspnea in pleural TB
- Pain and swelling of the joints in bone tuberculosis (fever, backache, deformity in spinal TB).
- Signs of raised intra-cranial tension like irritability, headache, vomiting, fever, stiffness of the neck and mental confusion in TB meningitis
- Painless hematuria or sterile pyuria in renal tuberculosis and, infertility in genito-urinary TB.

Presumptive TB Cases

Presumptive TB refers to a person with **any of the** symptoms and signs suggestive of TB including cough >2 weeks, fever > 2 weeks, significant weight loss, **night sweats,** haemoptysis etc. and any abnormality in chest radiograph.

*A **Pulmonary Presumptive TB cases** is defined as*

- An individual having cough of 2 weeks or more.
- Contacts of smear positive TB patients having cough of any duration
- Suspected/confirmed extra-pulmonary TB having cough of any duration
- **HIV positive patient having cough of any duration**

Importance of properly identifying Presumptive TB cases

Most patients with TB attend health facilities promptly for seeking relief of symptoms. It is important to suspect tuberculosis among these chest symptomatics and subject them for sputum examination. **If TB is not suspected/ presumed, patients with smear-positive pulmonary TB will not be identified.** These patients will continue to spread the infection and it is likely that more than half of them die by three years. Hence, every pulmonary TB suspect should be referred for sputum examination in time.

Therefore, all health workers and community volunteers should be encouraged to identify and refer presumptive TB cases to DMCs for early diagnosis and treatment to prevent further spread of the infection

Screening of presumptive pulmonary TB cases

Patients attending health institutions - government/private need to be systematically screened for cough of two weeks or more by the health facilities. Persons with cough of 2 weeks, or more, with or without other symptoms suggestive of TB, should be promptly identified as presumptive pulmonary TB. They are to be referred to the designated microscopy centre (DMC) for sputum examination using the RNTCP laboratory form for sputum examination.

Sustained efforts have to be taken to examine as many **Presumptive TB Cases** ***as possible to maximize case detection under the program***

Referral for sputum examination

Presumptive Pulmonary TB cases (Presumptive PTB cases) at designated microscopy centers are subjected for two sputum examinations. Presumptive PTB cases attending peripheral health institutions other than DMC are either referred to nearest DMC for sputum examination or their sputum specimens are collected and transported to the DMC as per guidelines.

RNTCP laboratory form for sputum examination has to be filled by the Medical Officer/ Health worker of the health facility appropriately and sent along with the patient for sputum examination. Referral for sputum examination form is annexed **(Annex- 11)**

Tools for diagnosis of Pulmonary TB in adults:

The current diagnostic modalities are directed both towards improving the "patient-initiated pathway" of TB case detection that is currently in place, as well as the introduction of the "screening pathway" for early detection among clinical and social risk groups.

One of the first responsibilities of the TB program is to aim at early diagnosis of microbiologically confirmed TB, if at all possible. Acceptable methods for microbiological diagnosis of TB in RNTCP include

- Sputum smear microscopy (both conventional and fluorescent),
- Molecular technologies
- Line probe assay (LPA) or
- Cartridge Based Nucleic Acid Amplification Test (CB NAAT).
- Culture (on solid or liquid media) (referral form for culture and drug sensitivity test is enclosed at **annex 12**)

The most commonly-used method for microbiological diagnosis of TB for the last several decades, sputum smear microscopy, has had enormous value in TB diagnosis, but has limited sensitivity, particularly in children. Sputum culture remains a highly sensitive and specific method for TB diagnosis, but requires weeks to yield results and hence alone does not help clinicians with initial diagnostic suspicion. Nucleic acid amplification testing (NAAT) offers enormous potential for accurate rapid diagnostic testing. With the advent of CBNAAT, the sensitivity and specificity of rapid TB diagnosis has increased, particularly valuable for the assessment of children and PLHIV. In addition to this, other advantages of CBNAAT are its rapid turnaround time within 90 min., minimal bio-safety conditions, minimal training for the technician and inbuilt quality control for processes.

Chest radiograph is a sensitive test for the detection of pulmonary TB in adults and children, and is recommended as a screening tool for TB. Due to the non-specific nature of radiographic testing for TB, any abnormal chest radiograph should prompt further microbiologic and clinical assessment for TB diagnosis.

In Indian settings, Tuberculin Skin Test (TST) and Interferon-Gamma Release Assays (IGRA) are not recommended for diagnosis of TB, although in certain cases, TST may be useful as an additional test for the diagnosis of TB in children.

Commercial serological tests for diagnosis of TB provide inconsistent and imprecise estimates of sensitivity and specificity, hence, are **banned** for diagnosis of any form of TB (**Annex 28**).

Diagnosis of Drug Resistant TB (MDR/XDR) is a laboratory based diagnosis either phenol typical i.e. growing the bacteria(culture) and demonstrating the ability of bacteria to grow in the presence of anti TB drugs(Drug susceptibility testing) or Geno typically by demonstrating the presence of resistant genes using molecular methods(CBNAAT)

Use of Cartridge Based- Nucleic Acid Amplification Test (CB-NAAT) for Early Diagnosis of TB among PLHIVs.

Cartridge based nucleic acid amplification testing (CB-NAAT) is a rapid molecular beacons-based Xpert MTB/RIF assay technology. The test detects Mycobacterium Tuberculosis (MTB) and Rifampicin (Rif) resistance conferring mutations directly from untreated sputum specimen. It is designed to extract, amplify and identify targeted rpoB nucleic acid sequences automatically with minimal specimen handling.

From the patient management perspective, it provides results within 2 hours that enables same day diagnosis and prompt treatment initiation. This is the fastest turn around time with any technology as compared to three days (72 hrs) in Line Probe Assay (LPA), 40-42 days (two and half months) in Liquid culture and DST (MGIT) and 120 days (four months) in solid culture and DST technology.

Collection of sputum from Presumptive TB cases and Transportation to Nearest DMC:

Presumptive TB cases attending the DMC will be referred for sputum examination at the same facility. There are two options for patients attending PHI, which is not a DMC.

- Either the patient may be referred to the nearest DMC for sputum examination or

- Sputum sample may be collected from such patients and transported to the DMC.

The above options may be left to the convenience of the patient in order to minimize the possible delay in diagnosis and initiation of treatment or avoid repetition of visits by the patient. If sputum microscopy is not possible on the day the patient visits the PHI due to any unavoidable reason, his/her sputum sample should be collected on the same day and sputum microscopy may be done on the following day.

Guidelines for collecting sputum

The patients are given the sputum container with laboratory serial number written on its side. The person collecting the sputum demonstrates how to open and close the container, takes the patient to an open space away from other people, and demonstrates how to bring out sputum from the depth of chest. The patient is instructed to inhale deeply 2–3 times with mouth open, cough out deeply from the chest, open the container and spit out the sputum into it, and close the container. This is the spot specimen labeled as 'a'.

• Further, patient is given a labeled container with instructions to cough out sputum into the container early in the morning after rinsing the mouth with water. This is the early morning specimen. This is labeled as specimen 'b'.

• If the health facility is not a DMC, then the patient is given a sputum container with instructions to collect an early morning specimen and go with the sputum specimen to the DMC where the spot specimen can be collected. In case the patient is not able to travel to the DMC, then the spot specimen could be collected at the nearest health facility or sputum collection center and transported to the DMC.

• These two samples should be collected within a day or two consecutive days.

• To obtain good quality sputum specimens and to prevent contamination, the staff must perform certain tasks:

- Before sputum collection,
- During sputum collection, and
- After sputum collection.

1. Tasks performed before sputum collection

Before collecting the sputum specimen, the health worker should briefly explain to the patient the reasons for sputum collection. The Laboratory Form for sputum Examination should be

filled up completely, generally by the MO. This form is sent to the DMC along with the sputum specimens. Only one form needs to be filled for two sputum specimens collected from a patient. The form accompanies the patient's sputum specimens when they are transported from the peripheral health facility to the DMC for examination.

2. Tasks performed during sputum collection

Person collecting the sputum specimen should follow the guidelines specified below:

- A specimen collected under supervision is likely to be of good quality and yield better results. The person guiding the patient for specimen collection should stand behind and encourage him to cough from the depth of the chest and produce a quality specimen.
- Wherever possible, sputum should be collected in an open space / well ventilated room meant for this purpose away from other crowded places in a health facility.
- The patient should be given a sputum container with the Laboratory Serial Number written on its side. If the sputum is being collected at a location other than the DMC, then the Specimen Identification Number (or patient's name) is written on the side of the container.
- For the diagnosis of tuberculosis, the two specimens of a patient i.e., one "SPOT-and the other an early MORNING" sample are collected. The spot sample is designated as 'a' and the early morning sample as 'b' adjacent to lab serial number. For follow-up sputum examination of patients, two specimens of sputum are collected. The specimen collected in the early morning is marked as 'b' and Spot samples collected subsequently is marked as 'a'.
- The person collecting the specimen demonstrates how to open and close the container. The patient is instructed to inhale deeply (2–3 times), cough out sputum from the chest, spit into the container and close it.
- The person collecting the specimen should make sure that no one stands in front of the patient who is trying to collect sputum. Sputum should not be collected in closed rooms, toilets and ill-ventilated rooms.
- When a patient has only coughed up saliva or has not coughed up at least 2 ml of sputum, the patient should be encouraged to give good specimen

3. In case the container is soiled outside, is should be wiped dry using cotton swab and the same is disinfected in a bin containing 5% phenol solution. Tasks performed after sputum collection

The person collecting the sputum specimens should follow the guidelines specified below:

- If the sputum specimens are to be sent immediately to the laboratory, the person should put the container into a special box meant for transport
- If the sputum specimens are not being sent immediately to the laboratory, these should be stored in a cool and dark place in the referring health facility
- The person should wash hands thoroughly with soap and water whenever infectious material is handled.
- Patients should be instructed to collect the results of sputum examination. Alternatively, sputum results may be sent to the referring health facility by hand.

3.2.2 Diagnosis of Pulmonary TB

A case of Presumptive TB shall be identified by health care providers (Govt/Non Govt) or community volunteers or those who present on their own initiative for TB diagnosis. The referral for the required investigation is done using the prescribed RNTCP lab form, which is filled by the referring health care provider and sent along with patient/specimen.

A. All cases of presumptive pulmonary TB will undergo sputum smear exam (Zeihl Neelsen / Fluorescent Microscope). Two specimens will be collected (spot-early morning or spot – spot).Obtaining a good sputum specimen is crucial for quality sputum microscopy. Chest X-ray, if available, will be done simultaneously.

B. If smear is positive with or without X-ray suggestive of TB, he will be categorized as microbiologically confirmed TB.

C. If smear is positive with X-ray not suggestive of TB or X-ray not available will also be categorized as microbiologically confirmed TB

D. If smear is negative but chest X-ray is suggestive of TB will undergo CBNAAT using a fresh single sputum sample in falcon tube However if the facility of CBNAAT is not available the patient will be categorized as a probable TB case depending on the treating physicians decision and will be treated with a full course of anti TB drugs.

E. A patient with smear negative /smear not available and Chest X-ray is not suggestive of TB/Not available but still with high clinical suspicion will undergo CBNAAT. However if the facility of CBNAAT is not available the patient will be categorized as a probable TB

case depending on the treating physicians decision and will be treated with a full course of anti TB drugs.

F. A patient with CBNAAT examination if found MTB positive, will reported as Rifampicin sensitive, Rif Resistant or Rif indeterminate.

a) Rifampicin sensitive patient would be categorized as microbiological TB.

b) Rifampicin indeterminate patient will undergo a repeat CBNAAT test on a fresh sample and if found to be indeterminate on second sample, an additional sample will be collected and sent to the nearest Culture DST lab for LC/LPA.(Wherever the facilities are available efforts should be made to obtain DST results for all drugs by collecting additional samples and sending to nearest culture and DST lab(subject to lab capacity)

c) If Rifampicin resistance is reported the patient will be treated as per PMDT guidelines.

d) All diagnostic health care facilities should have TB labs that are quality assured by competent authority.

G. If CBNAAT result is MTB negative/Not available the patient is referred to the treating physician for considering differential diagnosis for other etiologies

H. If the X-ray facilities are not available at the health institution, use of mobile X-rays, outsourcing mechanisms, Corporate Social Responsibilities, etc., can be .considered to make these services accessible and affordable to the patients

I. All presumptive TB cases that are HIV positive will preferentially be offered an upfront CBNAAT as per approved algorithm for PLHIV. If CBNAAT is not available then patient undergoes sputum microscopy/Chest X-ray for further diagnosis.

J. All presumptive TB cases will be offered HIV counselling and testing while being diagnosed for TB.

K. In settings of high MDR TB (eg MDR TB rates > 5% among new cases and >20% among re-treatment cases), a CBNAAT will be performed to rule out rifampicin resistance before initiation of Rx where patients will be categorized as microbiologically confirmed Drug Sensitive (DS) TB or RIF resistant TB.

Patients diagnosed with pulmonary TB will be treated with a full course of Anti TB drugs as per the standard treatment regimens.

Diagnostic Algorithm for Pulmonary TB is enclosed at **Annex-13**

3.2.3 Diagnosis of Extra-pulmonary Tuberculosis

Extra Pulmonary tuberculosis (EPTB) refers to any microbiologically confirmed or clinically diagnosed case of TB involving organs other than the lungs such as pleura, lymph nodes, intestine, genitourinary tract, joint and bones, meninges of the brain etc.

Testing for Extra-pulmonary TB:

All presumptive TB cases with extra-pulmonary symptoms and signs, appropriate specimens from the presumed sites of involvement must be obtained for –

- Smear Microscopy
- Culture for Mycobacterium tuberculosis
- Molecular test
- Histopathology examination
- Drug Sensitivity testing

The use of CBNAAT has been recommended as the preferential test for diagnosis of Extrapulmonary TB for microbiological confirmation

Chest X-ray, Ultrasonography, CT scan, MRI are other investigations which can be used for diagnosing Extra-pulmonary TB (supporting tools)

Extra-pulmonary TB is more common in PLHIV (approximately 30% of the cases) which often presents non-specific symptoms and low yield of mycobacteria due to which the use of CBNAAT has been recommended as a preferential test in these patients.

Recently, the use of CBNAAT has been recommended for testing specimens other than sputum and it performs well on these samples as compared to sputum microscopy.

Diagnostic Algorithm for Extra Pulmonary TB is enclosed at **Annex 14**

Chest X-ray, Ultrasonography, CT scan, MRI are other investigations which can be used for diagnosing Extra-pulmonary TB (supporting tools). Extra-pulmonary TB is more common in PLHIV (approximately 30% of the cases) which often presents non-specific symptoms and low yield of Mycobacteria due to which the use of CBNAAT has been recommended as a preferential test in these patients. Recently, the use of CBNAAT has been recommended for testing specimens other than sputum and it performs well on these samples as compared to sputum microscopy.

TB Notification at diagnosis

All TB patients should be notified at time of diagnosis at either public or private sector as compared to only those patients put on treatment registered currently. This newer surveillance system will help to notify all TB cases identified and will be based at health facility level as against TU level. The current system is driven largely by RNTCP contractual staff; the newer surveillance system intend to be driven largely by general health staff i.e. laboratory technician, pharmacist, staff nurse, medical officer of health facility. As patients will be notified at time of diagnosis, it will be compulsion to complete the loop of referral for treatment. This mechanism necessitates use of electronic reporting which allow de-duplication and tracking of notified patient's right up to completion of treatment.

3.2.4 Diagnosis of Pediatric TB:

Background

Estimated 0.55 million children become ill with tuberculosis (TB) each year (6% of global TB burden), of them Up to 80000 children die of TB every year (200/day)-7% of global deaths. 70-80% of children with TB have pulmonary TB and the rest are extra-pulmonary TB.

The burden of TB in children is likely to be higher and TB in children is often missed or overlooked due to non-specific symptoms and difficulties in diagnosis - getting an appropriate sample for testing, clinical diagnosis predominates without lab confirmation etc. In settings with a high burden of TB, around 10–20% of all TB cases are expected to occur in children. Extent of childhood TB in India is estimated to be 10.2% of the total adult incidence.

In January 2012, based on the national consultation on diagnosis and treatment of pediatric TB, the national guidelines on diagnosis and treatment of Pediatric were updated in consultation with Indian Academy of Pediatrics and other National experts. NTWG in 2013, recommended CBNAAT to be preferentially used for the diagnosis of pediatric TB.

When to suspect childhood pulmonary TB?

Fever and / or cough of recent onset lasting for > 2 weeks, recent unexplained loss of weight and history of exposure to an infectious TB patient (smear positive). However, in a symptomatic child, contact with a person with any form of active tuberculosis within last two years may be significant as many a times there can be a coexisting pulmonary involvement that went unrecognized due to lack of chest symptoms. In addition, diagnosis is more likely in presence of risk factors such as recent history of measles or whooping cough, immunocompromised state including steroid therapy and persistent pneumonia not responding to antibiotic therapy. Significant superficial lymphadenopathy must be specially looked for, as it may often coexist. Therapeutic trial with anti-TB drugs is not recommended and instead every attempt must be made to prove the diagnosis.

Bacteriology

Diagnosis of tuberculosis can never be reliably made only on clinical features. The subject with above-mentioned clinical features- in isolation or in combination - is only a presumptive TB. Further investigations are always necessary to establish the diagnosis. Therapeutic trial with anti-TB drugs is therefore, not recommended and instead every attempt must be made to prove the diagnosis. Demonstration of AFB from any body fluid or tissue is confirmatory of tuberculosis. Such a proof is often lacking in childhood tuberculosis because of difficulty in collection of sputum and due to paucibacillary primary disease in children. However, studies do report that the yield of a positive test in advanced cases may be as high as in adults. Therefore, every attempt must be made to bacteriologically prove the diagnosis in every case of suspected tuberculosis.

In all children with presumptive intra-thoracic TB, microbiological confirmation should be sought through examination of respiratory specimens (e.g. sputum by expectoration, gastric aspirate, gastric lavage, induced sputum, Broncho-alveolar lavage or other appropriate specimens) with a quality assured diagnostic test, preferably CB-NAAT, smear microscopy or culture. Recent evidence from the four implementing sites [Delhi, West Bengal (Kolkata), Andhra Pradesh (Hyderabad) and Tamil Nadu (Chennai)] of pediatric pilot project using CBNAAT suggested threefold increase in detection rates using CBNAAT with low proportion of invalid results in comparison to sputum microscopy and detection of significant numbers of Rifampicin resistance pediatric cases.

In the event of negative or unavailable microbiological results, a diagnosis of probable TB in children should be based on the presence of abnormalities consistent with TB on radiography, a history of exposure to pulmonary TB case, evidence of TB infection (positive TST) and clinical findings suggestive of TB.

For children with presumptive extra-pulmonary TB, appropriate specimens from the presumed sites of involvement should be obtained for rapid molecular test, microscopy, culture and DST, and histo-pathological examination.

Diagnostic Algorithm for Pediatric TB is enclosed at Annex 15

3.2.5. Diagnosis of Drug Resistant TB

Drug Resistant TB can be one of the following:

MDR-TB case: A TB patient whose sputum is culture positive for *Mycobacterium tuberculosis* and is resistant *in-vitro* to isoniazid and rifampicin with or without other anti-tubercular drugs based on DST results from an RNTCP-certified Culture & DST Laboratory.

XDR TB case: An MDR TB case whose recovered *M. tuberculosis* isolate is resistant to at least isoniazid, rifampicin, a fluoroquinolones (Ofloxacin, levofloxacin, or Moxifloxacin) and a second-line injectable anti-TB drug (kanamycin, Amikacin, or Capreomycin) at a RNTCP-certified Culture & DST Laboratory.

Drug Resistant TB is a laboratory based diagnosis and is performed either by phenotypic Drug Susceptibility Testing (Solid/liquid) or genotypic detection of resistance (LPA/CBNAAT).

Diagnostic Algorithm for Universal DST guided Rx is enclosed at **Annex 16**

Basis for testing of presumptive MDR TB cases

- Use of Molecular Drug susceptibility Testing by LPA and CBNAAT technology:
    - For rapid detection of Rifampicin resistance for deciding Cat IV regimen
    - To decide whether only first line DST or both first Line and second line DST needs to be done.
- Use LPA for rifampicin sensitive patients to detect resistance to Isoniazid, if both isoniazid and rifampicin are sensitive continue treatment with First line drugs.
- Use Liquid Culture for all rifampicin resistant and isoniazid resistant patients at baseline to detect additional drug resistance or Mono/Poly drug resistance.

Plan and Flow for initial testing of presumptive MDR TB cases

Diagnose rifampicin resistance among presumptive Multi Drug Resistant TB using a rapid molecular Drug Susceptibility Test (DST)- CBNAAT or Line Probe Assay (LPA). Two specimens to be collected (spot-early morning or spot – spot) for LPA and obtain a single good quality sample for CBNAAT.

Presumptive MDR TB includes TB patients who have failed treatment with first line drugs, pediatric non-responders, TB patients who are contacts of MDR-TB (or Rifampicin resistance), TB patients who are found positive on any follow-up sputum smear examination during treatment with first line drugs, diagnosed TB patients with prior history of anti-TB treatment, TB patients with HIV co-infection and all presumptive TB cases among People Living with HIV.

If Rifampicin Resistance is detected by CBNAAT or LPA,

Start Standardized Regimen for MDR TB and perform Liquid Culture DST at base line to Ethambutol, Pyrazinamide, Kanamycin, Amikacin, Capreomycin, Levofloxacin and Moxifloxacin with the next available sample. Perform extended DST for Ethionamide, Para Amino Salicylic acid,

Linezolid and Clofazamine if resistance is detected to all second line injectable and/or all fluoroquinolones. Start treatment as per Drug susceptibility testing results.

If Rifampicin sensitive is detected by CBNAAT,

Subject the second sample to LPA. All Isoniazid sensitive patients after testing with LPA or those while awaiting results of LPA should continue treatment with first line drugs as per RNTCP guidelines. However, for diagnostic samples reported by LPA, result report must mention Isoniazid resistance by *Kat G* or *INH A* mutation.

***If Isoniazid resistance* is detected by LPA,**

Perform Liquid Culture DST to Ethambutol, Pyrazinamide, Kanamycin, Amikacin, Capreomycin, Levofloxacin and Moxifloxacin. Perform extended DST for Ethionamide, Para Amino Salicylic acid, Linezolid and Clofazamine if resistance is detected to second line injectable and/or fluoroquinolones. Start treatment as per Drug susceptibility testing results or modify treatment as per recommendations.

For new patients who do not fall under presumptive MDR TB category,

If diagnosed as TB with Rifampicin Resistance by CBNAAT, a second CBNAAT test to be offered along with Liquid culture DST. In addition to other drugs, isoniazid resistance (high and low concentrations) will also be done by liquid culture and treatment modified accordingly.

3.3 INTENSIFIED CASE FINDING FOR TB

All people living with HIV should be regularly screened for TB using a clinical symptom-based algorithm consisting of current cough, fever, weight loss or night sweats at the time of initial presentation for HIV care and at every visit to a health facility or contact with a health-care worker afterwards.

Adults and adolescents living with HIV who report any one of the symptoms of current cough, fever, weight loss or night sweats may have active TB and should be evaluated for TB and other diseases. Screening for TB is important regardless of whether they have received or are receiving IPT or ART. Similarly, children living with HIV who have any one of the following

symptoms – poor weight gain, fever or current cough or contact history with a TB case – may have TB and should be evaluated for TB and other conditions.

Four symptom based screening algorithm as described above should be used and people living with HIV who are attending ART/LAC centers .Care Coordinators ,Staff nurse, MO ART at ART centre identify the presumptive TB cases and Fast Track the PLHIV for TB diagnosis at the nearest CBNAAT facility .

Presumptive TB cases among the PLHIVs should be prioritized / Fast-tracked for TB diagnosis considering the risk of transmission at TB Diagnostic facilities .TB and HIV Diagnostic facility at same centre a "one-stop service" should be ensured for patient centred care by the same trained health care provider at the same visit to reduce diagnostic delays and facilitate early diagnosis of TB among PLHIVs & those who are unlikely to have active TB can be linked to IPT services.

Capacity should also be enhanced in the health-care system, for example in the laboratory, supply management, health information, referral and integrated service delivery systems, to enable them to cope better with the increasing demands of collaborative TB/HIV activities. Early identification of signs and symptoms of TB followed by diagnosis and prompt initiation of treatment in people living with HIV, their household contacts, groups at high risk for HIV and people living in congregate settings (e.g. prisons, workers' hostels, police and military barracks) increases the chances of survival, improves quality of life and reduces transmission of TB in the clinic and the community.

Smear negative pulmonary and extra pulmonary TB is common among people living with HIV and associated with poor treatment outcomes and excessive early mortality.

Routine HIV testing should be offered to all patients with presumptive and diagnosed TB;

Majority of people living with HIV do not know their HIV status and seek health care from general service providers. HIV testing and counselling for people with diagnosed or presumptive TB offers an entry point for a continuum of prevention, care, support and treatment for HIV and for TB

HIV services refer people living with HIV for TB screening, diagnosis and treatment.

Intensive case finding for TB should be undertaken in clinically and socially vulnerable populations. The clinically vulnerable population includes people living with HIV, household contacts of TB cases, malnourished children, diabetics, tobacco users, health care workers, certain occupational groups such as miners and those living in houses with indoor air pollution. The socially vulnerable population includes migrants, indigenous populations in the tribal areas, slum dwellers and prisoners. All such screening has to be recorded in the prescribed RNTCP recording format.

3.3.1 Intensified TB case finding at ICTCs, ART and Community Support Centres (CSCs)

Intensified TB case finding (ICF):

ICF at ICTCs

All ICTC clients should be screened by ICTC counsellors for presence of TB symptoms at every encounter (pre, post, or follow-up counselling). Clients who have symptoms or signs, irrespective of their HIV status, should be referred to RNTCP diagnostic and treatment facility located in same institution. Therefore, NACP and RNTCP promote establishing co-located facilities, for better coordination between the two programmes. Hence, as network of HIV testing facilities is being expanded, consideration should be given to establish them at sites, which already have RNTCP, designated microscopy centres (DMC).

The referrals of presumptive TB cases from ICTCs to TB diagnosis facility should be recorded on a line list (**Annex 17)** to facilitate exchange of information with RNTCP and track the client thorough the process of TB diagnosis and initiation of DOTS. To streamline this process further RNTCP programme staff should stay in touch with ICTC counsellors to complete the exchange of information in time and should enter information in TB/HIV register (**Annex 18).** In addition, ICTC counsellors and RNTCP programme staff participate in monthly HIV/TB coordination meeting at district level to validate line-lists and monthly HIV/TB reports (**Annex 19**) and resolve operational issues if any.

ICF at ART Centres

HIV-infected persons attending ART centres for pre-ART registration have a high prevalence of TB disease (6 to 8%). The incidence of TB among ART clients is also very high, even when on ART. Although ART reduces risk of incident TB, it remains many times higher compared to general population. In addition, HIV-infected clients having undiagnosed or untreated TB may seek care at ART centres and thus exposing other HIV-infected persons to the risk of acquiring TB. Therefore active efforts for intensified TB case finding (ICF) at ART centres is critical for early suspicion and detection of TB, linkage to treatment and thus for prevention of transmission of infection to other clients. The national ART guidelines clearly state that all patients coming to ART centres should be actively screened for opportunistic infections, particularly tuberculosis. The presumptive TB cases identified at ART centres or Link ART centres should be prioritized and "fast-tracked" for evaluation by SMO/MO to minimize opportunities for airborne transmission of infection to other PLHIV.

In addition, the referrals presumptive TB cases should be recorded on an ART centre TB-HIV line list (**Annex 20**) to facilitate coordination with RNTCP programme staff and to track the patient closely through the process of TB diagnosis and DOTS initiation. It is also crucial that ART Centre staff members attend monthly HIV/TB coordination meeting. The HIV/TB monthly reporting format to be generated at ART centres is incorporated into the ART centre monthly report (CMIS) (**Annex 21**).

Information of all HIV infected TB patients in HIV care should be recorded in the ART centre HIV/TB register (**Annex 22**). These include TB patients detected by ART centre staff as well as those TB patients found HIV infected while on DOTS treatment and referred to ART centre by the RNTCP. TB-HIV register is an important monitoring tool to track timeliness of initiation of CPT and ART the TB treatment outcome to modify ARV regimens as per guidelines. It is also important that ART centre staff carry this register when they attend monthly HIV/TB coordination meeting to update information on TB treatment outcome from RNTCP staff and share information pertaining to CPT and ART with them for recording into RNTCP TB registers.

ICF at Link ART Centres (LAC)

The ICF activity is also implemented at all Link ART plus and Link ART centres in the country. As in ART centres LAC-Plus and LAC should 1) implement ICF using symptom screening on every encounter 2) promptly refer presumptive TB case to RNTCP diagnostic facilities, and 3) refer the patient to ART centre promptly if TB is detected for initiation of ART or modify current ARV

regimen. Similar to ART centre, the LAC staff nurse /counsellor should maintain line-list, exchange with local RNTCP staff to seek information on TB diagnosis and treatment and complete the line-list.

The LAC Plus use same line-list format as the ART centre **(Annex-20)** while at LAC Plus centre the ICTC line-list format is used (since ICTC counsellor runs the LAC) **(Annex 17)**. The completed line-list from LAC-plus is merged with ART centre line-list whereas that from LAC is merged into ICTC line-list for the same period and monthly report is generated accordingly.

These mechanisms are designed considering operational feasibility but key point is if TB is detected among patients at LAC plus of LAC, they **must be promptly referred to ART centre** for further management.

ICF among HIV high risk groups (HRG)

Operational research conducted in high HIV prevalent states have shown that HRG's like female sex workers (FSW), men having sex with men (MSM), injection drug users (IDU) etc. are more likely to have tuberculosis compared to general population. In addition, it is known that HIV prevalence among the HRG is several times higher than general population. While NACP provides HIV prevention interventions for the HRG through its targeted interventions, the ICF provides an opportunity to provide additional services to this population. This intervention is likely to help in detection HIV/TB cases early and link to care support and treatment. Among the HRG's, IDU have highest HIV prevalence therefore the programmes aim to provide ICF services and prompt linkage to care support and treatment to IDU as a priority.

EXERCISE:

1. Name three HIV antibody tests:
    i._____
    ii._____
    iii._____
2. List the limitations of HIV antibody tests for diagnosis:
    i._____
    ii._____
3. Tools of diagnosis of TB in adults
    i._____
    ii._____
    iii._____
    iv._____
    v._____
4. Tools of diagnosis of EP TB in adults
    i._____
    ii._____
    iii._____
    iv._____
    v._____
5. Tools of diagnosis of TB in children
    i._____
    ii._____
    iii._____
    iv._____
    v._____
6. Presumtive TB case is defined as:
    i._____
7. Tools of diagnosis of MDR TB are
    i._____
    ii._____
    iii._____

8. Intensive case finding for TB is conducted at**:**

i._____

ii._____

iii._____

PART B

Chapter 4: TREATMENT OF HIV INFECTED TB PATIENTS:

HIV and TB:

- HIV infection fuels the TB epidemic in several ways. HIV infection promotes progression to active TB in people with recently acquired as well as latent TB. HIV infection is the most powerful known risk factor for reactivation of latent TB infection to active disease manifestation.
- The annual risk of developing TB in persons living with HIV (PLHIV) who are co-infected with Mycobacterium tuberculosis ranges from 5% to 15%. Up to 60% of PLHIV develop active TB during their lifetime compared to about 10% of HIV-negative individuals.
- HIV infection increases the rate of recurrent TB, which may be due to either endogenous reactivation (true relapse) or exogenous re-infection.

Anti-retroviral therapy must be offered to all patients with HIV and TB co-infection as well as drug-resistant TB, irrespective of CD4 cell-count, as early as possible (as early as 2 weeks to 2 months as soon Anti TB/DRTB Treatment is tolerated) following initiation of anti-TB/DRTB treatment. All patients with HIV with a past history of TB also need to be initiated on ART irrespective of CD4 count. Appropriate arrangements for access to anti-retroviral drugs should be made for patients. However, initiation of treatment for TB should not be delayed.

4.1. Treatment of HIV:

Since the time AIDS was first recognized, the second decade of the epidemic has witnessed extraordinary progress in developing combined antiretroviral therapy (ART) as well as continuing developments in preventing and treating Opportunistic Infections. ART has reduced the incidence of OIs and extended life substantially.

4.1.1 WHO staging system for HIV infection in adults and adolescents >13 years of age

- Clinical stages I–IV.

CLINICAL STAGE1
Asymptomatic Persistent generalized lymphadenopathy
CLINICAL STAGE 2
Unexplainedmoderateweightloss(<10%ofpresumedormeasuredbodyweight)i Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media and pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulceration Papularpruritic eruptions Seborrhoeic dermatitis Fungal nail infections
CLINICAL STAGE 3
Unexplained severe weight loss (>10% of presumed or measured body weight) Unexplained chronic diarrhoea for longer than one month Unexplained persistent fever (above 37.5°C intermittent or constant, for longer than one month) Persistent oral candidiasis Oral hairy leukoplakia Pulmonary tuberculosis Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis or bacteraemia) Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis Unexplained anaemia (<8 g/dl), Neutropaenia (<0.5 × 109 per litre) and/or chronic thrombocytopaenia (<50 × 109 per litre)
CLINICAL STAGE 4

HIV wasting syndrome

Pneumocystis pneumonia

Recurrent severe bacterial pneumonia

Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)

Oesophageal candidias is (or candidias is of trachea, bronchi or lungs)

Extra pulmonary tuberculosis

Kaposi's sarcoma

Cytomegalovirus infection (retinitis or infection of other organs)

Central nervous system toxoplasmosis

HIV encephalopathy

Extrapulmonarycryptococcosis including meningitis

Disseminated non-tuberculous mycobacterial infection

Progressive multifocal leukoencephalopathy

Chronic cryptosporidiosis Chronic isosporiasis

Disseminated mycosis (extrapulmonaryhistoplasmosis or coccidiomycosis)

Recurrent septicaemia (including non-typhoidal Salmonella)

Lymphoma (cerebral or B-cell non-Hodgkin)

Invasive cervical carcinoma

Atypical disseminated leishmaniasis

Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy

ART is-

- Life-long.
- Not to be given with single or dual drug but with a combination of three or more drugs due to the rapid emergence of drug resistance.
- ART is not a cure.
- Does not prevent HIV transmission

ART and its benefits:

- Prevents opportunistic infections.
- Alters/reverses the course of existing opportunistic infections.
- Decreases hospitalization.
- Increases survival.

- Improves the quality of life.
- Restores hope.
- Benefits both adults and children.

4.1.2 Goals of Antiretroviral Therapy

The goals of the therapy areas follows.

• **Clinical goals:** Prolongation of life and improvement in quality of life
• **Virological goals**: Greatest possible reduction in viral load for as long as possible
• **Immunological goals**: Immune reconstitution that is both quantitative and qualitative
• **Therapeutic goals:** Rational sequencing of drugs in a fashion that achieves clinical, virological and immunological goals while maintaining treatment options, limiting drug toxicity and facilitating adherence
• **Reduction of HIV transmission in individuals:** Reduction of HIV transmission by suppression of viral load

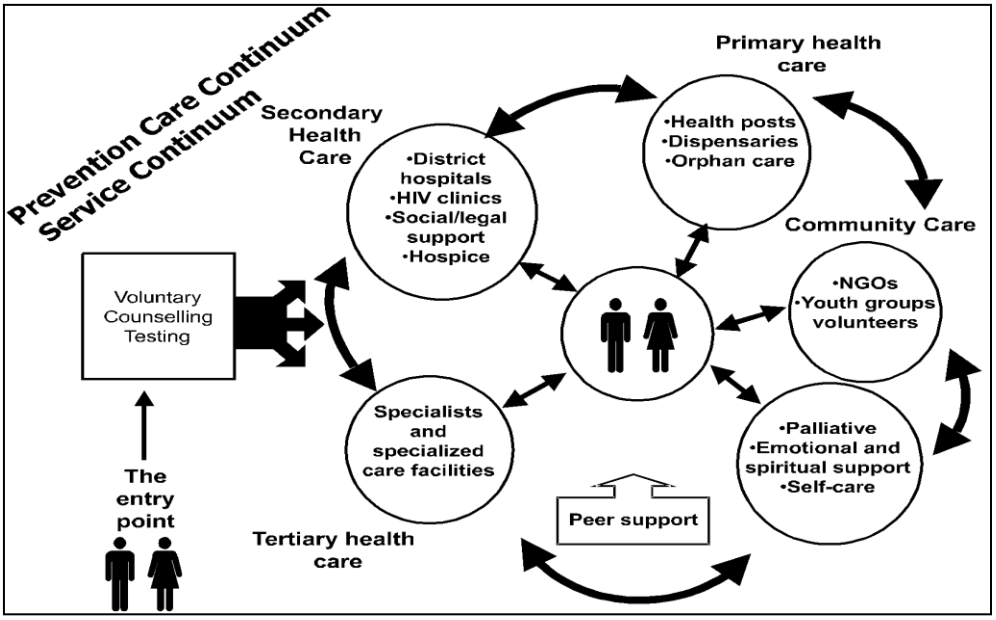


Figure: HIV AIDS care continuum

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

Antiretroviral drugs are medications for the treatment of infection by retro viruses, primarily HIV. Different classes of anti retro viral drugs action different stages of the HIV lifecycle. These drugs act at various stages of the lifecycle of HIV in the body and work by interrupting the process of viral replication. Theoretically, ARV drugs can action any of the following ways during different stages of viral replication.

<table>
<tr><th>Entry Inhibitors</th><th>NRTIs</th><th>NNRTIs</th><th>Protease Inhibitors</th></tr>
<tr><td rowspan="2">Chemokine Co Receptor
(CCR5 / CXCR4) Antagonists</td><td>NsRTI</td><td rowspan="3">Nevirapine(NVP)*
Efavirenz (EFV)*
Etravirine
Rilpivirine
Delavirdine, DLV</td><td rowspan="5">Atazanavir (ATV)*
Ritonavir (RTV)*
Lopinavir (LPV)*
Saquinavir (SQV)
Indinavir (IDV)
Nelfinavir (NFV)
Amprenavir (APV)
Fosamprenavir, (FPV)
Tipranavir (TPV)
Darunavir (DRV)</td></tr>
<tr><td rowspan="3">Zidovudine (AZT)*
Stavudine (d4T)*
Lamivudine (3TC)*
Abacavir (ABC)*
Didanosine (ddI)
Emtricitabine (FTC)</td></tr>
<tr><td>Maraviroc
(CCR5coreceptor antagonist)</td><td>Integrase Inhibitors</td></tr>
<tr><td>Fusion Inhibitor</td><td rowspan="3">Raltegravir RGV
Elvitegravir ELV
Dolutegravir DTG</td></tr>
<tr><td rowspan="2">Enfuviritide(T-20)</td><td>NtRTI</td></tr>
<tr><td>Tenofovir (TDF)*</td></tr>
<tr><td colspan="4">* The highlighted drugs are NOW available in the NACO ART programme</td></tr>
</table>

4.1.3 When to start ART in Adults and Adolescents

All persons registered for care and treatment at ART centres should have their full history taken and undergo clinical examination, including determining the clinical stage of HIV (see Table 5.3). The initiation of ART is basedon the clinical stage and the CD4 count is used to guide treatment and follow-up. The lack of a CD4 result should not delay the initiation of ART

if the patient is clinically eligible according to the WHO clinical staging, but a CD4 test should be done as soon as possible.

All HIV-positive persons should undergoCD4 testing for the purpose of screening for ART eligibility, under the national programme

For **Patients with HIV and TB co-infection (Pulmonary/ Extra-Pulmonary), Start ART irrespective of CD4 count and type of tuberculosis (Start ATT first, initiate ART as early as possible between 2 weeks to 2 months when TB treatment is tolerated). In addition, all PLHIV who have a history of TB need also to be initiated on ART irrespective of CD4 count.**

Table: Initiation of ART based on CD4 count and WHO clinical staging

WHO Clinical Stage	Recommendations
HIV infected Adults &Adolescents (Including pregnant women)	
Clinical Stage I and II	Start ART if CD4 <350cells/mm3
Clinical Stage III and IV	Start ART irrespective of CD4 count
For HIV and TB co-infected patients	
Patients with HIV and TB co-infection (Pulmonary/ Extra-Pulmonary) or history of HIV & TB co-infection	Start ART irrespective of CD4 count and type of tuberculosis (Start ATT first, initiate ART as early as possible between 2 weeks to 2 months when TB treatment is tolerated)
For HIV and Hepatitis Band C co-infected patients	
HIV and HBV/HCV co-infection–without any evidence of chronic active Hepatitis	Start ART if CD4<350cells/mm3
HIV and HBV/HCV co-infection–With documented evidence of chronic active Hepatitis	Start ART irrespective of CD4 count

All HIV- confirmed persons should be referred to ART centres for registration in to care and screening for medical eligibility for ART by CD4 test and other baseline investigation.

All patients should undergo **at least two preparedness counseling sessions** before the initiation of ART. The period of investigations should be utilized for counseling and treatment preparation. All efforts should be made to trace patients who have defaulted or are lost to follow-up. NGO and positive network linkages should be established by each ART centre for the respective locality.

4.1.4 Considerations for Co-infection of Tuberculosis and HIV

HIV-TB co-infection is one of the most challenging issues in the effort to scale up ART since more than 60% of PLHIV develop TB. Patients with TB merit special consideration because the co-management of HIV and TB is complicated by drug interactions between rifampicin and NNRTIs and PIs; **Immune reconstitution inflammatory syndrome (**IRIS); pill burden; adherence; and drug toxicity. Active TB is the commonest OI among HIV-infected individuals and is also the leading cause of death in PLHIV.

The management of patients with HIV and TB poses many challenges, including patient acceptance of both diagnoses. HIV-infected persons with TB often require ART and WHO recommends that ART be given to all HIV TB co- infected (pulmonary/Extra pulmonary) regardless to the CD4 count.

ART reduces the incidence and recurrence of TB, as well as the fatality rates. Co-trimoxazole prophylaxis should be given to HIV-TB patients as per the guidelines.

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

If a patient with active TB is diagnosed with HIV and requires ART, the first priority is to start TB treatment in accordance with the RNTCP guidelines.

Table: Initiation of first-line ART in relation to anti-TB therapy (Based on OM dated 11th November 2014, NACO)

CD4 cell count (cells/mm3)	**Timing of ART in relation to initiation of TB treatment**	**ART Recommendations**
CD4 count of any value	Start ATT first Start ART as soon as TB treatment is tolerated(between2 weeks and 2 months)	Recommended ART – TLE FDC tab
Rationale for ART recommendation during TB treatment : In the absence of ART, TB therapy alone does not significantly increase the CD4 cell count. Nor does it significantly decrease the HIV viral load. Thus, CD4 counts measured during active TB are likely to reflect the actual level of immune suppression The use of HAART in patients with TB can lead to a sustained reduction in the HIV viral load. It can also facilitate immunological reconstitution, and decrease AIDS-defining illness and mortality. This benefit is seen across different ranges of CD4 counts		

The use of the standard 600mg/day dose of EFV is recommended for patients receiving EFV and Rifampicin.

Immune reconstitution inflammatory syndrome (IRIS)may occur in up to one-third of patients who have been diagnosed with TB and who have started ART. It typically presents within three months of the initiation of ART but can occur as early as five days. Patients with TB-associated IRIS most commonly present with fever and worsening of pre-existing lymphadenopathy or respiratory disease. The symptoms are similar to the paradoxical reactions seen in immuno-competent patients on ATT, but occur more frequently. Most cases resolve without any intervention and ART can be safely continued. Serious reactions, such as tracheal compression caused by massive adenopathy or respiratory difficulty, may occur. Therapy may require the use of corticosteroids.

There are two issues to be considered if TB is diagnosed in patients already receiving ART.

First Line ART for HIV-TB in India

TENOFOVIR 300mg + LAMIVUDINE 300 mg + EFAVIRENZ 600 mg (FDC)		
Regimen	Tenofovir + Lamivudine + Efavirenz	All new co-infected patients should be initiated on FDC of TLE single pill based regimen irrespective of HB level/ CD4 count. Those patients who are already on ART on ZLN regimen at the time of TB diagnosis need to be changed to regimen ZL+E at the initiation of ATT due to interaction of ATT & NVP. Such patients will not be changed from EVF to NVP after ATT is completed and will continue on ZLE regimen. There is no change of regimen for patients who are already on ZLE at the time of TB diagnosis & treatment

Table: Initiation of ART in PLHIV with TB Co-infection

Type of Tuberculosis	**Eligible Clinical Staging and CD4 Counts**	**Timing of ART in relation to start of TB treatment**	**ART Regimen**
Pulmonary TB (Stage III)	Start ART irrespective of any clinical stage and irrespective of any CD4 count	Start ATT first (Category I or II) Start ART as soon as TB treatment is tolerated (after 2 weeks & before 2 months)	Start ART Regimen TLE for patients not on ART. For patients already on 1st line ART,ZLN ,shift to ZLE & continue ZLE even after ATT is stopped.
Extra pulmonary TB (Stage IV)			
Past h/o TB		**NA**	

*In women of child-bearing age, the use of contraceptives should be ascertained because of drug reaction, as and when NNRTIs and Rifampicin are being used

*Special Attention to be paid for monitoring Hepato toxicity

Second Line ART for HIV-TB in India:

The following regimens are available under the National Programme currently for second line ART:

Tenofovir + Lamivudine + PI (Atazanavir/ritonavir or Lopinavir/Ritonavir)

Zidovudine + Lamivuidne+ PI (Atazanavir/ritonavir or Lopinavir/Ritonavir)

Stavudine+ Lamivudine + PI (Atazanavir/ritonavir or Lopinavir/Ritonavir)

Abacavir+ Lamivudine+ PI (Atazanavir/ritonavir or Lopinavir/Ritonavir)

Rifampicin alters the metabolism of Protease Inhibitors, including Atazanavir and Ritonavir and reduces their effectiveness in standard doses

Recommended substitution of Rifabutin for Rifampicin for the duration of TB treatment (Management of Supplies of Rifabutin is placed **at Annex 23**)

Special considerations:
As per National ART guidelines, the following categories of patients will be on PI based ART regimens although not on second line and will need Rifabutin in place of Rifampicin in case of HIV-TB co-infection-

- **Pregnant/Breast Feeding ladies put on ART with prior exposure to NVP in previous pregnancy,**
- **PLHIV with severe sensitivity to NVP/EFV**
- **HIV 2 infection/HIV1+2 mixed infections**
- **CLHIV less than 3yrs age as 1st line ART is PI based**

- TB treatment
  - Patient and treatment supporter should be informed and counselled regarding the substitution using Rifabutin, by the treating medical officer
  - Rifabutin dose: 300 mg, three times a week/150 mg daily
  - TB treatment may be started at CoE using RNTCP prolongation pouches and then referred to PHI nearest to patient's residence for continuation of treatment with email communication to concerned DTC; 3 additional doses may be issued to patient to cover the transit period (care should be taken to replace Rifampicin by Rifabutin in prolongation pouches)

- On receiving the prescription and patient's details from CoE (by email), State TB Drug store will supply Rifabutin to the concerned DTC where the patient will continue TB treatment
- DTO of the concerned district will ensure reconstitution of Patient Wise Box by replacing Rifampicin with Rifabutin and mobilise it to the DOT Centre through the concerned TU and PHI; the same to be recorded in TB treatment card and TB register (Remarks)
- Senior DRTB HIV supervisor/MOTC/STS/MOPHI to train the DOT provider and supervise.

Timing of referral to ART Centre

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

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

Process at ART Centre

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

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

3. The ART Centre Staff Nurses are to record the patient in the **"ART Centre TB-HIV Register" (Annex 22)**, and include information on whether or not ART was initiated.

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

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

Mechanism for feedback from ART centres to the referring physician:

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

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

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

At the PHI, the initiation on ART should be recorded on the original TB treatment card with the date of ART initiation and ART registration number. If the HIV-infected TB patient is not been initiated on ART after their initial referral, s/he should be again referred to the ART centre after completion of TB treatment for ART re-evaluation, and for continuation of CPT.

4.1.6 Immune reconstitution inflammatory syndrome (IRIS): This is a spectrum of clinical signs and symptoms resulting from the body's ability to mount an inflammatory response associated with immune recovery. Antiretroviral therapy partially restores immune defects caused by chronic HIV infection, including the restoration of protective pathogen-specific immune responses. The protective response sometimes causes (atypical) inflammatory manifestations to concurrent infective or non-infective conditions, e.g. TB, MAC or CMV. Clinically, IRIS manifests itself as the occurrence or worsening of clinical and/or laboratory parameters, despite a favourableCD4 count (and viral load). The temporal association between the commencement of HAART (or change from a previously failing regimen) and the development of an unusual clinical phenomenon often provides a strong clue

to the diagnosis of IRIS.

Experience has shown IRIS can manifest itself in a variety of ways. **In India, the agreed practical definition of IRIS would be the "occurrence or manifestations of new OIs or existing OIs within six weeks to six months after initialing ART; with an increase in CD4 count".**

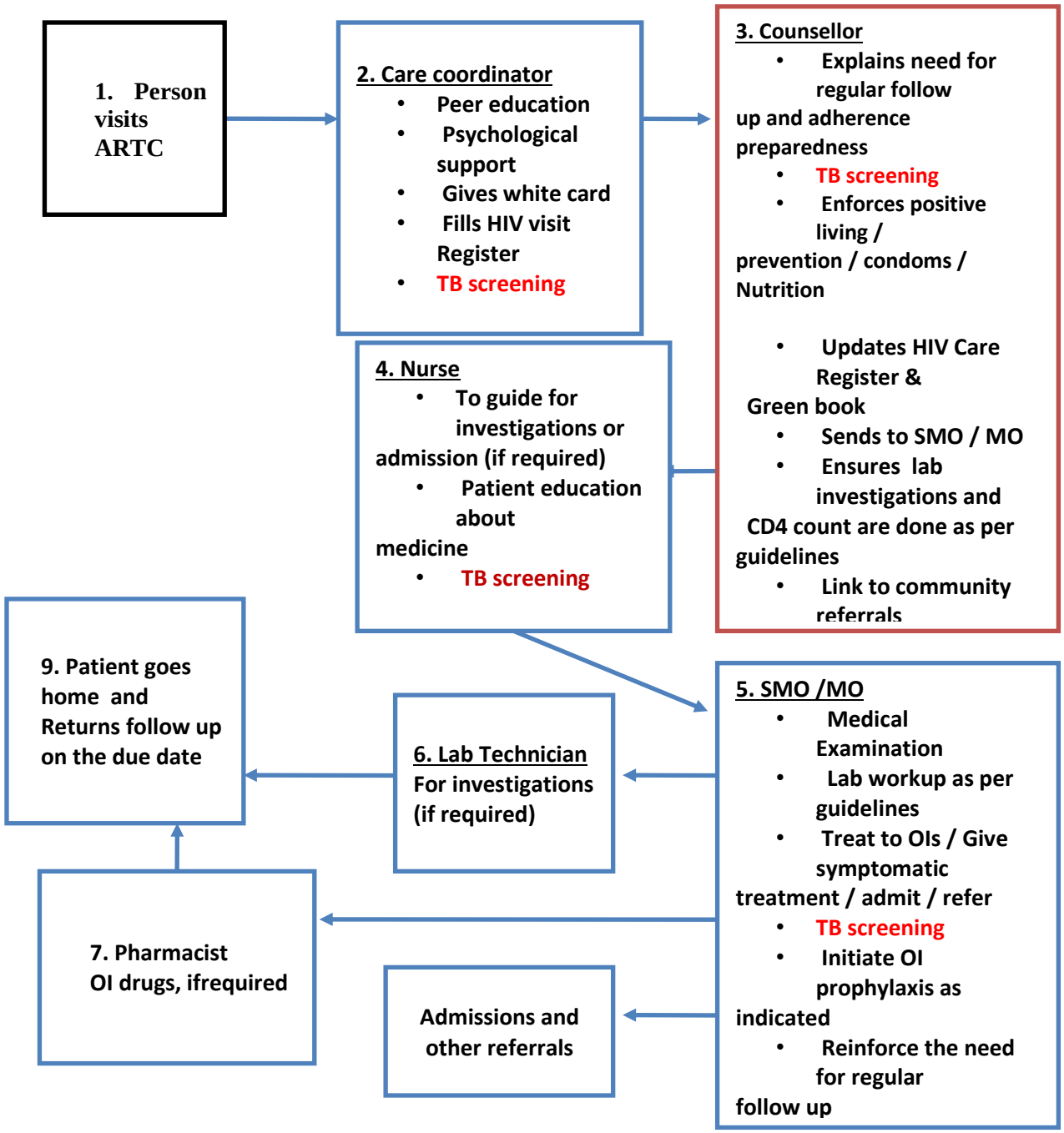


Figure 5.3: Patient Flow in the ART centre "Pre-ART" subsequent visits

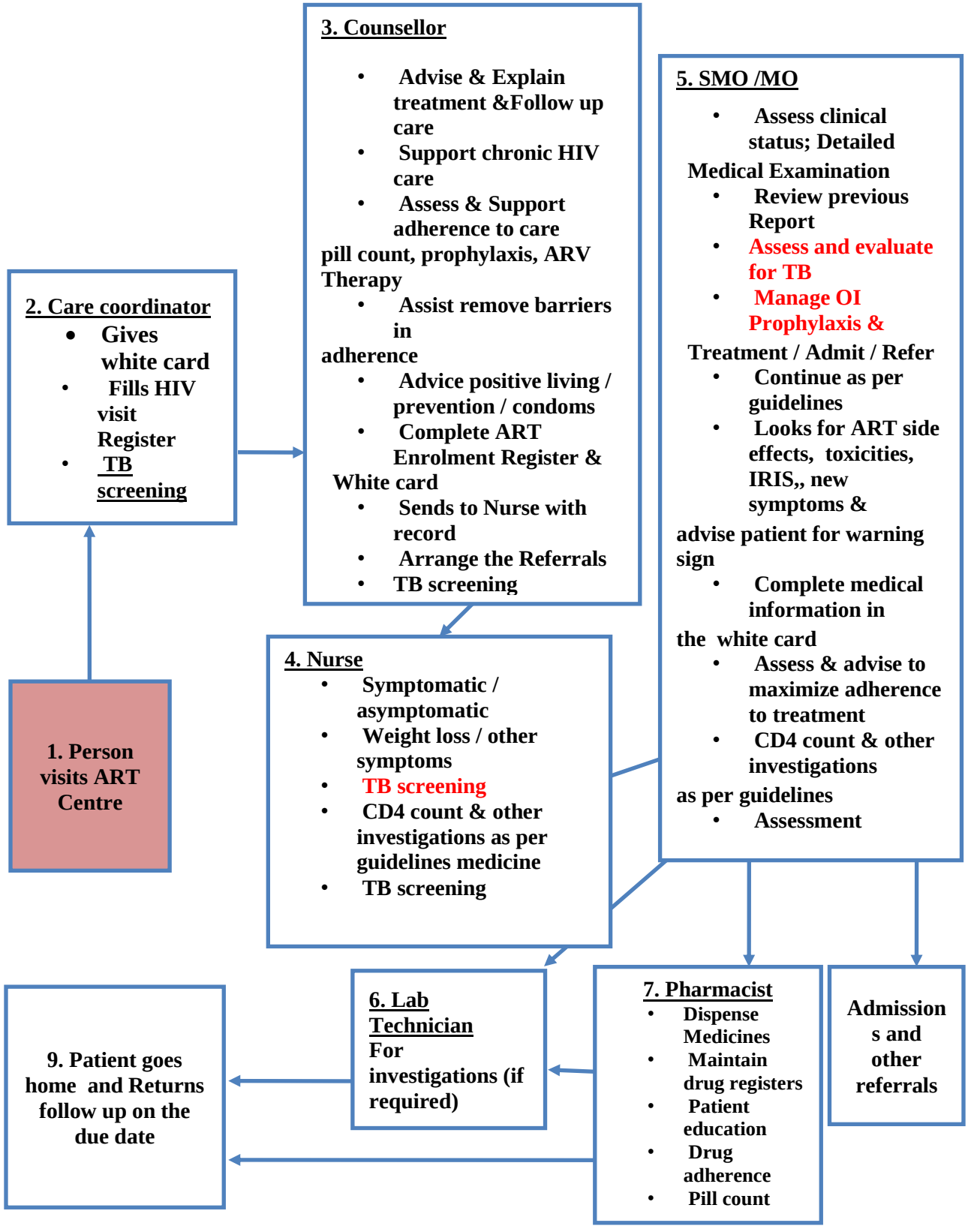


Figure 5.4: Patient Flow at ART centre for patients "onART"

KEY POINTS

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

What should providers and paramedical staff do?

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

What should programme officers know?

- Ensure that all the staff are trained in Intensified TB/HIV package
- Ensure uninterrupted supply of referral forms and CPT pouches.
- Ensure that the ICTCs are functional and conveniently located (Counselors and LTs in place and trained; uninterrupted supply of testing kits and consumables)
- CPT should be stocked at PHIs, and indented from the TU/DTC as per consumption, in a similar manner as with RNTCP Prolongation Pouch.
- HIV status and CPT/ART information will be recorded on TB treatment cards, TB registers, and for the cohort will be reported on quarterly reports.

- Supervision of the recording of HIV status and updating of CPT and ART information on TB treatment cards must be included in routine monitoring and supervision activities.

4.2. Treatment of TB

Goal of TB Treatment

The goals of Tuberculosis treatment are:

- To decrease case fatality and morbidity by ensuring relapse free cure
- To minimize and prevent development of drug resistance
- To render patient non-infectious , break the chain of transmission and to decrease the pool of infection

Case definitions

Bacteriological confirmed TB case (Definitive TB Case) refers to a presumptive TB patient from whom a biological specimen is positive for acid fast bacilli, or positive for Mycobacterium tuberculosis on culture, or positive for tuberculosis through Quality Assured Rapid Diagnostic molecular test.

Clinically diagnosed TB case (probable TB) refers to a presumptive TB patient who is not bacteriologically confirmed, but has been diagnosed with active TB by a clinician on the basis of X-ray abnormalities, histopathology or clinical signs with a decision to treat the patient with a full course of Anti-TB treatment.

Bacteriologically confirmed or clinically diagnosed cases of TB are also classified according to:

- anatomical site of disease;
- history of previous treatment;
- drug resistance;

Classification based on anatomical site of disease

Pulmonary tuberculosis (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheo-bronchial tree eg.

Extra Pulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs such as pleura, lymph nodes, intestine, genitourinary tract, joint and bones, meninges of the brain etc., is called as extra-pulmonary TB

Milliary TB is classified as PTB because there are lesions in the lungs. A patient with both pulmonary and extra pulmonary TB should be classified as a case of PTB.

Classification based on history of previous TB treatment

New case

A TB patient who has never had treatment for TB or has taken anti-TB drugs for less than one month is considered as a new case.

Previously treated patients have received 1 month or more of anti-TB drugs in the past.

Recurrent TB case

A TB Patient previously declared as successfully treated (cured/treatment completed) and is subsequently found to be bacteriologically confirmed TB case is a recurrent TB case.

After Treatment failure patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.

Treatment after loss to follow-up patients has previously been treated for TB and was declared lost to follow-up at the end of their most recent course of treatment

Other previously treated patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

Transferred In: A TB patient who is received for treatment in a Tuberculosis Unit, after registered for treatment in another TB unit is considered as a case of transferred in.

Classification based on drug resistance

Mono resistance: ATB patient, whose biological specimen is resistance to one first-line anti-TB drug only

Poly drug resistance: ATB patient, whose biological specimen is resistance to more than one first-line anti-TB drug (other than both isoniazid and rifampicin).

MDR TB case: A TB patient, whose biological specimen is resistant to both isoniazid and rifampicin with or without resistance to other first line drugs, based on the results from a quality assured laboratory.

> **Rifampicin resistance (RR):** resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs.

Rifampicin Resistant TB not be defined independent from MDR TB and recommended its inclusion in the definition of MDR TB

XDR TB Case An MDR TB case whose recovered M. tuberculosis isolate is additionally resistant to a fluoroquinolone (ofloxacin, levofloxacin, or moxifloxacin) and a second-line injectable anti TB drug (kanamycin, amikacin, or capreomycin) at a quality assured Laboratory

Probable Peadiatric TB is a case diagnosed based on the presence of abnormalities consistent with TB on radiography, a history of exposure to an infectious case, evidence of TB infection (positive TST) and clinical findings suggestive of TB in children in event of negative or unavailable microbiological results.

Treatment regimen

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
Drug Sensitive TB		
New	(2) HRZE	(4) HRE
Previously treated	(2) HRZES + (1) HRZE	(5) HRE
Drug Resistant TB		
MDR TB	(6-9) Km LvxEto Cs Z E	18 LvxEto Cs E
XDR TB	(6-12) Cm, PAS, Mfx, High dose- H, Cfz, Lzd, Amx/Clv	(18) PAS, Mfx, High dose- H, Cfz, Lzd, Amx/Clv

For drug sensitive TB patients, duration of CP should be extended by 12 weeks (3 months) in special situations like Bone & Joint TB, Spinal TB with neurological involvement and neuro-tuberculosis. Extension beyond 3 months should only be on recommendation of experts of the concerned field. Extension of intensive phase will no longer be required. Loose Drugs would be needed as substitutions and with co-morbid conditions
Reserve/Substitute drugs for MDR-TB : PAS, Mfx,Cm
Reserve/Substitute drugs for XDR-TB : Clarithromycin, Thiacetazone

Drug Dosage for Adult TB

Weight category	Number of tablets		Inj. Streptomycin
	Intensive phase	Continuation phase	
	HRZE	HRE	
	75/150/400/275	75/150/275	gm
25-39 kg	2	2	0.5
40-54 kg	3	3	0.75
55-69 kg	4	4	1
≥70	5	5	1

Inj. Streptomycin to be added in IP phase for 2 months in the retreatment regimen of drug sensitive patients. In patients above 50 years of age, maximum dose of streptomycin should be 0.75gm and dose should be reduced by 0.25 gm in each weight band.

Drug Dosage for pediatric TB[1]

Weight category	Number of tablets (dispersible)			Inj. Streptomycin
	Intensive phase		Continuation phase	
	HRZ	E	HRE	
	50/75/150	100	50/75/100	mg
4-7 kg	1	1	1	100
8-11 kg	2	2	2	150
12-15 kg	3	3	3	200
16-24 kg	4	4	4	300
25-29 kg	3 + 1A*	3	3 + 1A*	400
30-39 kg	2 + 2A*	2	2 + 2A*	500

****A=Adult FDC (HRZE = 75/150/400/275; HRE = 75/150/275)***

Dosage for MDR-TB

S.No	Drugs	16-25 Kgs	26-45 Kgs	46-70 Kgs	>70 Kgs
1	Kanamycin	500 mg	500 mg	750 mg	1000 mm
2	Levofloxacin	250 mg	750 mg	1000 mg	1000 mg
3	Ethionamide	375 mg	500 mg	750 mg	1000 mg
4	Ethambutol	400 mg	800 mg	1200 mg	1600 mg
5	Pyrazinamide	500 mg	1250 mg	1500 mg	2000 mg
6	Cycloserine	250 mg	500 mg	750 mg	1000 mg
7	Pyridoxine	50 mg	100mg	100mg	100 mg
	Na-PAS (80% weight/vol)[2] Moxifloxacin (Mfx) Capreomycin (Cm)	5 gm 200 mg 500 mg	10 gm 400 mg 750 mg	12 gm 400 mg 1000 mg	12 gm 400 mg 1000 mg

In case of PAS with 60% weight/volume the dose will be increased to 7 gm (16-25 Kg); 14 gm (26-45 Kg) and 16 gm (> 45 Kg)

[1]Daily regimen formulation not yet available.. Till the time children will receive the intermittent regimen as per RNTCP guideline

Dosage for MDR-TB in pediatric age group (less than 16 kg body weight)

Drug	Daily Dose – mg/kg body weight
Kanamycin / Capreomycin	15-20 mg/kg
Levofloxacin / Moxifloxacin	7.5-10 mg/kg
Ethionamide	15-20 mg/kg
Cycloserine	15-20 mg/kg
Ethambutol	25 mg/kg
Pyrazinamide	30-40 mg/kg
(Na-PAS)	150 mg/kg

Drug dosage for XDR TB patients

Drugs	Dosage/day	
	≤ 45 Kgs	**> 45 Kgs**
Inj. Capreomycin (Cm)	750 mg	1000 mg
PAS	10 gm	12 gm
Moxifloxacin (Mfx)	400 mg	400 mg
High dose INH (High dose-H)	600 mg	900 mg
Clofazimine (Cfz)	200 mg	200 mg
Linezolid (Lzd)	600 mg	600 mg
Amoxyclav(Amx/Clv)	875/125 mg BD	875/125 mg BD
Pyridoxine	100 mg	100 mg
Reserve/Substitute drugs		
Clarithromycin (Clr)	500 mg BD	500 mg BD
Thiacetazone (Thz)[#]	150 mg	150 mg

Depending on availability, not to be given to HIV positive cases

Operational guidelines for treatment initiation:

By suspecting TB in a patient, the clinician assumes an important role of providing complete care to the patient including long-term relapse free cure from TB. S/he also assumes an important public health responsibility of preventing the transmission of disease. If the clinician is waiting passively for the patient to report with the result of diagnostic test, it may cause significant delay in initiation of treatment or the patient may be lost to follow up. Hence clinicians who refer the presumptive TB/ drug resistant TB case for diagnosis is encouraged to actively trace the patients. Health facilities that diagnose patients who do not reside in their service delivery area have to refer the patient to the facility where the patient would undergo monitoring of treatment.

All TB patients are to be offered quality assured anti-TB drugs. Treatment should be initiated by a trained medical officer. In most of the situations, treatment process may be initiated in the peripheral health institution which caters to the patient's residential area. In special circumstances, patients may have to be initiated on treatment in institutions outside their residential areas eg. patient admitted in medical college hospital.

The information required for treatment initiation of TB patients are drug sensitivity pattern and history of anti-TB treatment. Based on it, decision on treatment to be taken as follows:

History of treatment	Drug sensitivity status	Type of regimen
New	Drug sensitive or DST unknown / awaited	Regimen for new case
Previously treated	Drug sensitive or DST unknown* / awaited	Regimen for previously treated case
New or previously treated	Drug resistant	Regimen based on DST pattern (regimen for MDR / XDR case)

*If DST is unknown, the patient should be offered DST based on current criteria of presumptive DR-TB patient. Four sets of drug sensitivity patterns may be offered based on availability of DST services.

-Rifampicin alone, where a CBNAAT is used for diagnosis.

-Isoniazid and Rifampicin where a LPA is used for diagnosis.

-A detailed first line pattern with Isoniazid, Rifampicin, Ethambutol and Streptomycin if a first line liquid DST is used.

-A second line DST pattern for second line drugs may be available

The medical officer should record the weight of the patient. It is ideal to record the height also, to assess the Body Mass Index (BMI), which would provide a good indicator for prognosis of the disease. The patients should be given dosages depending on body weight in weight bands.

The medical officer of peripheral health facility can initiate treatment based on abovementioned information. However, all DR-TB patients should be treated with active involvement of DR-TB centre.

Pre-treatment evaluation for DR-TB patients

Since the second line anti-tuberculosis drugs are known to produce adverse effects, a proper pre-treatment evaluation is essential for each DR-TB patients (Rifampicin resistant / mono-/poly-resistant TB / MDR / XDR) to identify those who are not fit to consume drugs to be used in regimen of treatment. For pre-treatment evaluation, a patient needs to be referred to appropriate health facilities where clinical competency to carry out such assessment. The pre-treatment evaluation includes a thorough clinical evaluation by a physician, chest radiograph, and relevant hematological and bio-chemical tests detailed in the box below.

Pre-treatment evaluation

1. Detailed history (including screening for mental illness, drug/alcohol abuse etc.)
2. Weight
3. Height
4. Complete Blood Count with platelets count
5. Blood sugar to screen for Diabetes Mellitus
6. Liver Function Tests
7. Blood Urea and S. Creatinine to assess the Kidney function
8. TSH levels to assess the thyroid function (TSH levels alone are usually sufficient to assess the thyroid function of the patient)
9. Urine examination – Routine and Microscopic
10. Pregnancy test (for all women in the child bearing age group)
11. Chest X-Ray
12. ECG (if Moxiflocaxin is to be used)
13. Serum electrolytes (if Capreomycin is to be used)

- All MDR-TB cases will be offered referral for HIV counselling and testing at the nearest centre if the HIV status is not known or the HIV test is found negative with results more than 6 months old. If patient is HIV positive refer her/him to ART centre (if not on ART)
- All patients of M/XDR-TB should be evaluated for surgery at the initiation of treatment and/or during follow up.
- Preferably, pre-treatment evaluation should be carried out at DR-TB centre where DR-TB committee with group of experts are available. In this case, the patient should be referred to the DR TB center for admission & initiation of treatment with their DST result and referral for treatment form. Alternatively, district TB Officer can arrange pre-treatment evaluation at district level linked DR-TB centre or even at sub-district level health facility, in case the patient is unable to get hospitalized and to avoid any delay in initiation of treatment. In such case, the results of pre-treatment evaluation are communicated to DR-TB Centre Committee and on approval; the regimen for DR-TB can be initiated at the DTC.

Before initiating the treatment, all the TB patients should be counselled thoroughly. It is advisable to involve close family members during the counselling, since family support is an essential component in the management. Educate the patient and family members about the disease (type of disease and mode of spread) and the treatment (dosage schedule, duration, common side effects and methods to prevent them). Counsel the patient and family members to ensure treatment adherence (importance of need for regular treatment and consequences of irregular treatment or premature cessation of treatment, monitoring of progress until completion of treatment). Explain patients on prevention of transmission of disease (cover cough, proper disposal of sputum) and encourage him/her to get all his/her close contacts (especially household contacts) screened at the earliest.

Child contacts under 6 years who are contact of pulmonary TB patients have to be screened for TB and those without TB should be offered INH preventive treatment. It is also important to look for co-morbidities like diabetes, liver or renal diseases, neurological disorders etc.It is also important to look for substance abuse especially Tobacco (in any form) & alcohol. Socioeconomic status of the patient may be assessed to link him/her with appropriate treatment support schemes.

Medical Officer needs to open a treatment card (in duplicate when required) for each patient at the time of initiation of treatment. Each patient should be given TB Identity Card. Drugs either patient-wise box / FDC strips should be made available at the DOT Centre/ treatment centre along with the TB treatment Card. Appropriate treatment adherence and monitoring mechanisms [i.e. DOT (Family/Community/institutional) or other (as described in treatment adherence section)] should be planned by the MO at the time of treatment initiation in consultation with the patient and the peripheral health worker who is responsible for monitoring treatment adherence. Assure the patient that s/he will be supported during the entire course of treatment by the MO and peripheral health care workers.

Details of every patient initiated on treatment must be updated in NIKSHAY. If the patient has not been registered in NIKSHAY at the time of suspecting TB /referral for diagnosis/examination at the diagnostic centre, s/he may be registered/ notified afresh. Look for a NIKSHAY ID for the patient who has already been registered. If not available, registering/notifying afresh will generate a new ID. This ID is unique and is important for further follow up and linkages with treatment support programs. All health establishments must report all TB cases and their treatment outcomes to public health authorities (District Nodal Officer for Notification).

Treatment support program

Adherence to regular and complete treatment is the key to relapse free cure from TB. To assess and foster adherence, a patient-centered approach to administration of drug treatment, based on the patient’s needs and mutual respect between the patient and the provider, should be developed for all patients. A good treatment support plan should be developed at the time of initiation of treatment. This plan should include initial and frequent follow-up counselling of the patient and family members, supervision of treatment by a trained health worker including community volunteers, locally managed additional nutritional support, retrieval of treatment interrupters, screening for adverse reactions, psycho-social support, co-morbidity management and follow up laboratory investigations.

Direct observation of treatment is one of the best practices to promote adherence. It ensures that the patient consumes every dose of the treatment at least during the intensive phase (and one third of continuation phase doses) before a trained health worker and provides additional opportunity to support treatment. However, the principle of direct observation is to be applied logically and judiciously. A treatment supporter (a health worker or community volunteer) who is acceptable, accessible and accountable to the patient and to the health system should be identified and trained. A health worker in the hospital/health centre may be the best person to provide all the envisaged components of treatment support program. However, access to such a health worker in person, place and time may be limited since the centre may be far away from patient's residence, working hours may be restricted and the worker may be away on field visits. Compelling the patient to travel long distance to avail directly observed treatment is against the principles of patient centric approach. Hence, all efforts must be put in to find a treatment supporter close to the patient's residence. Accumulating evidence has pointed to the effectiveness of a wide variety of approaches including community and family-centered DOTS, which is more achievable for most developing healthcare systems and produce comparable outcomes to healthcare worker supervised DOTS. Wherever appropriate, an adult family member can also be assigned with the responsibility of observing treatment. Such situations may arise with children, women, sick and bed-ridden patients, long-day workers etc. In such situations, the family member who is assigned with the responsibility to observe treatment should be trained well and supported during the process by a health worker by frequent visits to the house. Each patient and his/her treatment supporter should be supervised by a health worker. It may be a peripheral health worker in the public health system. If the patient is initiated on treatment by a private health care provider, public health system may offer this supportive role when requested.

While observing treatment is one of the best modalities of promoting treatment, other modalities also may be deployed to further enhance adherence to treatment. Intelligent deployment of information communication technologies (ICT) is an example of such modalities.

A patient who is unable to undergo supervised treatment should not be denied treatment. Frequent on-job travelers, truck drivers, sailors etc may require self-administered treatment. To promote treatment adherence among these patients, ICT modalities like frequent phone calls, SMS reminders, IVRS etc. may be deployed.

Treatment support program is not restricted to observation of treatment alone. Patient may require mobility support if s/he prefers observation of treatment outside his residence. Supplementary nutrition, ancillary drugs, co-morbidity management, compensation for lost wages etc. are some other requirements. Counselling may be required to quit substance abuse. To avail these, patient has to be linked to appropriate social support schemes like RSBY, TB pension schemes, CSR initiatives, counselling centres etc. Linkages for extra nutritional support for TB patients or of his/her contacts on IPT may be explored with existing govt schemes like PDS or Food security act. Compensation may be provided for transport costs incurred by the patient for sending follow up sputum samples in case of DR TB . Similar compensation may be given to TB HIV patients for visits to ART centers. If required, linkages with various social support systems to be explored and ensured, for additional treatment support. Capacity building and engaging with local community based organizations, self-help groups, patient support groups, PRI could prove to be effective intervention to promote treatment adherence.

Box: Choices for Treatment adherence

The treating doctor/counsellor/ health care provider etc. has to provide the cafeteria of options to the patients under which s/he can take the treatment. The existing system of treatment provision can be utilized for providing daily regimen to the patients.

If DOT is the preferred by the patient, then s/he should be provided with a list of trained DOT providers, and s/he should be assisted to select an acceptable and accessible DOT provider. Convenient location for provision of DOT has to be identified mutually by the patient and the DOT Provider

For the patients who are willing to take treatment under supervision of any adult family member, the patient and the treatment supporter have to be counseled about the disease, treatment and importance of regular uninterrupted treatment.

In settings where in the patient cannot be supervised/ supported by anyone and s/he opts to self-administer the treatment, the patient has to be advised in detail about the condition and a mechanism for timely feedback about the progress of the treatment has to be agreed upon.

"99 DOT"which is a mechanism to ICT supported self-reporting of treatment adherence. In this mechanism, each time a patient takes a dose of medication, a hidden number appears which is printed on the strip behind the drug. The patient need to send a missed call to a particular contact number with the digits appeared on drug package. This will be documented at a centralized ICT unit. And thus, an electronic treatment record of each patient will be maintained to monitor the treatment adherence.

Similarly, patients may be given the options such as giving a missed call on a toll-free number with an inbuilt check mechanism. Patients send a **missed call** to phone number after ingesting each dose from a pre-printed blister pack with hidden numbers behind selected pills. Because the sequence of hidden numbers cannot be predicted by patients, but are known by the system for each month of medication prescribed, the system offers high confidence that patients who respond correctly have indeed dispensed their medication.

S/he can also be providing the option of where in the patients treatment would be remotely followed up with help of Interactive Voice Response (**IVR**), **SMS** reminders.

Specially designed **electronic pill boxes** or strips with GSM connection and pressure sensor can be used to monitor the pill consumption by tracking the weight of the remaining pills.

The treatment provider can use the **Patient Compliance toolkit;** a mobile app for patients to report treatment compliance using video, audio or text message.

Automated pill loading system, which will load the dosage as per the pre-programmed settings. Medication dispenser: a color-coded reminder system built in the dispenser that will hold drugs.

Treating doctors can be provided with **innovatively designed cards** to educate them on correct TB prescription methods. Doctors will then give these cards to TB patients, instructing them to SMS the server/ customer care centre (CCC) the unique code on the card which will register them on the network and also SMS the unique codes printed on their TB drugs as they take them. The CCC will then deliver phone interventions like reminders to take medicines, financial incentives, follow up calls, and TB health tips via SMS and phone balance recharge, mobile APP for scheduled dose reminders and alerts.

A Short Messaging service **(SMS) gateway** to be made available by which the patient can report day to day events like pill consumption, minor side effects or his need for help through simple and shortcut SMS templates. The gateway can allow incoming services in pre-recorded or Interactive Voice Response (IVR) mode to inform patients about their test results, as follow up reminders and as periodic counselling messages.

Follow up of Treatment

Patients should be followed up closely to ensure the treatment progresses well and the disease responds to treatment. There are two components of follow up. (1) Clinical follow up by a medical officer (2) Laboratory follow up

1. Clinical follow up should be done at least monthly. Patient may visit the clinical facility for reviews or the medical officer may conduct the review when he visits the house of the patient.

Improvement on chest symptoms, increase in weight etc. may indicate good prognosis. Control of co-morbid conditions like HIV and diabetes by appropriate treatment is essential for getting a better prognosis to TB treatment. Symptoms and signs of adverse reactions to drugs should be specifically asked. Detailed description of symptoms and signs of adverse reaction to anti-TB drugs and pharmacovigilance program is described elsewhere in this document.

2. Laboratory investigations may be those to assess the prognosis of the disease or to manage co-morbidities or adverse reaction. In case of pulmonary tuberculosis, sputum smear microscopy should be done at the end of IP and end of treatment. A negative sputum smear microscopy result at the end of IP may indicate good prognosis. However, in the presence of clinical deterioration, the medical officer may consider repeating sputum smear microscopy even during CP. This will provide the patient an early opportunity to undergo drug susceptibility testing if s/he is found to be sputum smear positive.

Chest x-ray may be a good tool to assess the progress and it is to be offered to drug sensitive pulmonary TB patients whenever required and available. For drug resistant TB patients, it is to be carried out at end of IP, at end of treatment and whenever required.

Response to treatment in extra pulmonary TB may be best assessed clinically. Help of radiological and other relevant investigations may be taken.

Response to treatment in children: In children in their early ages are unable to produce sputum, the response to treatment among them may be assessed clinically. The help of radiological and other relevant investigations may also be taken.

Long term follow up: After completion of treatment, the patients should be followed up with clinical and/or sputum examination at the end of six and 12 months. In presence of any clinical symptoms and/or cough, sputum smear/culture should be considered. This is important in detecting recurrence of TB at the earliest.

Contact investigation

- All close contacts, especially household contacts should be screened for TB.
- In case of paediatric TB patients, **reverse contact tracing** for search of any active TB case in the household of the child must be undertaken.
- All close contacts of DR-TB cases should be identified through contact tracing and evaluated for active TB disease as per RNTCP guidelines. If the contact is found to be suffering from pulmonary TB disease irrespective of the Smear results, he/she will be identified as a "Presumptive MDR-TB case". The patient will be initiated on Regimen for new or previously treated case based on their history of previous anti-TB treatment. Simultaneously, two sputum samples will be transported for culture and DST to a RNTCP-certified C&DST laboratory.

INH chemoprophylaxis:

Children are more susceptible to TB infection, more likely to develop active TB disease soon after infection, and more likely to develop severe forms of disseminated TB. Children <6 years of age, who are close contacts of a TB patient, should be evaluated for active TB by a medical officer/paediatrician. After excluding active TB he/she, should be treated with isoniazid (10 mg/kg body weight) for a minimum period of six months to be collected monthly. The contacts should be closely monitored for TB symptoms.

Close contacts of index cases with proven DR-TB should be monitored closely for signs and symptoms of active TB as isoniazid may not be prophylactic in these cases. Although alternative prophylaxis treatments have been suggested, there is no consensus regarding the choice of the drug(s) and the duration of treatment. Prompt treatment of MDR-TB is the most effective way of preventing the spread of infection to others. The following measures should be taken to prevent spread of DR-TB infection:

1. Early diagnosis and appropriate treatment of MDR-TB cases;
2. Screening of contacts as per RNTCP guidelines
3. Further research into effective and non-toxic chemoprophylaxis in areas of high MDR-TB prevalence.

Side effects (Pharmacovigilance)

Adverse Reactions to Anti-TB drugs

Adverse Drug Reactions (ADR) observed during treatment for tuberculosis are comparatively less. Trivial side effects may lead to reduced compliance with treatment. DOT providers should be aware of the commonly occurring adverse reactions so that they can identifyit promptly and refer the patient to the medical officer for further management. Any adverse reactions reported during treatment are recorded in the remarks column of the treatment card. Orange / red discoloration of the body fluids especially urine, which is commonly encountered, is not an adverse reaction and patient should be made aware of this.

Symptom	Drug	Action to be taken by HW	Action to be taken by MO
Gastrointestinal(vomiting Or epigastric *discomfort)*	(abbreviation) Any oral medication	Reassure patient. Give drugs with less water and over a longer period (e.g. 20 minutes). Do not give drugs on an empty stomach If the above fails, refer to MO	• Maintain hydration. • Consider treatment with anti-emetics (e.g. domperidone) and proton pump inhibitors (eg. Omeprazole)
Itching/Rashes	Isoniazid (and other drugs also)	Reassure patient If severe, stop all drugs and refer patient to MO	Itching without rash or a mild rash • Continue treatment and give antihistamines • Itching with moderate to severe rash
			• Stop all drugs till Symptoms subside • Treat with antihistamines • Patients with mucosal involvement, fever and hypotension will require treatment with corticosteroids • When the reaction subsides, reintroduce drugs one by one in

			this order INH. Rifampicin Pyrazinamide Ethambutol • Re-introduce each drug in a small dose and gradually increase over 3 days before introducing the next drug.
Tingling / burning / numbness in the hands and Feet	Isoniazid	Refer to MO	• Give pyridoxine 100 mg/day orally or parenterally until symptoms subside. • Patients not responding to pyridoxine will require treatment with amitryptiline
Joint pains	Pyrazinamide	Reassure that it is a self-limiting condition. Encourage patients to increase intake of liquids. If severe, refer patient to MO for evaluation	• Give NSAIDs like paracetamol, Aspirin or ibuprofen and in severe cases Indomethacin for a week to 10 days • In severe cases estimate serum uric acid levels o If uric acid levels. Are significantly Raised treat with NSAIDs andcolchicine. All opurinolis not effective • In severe cases with normal or slightly elevated uric acid consider reduction of the dose of
Impaired Vision	Ethambutol	STOP Ethambutol, refer patient for evaluation	• Refer to ophthalmologist for evaluation • Impaired vision usually returns to normal within a few weeks of stopping ethambutol.
Ringing in the ears	Streptomycin	STOP Streptomycin,	• Refer to otorhinolaryngolo gist

Loss of hearing Dizziness and loss of balance		refer patient for evaluation	for opinion • As hearing loss is usually not reversible do not restart Streptomycin
Hepatitis: Anorexia / Nausia / vomiting / Jaundice	Isoniazid, Rifampicin or Pyrazinamide	STOP all drugs, anti TB drugs, Refer patient for evaluation	Rule out other causes of hepatitis. Do not restart treatment till symptoms resolve and liver enzymes return to baseline levels. If liver enzymes cannot be, performed wait for 2 weeks after Jaundice has appeared to restart treatment.

Table 6.2: Symptom-based approach to evaluation of possible side effects of anti-TB drugs

- If liver enzymes cannot be performed wait for 2 weeks after jaundice has disappeared to restart treatment
- Restart treatment with one drug at a time starting with Rifampicin INH Pyrazinamide.
- In patients with severe disease in whom treatment cannot be stopped use a non-hepatotoxic regimen consisting of Streptomycin and Ethambutol

Information on identification and management of adverse drug reactions when patients are treated for M/XDR TB is provided in annexure.

In cases of jaundice, all anti-TB drugs should be stopped immediately and the patient referred for evaluation.

Treatment in special situations

TB in Pregnant and breastfeeding women

Before initiating treatment for tuberculosis, women of childbearing age should be asked about current or planned pregnancy and counseled appropriately. A successful treatment of TB is important for successful outcome of pregnancy. With the exception of streptomycin, the first line anti-TB drugs are safe for use in pregnancy. Streptomycin is ototoxic to the fetus and should not be used during pregnancy.

A breastfeeding woman should receive a full course of TB treatment. Correct chemotherapy is the best way to prevent transmission of TB to baby. Breast feeding has to be continued. After ruling out active TB, the baby should be given 6 months of isoniazid preventive therapy, followed by BCG vaccination. Breast-feeding should not be discouraged. The mother should be advised about cough hygiene measures such as covering the nose and mouth while coughing, sneezing or any act, which can produce sputum droplets.

Pyridoxine supplementation is recommended for all pregnant or breastfeeding women taking isoniazid.

TB and Contraceptive pills usage

As Rifampicin is a potent inducer of hepatic enzymes, the protective efficacy of oral contraceptive pills may be decreased. Such women suffering from TB and using contraceptive pills should be advised either to use some alternative anti-contraception method.

Oral contraceptives might have decreased efficacy due to vomiting and drug interactions with second line anti-TB drugs. Thus for prevention of pregnancy the use of barrier methods (Condoms/diaphragms), IUDs (CuT) or depot-medroxyprogesterone (Depo-provera) are recommended based on individual preference and eligibility.

DR-TB in pregnancy

Teratogenicity has been demonstrated with only some of the drugs used to treat MDR-TB. Women of childbearing age identified as MDR TB suspects should be advised to use a reliable and appropriate contraceptive method until the results of culture and DST are available. In addition, if a woman is diagnosed with DR-TB and receiving second line treatment, she should be intensively counselled to use birth control measures because of the potential risk to both mother and foetus. All women of childbearing age should be tested for pregnancy as part of the pre-treatment evaluation and whilst on treatment if there is a history of amenorrhea of any duration. MDR-TB patients found to be pregnant prior to treatment initiation or whilst on treatment are evaluated in consultation with a Gynaecologist/Obstetrician taking into consideration the following factors:

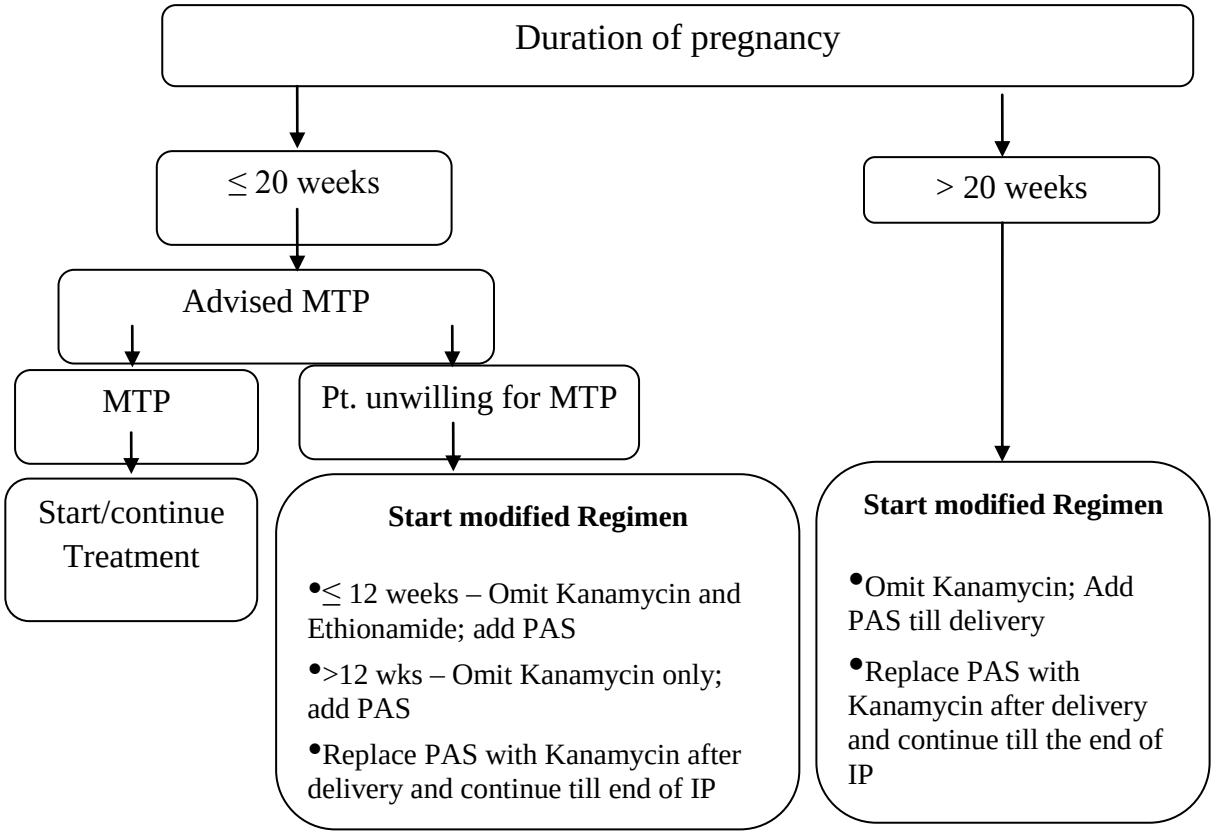
- Risks and benefits of MDR-TB treatment
- Severity of the MDR-TB
- Gestational age
- Potential risk to the foetus

Further management of MDR-TB patients who are pregnant prior to initiation of treatment or whilst on treatment are based on the duration of pregnancy.

- If the duration of pregnancy is <20 weeks, the patient should be advised to opt for a Medical Termination of Pregnancy (MTP) in view of the potential severe risk to both the mother and foetus. If the patient is willing, she should be referred to a Gynaecologist/Obstetrician for MTP following which treatment can be initiated (if the patient has not started treatment) or continued (if the patient is already on treatment) by the DR-TB Centre Committee.
- For patients who are unwilling for MTP or have pregnancy of >20 weeks (making them ineligible for MTP), the risk to the mother and foetus needs to be explained clearly and a modified Regimen for MDR TB should be started as detailed below:
  - For patients in the first trimester (⩽ 12 weeks), Kanamycin and Ethionamide are omitted from the regimen and PAS is added.
  - For patients who have completed the first trimester (>12 weeks), Kanamycin is replaced with PAS. Post partum, PAS may be replaced with Kanamycin and continued until the end of the Intensive Phase.

Pregnant MDR-TB patients need to be monitored carefully both in relation to the treatment and the progress of the pregnancy. This approach should lead to good results, since the patient should be smear-negative at the time of parturition, and mother and infant do not need to be separated. Breast-feeding should be encouraged as long as the patient is sputum negative.

The management of MDR-TB patients with pregnancy is summarised in the flow chart:



Management of TB in patients with liver disorders

Patients with hepatitis virus carriage, a past history of acute hepatitis, current excessive alcohol consumption can receive the usual TB regimens provided that there is no clinical evidence of chronic liver disease. However, hepatotoxic reactions to anti-TB drugs may be more common among these patients and should therefore be anticipated. In patients with unstable or advanced liver disease, liver function tests should be done at the start of treatment. If the liver disorder is severe, lesser hepatotoxic drugs have to be used. Expert consultation is advisable in treating patients with advanced or unstable liver disease. Clinical monitoring (and liver function tests, if possible) of all patients with pre-existing liver disease should be performed during treatment. If

the serum alanine aminotransferase level is more than 3 times normal before the initiation of treatment, the following regimens should be considered:

- *Two hepatotoxic drugs:*

  9 months of isoniazid and rifampicin, plus ethambutol (until or unless isoniazid susceptibility is documented);
  2 months of isoniazid, rifampicin, streptomycin and ethambutol, followed by 6 months of isoniazid and rifampicin;
  6–9 months of rifampicin, pyrazinamide and ethambutol.
- *One hepatotoxic drug:*

  2 months of isoniazid, ethambutol and streptomycin, followed by 10 months of isoniazid and ethambutol

- *No hepatotoxic drugs:*

  18–24 months of streptomycin, ethambutol and a fluoroquinolone.

DR-TB in patients with pre-existing liver disease

Pyrazinamide, PAS and Ethionamide are potentially hepatotoxic drugs. Hepatitis occurs rarely with the fluoroquinolones. The potential for hepatotoxicity is increased in elderly, alcoholics and in patients with pre-existing liver disease. In general, most of second line drugs can be safely used in presence of mild hepatic impairment, as they are relatively less hepatotoxic than the first-line drugs. However, pyrazinamide and ethionamide should be avoided in such patients.

Once a patient on second line drugs develops hepatitis, other aetiologies should also be excluded such as viral hepatitis, alcoholic hepatitis, drug induced hepatitis by non-TB drugs etc. The further management should be on the same guidelines as in non- MDR-TB patients. MDR patients having deranged liver function test (LFT) during pre-treatment evaluation should be strictly monitored through monthly LFTs while on treatment. However, routine LFT is not recommended in all cases.

TB patient with renal failure and severe renal insufficiency

The recommended initial TB treatment regimen for patients with renal failure or severe renal insufficiency is 2 months of isoniazid, rifampicin, pyrazinamide and ethambutol, followed by 4 months of isoniazid and rifampicin. Isoniazid and rifampicin are eliminated by biliary excretion, so no change in dosing is necessary. There is significant renal excretion of ethambutol and metabolites of pyrazinamide, and doses should therefore be adjusted. Three times per week, administration of these two drugs at the following doses is recommended: pyrazinamide (25 mg/kg), and ethambutol (15 mg/kg). These doses are the ones used in daily regimens. While receiving isoniazid, patients with severe renal insufficiency or failure should also be given pyridoxine in order to prevent peripheral neuropathy. Because of an increased risk of nephrotoxicity and ototoxicity, streptomycin should be avoided in patients with renal failure. If streptomycin must be used, the dosage is 15 mg/kg, two or three times per week, to a maximum of 1 gram per dose, and serum levels of the drug should be monitored.

DR-TB in patients with renal impairment

Renal insufficiency due to longstanding TB disease itself, previous use of aminoglycosides or concurrent renal disease is not uncommon. Great care should be taken in the administration of second-line drugs in patients with renal impairment. Consideration needs to be taken that MDR-TB patients require aminoglycosides for 6 months or more. Other drugs, which also might require dose or interval adjustment in presence of mild to moderate renal impairment, are Ethambutol, Quinolones, Cycloserine and PAS. In the presence of severe renal impairment, many other drugs may also require adjustments.

In patients with mild renal impairment, the dose of aminoglycosides may be reduced. In the presence of severe renal failure, the aminoglycoside therapy should be discontinued and replaced with other potent non-nephrotoxic antituberculosis drugs.

TB in patients with seizure disorders

Use of isoniazid and rifampicin may interfere with many of the antiseizure medications. Drug interactions should be checked before their use.

High dose isoniazid also carries a high risk of seizure and should be avoided in patients with active seizure disorders.

The prophylactic use of oral pyridoxine (vitamin B6) can be used in patients with seizure disorders to protect against the neurological adverse effects of isoniazid or cycloserine. The suggested prophylactic dose for at-risk patients on isoniazid is 10 to 25 mg/day and for patients on cycloserine is 25 mg of pyridoxine for every 250 mg of cycloserine daily. The optimal prophylactic dose of pyridoxine for children has not been established, nonetheless 1–2 mg/kg/day has been recommended in some reports (14) with a usual range of 10–50 mg/day for pediatric patients at risk for neurological sequel.

DR-TB in patients with seizure disorders

Some patients requiring treatment for DR-TB will have a past or present medical history of a seizure disorder. The first step in evaluating such patients is to determine whether the seizure disorder is under control and whether the patient is taking anti-seizure medication to control the disorder. If the seizures are not under control, initiation or adjustment of anti-seizure medications will be needed prior to the start of DR-TB therapy. In addition, if other underlying conditions or causes for seizures exist, they should be corrected.

Among second line drugs, Cycloserine, Ethionamide and fluoroquinolones have been associated with seizures, and hence should be used carefully amongst MDR-TB patients with history of seizures. Pyridoxine should be given with Cycloserine to prevent seizures. Cycloserine should however be avoided in patients with active seizure disorders that are not well controlled with medication. In cases where no other drug is appropriate, Cycloserinecan be given and the anti-seizure medication adjusted as needed to control the seizure disorder. The risk and benefits of using Cycloserineshould be discussed with the patient and the decision on whether to use Cycloserine are made together with the patient.

Antiepileptic drugs may have drug interactions with Cycloserine and fluoroquinolones. Hence close monitoring of serum levels of anti-epileptic drugs should be done. One should remember that TB might itself involve central nervous system and may cause

seizures. However when seizures present for the first time during anti-TB therapy, they are likely to be the result of an adverse effect of one of the anti-TB drugs.

DR-TB in patients with psychosis

For DR-TB patients with a concurrent psychiatric illness, it is advisable to have an evaluation carried out by a psychiatrist before the start of treatment for DR-TB. The initial evaluation documents any pre-existing psychiatric condition and establishes a baseline for comparison if new psychiatric symptoms develop while the patient is on treatment. Any identified psychiatric illness at the start or during treatment should be fully addressed. There is a high baseline incidence of depression and anxiety in patients with DR-TB, often connected with the chronicity and socioeconomic stress factors related to the disease. If a health care worker with psychiatric training is not available, the treating healthcare provider should document any psychiatric conditions the patient may have at the initial evaluation.

Treatment with psychiatric medication, individual counselling, and/or group therapy may be necessary to manage the patient suffering from a psychiatric condition or adverse psychiatric effect due to medication. Group therapy has been very successful in providing a supportive environment for DR-TB patients and may be helpful for patients with or without psychiatric conditions (adequate measures to prevent infection risk should be in place for the group therapy).

Fluoroquinolones and Ethionomide have been associated with psychosis. Pyridoxine prophylaxis may minimize risk of neurologic and psychiatric adverse reactions.

Cycloserine may cause severe psychosis and depression leading to suicidal tendencies. However the use of Cycloserine is not absolutely contraindicated for the psychiatric patient. Adverse effects of Cycloserine may be more prevalent in the psychiatric patient, but the benefits of using this drug often outweigh the potential higher risk of adverse effects. Close monitoring is recommended if Cycloserine is used in patients with psychiatric disorders.

If patient on Cycloserine therapy develops psychosis, anti-psychotic treatment should be started and Cycloserine therapy should be temporarily suspended. Once symptoms resolve and patient is stabilized Cycloserine therapy may be resumed. Such patients may require anti-psychotic treatment till anti-TB treatment is completed. When any patient on MDR-TB treatment develops psychosis, other aetiologies such as psycho- social stresses, depression, hypothyroidism, illicit drug and alcohol use, should also be looked for.

All healthcare workers treating drug-resistant TB should closely work with a psychiatrist and have an organized system for psychiatric emergencies. Psychiatric emergencies include psychosis, suicidal ideation, and any situation involving the patient's being a danger to him/her self or others. Mechanisms to deal with psychiatric emergencies (often inpatient psychiatric hospital admissions) should be available twenty-four hours per day. Proper infection-control measures must be taken for the smear-positive patient who requires any hospitalization.

Extension of Continuation Phase

The duration of continuation phase may be extended by 3 to 6 months in special situations like Bone & Joint TB, Spinal TB with neurological involvement and neuro- tuberculosis.

Hospitalization

The usual mode of TB treatment is domiciliary, but in patients with pneumothorax or large accumulations of pleural fluid leading to breathlessness; massive haemoptysis etc. the patients might need hospitalization. These patients can be managed in general hospitals preferably in wards where adequate air borne infection control measures are taken to prevent the spread.

A. Daily regimen for HIV/TB patient in India

PLHIV are more susceptible to TB infection, more likely to develop active TB disease after infection and more likely to suffer from severe TB and disseminated, extra-pulmonary TB. People living with HIV (PLHIV) should be screened for TB using four symptom complexes (current cough or fever or weight loss or night sweats) at HIV care settings and those with any of

these symptoms should be evaluated for ruling out active TB. All asymptomatic patients in whom active TB is ruled out, Isoniazid Preventive Therapy (IPT) should be offered to them for six months or longer.

The policies and guidelines for TB Control under the Revised National TB Control Programme (RNTCP) of India are based on the emerging scientific evidences for Tuberculosis control. RNTCP has a strong collaboration with NACO for developing mutually acceptable and scientifically sound approaches to TB HIV Co-infection Management. These services which are considered "Standard of Care" by RNTCP and over the last years these services have been scaled up to cover entire country by June 2012. Based on high grade of evidence of similar findings noted in systematic review which showed that the incidence of relapse and failure among HIV-positive TB patients who were treated with intermittent TB therapy throughout treatment was 2–3 times higher than that in patients who received a daily intensive phase. WHO has strongly recommended daily regimen for HIV associated TB patient in their treatment guideline.

Deliberations by Indian Committees on Anti TB treatment regimen in HIV/TB coinfected patients

i National Technical Working Group TB-HIV

Considering the evidence above, NTWG on TB-HIV committee has recommended using daily regimen for PLHIV suffering from TB.

ii Expert Committee on developing Indian Standards of TB Care

A workshop was held from 12-14 December, 2012 to develop Indian Standards of TB Care. About 140 experts participated in this meeting wherein this issue was also discussed. The following were used as a baseline documents to initiate the discussion.

- International Standards for TB Care (2nd Edition – 2009);
- American Thoracic Society Standards;
- European Standards for TB Care (Adaptation in December 2011);
- WHO Guidelines on Treatment of Tuberculosis (4th Edition – 2010) and
- WHO Guidelines for the programmatic management of drug-resistant tuberculosis (2011 update).

The consideration of the above studies which favoured expert opinion to favour daily regimen and gave conditional (depending upon available resources and operational consideration) recommendation that "All patients should be given daily regimen under direct observation".

iii National Expert Committee on Diagnosis & Management of Tuberculosis under RNTCP

This was further debated by the National Expert Committee on Diagnosis & Management of Tuberculosis under RNTCP on 3rd -4th January 2013. The committee examined the issues in a greater detail and suggested to provide daily regimen in HIV associated TB patient to prevent high mortality in this special group.

Daily regimen for HIV/TB co-infected patients has been approved by DGHS, MOHFW, and GOI and launched on 24 March 2014.

HIV status in TB treatment Card

- HIV Status as provided in the original TB treatment card should be recorded in the space provided at the time of registration. Status is recorded as 'P' for HIV-positive; 'N' for HIV-negative; 'U' for unknown.

- At the time of preparation of the quarterly report on case finding, all 'blank' entries in the HIV Status column in the TB register should be considered as 'Unknown' for the purpose of reporting.

- If the HIV status of the TB patient is initially not known and is later ascertained and updated during the course of TB treatment, the same should be updated in the TB register.

- Treatment cards and TB register should have been updated with the HIV status information before the preparation of quarterly report on treatment outcome

  Patient ID Card , TB Treatment card ,TB Register etc. are enclosed in chapter 5

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

Co-trimoxazole is a fixed dose combination of sulfa methoxazole and trimethoprim; it is a broad spectrum antibiotic that targets a range of gram-positive and gram-negative organisms, fungi, and protozoa. Co-trimoxazoleis given routinely for the prevention of opportunistic infections in HIV-infected persons; this strategy is called **Cotrimoxazole prophylaxis therapy**. This section describes the mechanism of decentralized delivery of CPT for HIV-infected TB patients. 'Decentralized' in this context means from all PHIs (Peripheral Health Institutes) having a Medical officer and an institutional DOT centre.

Why provide CPT?

CPT reduces morbidity and mortality of HIV-infected patients in general and HIV-infected TB patients in particular. NACO makes CPT available from ART centres and Link-ART Centres, but in most settings CPT is not available through the general health system. To improve access to CPT, CPT is to be made available to HIV-infected TB patients through the general health system in settings implementing the intensified TB/HIV package.

Eligibility for CPT

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

- Pregnant patients are also eligible, regardless of foetus gestational age.
- Patients should have no history of a serious drug allergy to sulpha drugs or glucose-6 phosphate dehydrogenase (G6PD) deficiency.
- Patients who are already on ART but not currently on CPT should have CPT initiated from the PHI as for any HIV-infected TB patient.
    - The ART centre can consider whether or not to continue CPT.
- **For children and very low-weight adults (<30 kg),** because alternate formulations of CPT are not provided under this decentralized mechanism, CPT for these patients is to be managed by ART centres.

How is CPT to be prescribed?

- Dose for prophylaxis for adults ($\geq$ 14 years old) and $\geq$ 30 kg body weight): 960 mg (800 mg sulfamethoxazole + 160 mg trimethoprim) daily.
- CPT is provided to patients in **monthly pouches**.
- CPT is **self-administered** by the patient on a **daily** basis, and not under direct observation.
- CPT can be taken**alongside anti-tuberculosis treatment (ATT) and ART**. Many patients who are eligible for ART would also have CPT continued at ART center.

Duration of CPT provision from PHI

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

Treatment interruptions

Patients who do not take CPT do not get the prophylactic benefits. If patients are noted to have interrupted CPT, counselling by the health staff (including medical officer) is recommended to promote adherence at the next available opportunity. There is no "Default" in CPT; please note that it is 'prophylaxis' and not 'treatment'. Patients who have interrupted CPT may choose to re-start and continue later.

Clinical and laboratory monitoring of patients on CPT

- No baseline laboratory investigations or laboratory monitoring of CPT is required.
- Drug-related side effects to Cotrimoxazole are uncommon and usually occur within first 2 weeks of starting treatment.
- Clinical monitoring should be carried out regularly, at least once every three months. During clinical monitoring visits, adherence should be encouraged.
- Although Cotrimoxazole can induce haemolyticanaemia in patients with G6PD, routine testing for G6PD deficiency is not indicated.

Side effects

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

Mechanisms for CPT delivery to HIV-infected TB patients

CPT delivery sites:

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

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

The treating physician should:

a. Initiate him/her on CPT from the institutional DOT centre, while also assessing the relevant history of adverse reaction to sulpha drugs.

b. The treating physician prescribes CPT by ticking the relevant cell on the TB patient identity card (**Chapter 6; Page 123**).

c. Records the prescription of CPT on the PHI-held, original TB treatment card (**Chapter 6, page no.121**).

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

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

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

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

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

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

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

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

STS during their each monthly visit to each PHI should:

1. Collect data on HIV test result of the TB patient, initiation on CPT, referral for ART, and initiation on ART from each TB treatment card and update the same in TB register

2. This information shall be reported in the quarterly Case Finding and Results of Treatment reports of RNTCP .

Discontinuing Cotrimoxazole prophylaxis

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

Transition of CPT for HIV-infected TB patients

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

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

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

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

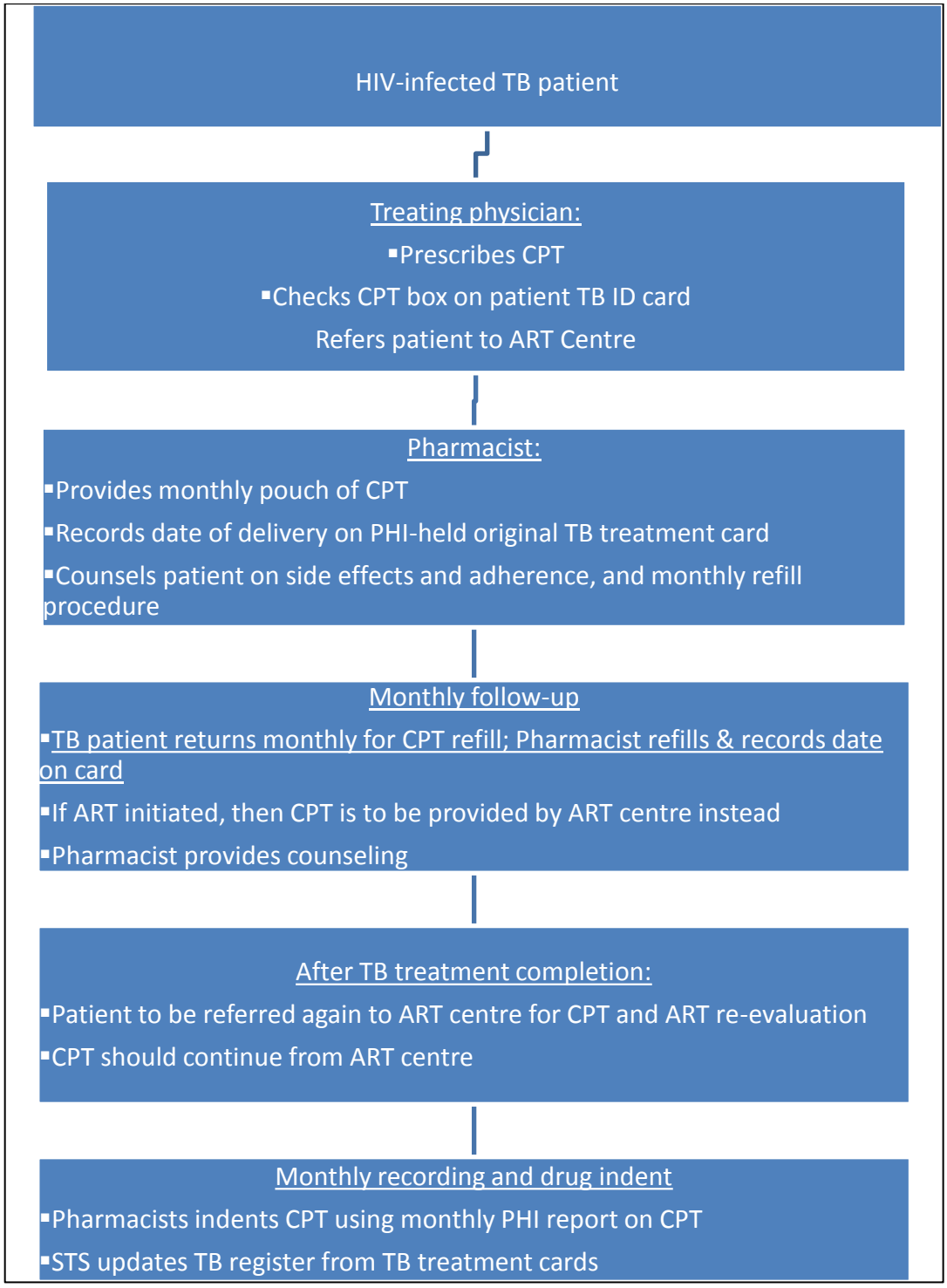


Figure 5.1: Summary of mechanism for providing CPT for HIV-infected TB patients

CPT Drug supply management

Management of drug supply of cotrimoxazole (CTX) is challenging due to the irregular duration of treatment. Patients may start CPT late, may begin to receive CPT from the ART centre at any time during TB treatment, may die or default from TB treatment, may interrupt CPT, or may even require more than 6 months in the case of Cat II patient or extensions of TB treatment. Therefore the system for CTX supply management is similar to RNTCP prolongation pouches.

- At the time of initiation of Intensified TB/HIV package in a district:
    - All PHIs should be supplied with 10 CPT monthly pouches, to account for patients immediately eligible for CPT and to have a CPT buffer supply.
    - All TUs should maintain a stock of one quarter's requirement, which should be a number pouches equal to [6*(5% of the number of TB patients registered the previous quarter)].
    - All Districts should maintain a stock of one quarter's requirement, which should be a number pouches of equal to [6*(5% of the number of TB patients registered the previous quarter)].
- The CPT should be stored in the Pharmacy of the PHI; the Pharmacist is to maintain a record of stock in the regular PHI Stock Register.
- On a regular monthly basis, PHIs should obtain CPT pouches from the concerned TU based on their actual requirements, considering the number of CPT pouches consumed, and the number HIV-infected TB patients detected. Regular re-supply of CPT pouches are requested from the TU headquarters using the monthly PHI CPT Indent
- TU will supply CPT monthly pouches to the PHI on the basis of the number of pouches requested.
- The stock and requirement of the TU for CPT monthly pouches should be reported by the TU to the district level in **Quarterly TU CPT Report**.
- The District TB cell based on these requests, supplies CPT monthly pouches to TU.
- On a quarterly basis, the District TB Cell is to indent supply requirement of CPT monthly pouches from the CMSD by the '**Quarterly District CPT Report'**

- In addition, emergency indent can also be made in case of urgent requirements.

EXERCISE :

1.Name three big groups of antiretroviral drugs available at present:

i._____

ii._____

iii._____

2.……should not be used in the first trimester of pregnancy. In women of childbearing age, the use of contraceptives should be ascertained

3. When to start first-line ART in patients with active TB &mention the name of drug combination.

i._____

ii._____

iii._____

iv._____

4.Write three actions of Anti TB drugs

i._____

ii._____

iii._____

5.CPT (Cotrimoxazole Prophylactic therapy) delivery for TB HIV patient

i._____

ii._____

6.List five eligibility criteria for CPT

i._____

ii._____

iii._____

iv._____

v._____

7.Name the CPT delivery sites to HIV-infected TB patients

i._____

ii._____

8.How is CPT to be prescribed?

i._____

ii._____

iii._____

iv._____

9.When to discontinue CPT ?

i._____

ii._____

Chapter 5. PREVENTION OF TB IN PLHIV:

5.1 Isoniazed Preventive Therapy (IPT) For PLHIVs

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

a) Adults and adolescents living with HIV should be screened for TB with a clinical algorithm and those who **do not report any one** of the symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered IPT. The guideline group **s**trongly recommend use of Isoniazid 300 mg once daily for 6 months, in adult and adolescents,
b) Although IPT is more effective among Tuberculin Skin Test positive individuals (TST), it is not a requirement for initiating IPT intervention among the PLHIV considering difficulty in logistics and administration of the TST,
c) Providing IPT to people living with HIV does not increase risk of developing isoniazid (INH) resistant TB later. Therefore, concerns regarding development of INH resistance should not be a barrier to providing IPT
d) Children living with HIV who do not have poor weight gain, fever or current cough are unlikely to have active TB
e) Children living with HIV who have any one of above symptoms may have TB and should be evaluated for TB and other conditions. If evaluation shows no TB, such children should be offered IPT regardless of their age.

f) Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening, and have no contact with a TB case should receive six months of IPT (10 mg/kg/ day) as part of a comprehensive package of HIV prevention and care services

g) All children living with HIV who have successfully completed treatment for TB disease should receive INH for an additional six months

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

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

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

a) Adult and Adolescent: Isoniazid 300mg +Pyridoxine 50mg (Vitamin B6) per day for 6 months

b) Children above 12 months: Isoniazid 10mg/kg +Pyridoxine25 mg (Vitamin B6) per day for 6 months

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

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

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

Systematic recording and reporting:

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

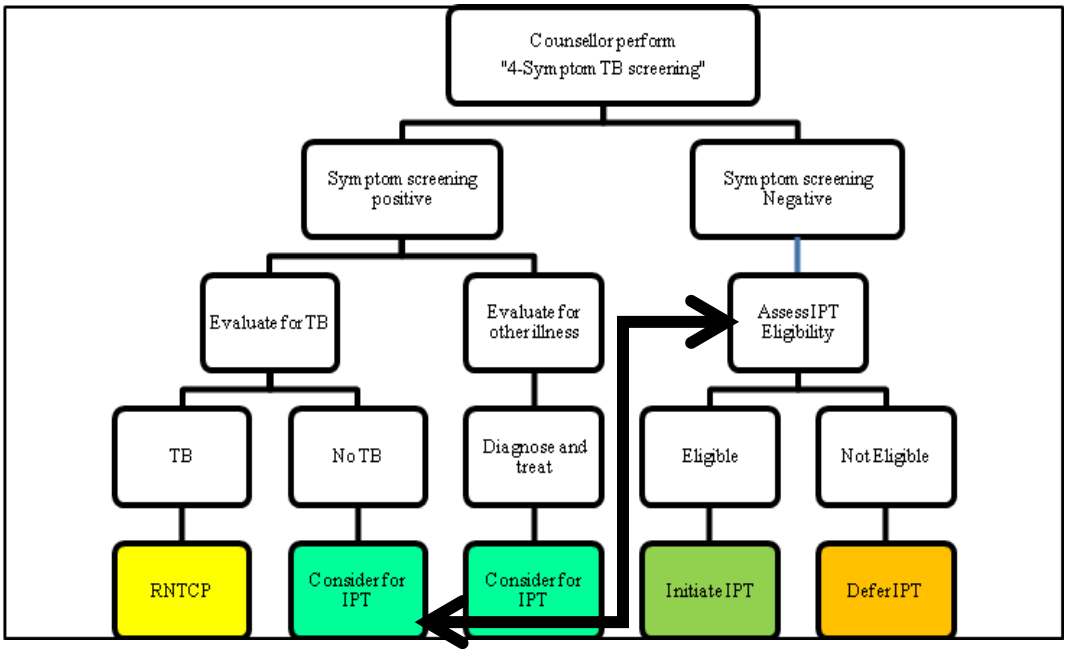


Figure: Overview of IPT implementation strategy

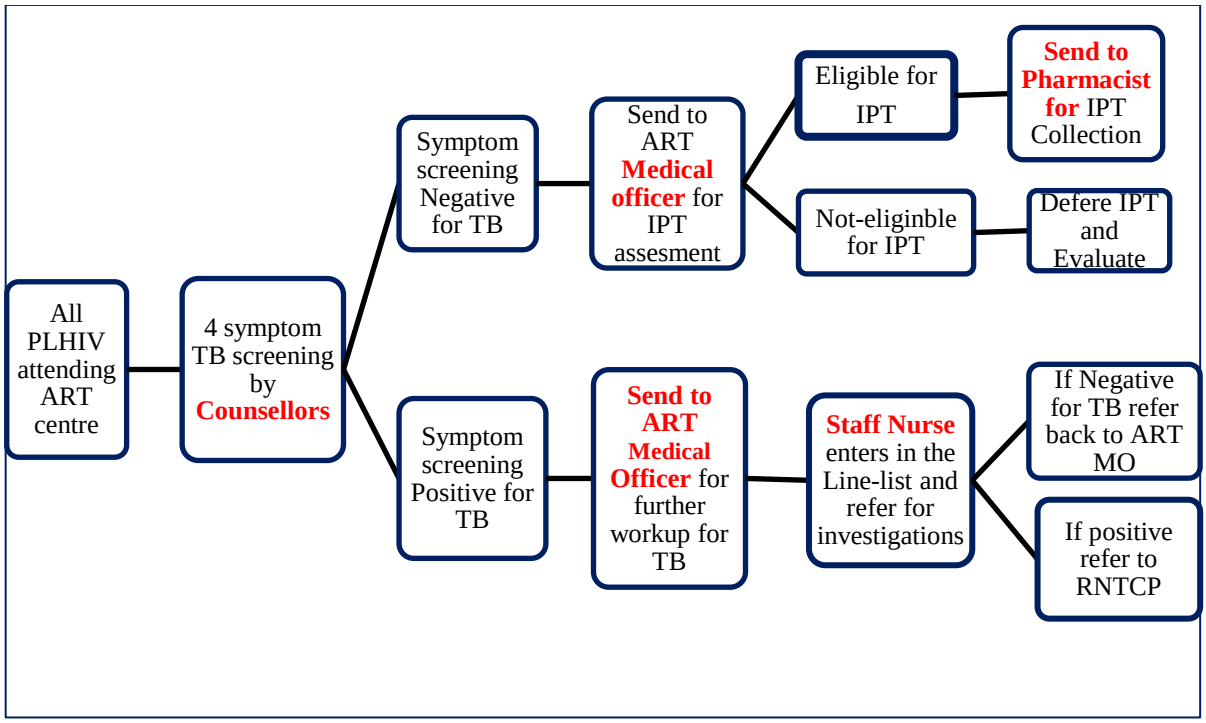


Figure:2 Patient Flow in initial screening for IPT Eligibility at ART centres

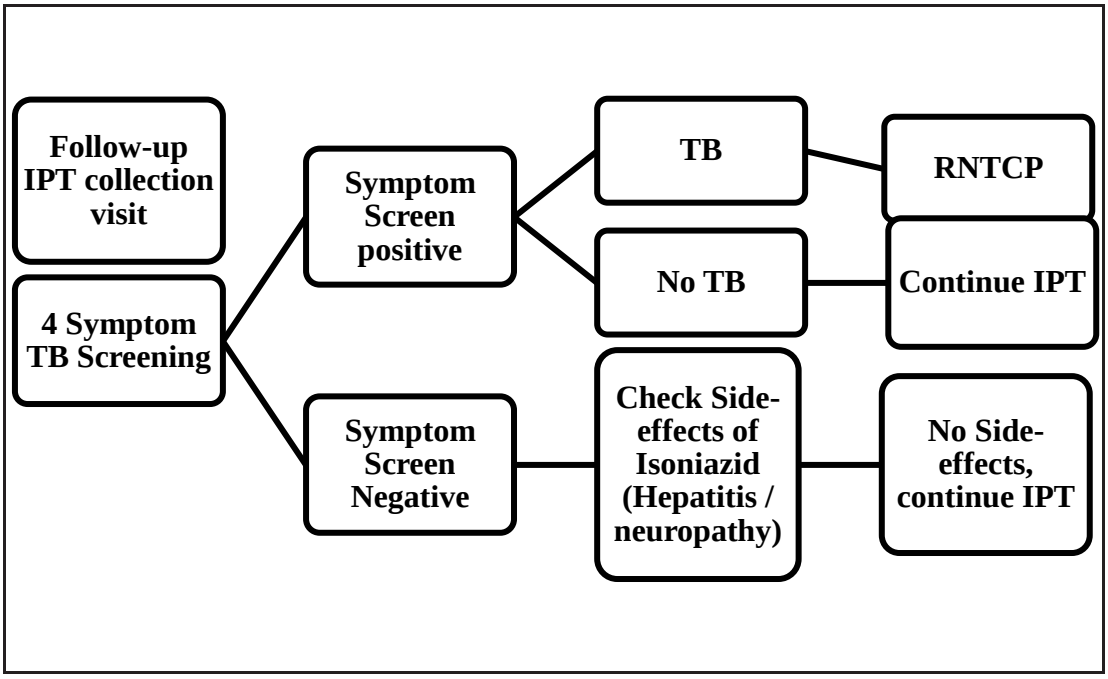


*Figure:**Patient Flow at Follow-up visit for collection at ART centre or Stand alone-ICTC***

Roles and Responsibilities in implementation of activities in IPT cascade

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

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

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

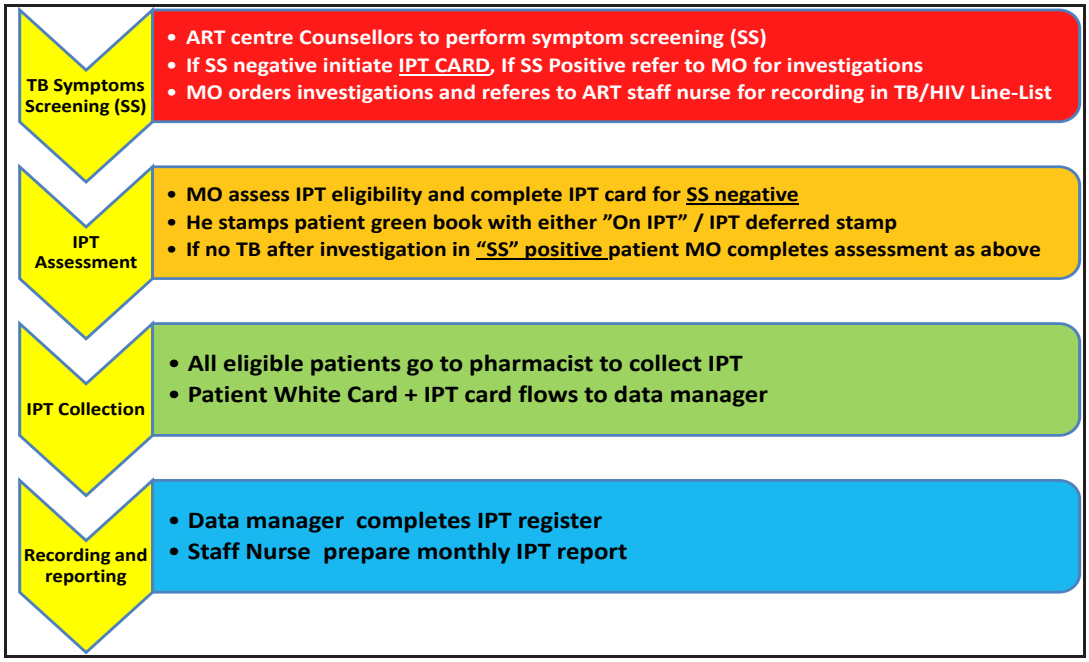


Figure: Responsibility of ART/ICTC staff in implementation of activities in IPT cascade

Supervising & Monitoring:

Implementation of IPT is to be coordinated by the ART centre SMO. The SMO is to undertake review of all the activities implemented at the ART centre, Link ART centres and the stand-alone ICTC every month

5.2. Air Borne Infection Control of TB/DRTB in HIV care setting and Bio-medical waste management:

TB Infection control

Prevent spread of TB in facilities caring for HIV-infected persons

In health care settings frequented by high numbers of HIV-infected persons, measures to reduce airborne tuberculosis transmission should be undertaken. These include simple administrative and environmental measures aimed at generally reducing exposure of HIV-infected patients to M. tuberculosis.

Administrative measures should first include early recognition, diagnosis and treatment of tuberculosis cases, particularly those with smear positive pulmonary tuberculosis. It should also include separation of presumptive pulmonary TB cases from other HIV-infected patients e.g. in patients waiting areas, until TB diagnosis is excluded or confirmed and effective TB treatment is initiated. Environmental protection should include maximizing natural ventilation. The general guidelines for infection control are summarized below:

1. ART centres should not be located in close proximity DMC/DOT centres i.e. they should not share waiting areas
2. ART centres should have a well-ventilated waiting & seating area. More than 12 air-changes per hour required for ART settings as per the National Airborne infection control guidelines.
3. Screening of all patients for respiratory or other TB symptoms should be done at every visit to the ART centre to ensure early identification, referral for diagnosis and initiation of treatment.
4. Fast-tracking of chest symptomatic cases should be done through all waiting areas in ART centres and RNTCP DMC to minimize time spent around other waiting patients or risk of acquiring infection (DMC).
5. Separate, well-ventilated waiting area for respiratory symptomatic should be made available wherever possible.
6. Health education on cough hygiene should be stressed by counsellors, medical officers, staff nurse etc. simple measures like covering mouth while coughing should be demonstrated
7. As far as possible, use of re-circulating air conditioners in the waiting area should be avoided as these have been found to leading to no air exchange.
8. Display of IEC material reminding the patients to follow cough hygiene practices, need for fast-tracking etc.

Infection Control

There is the risk of transmission of tuberculosis infection occurring in health care facilities including the laboratory when patients remain undiagnosed and untreated for tuberculosis. This may be curtailed by early diagnosis and immediate initiation and adherence to RNTCP treatment regimens. This prompt and timely action will make infectious TB patients rapidly non-infectious.

It is now mandatory that any Infection Control plan of the facility should include infection

control for TB and TB/ HIV. Broadly, infection control needs to be addressed at three different levels: administrative, environmental and personal.

Administrative control normally relies on the extent of complete implementation ofRNTCP diagnostic and treatment guidelines in the health care facility. TB infection control plan includes the following:

- Giving priority for patients with cough for clinical and laboratory investigations for early detection of smear-positive pulmonary tuberculosis patients

- Reducing delay in starting appropriate RNTCP treatment once diagnosed

- Avoiding unnecessary admission for inpatient care

- Assessment of health care workers training needs requirements under RNTCP

Sputum collection should ideally be done outside the facility and away from the people. It should not be done in closed areas such as toilets and in ill-ventilated rooms. Processing specimens for smear microscopy (after sputum collection) has not been documented to cause any increased risk to laboratory personnel. However, TB suspects amongst health care workers should be subjected to screening procedures.

Second priority is **environmental control**, which is used to reduce the generation and concentration of droplet nuclei in the air in high-risk areas. High-risk areas that increase transmission include exposure in relatively small, enclosed rooms in health facilities, which lack adequate cross ventilation in the form of open windows and doors to “clean” the environment through dilution or removal of infectious droplet nuclei. Hence, the TB IC plan should also include educating the patients regarding cough hygiene (covering the face while coughing and avoiding indiscriminate spitting), frequent identification of risk areas within the facility and providing good cross-ventilation to the area.

Wearing of surgical masks made of cotton wool/ gauze/ paper for **personal protection** does not protect the person who is wearing the mask from inhaling the droplet aerosols and hence is not

recommended as a means to prevent hospital infection. As mentioned above, early identification and prompt initiation of RNTCP treatment under direct observation would protect all health care workers from hospital TB infection.

The key to reduce the risk of Tuberculosis transmission at health facilities is early diagnosis and prompt initiation of RNTCP treatment until cure. Infectious TB patients become rapidly non – infectious once they are started on directly observed treatment under RNTCP.

All health care workers working at the district level should receive onsite training at least once in two-years regarding the basic concepts of M. tuberculosis transmission and pathogenesis. The training should include the following: Signs and symptoms of TB, increased risk of TB disease in persons who have HIV infection and other immunosuppressive conditions and infection with M. tuberculosis.

An Infection control plan for TB-HIV may include precautions to be observed for HIV, in addition to that observed for TB, especially when streptomycin injections are being provided. The risk of acquiring HIV following percutaneous exposure (needle stick/ needle prick with inoculation) from an HIV -positive source is extremely low: 0.25- 0.3%. This is because the concentration of HIV in peripheral blood is extremely low (104 infectious virions /ml). On the other hand, the risk of acquiring hepatitis virus (HBV) following similar exposure ranges from 9-30% because the concentration of HBV in blood is high (>10,000,000 infectious doses /ml). The chance of acquiring Hepatitis C is approximately 3-10%. Disposable/ adequately sterilized needles and syringes should be used for streptomycin injection. Following streptomycin injection needles should be destroyed using needle cutters/ destroyers wherever available. Needles and syringes should be disposed using prevailing hospital waste management system.

Health care workers can effectively prevent infections acquired through contaminated blood by the adoption of "Universal Precautions" or "Bio-safety Precautions".

Prevent spread of HIV through safe injection practices in state and district health facilities providing services

Measures to reduce parenteral HIV transmission include use of sterilized injection and surgical equipment in all medical settings. Steps should be undertaken by concerned authorities (State and District) to ensure availability of sterilized disposable needles and syringes for administration of injectable drugs and needle destroyers for safe disposal at all times and in all facilities.

Bio-Medical Waste Management under RNTCP by PHIs:

The Government of India (GoI) under its Environment Protection Act (1986), passed the Biomedical Waste (Management and Handling) Rules in 1998 and a subsequent amendment followed in 2000. The rules form the legal framework for the collection, segregation, transportation, treatment and disposal of biomedical waste throughout the country. The State Pollution Control Boards (SPCBs) in the states and the Pollution Control Committees (PCCs) in the Union Territories are monitoring the compliance to the rules in the respective states.

The RNTCP is integrated into the general health system of the states. Waste management is a component of overall facility management of the respective state health system institutions where RNTCP centres are located. Accordingly, **the waste generated by RNTCP should not be viewed in isolation, but is to be integrated in the broad framework of the peripheral institutions' waste management practices.** The peripheral health institutions would be responsible for disposal of the wastes and reporting to their respective PCBs.

Types of wastes generated by the RNTCP

- Human/biological waste (sputum)
- Sharp waste (needles, glass slides etc.);
- Used blister packs, drug packaging material;
- Plastic waste (waste generated from disposable syringes, cups and glasses); and
- Laboratory and general waste such as liquid waste, broomsticks, and paper waste; and
- Construction waste (waste generated from civil work activities).

Waste Management for RNTCP

Waste generated under RNTCP will be discarded with the overall waste of the health facility in which services under RNTCP are provided. The staff carrying out RNTCP activities like LTs and DOT providers in PHIs will adopt infection control techniques as detailed in these guidelines and will take action to integrate waste generated under RNTCP into the waste management activities of the concerned PHI. The activities by the PHIs will include organized waste collection, information dissemination, reporting and monitoring of disposal of the waste.

Disposal of sputum container with specimen and wooden sticks

Step 1: After the smears are examined, remove the lids from all the sputum cups.

Step 2: Put the sputum cups, left over specimen, lids and wooden sticks in foot operated plastic bucket/bin with 5% phenol or phenolic compound diluted to 5%. The cups and lids should be fully immersed in the solution. Keep it overnight/ for about 12 hours.

Step 3: Next day/ at the end of the day, drain off the phenol solution in to the drain.

Step 4: Take out the sputum cup/lid/wooden sticks and put into a reusable metal or autoclave-able plastic container or red bag. The red bag should have a biohazard symbol and adequate strength so that it can withstand the load of waste and be made of non-PVC plastic material.

Step 5: Put this container/bag into the autoclave with other autoclavable BMW and the contents should be autoclaved at 121°C at 15 psi pressure for 15 – 20 minutes. The autoclave shall comply with the standards stipulated in the rules. Under certain circumstances, if autoclaving is not possible, boil such waste in a pressure cooker of approximately 7litrecapacity containing adequate amount of water to submerge the contents and boiled for at least 20 minutes using any heating source, electrical or non-electrical. However the District Hospital/CHC/PHC etc. shall ultimately be

expected to make the necessary arrangements to impart autoclaving treatment on regular basis.

Step 6: After adequate cooling, the material can be safely transported to a common waste treatment facility for mutilation/shredding/disposal.

lf a common waste treatment facility is not available in the area, the sputum cups/lids/ wooden sticks after autoclaving can be buried in a deep burial pit.

LTs and support staff handling biological waste should wear gloves.

Disposal of stained slides

Step 1: The slides should be put into a puncture proof container and red bag. The red bag should have a biohazard symbol and should be made of non-PVC plastic material. This bag/sharp container should then be put in to an autoclave or pressure cooker for autoclaving/boiling.

Step 2: Dispose off the autoclaved/ pressure boiled slides into a pit for sharps.

EXERCISE:

1. **Why INH is given for prophylaxis in PLHIV patients & why?**

   ……

   ……

   ……

2. **What is the dose of INH given for prevention in PLHIV?**

   a. 5 mg/ kg
   b. 10 mg/ kg
   c. 15 mg/ kg
   d. 20 mg/ kg
   e. 25 mg/ kg

3. **INH is used as it is-**

   f. Bactericidal drug
   g. Bacteriostatic drug
   h. Sterilizing drug
   i. Macrolite

4. **Regarding INH Preventive therapy, which is True/ False. That it prevents-**

   j. Incidence of TB
   k. Prevalence of TB
   l. Mortality of TB
   m. Morbidity of TB

5. **INH preventive therapy is given to**

   n. Patients on ART only
   o. Patients on Pre ART only
   p. Patients on either ART or pre ART
   q. Both ART & pre ART

6. **INH is given for-**

   r. 6 months daily once in a day
   s. 12 months daily twice in a day

t. 6 months once daily
u. 1 months once daily
v. Whole of life once daily
w. Whole of life twice daily

7. Why do we require Airborne infection control measures at HIV TB care settings ? Give two reasons

……

……

8. What are the 3 levels of control recommended in the guidelines of Airborne infection control

i……

ii……

iii……

9. What are the Air Changes per hour for different settings

i……

ii……

iii……

iv……

v……

10. What are Airborne infection control recommendations for ART centers

i……

ii……

iii……

iv……

v……

vi……

11. What precautions should be taken while sputum collection to prevent infection

i……

ii……

iii……

Chapter 6: HIV/TB RECORDING, REPORTING, MONITORING AND EVALUATION

Recording of TB HIV collaborative activities

Original TB treatment card

Information on HIV status, CPT delivery and ART referral and initiation of the TB patient is to be documented on the original TB treatment card and kept confidential within health system. This should not be disclosed to the community DOT provider.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

TB Notification No _____ **Treatment Card** TB No / Year _____

State_____ City / District _____ TB Unit _____ PHI _____

Name _____ Sex ☐ M ☐ F ☐ T Age:____ Occupation_____

Complete Address: House No. _____ Road: _____Ward/Village: _____ Town/City: _____ Taluka/Mandal:_____ District:____ State: _____ Pin code ____ Important landmark:_____ Mobile:- _____ Aadhar No. _____

Name and Address of contact person _____Mobile No. _____

Name and designation of Treatment Supporter _____Mobile No.: _____

Treatment Support Centre _____ Initial home visit by _____ Date _____

Disease Classification
☐ Pulmonary
☐ Extra Pulmonary
Site _____

Type of Patient
☐ New ☐ Recurrent
☐ Transfer in ☐ Treatment After Failure
☐ Others, previously treated (Specify)_____

Basis of Diagnosis
☐ Bacteriologically confirmed
☐ Clinical TB

Investigations (ZN / FM / CBNAAT / Liquid C / Solid C / CXR / Histopathology)	Labor atory	Lab. No.	Test result	CBNA AT

H/O of Previous ATT: __ months of treatment __ months since end of last episode Source of treatment:- ❑ Public ❑ Private
Previous regimen: _____

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._____
Addiction related information
Smoking status ❑ Yes ❑ No
If smoker, linked for cessation ❑ Yes ❑ No

	<6yrs	>6yrs
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

Signature of MO with date _____

Initial weight of patient: _____ kg height _____ cm Date of initiation of intensive phase _____ Date of initiation of continuation phase _____

☐ Regimen for new case ☐ Regimen for previously treated ☐ Daily ☐ Intermittent

Dosage

H	R	Z	E	S

Mark ✓ when doses are taken, O when missed the dose Record CP from 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	Smear / Culture	ADR

Retrieval Actions for Missed Doses

Date	By Whom	Whom contacted	Reason for missed doses	Outcome of retrieval action

Remarks _____

_____

_____

_____

Post treatment follow up clinical & sputum

6 months after Rx	
12 months after Rx	
18 months after Rx	
24 months after Rx	

Treatment outcome with date: _____ signature of the MO with date:_____

Additional Treatments

1. HIV status: ☐Unknown ☐Pos ☐Neg (date) _____
2. CPT delivered on (date): (1) (2) (3) (4) (5)
3. Pt referred to ART centre (date): _____

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

1. HIV Status:

i. HIV testing is a voluntary procedure and not mandatory. Patients not willing for HIV testing or sharing their HIV test result should not be forced to undergo testing or disclose their HIV status.

ii. If HIV status of the patient is known, tick the appropriate box ('Pos' or 'Neg') and record the date of test along with PID Number if available. If the HIV status is not known, don't tick any box initially.

iii. Patients already on HIV care should not be required to show proof of HIV test result

iv. If the HIV status is ascertained during the course of TB treatment, the latest information should be updated on the card.

v. If HIV status of the patient remains unknown at the end of the treatment, tick the appropriate box ('unknown'), at the time of declaring treatment outcome for the patient.

2. CPT (Cotrimoxazole Prophylactic therapy) delivery

i. All known HIV-infected TB patients are to be provided access to CPT.

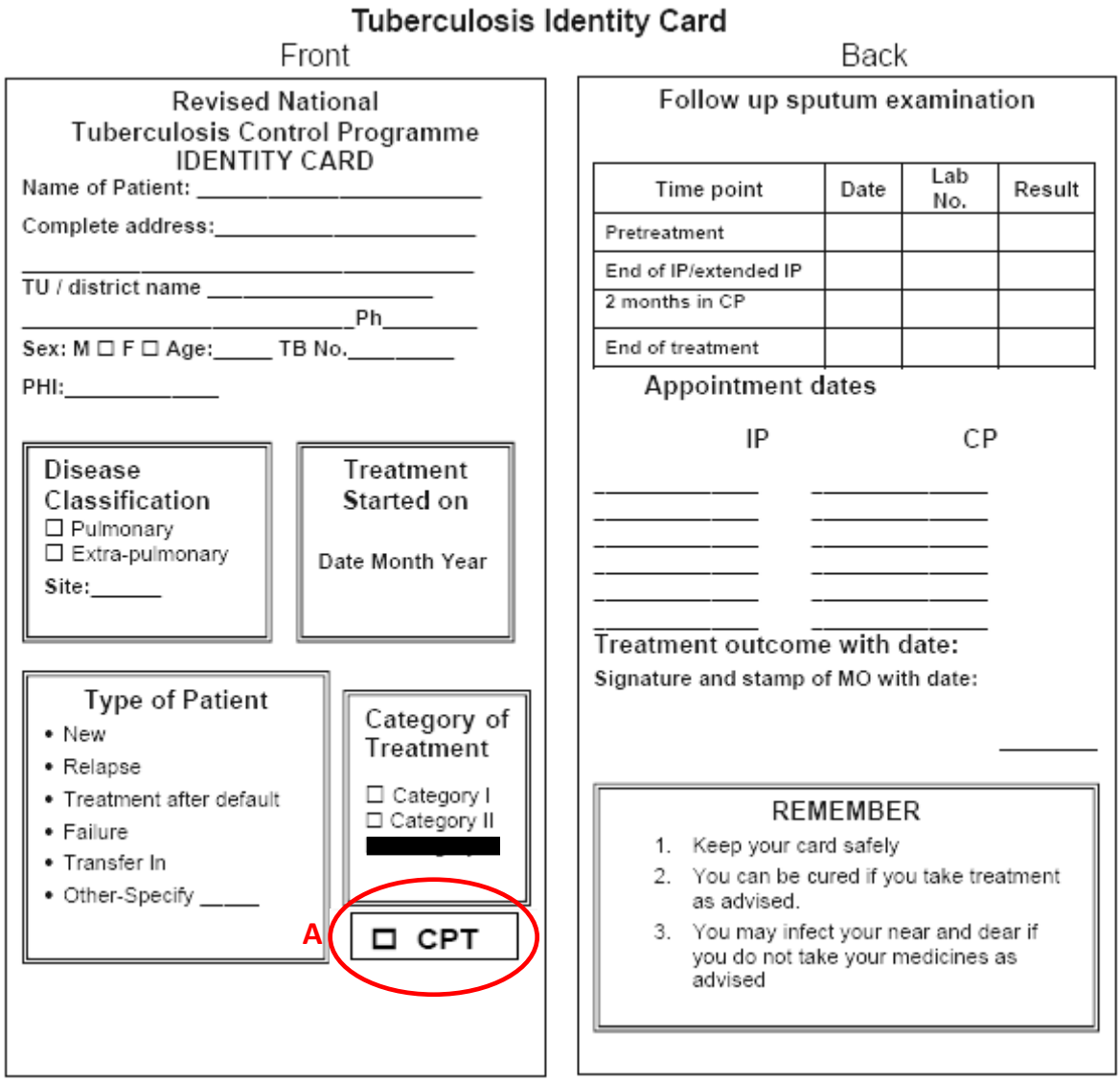
ii. If CPT provided from the PHI, record dates of each monthly delivery in the space provided.

iii. In case the TB patient is already on CPT before the initiation of TB treatment, record most recent date of CPT pickup.

3. Referral and initiation on ART

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

Figure 2: TB Identity card



A. CPT:

- If the patient is HIV-infected, and not already being provided CPT from any other source, MO (PHI) is to prescribe CPT by ticking in the section on CPT in TB ID Card.

- Institutional DOT provider on seeing the ticked box provides monthly supply of CPT and records the same on Original treatment card.

Figure 3: TB Register

Left side of the TB register

Revised National Tuberculosis Control Programme – TB Register Quarter_____ Year_____

TB No.	Date of Regis-tration	Name (in full)	Sex (M/F)	Age	Complete Address & Telephone Number	Name of PHI	Date of Starting Treatment	Category (I/II/III ND1/ND2)	Class (P/EP)	Type*	Pre-treatment sputum exam				HIV Status† (P/N/U)
											Date	DMC Name	Lab No	Smear	

A

Summary for Case Finding (DOTS Cases Only)								
	NSP	NSN	NEP	New Others	Relapse	Failure	TAD	Cat II Others
0–14 yrs								
≥15 yrs								
Male								
Female								

*** Type of Patient (use complete words)**
New; Relapse; Transferred in; Failure; TAD; Others

† HIV status
HIV status as reported before or during TB treatment.
P–Positive; N–Negative; U–Unknown;

Right side of the TB register

Revised National Tuberculosis Control Programme – TB Register Quarter_____ Year_____

B

End of I.P. / Extended I.P.				2 Months in C.P. Exam				End of Treatment Exam				Treatment Outcome#		[If HIV-pos]‡		Remarks
Date	DMC Name	Lab No	Smear	Date	DMC Name	Lab No	Smear	Date	DMC Name	Lab No	Smear	Outcome	Date	CPT	ART	

DOTS SUMMARY	Cured		Comp Tx.		Died		Default		Failed		Transfer Out	
NSP												
NSP [M|F]	M	F	M	F	M	F	M	F	M	F	M	F
NSN												
NEP												
New Others												
Relapse												
TAD												
Failure												
Cat II Others												

 # Treatment Outcome – use complete words
Cured, Completed treatment, Died, Defaulted, Failure, or Transferred out

‡ Additional treatments if patient HIV-positive
Required only for patients known to be HIV-positive.
If provided by any source during TB treatment, enter "Y" and approximate date. If not provided/unknown, enter "N".

A: HIV status:

- HIV Status (as provided in the original TB treatment card) should be recorded in the space provided at the time of registration. Record ‘P’ for HIV-positive; ‘N’ for HIV-negative; If the HIV status is not known at the time of registration leave the cell blank.
- At the time of the case finding report preparation, all ‘blank’ entries in the HIV Status column in the TB register should be counted as 'Unknown' for the purposes of reporting.
- If the HIV status is later ascertained and updated on the treatment card during the course of TB treatment, the same should be updated in the TB register.
- By the time of Results of Treatment quarterly report preparation, ALL TB treatment cards should have an entry for HIV status (P, N, or U). Similarly, the TB register should reflect the entry on the TB treatment cards. If the HIV status information on the TB treatment card for whatever reason remains blank, that is to be recorded as 'Unknown'(U) in the TB register.

B: CPT and ART delivery:

- The section is to be filled up for all TB patients known to be HIV-infected and should be left blank for others.
- CPT and ART information should be updated on the register as the information gets recorded in the treatment card but not later than the time of recording the treatment outcome i.e. within a month of TB treatment completion.
- Record CPT started as ‘yes’, with the date, if at least one month of CPT delivery is recorded in the original treatment card.
- Record ART started as ‘yes’ if recorded as ‘yes’ in the original TB treatment card. Record the documented approximate date of ART initiation from the original TB treatment card.
- For patients who were already taking CPT or ART at the time of TB diagnosis, the dates for CPT and/or ART initiation would be expected to be earlier than the date of initiation of TB treatment.
- This information on the evaluation and initiation of ART may also be obtained from the ‘TB/HIV register’ maintained at ART centre during the monthly co-ordination meetings or

during the visits of STS to the ART centre. The same information should be communicated to the concerned MO-PHI for updation of the treatment card.

Reporting in RNTCP case finding report: Key points to remember

Block 3: TB/HIV Collaboration

Of all Registered TB cases no. known to be tested for HIV before or during the TB treatment (a)	Of (a), No. known to be HIV infected (b)

The purpose of this block 3 is to provide information on the process of ascertainment of HIV status of TB patients:

- In cell **'a'**, enter the sum of all TB patients registered in this quarter, with their HIV status recorded as either positive (P) or negative (N) in the TB register. Do not include those patients with HIV status recorded as (U) unknown, or those patients with no information available regarding HIV status.
- In cell **'b'**, enter the sum of all TB patients registered in this quarter, with their HIV status recorded as positive (P) in the TB register.

It is to be noted that the number of patients known to be HIV-infected may be less than the number that will ultimately be reported in the Results of Treatment quarterly report, as it is expected that some patients will undergo HIV testing during the course of treatment after the case finding report is prepared.

Reporting in RNTCP treatment outcome report: Key points to remember

1. Treatment outcomes of HIV positive TB patients:

Type of TB case	Total No. known to be HIV infected	Treatment outcomes					
		Cure	Treatment completed	Died	Treatment failure	Default	Transfer out
NSP							
All TB cases							

a. In this section TB treatment outcomes of HIV-infected TB patients are to be reported
b. In the first column 'Total No known to be HIV-infected', enter the sum of all TB patients registered in the relevant quarter, whose HIV status was recorded as positive (P) in the TB register, for 'NSP' only in the first row, and for 'All TB cases' (including NSP) in the second row.
c. Record the treatment outcomes of the known HIV-infected TB patients as indicated.

Note:

d. This number of known HIV-infected TB cases may be greater than reported in block 3 of case finding reported for this quarter, as more TB patients will have been identified as HIV positive during the course of treatment subsequent to the time of submission of the quarterly CF report.
e. **However, all efforts should be made to gradually decrease this difference and ensure that an increasing proportion of TB patients get their HIV status ascertained as early as possible after TB diagnosis**

2. Provision of CPT & ART to HIV-infected TB patients

Total no of TB patients known to be HIV infected	No. given CPT#	No. given ART#

During TB treatment

a) Enter the sum of HIV-infected TB patients that had 'yes' recorded in the CPT started column of the TB register and record in the space provided.

b) Enter the sum of HIV-infected TB patients that had 'yes' recorded in the ART started column of the TB register and record in the space provided.

HIV/TB activities are implemented with close coordination between two national programmes having different reporting systems. HIV/TB recording and reporting involves staff of both programmes, hence it is little complex. Following table clarifies the reporting responsibilities:

	Essential HIV/TB recording and reporting
HIV/TB coordination activities	• Quarterly report on HIV/TB collaborative activities by SACS sent to NACO at tbhiv@rntcp.org* **(Annex-6)** • Minutes of State Coordination Committee meetings sent to centre (at tbhiv@rntcp.org.) and reported in RNTCP state PMR • Minutes of state TB/HIV working group meeting sent to centre at tbhiv@rntcp.org. • Minutes of District Coordination Committee meeting sent to State TB Cell and SACS and reported on RNTCP District PMR • Minutes of Monthly HIV/TB meeting sent to State TB Cell and SACS by district
Intensified TB case finding at ICTCs /LAC	• Monthly line-list of ICTC referrals of presumptive TB cases and TB diagnostic outcomes jointly prepared by ICTC counsellor and STS (**Annex 17**) • Monthly ICTC TB-HIV Register (**Annex 18**) • Monthly ICTC TB-HIV Report (**Annex 19**) • Consolidated state ICF at ICTC monthly report sent at tbhiv@rntcp.org.

Intensified TB case finding at ART centres/LAC Plus centre	• Monthly line-list of ART referrals of presumptive TB cases and TB diagnostic outcomes jointly prepared by ART centre staff nurse and RNTCP STS (**Annex 20**) • Monthly ART centre TB-HIV report as a part of 4-page monthly report of ART centres (**Annex 21**) • TB/HIV **register** at ART centre jointly maintained by ART centre staff nurse and RNTCP STS (**Annex 22**) • Consolidated state ICF at ART centre monthly report sent at tbhiv@rntcp.org
HIV-testing of TB /DR TB patients	RNTCP Quarterly Reports (Case Finding Report)(**Annex 24A**), PMDT reports (**Annex 24 B**)
HIV-testing of presumptive TB cases	RNTCP laboratory register, RNTCP Quarterly Report (Programme management report PHI, TU, District and state) (**Annex 24A**)
Provision of CPT to HIV-infected TB patients	RNTCP Quarterly Report (Results of Treatment Report) (**Annex 24 A**)
Provision of ART to HIV-infected TB patients	RNTCP Quarterly Report (Results of Treatment Report) (**Annex 24A**)

1. * *tbhiv@rntcp.org. email ID will change to tbhiv@rntcp.nic.in - in future*
2. *All ICF at ICTC reports from state to NACO should be done using standard reporting excel formats until NACO SIMS system is established for TB/HIV*

ICTC – RECORDING, REPORTING AND EVALUATION MECHANISM

Registers maintained in ICTC

- PID Registers for General clients
- PID Registers for Pregnant women
- ICTC Register for General Clients
- ICTC Register for Pregnant Women
- ICTC PPTCT Linelist Register
- **ICTC HIV/TB Line List Register**
- **ICTC HIV-TB Register**
- Laboratory Register
- Stock Register

ICTC Monthly Reporting Formats

- Summary Table
- Progress made during the month- General Clients
- Lab information, Equipment, Consumables and Staffing
- Progress made during the month- Pregnant Women
- **Progress during the month- HIV-TB coordination**

Main Performance Indicators

- Number of ICTCs established (Stand Alone and Facility Integrated)
- Number of general clients counselled and tested
- Number of clients found positive
- Number of pregnant women counselled and tested
- Number of pregnant women found positive
- % mother-baby pairs provided prophylaxis
- Number of exposed infants tested on EID

- **% of TB patients tested for HIV**
- **Number of HIV infected TB cases detected**

ART – Recording, reporting and Evaluation mechanism

- ICF activity is also implemented specifically in HIV infected pregnant women since TB is independent risk factor for transmission of HIV infection from mother to the baby. This activity is therefore incorporated in NACO PPTCT line-list
- To allow complete diagnosis of TB in a presumptive TB case and initiation of TB treatment, TB-HIV monthly reporting is done for a month previous to the ICTC/ART centre monthly report. For e.g. in monthly ICTC report submitted to NACO for March 2012, the TB-HIV data belongs to February 2012
- All TB-HIV reporting from RNTCP is done through routine quarterly reports in Epi-Centre software (Case Finding (CF), Sputum Conversion (SC), Results of Treatment (RT), Programme Management Report (PMR) and PMDT quarterly report).
- RNTCP has developed web based case based electronic reporting system has been developed by RNTCP(NIKSHAY) and reports are generated through this system now.

RNTCP (NIKSHAY) and SIMS (Strategic Information Management system) by NACO.

Joint HIV/TB monitoring and evaluation

To strengthen implementation of collaborative activities at all levels joint field visits would be undertaken by a national team (NACO & CTD) to at least one state per quarter. Similarly state teams (SACS & STC) should visit at least one district every quarter. These states and districts are chosen based on key HIV/TB performance indicators. Observations made in joint visits should be discussed in state review meetings and the SWG. A copy of the same should also be submitted to NACO and CTD.

To aid in joint field visits and review meetings RNTCP and NACP jointly developed monitoring indicators and targets.

Methodology of monitoring & evaluation of HIV/TB collaborative activities

There are various methods by which monitoring and evaluation of TB /HIV activity occurs. The major ones are listed below.

a)Routine monitoring systems:

Both the TB and HIV programmes use line list , treatment cards as the information source for disease specific patient registers. The registers are used to monitor patient progress, and allow regular programme monitoring. These reports are analyzed locally, preferably in conjunction with supportive supervision or quarterly review meetings, and are then sent to district and national levels for further aggregation, analysis, dissemination and management of the programme.

These registers also contain variables used in measuring TB/HIV collaborative activities. These variables are also routinely reported on in the quarterly summary reports of both programme and this allows assessment of TB/HIV collaborative activities.

b) Surveillance and surveys.

These are important tools to measure disease burden such as the prevalence of HIV related tuberculosis. These are sentinel surveillance from selected treatment sites .NACO has guidelines

for carrying out these activities in a standard way. Similarly, TB and Drug resistant TB survey are conducted by Central TB division.

c) Country situational analysis

This important tool brings together all the available information on disease epidemiology (including surveillance and survey data), and programme structure, function, output and impact within the context of the overall health system. The analysis identifies strengths weaknesses and gaps in the programme and is often carried out as part of the planning cycle in preparation of a strategic multi year programme plan.

d) **External programme reviews:**

External programme reviews like Joint Monitoring Mission and other external program reviewsusually lasting one to two weeks, are organized often in preparation of a multi-year strategic program plan. It usually involves forming a team of international and national experts on programme management or technical aspects of the programme, with local implementation partners, MoH programme staff, civil society and donors are also represented. The team meets at national level for one to two days, to be orientated with a pre-prepared situational analysis, and to agree on a review methodology. The reviewers then travel throughout the country in sub- teams to observe the programme at all levels (national regional district health centre and community), using agreed tools to examine records, observe activities, and interview key informants including health staff, clients, other care providers and civil society All this information is then synthesized and brought together at national level to inform the final report with key findings and recommendations to government and stakeholders. Usually a summary of key findings is presented to MoH senior representatives prior to the teams departure.

One specific issue to note for TB/HIV activities is that they should form part of both TB and HIV programme reviews, preferably bringing key staff from both programmes together. Reviewers should ensure that review findings are shared with and owned by both TB and HIV programmes.

e)Program Internal Evaluation Protocol

Internal Evaluation forms an integral component of RNTCP & NACP supervision and monitoring strategy. It acts as a tool to evaluate if good program practices are adopted and quality services are provided to the community. The evaluations also offer an opportunity for program managers to look into all aspects of program critically and swiftly. These activities help program managers in understanding determinants of good as well as poor performance for replication of good practices in other states /districts and take appropriate measures for improvement.

a) Objectives of IE

1. To provide a systematic framework for assessment of program performance, financial & logistics management, recording and reporting, and quality of care received by patients

2. To give recommendations for improving the quality of program implementation and performance with a realistic action plan and time line

3. To monitor efforts to improve and maintain program quality and performance over time

a. Centrally driven Internal evaluation (CIE): NACO and Centre TB division (CTD) jointly select 1 state per month for evaluation HIV/TB collaborative activities based on the performance so that all big states are visited once in every 2 years. In the selected state at least 2 districts are evaluated. CIE provides an opportunity to review performance in select district and to review overall performance of the state, programmatic challenges. It facilitates the centre to understand, address and support actions for improving quality of HIV/TB collaborative activities in the state and its implementation. The CIE team consists of representatives from NACO, CTD, WHO, SACS's Officers from other state etc.

b. State Internal Evaluation: Similarly State level internal evaluations are conducted which includes following team members

- State TB Officer or Deputy STO
- SACS HIV/TB Coordinator
- STDC Director / representative (where STDC exists)
- One DAPCU & One DTO of a district other than the one being evaluated

- WHO RNTCP consultants
- Medical college representative
- Consultant from other programme partners (IMA, CBCI etc.)
- State Accountant and State IEC Officer

Internal Evaluation Methodology

Selection of districts: Up to 30 million – 2 districts per quarter; 30-100 million – 3 districts per quarter; >100 million – 3-4 districts per quarter. Aim to cover all districts at least once in 3-4 years. In States/UTs with 4 or less districts, 1 district or TU per quarter may be evaluated alternating selection between a well performing district and an underperforming district

Joint Program Reviews RNTCP and NACP :

RNTCP and NACP conducts regular review meetings at national and state level. In one of these meetings at national level, joint review of HIV/TB activities should be done with participation of state programme managers of both programmes. This meeting should be held jointly by NACO and CTD. Review Checklist for TB/HIV activities at state level is place at **Annex 25.**

Similar joint review meeting should be held at state level by adding one additional day to one of the quarterly RNTCP review meetings, inviting all district nodal officers for HIV/AIDS or DAPCU officer and SACS officials. The joint review meetings should be organised in close coordination by SACS and STC. The schedule of joint meetings should be communicated to NACO and CTD and representatives from CTD or NACO should participate in the same. The expenditure incurred on TA/DA of officers for both these meetings should be borne by respective national programme while organizational cost should be borne by RNTCP.

Chapter 7: ROLES AND RESPONSIBILITIES:

Role of SACS:

• **Organize training of trainers for DTOs and DNOs in coordination with State TB Cell on intensified TB/HIV package.**
• **In coordination with DNOs, organize training for MOs-TCs, MOs, STS, Counsellors, ART centre staff and Pharmacist on intensified TB/HIV package**
• **Overall supervision and ensuring smooth implementation of intensified TB/HIV package, as per National framework of joint TB/HIV collaborative activities**
• **Ensure optimal availability of HIV test kits, Cotrimoxazole (in monthly packs), training modules and referral forms (for referral of all TB patients for VCT and referral of HIV-infected patients to ART centre).**

Role of State TB Cell and STDC :

• **Organize training of trainers for DTOs and DNOs in coordination with SACS on intensified TB/HIV package.**
• **In coordination with DTOs, organize training for MOs-TCs, MOs, STS, Counsellors, ART centre staff and Pharmacist on intensified TB/HIV package.**
• **Overall supervision and ensuring smooth implementation of intensified TB/HIV package, as per National framework of joint TB/HIV collaborative activities.**

Role of Nodal officer for TB/HIV in State AIDS Control Society /State TB office/State TB HIV coordinator:

•**Ensure close coordination between state TB office and SACS to facilitate universal coverage of TB patients with HIV testing services**
• **Ensure 100% co-location of HIV and TB testing facilities in the state**
• **Ensure national, state and district level trainings for implementation of WBFPT testing, as mentioned in this document**

• **Ensure uninterrupted supply of test kits and necessary logistics at the point of use**
• **Ensure storage and transportation of HIV test Kits in cold chain from state level to point of use**
• **Develop mechanism for review of implementation of HIV screening at district and state level**
• **Regular supervision, monitoring and evaluation for smooth implementation**
• **Ensure prompt and timely reporting to NACO and Central TB Division**

Role of DAPCU Officer (DNO):

• **In coordination with DTOs, organize training for MO-TCs, MOs, STS, Counsellors, ART centre staff and Paramedical staff on intensified TB/HIV package.**
• **Overall supervision and ensuring smooth implementation of intensified TB/HIV package, as per National framework of joint TB/HIV collaborative activities.**
• **Ensure adequate ICTC human resource management and supply of test kits and consumables.**
• **Supervise ICTC counsellor's provision of confidential feedback of HIV test results for TB patients to referring providers.**
• **Ensure seamless supply of Cotrimoxazole to the DTO in co-ordination with SACS.**
• **Ensure the availability of "referral forms" for referral of all TB patients for VCT and referral of HIV-positive TB patients to ART centre.**
• **Ensure that ART centre staffs attend the RNTCP monthly meeting.**
• **Ensure that ART centre staff maintain the TB/HIV register and share the information with RNTCP staff during the monthly meetings.**
• **Coordinate with ICTC counsellors and SACS, and ensure the compliance of counsellors.**
• **Coordinate with DTO and facilitate in resolving the issues emerging in the field.**

Role of District TB Officer (DTO):

• **In coordination with DNOs, organize training for MOs-TCs, MOs, STS, Counsellors, ART Centre staff and Pharmacist on intensified TB/HIV package.**
• **Overall supervision and ensuring smooth implementation of intensified TB/HIV package as per National framework of joint TB/HIV collaborative activities.**
• **Review the ascertainment of HIV status by medical officers, and the recording of HIV status on TB treatment cards.**
• **Ensure that HIV status is recorded only on PHI-held original treatment cards, and not on duplicate treatment cards held by community DOT providers, and that HIV status remains confidential within the health system.**
• **Monitor STS recording of HIV status, CPT, and ART from TB treatment cards onto TB registers.**
• **Supervise the recording of ART provision to HIV-infected TB patients from TB/HIV register maintained at ART centre.**
• **If TB patients from other districts are initiated on ART in this district, the DTO should provide feedback on the same to the concerned DTC.**
• **Indenting Cotrimoxazole from SACS/SDS and supply the same to the TUs**
• **Collect information on the delivery of CPT from all the STSs on a quarterly basis & compile a consolidated quarterly report on the same in the prescribed format.**

Joint Responsibilities of DAPCU officer (DNO) / District TB Officer/ Taluka or Block medical officer:

• **Prepare micro-plan to ensure 100% co-location of HIV and TB testing facilities for the district**
• **Ensure training of all DMCMO, LT and concerned institutional DOT providers at district level**
• **Ensure implementation of HIV screening using WBFPT at all RNTCP DMC not having testing facility**
• **Ensure recording and reporting at all screening facilities in their jurisdiction**
• **Ensure uninterrupted supply of test kits in cold chain**

• **Ensure 100% referral of TB patients found "reactive" to nearest stand-alone ICTC for confirmation**
• **Ensure provision of feedback by ICTC counselors on test results to referring doctor**
• **Ensure appropriate and timely linkages of all detected HIV positive individuals to care and support**
• **Review performance of this centres regularly during routine monthly review meetings**

District ICTC Supervisors / District DR-TB and TB-HIV Supervisor /ICTC Counselor /RNTCP STLS:

• **Facilitate training of all DMC LT's and institutional DOT providers at district level**
• **Facilitate implementation of HIV screening using WBFPTat all DMC'snot having a testing facility**
• **Facilitate recording and reporting at all screening facilities in their jurisdiction**
• **Facilitate uninterrupted supply of test kits in cold chain along with other required logistics**
• **Facilitate confirmation of HIV test results at nearest stand-alone ICTC for all patients found "reactive" at DMC**
• **Ensure provision of feedback by ICTC counsellor on test result to referring MO**
• **Ensure appropriate and timely linkages of all detected HIV positive individuals to care, support and treatment**

Role of District DR TB HIV Coordinator:

• **Assist DTO in organizing TB HIV co-ordination activities in the district**
• **Organizing training of staff in TB/HIV collaborative activities, including intensified TB-HIV package of services in the district**

• **Prepare and maintain a directory of ICTCs, ART Centres /LACs, Community Care Centres and NGOs working in NACP in the district and the collaborating RNTCP centres.**
• **Assist the nodal officer in coordinating regular sharing of the information related to TB-HIV coordination.**
• **Ensure complete, correct and timely compilation and transmission of PMDT/TB-HIV information.**
• **Establish linkages with DTC, DAPCU, collaborating NGOs and hospitals of the district.**
• **To facilitate change management with respect to use of ICT & NIKSHAY tools for concerned data entry, validation & its use for public health action**

Role of TB HIV Coordinator at ART centre:

• **Assist ART MOs, MOTC/HIV in organizing TB HIV co-ordination activities in the district**
• **Facilitate training of Nursing staff, Counsellors in TB/HIV collaborative activities, including IPT services in the district**
• **Prepare and maintain a directory of ICTCs, ART Centres /LACs, Community Care Centres and NGOs working in NACP in the district and the collaborating RNTCP centres.**
• **Assist the nodal officer in coordinating regular sharing of the information related to TB-HIV coordination at Sub district level and ART Centres assigned by NACO**
• **Ensure complete, correct and timely compilation and transmission of IPT , TB-HIV information.**
• **Establish linkages with DTC, DAPCU, ART, LAC, ICTCs/F-ICTCs TU, DMCs, DRTB centre and collaborating NGOs and hospitals of the district.**
• **To facilitate change management with respect to use of ICT tools for concerned data entry, validation & its use for public health action**

Role of Medical Officer:

• **Assess HIV status of TB patients, and refer all with unknown HIV status to the nearest NACO testing centre for voluntary HIV counselling and testing. Use the**

referral form.
• **Prescribe CPT to all known HIV-infected TB patients without contraindications. Counsel HIV-infected TB patients who have been prescribed CPT on possible side effects of Cotrimoxazole.**
• **Refer HIV-infected TB patients to the nearest ART Centre, preferably after at-least two weeks of TB treatment (especially smear positive pulmonary TB). Use the ART referral form.**
• **Monitor the updation of information on HIV status, CPT and ART delivery to HIV-infected TB patients on the TB treatment card.**
• **At the end of TB treatment, refer all HIV-infected TB patients not already taking ART again to the ART Centre for continuation of CPT and for re-evaluation of eligibility for ART. Use ART referral form.**
• **Ensure HIV status of the TB patients remains confidential with in the health system.**

Role of MO-TC/MO- HIVTB:

• **Provide support to DTOs and DNOs in training of MOs, STS, Counsellors and Institutional DOT providers on intensified TB/HIV package.**
• **Sensitize medical officers in the implementation of routine referral of TB patients for HIV testing, CPT provision, and ART referral, and the correct updation of TB records.**
• **Coordinate with all the PHI-MOs and ensure the availability of CPT at PHI.**
• **Indent Cotrimoxazole timely from the DTO and maintain adequate buffer at TU level.**
• **Monitor the linkage of HIV-infected TB patients to ART centres.**
• **Supervise field staff and sensitize them regarding their roles and responsibilities.**
• **Ensure HIV status of the TB patients remains confidential with in the health system.**

Role of Medical Officer DMC PHI:

• **Ensure availability of whole blood test kits at the DMC**
• **Ensure storage of kits at cool temperature (2 to 8 degrees centigrade)using refrigerator.**

• **Review performance of testing and referral fortnightly and ensure timely submission of reports**
• **Review records maintained by LT regularly**
• **Ensure those tested positive on WBFPT are linked to the nearest ICTC at the earliest**
• **Ensure universal precautions such as use of hand gloves, appropriate disinfection procedures, safe handling of sharps etc. by LT**
• **Ensure disposal of biomedical waste along with other hazardous hospital waste as per guidelines**

Role of Pharmacist/ Institutional DOT Provider

• **Assess HIV status of TB patients, and refer all with unknown HIV status to the nearest NACO testing centre for voluntary HIV counselling and testing. Use the referral form. Document the results on the PHI-held original TB treatment card.**
• **Check the TB identity card for CPT prescription.**
• **Provide monthly supply of CPT to the HIV-infected TB patients, who have been prescribed CPT by the attending MO and record the date of delivery on the TB treatment card.**
• **Indent from MO-TC and maintain stock of Cotrimoxazole to ensure uninterrupted supply of CPT for the HIV-infected TB patients.**
• **Encourage the HIV-infected TB patients, during their monthly visit to PHI for collecting CPT, to meet the Medical Officer for routine examination**
• **Refer HIV-infected TB patients to the nearest ART Centre, preferably after two weeks of TB treatment. Use the ART referral form. Record the referral and the result of ART evaluation in the original treatment card.**
• **At the end of TB treatment refer all HIV-infected TB patients not already taking ART again to the ART Centre for continuation of CPT and for re-evaluation of eligibility for ART. Use ART referral form.**

Role of Counsellor

• **Record referral from RNTCP in the counselling register.**
• **Emphasize, while counselling clients, on the importance of sharing HIV test result with the referring/ treating physician.**
• **Record the HIV test result on the referral form and send it back to referring physician through the TB patient.**
• **Communicate the HIV test result of TB patients to the referring/ treating physician either personally or telephonically unless the patient has requested that the HIV test results not be shared.**
• **Counsel HIV-infected TB patients on the importance of CPT, the availability of decentralized CPT through the RNTCP including adherence.**
• **Provide information to HIV-infected clients on the importance of ART, on the process of ART evaluation and the importance of completing the necessary steps to determine the need for ART including adherence and their free availability under the programme.**
• **The above roles are in addition to the existing ones – to provide information on TB to all the clients, screen all the clients for TB symptoms, refer TB suspects to RNTCP, prepare a line-list of such referrals, attend the monthly co-ordination meeting with RNTCP staff, co-ordinate with STS to get the line-list completed and prepare & submit the monthly TB/HIV report.**

Role of ART Centre :

• **Evaluate HIV-infected TB patients for ART on priority, including prioritization for CD4 testing.**
• **Record patients‟ TB number and name of referring unit in the pre-ART register (in the column “entry point code”, along with the appropriate code for RNTCP) and the ART- register.**
• **Ensure CPT is provided to all HIV-infected TB patients for the duration of TB treatment from either the PHI or from ART centre.**
• **Continue CPT after the end of TB treatment from ART centre as per NACO OI guidelines.**
• **Provide feedback on CPT continuation and ART initiation to the referring**

physician, using the same ART centre referral form if received and available.
• **Ensure that the TB/HIV register is maintained at the centre and the ART centre staff attend the monthly co-ordination meetings with RNTCP staff regularly.**

Role of Senior Treatment Supervisor RNTCP :

• **Update TB registers during monthly visits to PHIs with information on HIV status, and (for HIV-infected TB patients) provision on CPT and ART from the original TB treatment card.**
• **Coordinate with MO-PHIs and pharmacist and facilitate the availability of CPT at the PHIs.**
• **Supply cotrimoxazole to requesting PHIs on an as-needed basis.**
• **Coordinate with ART centre staff during monthly meeting to ascertain ART provision to HIV-infected TB patients.**
• **Visit ART centre as and when required to refer to the TB/HIV register maintained and update the TB register.**
• **Ensure HIV status of the TB patients remains confidential with in the health system**

Role of DMC Laboratory Technician:

• **Perform HIV screening test using whole blood finger prick test**
• **Document screening test results on DMC laboratory register**
• **Prepare monthly DMC report on HIV screening using WBFPT and submit to MO**
• **Ensure storage of testing kits at cool temperature (2 to 8 ^{0})**
• **Co-ordinate with RNTCP supervisors (STLS/STS) to ensure screening of all TB patients**
• **Maintain confidentiality of test results within health system (shared confidentiality)**
• **Follow universal precaution and ensure safe disposal of biomedical waste material**
• **Ensure that those tested "reactive" are linked to nearest stand -alone ICTC at the earliest**

ANNEXURES

Annex 1: National Tb HIV Coordination Committee (NTCC)

COMPOSITION OF COMMITTEE:

1. **Chairman:** Secretary/DG/NACO, Department of AIDS Control/NACO, Ministry of Health and Family Welfare, Government of India.
2. Vice chairperson of the NTCC is Additional Secretary, National AIDS Control Organisation (NACO), Ministry of Health and Family Welfare, Government of India
3. Nominee from Ministry of Health and Family Welfare, Government of India - concerned joint secretary
4. Deputy Director General (TB), Dte. GHS Ministry of Health and Family Welfare, Government of India
5. Deputy Director General, Care, Support and Treatment Division, National AIDS Control Organisation (NACO), Ministry of Health and Family Welfare, Government of India
6. Nodal person for HIV, WHO India
7. National Professional Officer (TB), WHO India
8. Director, National Institute of Research in TB (NIRT), Chennai
9. Director, National AIDS Research Institute (NARI), Pune
10. Project Director, Karnataka State AIDS Control Society, Bengaluru, Karnataka.
11. Project Director, Uttar Pradesh State AIDS Control Society, Lucknow, U.P.
12. Civil Society Organisation Representative – TB, Global Health Advocates, New Delhi
13. Civil Society Organisation Representative – HIV, President, Indian Network for Positive People (INP+)
14. National Program Officer (ART) , NACO.MOHFW.GOI
15. Program Officer (HIV-TB), NACO, MOHFW, GOI
16. Member secretary : Deputy Director General, Basic Service Division, NACO, Ministry of Health and Family Welfare, Government of India

The Terms of Reference for the committee are:

1. To strengthen co-ordination mechanisms between NACP and RNTCP at National, State and District level
2. To review and adopt policies for strengthening implementation of joint TB/HIV activities
3. To suggest strategies for roll out and scale up of activities aimed at minimizing mortality and morbidity associated with TB/HIV
4. To review implementation of joint TB/HIV activities and identify key areas for strengthening.

The NTCC will meet at least once in every quarter or as per need with the permission of the chairperson.

Annex 2: National Technical Working Group on TB HIV Collaborative Activities (NTWG)

COMPOSITION OF NTWG:

Chairperson: Deputy Director General, Basic Service Division, National AIDS Control Organisation (NACO), Ministry of Health and Family Welfare, Government of India

Members:

1. Deputy Director General (TB), Dte. GHS Ministry of Health and Family Welfare, Government of India
2. CMO-TB(in charge for the TB-HIV activities) at Central TB Division, MoHFW
3. Medical officer- HIV, WHO India country Office, New Delhi
4. Medical officer/National Professional Officer (TB), WHO India, New Delhi
5. National consultant ,TB/HIV, CTD, MoHFW, New Delhi
6. TB/HIV researcher, National Institute of Research in TB (NIRT), Chennai.
7. Joint Director/In charge TB/HIV activities at State AIDS Control Society nominated by DAC,(Annual rotation)
8. State TB officer Nominated by CTD(Annual rotation)
9. DDG(CST), NACO, MoHFW
10. National Program Officer (ART).NACO, MoHFW
11. National Program Officer (ICTC), NACO, MoHFW.
12. Civil Society organisation Representative – TB, Global Health Advocates, New Delhi
13. Civil Society organisation Representative – HIV, President, Indian Network for Positive People (INP+)
14. Member secretary: Program Officer (HIV-TB), DAC, MOHFW.

The Terms of Reference for the committee are:

1. To strengthen NACP-RNTCP co-ordination at National, State and District level.
2. To review, Optimize and plan for future TB/HIV collaborative activities as envisaged in NACP-IV and the National Strategic plan(2012-17)
3. To develop strategies for rollout and scale up TB/HIV interventions as recommended for implementation by NACP and RNTCP.
4. Strengthening mechanism for joint supervision and monitoring including standardized recording, reporting and data sharing between NACP and RNTCP as per the national framework for TB/HIV Collaborative activities.
5. Identify key areas for research and facilitate conduct of Operational research to improve programme implementation or research for impact assessment of TB/HIV interventions. The NTWG will meet at least once in every quarter.

Annex 3: State TB-HIV Co-ordination Committee (SCC)

Proposed composition:

1. Secretary, Health: **Chairman**
2. Director Health Services: Vice Chairman
3. Mission Director, National Rural Health Mission, Vice Chairman
4. Director Medical Education and Research: Member
5. Project Director, SACS: Member
6. Additional Project Director, SACS: **Member, Secretary**
7. State TB Officer: Member
8. Director, STDC: Member
9. DAPCU Nodal Officer at SACS : Member
10. Joint Director / Dy. Director, ICTC, SACS: Member
11. Dy. State TB Officer / Assistant Programme Officer (APO): Member
12. RNTCP and NACP consultants and Regional coordinators: Member
13. State HIV/TB coordinator
14. Representative of NGOs working with RNTCP: Member
15. Representative of NGOs working with NACP: Member

Note*: The Chairman of the Committee if need arises can invite a person as special invitee whenever required for the betterment of the programme. In case the Chairman is not available for the meeting, a nominee of the chairperson may preside over the deliberations*

Terms of Reference

1. To ensure implementation of collaborative TB-HIV activities as per national framework
2. To ensure that all District Nodal Officer for NACP and DTO for RNTCP **are in place**
3. To address issues related to sub-optimal detection of HIV/TB and linkage to DOTS and ART services
4. Policy decisions to implement all new initiatives recommended by the NTWG
5. To take measures to strengthen participation of general health system staff in HIV/TB activities
6. To take measures to strengthen TB infection control practices at all health facilities particularly those caring for TB and HIV/AIDS patients

Note: Expenditure for this meeting may be booked under the NACP budget for basic services division in SACS

Annex 4: State HIV/TB Working Group (SWG)

Proposed composition:

1. Project Director, SACS: Chairman
2. Additional Project Director, SACS: **Member, Secretary**
3. State TB Officer: Member
4. Director, STDC: Member
5. DAPCU Nodal Officer at SACS : Member
6. Joint Director / Dy. Director, ICTC, SACS: Member
7. Dy. State TB Officer / Assistant Programme Officer (APO): Member
8. RNTCP and NACP consultants and Regional coordinators: Member
9. State HIV/TB coordinator
10. Representative of NGOs working with RNTCP: Member
11. Representative of NGOs working with NACP: Member

Generic Agenda for quarterly SWG meetings

1. Review of actions taken by districts on recommendations of last SWG meeting
2. Review of progress in bridging service delivery gap like co-location of HIV and TB testing facilities, ART facilities, TB culture and DST facilities, etc.
3. Review of performance of Intensified TB case finding activities at ICTC, ART centers, Link-ART centers
4. Review performance of HIV testing of TB/DR-TB patients and presumptive TB cases (in HP states)
5. Review linkage of HIV infected TB/DR-TB patient to DOT, CPT and ART
6. Review of timeliness of ART initiation of HIV/TB cases enrolled at ART centers
7. Review implementation of Isoniazid Preventive Treatment (IPT)
8. Review of timeliness of reporting on HIV/TB from all facilities implementing ICF activities
9. Review implementation of co-ordination meetings at district level (DCC and monthly HIV/TB meeting) –specimen minutes of these meetings may be discussed
10. Discussion on observation of joint HIV/TB field visits made during the quarter and plan for the next quarter
11. Review of airborne infection control measures at all HIV and TB /DR-TB care settings
12. Review availability and supplies of logistics e.g. referral formats, CPT, HIV test kits, Rifabutin, Isoniazid etc.
13. Review issues in human resource management e.g. vacancies, appointment process, training, re-orientation etc.
14. Discussion and decisions on communications received from NACO and CTD during the quarter

Note: Expenditure for this meeting may be booked under the NACP budget for basic services division in SACS

Annex 5A: District Coordination Committee

Proposed composition:

1. *Chairman : District Magistrate/Collector or CEO Zilla Panchayat*
2. *Vice Chairman : Chief Medical Officer / District Health Officer or equivalent*
3. *Member Secretary : DAPCU Nodal Officer/ District TB Officer (in non A and B districts)*
4. *Member : Medical Superintendent, District Hospital*
5. *Member : Medical Superintendent, Medical College Hospital*
6. *Member : City TB Officers (where applicable);*
7. *Member : MS of Hospital providing ART Services (where applicable)*
8. *Member : ART Centre Medical Officer (where applicable)*
9. *Member : Representative of NGO / CBO involved in NACP*
10. *Member : Representative of NGO / CBO involved in RNTCP*

Note: Chairman of DCC, if need arises can invite a person as special invitee whenever required for betterment of programme. In case the Chairman is not available for the meeting, a nominee of the chairperson may preside over the deliberations.

Terms of Reference

1. To strengthen coordination between RNTCP and NACP staff in the District.
2. To review performance of all HIV/TB activities implemented in the district as per national framework, and provide guidance for improvement
3. To address issues related to human resources including filling of vacancies, training of key programme staff and general health staff in HIV/TB activities
4. To ensure participation of general health system staff in implementation of HIV/TB activities
5. To ensure that appropriate infection control measures are taken at all facilities providing HIV /TB /DR-TB care
6. To ensure safe injection practices in facilities providing health facilities to prevent HIV
7. To promote participation of NGO/CBO and Private Practitioners in implementation of TB-HIV activities

Generic agenda for DCC meeting

1. Review of actions taken on recommendations of previous DCC meeting
2. Review of progress to bridge service delivery gaps e.g. HIV testing facilities, ART facilities, TB culture and DST facilities etc.
3. Review of Number (%) of TB patients or presumptive TB cases (in HP states) offered HIV testing – TB unit wise and PHI wise
4. Review of Number (%) of referrals of presumptive TB cases out of total attendees from HIV care settings (ICTC, ARTC, Link ART centers and TI NGO etc.) to RNTCP DMCs –Unit Wise
5. Review of linkage of HIV infected TB cases to DOTS, CPT and ART
6. Review of performance indicators of the district specially - HIV-TB death rates –TB unit Wise
7. Review of implementation of Isoniazid Preventive Treatment (IPT)
8. Review of Airborne infection control activities at HIV and other health care settings
9. Performance of NGO/PP involved in HIV/TB activities in the district
10. Review of Joint ACSM activities conducted during the quarter
11. Any other priority issues

Note: SACS to provide budget to DAPCU officer/DNO or DTO to make the expenditure for organization of this meeting from NACP budget for basic services division

Annex 5B: Generic Agenda Items for monthly HIV/TB coordination meeting

Two-three days Prior to monthly meeting RNTCP STS should handover completed line-list of presumptive TB cases for previous month to the ICTC and ART center counsellor/staff nurse, and obtain Line-list for current month

1. The first agenda item should be validation of monthly report generated from completed line-list by ICTC counsellor or ARTC staff nurse. These validated reports should then be sent to SACS and STC
2. Counsellors at stand-alone ICTC will be responsible for sharing data for F-ICTC in their jurisdiction
3. Review of Number (%) of referrals of presumptive TB cases from all HIV care settings like ICTC, ART and Link ART center and the TI NGO, to RNTCP–Unit Wise
4. ART center MO/staff nurse should provide feedback on enrollment of HIV/TB patients at ART center and status of ART initiation to concerned STS by referring to ART center HIV/TB register
5. RNTCP STS should provide feedback on status of TB treatment initiation of patient referred outside the district
6. The RNTCP STS should provide TB treatment outcome of all patients in the HIV/TB register to ART staff nurse
7. Review of Number (%) of TB patients /presumptive TB cases offered HIV testing –TB unit /DMC wise
8. Review of linkage of HIV infected TB cases to DOTS, CPT and ART
9. Review of availability of logistics like, HIV test kits, referral formats, CPT, Rifabutin, Isoniazid etc.
10. Discussion on field observations of DTO/DNO /district ICTCT supervisors, District HIV/TB supervisor etc.

Note: SACS to provide budget to DAPCU officer/DNO or DTO to make the expenditure for organization of this meeting from NACP budget for basic services division

Annex 6: Quarterly report on HIV/TB collaborative activities

Name of SACS: _____ Quarter/Year _____

A. HIV/TB Co-ordination activities

State level:

State Coordination committee meeting	
• Date of last meeting	
• Are proceedings shared with NACO and CTD? (Yes/No)	
State Working group meeting	
• Date of last meeting	
• Are proceedings shared with NACO and CTD? (Yes/No)	

District Level:

Sr. No.	Name of District	Date of last District Coordination Committee (DCC) meeting	Are proceedings of DCC meetings received at SACS (Yes/No)	Number of Monthly HIV/TB meetings conducted during the quarter	Number of monthly meetings of which, proceedings are received at SACS
1					
2					
3					

**use additional sheet to cover all districts in the state*

Joint Supervision and monitoring:

1. **Joint supervision visits** conducted during the reporting quarter
   a. Name of districts visited: _____
   b. Date of visit: _____
   c. Are visit reports shared with NACO _____
2. **Joint review** of District nodal officer/DTO
   a. Is HIV/TB joint review done during the quarter (atleast once a year):_____
   b. Did SACS representative attend RNTCP quarterly DTO review meeting: _____
3. HIV/TB**reporting**:
   a. ICF at ICTC: Number of months of compiled state report sent to NACO in the quarter:___
   b. ICF at ART Centre: Number of months of compiled report sent to NACO:___
4. D**rugs and logistics**:
   a. Number of districts with CPT stock sufficient to last 3 months (information from RNTCP PMR at state level):____

Annex7: Integrated Counselling and Testing Centre Referral form

Integrated Counselling and Testing Centre referral form

Referral to Integrated Counselling and Testing Centre

Dear Counsellor,

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

Name _____*age/sex*

TB Number (if available) _____

Kindly do the needful and provide me feedback on the same, in a confidential manner.

Referring Provider

Name: **Contact Phone #:**

Date of referral:

Name and address of the PHI:

Feedback by the Counsellor to referring provider

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

Test result from ICTC

HIV positive ☐ **HIV negative** ☐

Indeterminate ☐ **Opted out** ☐

PID Number

Date of conducting test

Additional communication to the referring physician

Signature of MO ICTC/counsellor

Annex 8 Referral to ICTC form for clients screened by Whole Blood test

Referral to ICTC form for clients screened by Whole Blood test

(To be filledin triplicate –one copy for record, one copy for client/patient and one copy for feedback from ICTC counsellor to PHI MO)

Name of DMC PHI: -_____

Name of the Patient: _____

Age: _____ Sex: Male -☐ Female -- ☐

Address: _____

Type of the client screened:TB patients –☐;presumptive TB case :☐Other –Please Specify:_____

Name of ICTC referred to, for confirmation of HIV status:_____

Date of referral: _____

Remarks: _____

Name of referring doctor:

Phone Number:

Signature

……

Feedback from the ICTC

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

Name:_____

Age: _____ Sex: Male -☐ Female -- ☐

Address: _____

PID Number: _____

Date of testing _____

Test results from ICTC:

HIV positive _____ HIV negative --------

Indeterminate _____ opted out _____

Note: SACS/STC may consider using existing "referral to ICTC" forms used with provision of stamp to document additional information required for screening and feedback

Annex-9: NACO HIV Testing Report

Note: PID number should be left blank, and column 2and and3 are NA

Name and address of **screening** / ICTC centre:

Name : Surname _____ Middle name _____ First name _____

Gender: M / F / TG Age: _____ Years PID # _____ Lab ID #_____

Date and time blood drawn: _____ (DD/MM/YY)

_____ (HH:MM)

Test Details

Specimen type used for testing: Serum / Plasma / Whole Blood

Date and time specimen tested: _____ (DD/MM/YY) _____ (HH:MM)

Note :

- Column 2 and 3 to be filled only when HIV 1 & 2 antibody discriminatory test(s) used
- No cell has to be left blank; indicate as NA where not applicable.

Column 1	Column 2	Column 3	Column 4
Name of HIV test kit	Reactive/Nonreactive(R/NR) for HIV-1 antibodies	Reactive/Nonreactive (R/NR) for HIV-2 antibodies	Reactive/Nonreactive (R/NR) for HIV antibodies
Test I :			
Test II :			
Test III :			

Interpretation of the result : Tick(√) relevant

□ Specimen is negative for HIV antibodies

□Specimen is positive for HIV-1antibodies

□*Specimen is positive for HIV antibodies (HIV 1 and HIV 2; or HIV 2 alone)

□ Specimen is indeterminate for HIV antibodies. Collect fresh sample in two weeks.

**Confirmation of HIV 2 sero- status at identified referral laboratory through ART centres*

--End of report—

Name & Signature Name & Signature

Laboratory Technician Laboratory In-charge

Annex 10: Revised National Tuberculosis Control Programme Laboratory Register

Lab. Serial No.	Date	Name in Full	Age	Sex M/F	Complete address (for new patients) Phone No.	Name of referring Health Facility	Reasons for Examination*				Results		HIV status(P,N, U)	Signature	Remarks
							Diagnosis	Follow-up			A	B			
								TB No.	Regimen NT /PT	Month					

- *If sputum is examined for diagnosis, put a tick(□) mark in the space under "Diagnosis" sputum is examined for repeat diagnosis, put 'RE' in the space under "Diagnosis"*
- *If sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow up", treatment regimen and month of follow up*
- *Points to be mentioned in there marks column: date of starting treatment, treatment regimen, TB No, Referral details, MDR-TB suspect identified and remarks on unblended rechecking of slides during OSE visits by the STLS, etc.*
- *HIV status:P-Positive;N-Negative;U-Unknown*

Annex 11: Revised National Tuberculosis Control Programme*

Laboratory Form for Sputum Examination

Name of Referring Health Facility:_____Date:_

_____Name of patient:----------

----------Age:_____Sex: M☐F☐

Complete address:_____

Contact Phone number/Mobile No.:

_____Type of suspect /disease:

☐ ☐ ☐ Pulmonary

☐ ☐ Extra-pulmonary **Site**:_____

Reason for examination**:**

Diagnosis

Repeat Examination for Diagnosis

Follow-up examinations

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

Treatment Regimens(tick☐ appropriate box):

New cases ☐ ☐ previously treated ☐ ☐ MDR-TB

Patient's TB No._____ (Name and signature of referring person/official)

If sputum samples are being transported:

Specimen identification No.:_____Date of sputum collection:_____

Specimen Collector's name and signature_____

Sputum microscopy results(To be completed in the laboratory of DMC)

Name of DMC:__ Lab. Seria lNo.:_____ **Date of examination**	**Specimen**	**Visual appearance(M,B,S)***	**Results (Neg or Pos)**	**Positive(grading)**			
				3+	**2+**	**1+**	**Scanty****
	A						
	B						

*M=Muco purulent, B=Blood stained, S=Saliva

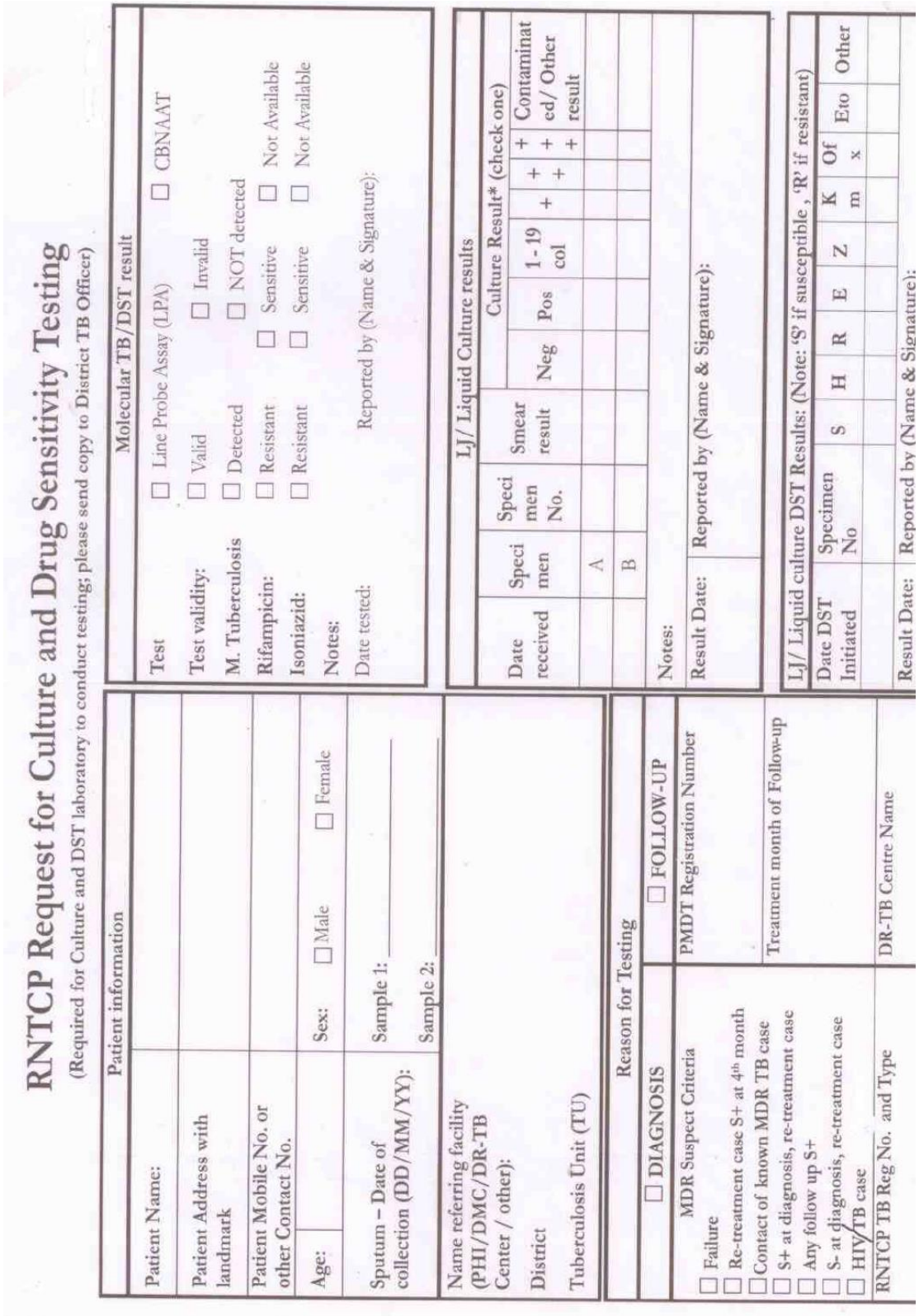
**WriteactualcountofAFBseenin100oilimmersionfields

Date:_____ Signature of Lab. Technician

HIV test results (To be completed by counselor / LT at HIV testing centre) HIV Test result: ☐☐Negative ☐☐Positive ☐☐Indeterminate ☐☐Opted out Date of HIV testing: PID Number official)

**Subject to change as per TOG RNTCP recommendation*

Annex 12: Referral form for Culture and DST*



RNTCP Request for Culture and Drug Sensitivity Testing

(Required for Culture and DST laboratory to conduct testing; please send copy to District TB Officer)

Patient information	
Patient Name:	
Patient Address with landmark	
Patient Mobile No. or other Contact No.	
Age:	Sex: ☐ Male ☐ Female
Sputum – Date of collection (DD/MM/YY):	Sample 1: _____ Sample 2: _____
Name referring facility (PHI/DMC/DR-TB Center / other):	
District	
Tuberculosis Unit (TU)	

Molecular TB/DST result		
Test	☐ Line Probe Assay (LPA)	☐ CBNAAT
Test validity:	☐ Valid	☐ Invalid
M. Tuberculosis	☐ Detected	☐ NOT detected
Rifampicin:	☐ Resistant	☐ Sensitive ☐ Not Available
Isoniazid:	☐ Resistant	☐ Sensitive ☐ Not Available
Notes:		
Date tested:	Reported by (Name & Signature):	

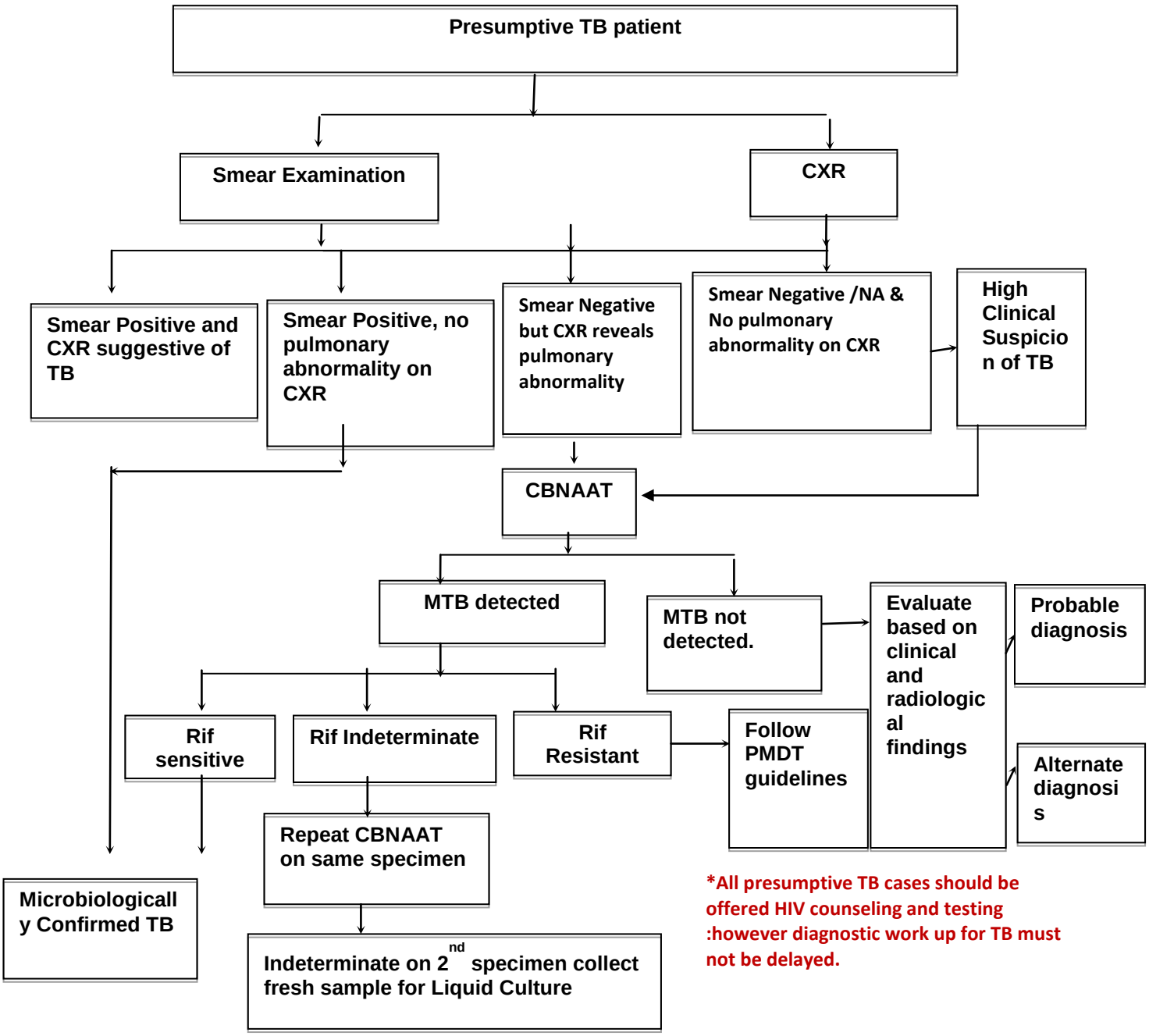
LJ/ Liquid Culture results												
				Culture Result* (check one)								
Date received	Specimen	Specimen No.	Smear result	Neg	Pos	1 - 19 col	+	+ +	+ + +	K mx	Of x	Eto	Other
	A												
	B												
Notes:													
Result Date:	Reported by (Name & Signature):												

Reason for Testing	
☐ DIAGNOSIS	☐ FOLLOW-UP
MDR Suspect Criteria ☐ Failure ☐ Re-treatment case S+ at 4th month ☐ Contact of known MDR TB case ☐ S+ at diagnosis, re-treatment case ☐ Any follow up S+ ☐ S- at diagnosis, re-treatment case ☐ HIV/TB case	PMDT Registration Number Treatment month of Follow-up
RNTCP TB Reg No. and Type	DR-TB Centre Name

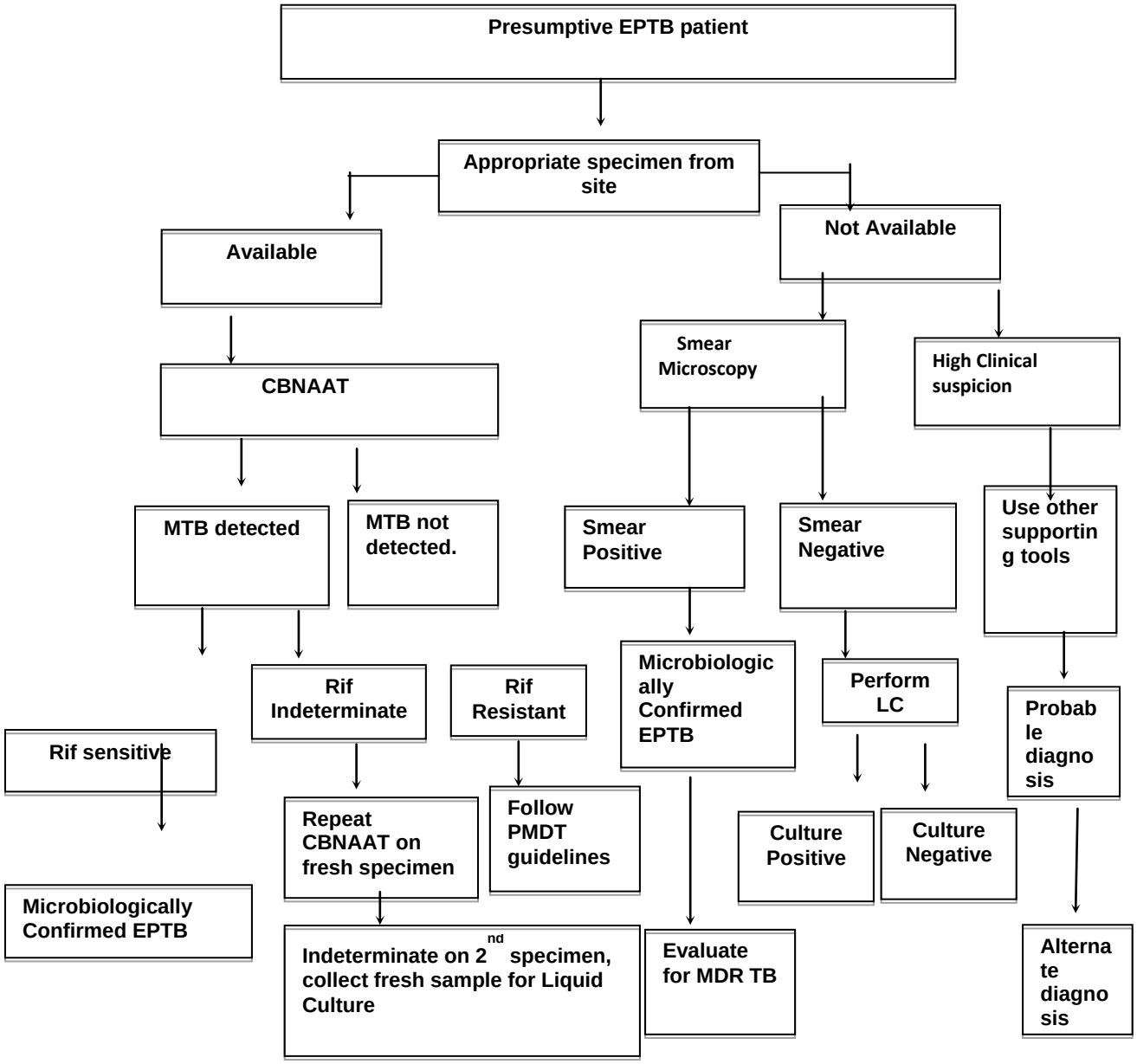
LJ/ Liquid culture DST Results: (Note: 'S' if susceptible , 'R' if resistant)									
Date DST Initiated	Specimen No	S	H	R	E	Z	K mx	Of x	Eto	Other
Result Date:	Reported by (Name & Signature):									

**Subject to change as per TOG RNTCP recommendation*

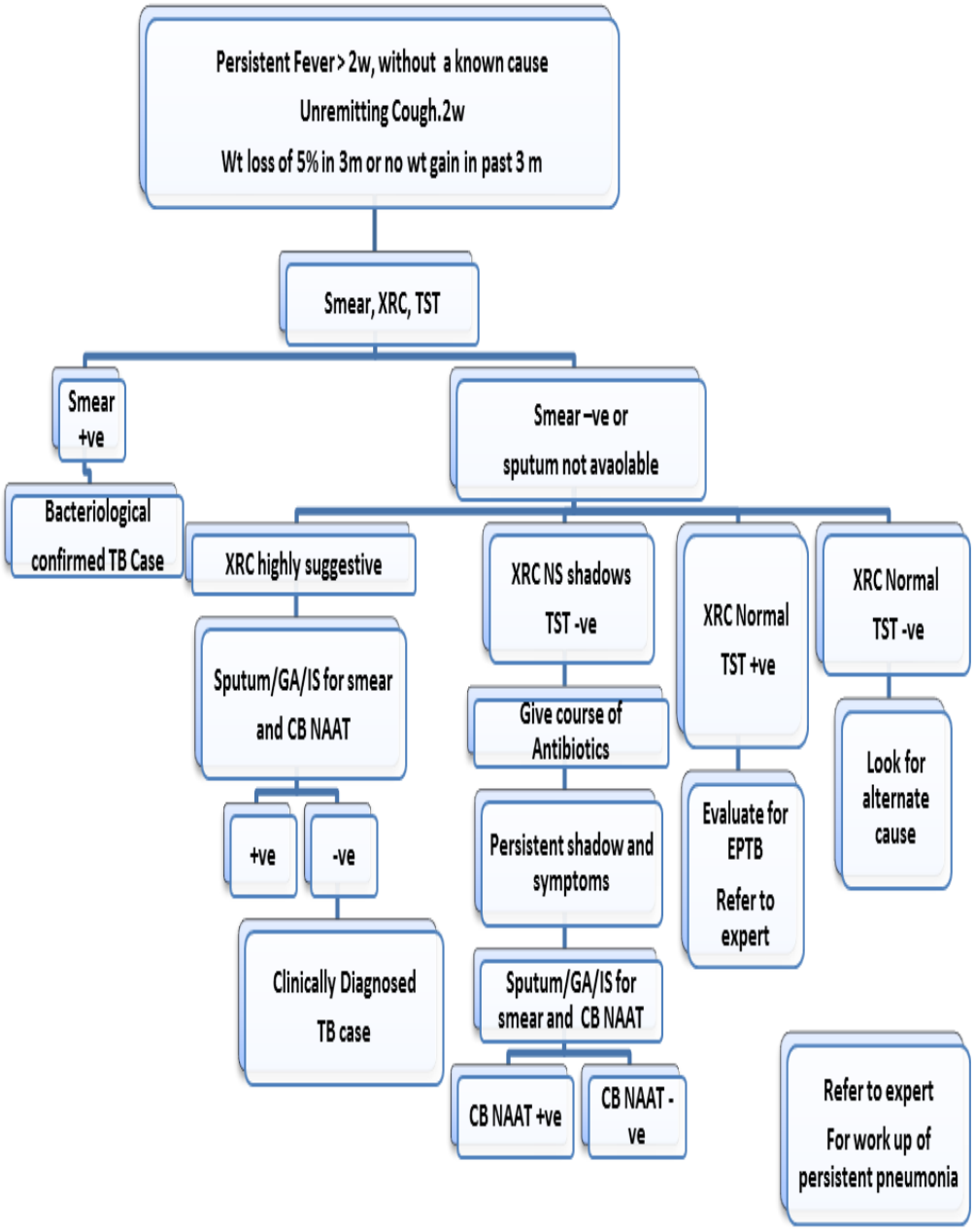
Annex 13: Diagnostic Algorithm Pulmonary TB *(subject to change as per TOG recommendations RNTCP)*



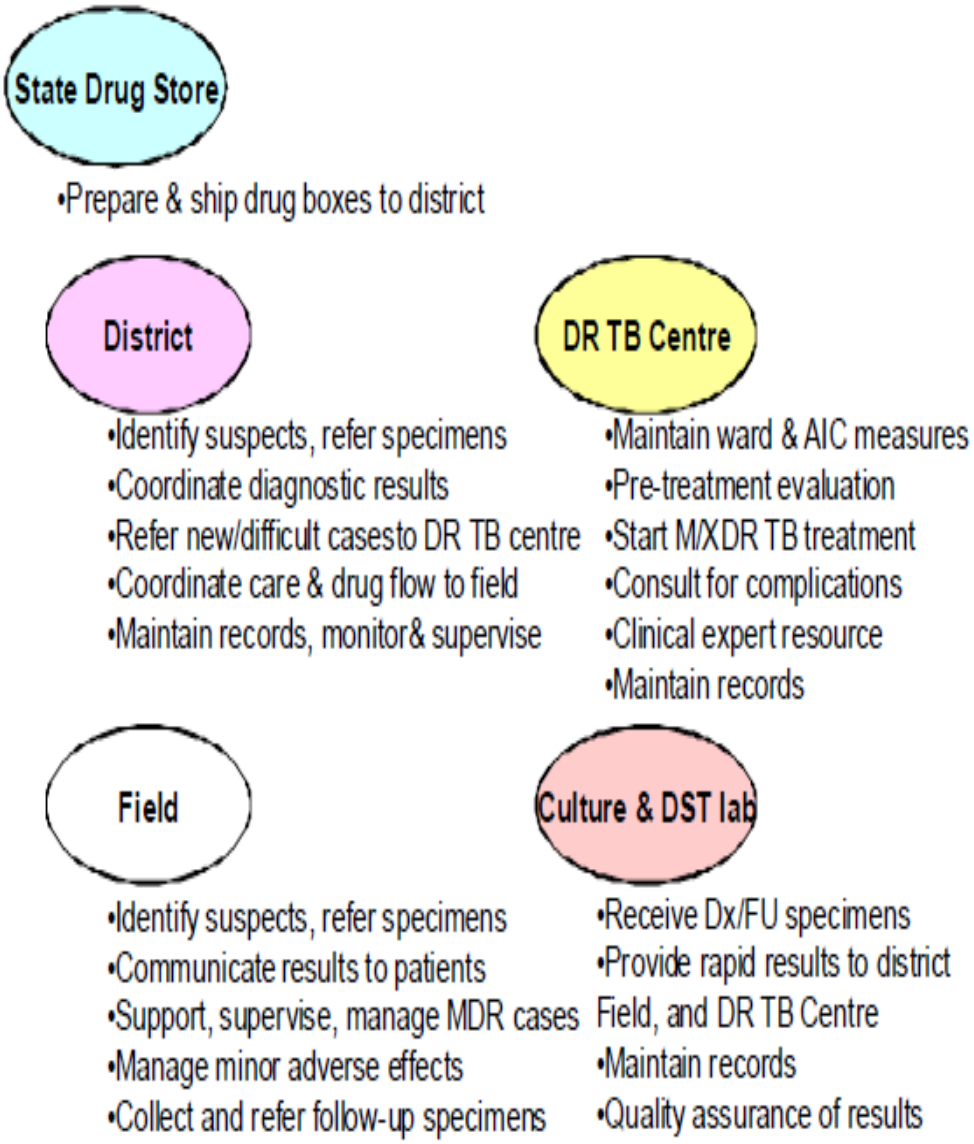
Annex 14: Diagnostic Algorithm Extra Pulmonary TB *(subject to change as per TOG recommendations RNTCP)*



Annex 15: Diagnostic Algorithm for Paediatric TB* *(subject to change as per TOG recommendations RNTCP)*



Annex 16: Drug Resistance Model of care in India



Annex17: Line-List Of Persons Referred From ICTC To RNTCP

REPORTING MONTH: YEAR NAME OF ICTC: NAMEOF DISTRICT:

TO BE COMPLETED BY ICTC COUNSELLOR							***TO BE COMPLETED BY the STS***					
1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***11***	***12***	***13***
Sr. No.	***PID NO***	***Complete Name & Complete Address***	***Age***	***Sex***	***Date of referral to RNTCP***	***Name of facility referred to***	***Is patient diagnosed as TB –Yes or No***	***If diagnosed as TB, specify whether patient is sputum positive TB, sputum negative TB or Extra-pulmonary TB***	***Is patient initiated on DOTS***	***Date of Starting Treatment***	***TB No.***	***Remarks***
Sign of Counsellor *Sign of MO-ICTC* *Date of completion:*							*Name of the TU:* *Signature of STS* *Signature of DTO/CTO/MO-TU* *Date of Completion:*					

Annex 18: ICTC –HIV/TB Register

Sl.No	PID No.	HIV Status 1-Positive 2-Negetive	Suspected to have TB/DRTB	Date of referral to RNTCP for TB/DRTB diagnosis	Result of Investigations			DRTB/Rif Resistant	Whether put on treatment (Anti TB/DRTB)	Registered TB Patient	Referral from RNTC for HIV testing			
					Sputum positive TB	Sputum Negative TB	Extra pulmonary TB				Drug Resistant TB/Rif R patient	TB Suspects	Date of Tested for HIV	Tested Positive
			(Y / N)	(DD/MM/ YY)	(Y / N)	(Y / N)	(Y / N)	(Y / N)	(Y / N)	(Y / N)	(Y / N)	(Y / N)	(Y / N)	(Y / N)
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
1														
2														
3														
4														
5														
6														
7														
8														

Annex19: ICTC TB-HIV monthly report

REPORTING MONTH: _____ *YEAR _____*

NAME OF ICTC:_____ *DISTRICT:_____*

I. TOTAL NUMBER OF GENERAL CLIENTS ATTENDING ICTC:

a) Total no. of clients who attended ICTC in the month (excluding PPTCT clients)	

II.REFERRAL OF SUSPECTED TUBERCULOSIS CASES FROM ICTC TO RNTCP

	HIV positive	HIV Negative
a) No. of persons suspected to have TB referred to RNTCP diagnostic services		
b) Of the referred TB suspects, No. diagnosed as having:		
(i) Sputum Positive TB		
(ii) Sputum Negative TB		
(iii) Extra-Pulmonary TB		
c) Out of above (b), diagnosed TB patients, number receiving RNTCP		

Signature of Medical Officer – In charge ICTC ***Name of Medical Officer In-charge ICTC***

Annex 20: HIV-TB Line List for ART Centres

HIV-TB Line list for 30 IICF ART sites

To be completed by ART Nurse																To be completed by STS		To be completed by ART Staff Nurse (In case of DRTB, to be completed by STS)
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Sr. No.	Pre-ARTI (if in Pre ART care at time of referral)/ART Number(If already on ART at time of referral)	Complete Name	Complete Address	Telephone Number	Age	Sex	Date of referral for TB investigation	Name of facility referred to (RNTCP/ Radiology / Histopathology/ Others)	Is patient diagnosed as TB –Yes/NO	If diagnosed as TB						TB Number / NIKSHAY ID	Date of starting DRTB Treatment at RNTCP	Reason, If not initiated on ATT **
										Date of TB diagnosis	If Yes, Specify whether sputum positive TB, sputum negative TB or Extra pulmonary TB	If Bacteriologically positive what test was performed (Microscopy/CBNAAT/other DST)	Rifampicine status (res/sensitive/NA)	Date of Starting TB Treatment at ART Centre	If Rif resistant, date of referralto DRTB Center			
Sign of ART Nurse Sign of SMO/MO-ART																		
Date of completion																		

*Bacteriological confirmed TB case (Definitive TB Case) refers to a presumptive TB patient from whom a biological specimen is positive for acid fast bacilli. or positive for Mycobacterium tuberculosis on culture. or positive for tuberculosis through Quality Assured Rapid Diagnostic molecular test

Reason** 1. Patient Transferred Out to Other ART Center. 2. Patient Not reporting for Treatment/LFU. 3. Patient died before ATT initiation. 4.Patinet ta

Note : Presently used in pilot sites, will be used countrywide once activities are rolled out.

Annex 21: ART Centre - HIV/TB Monthly Report

3 b. HIV/TB -Intensified TB Case Finding				
TB Diagnosis & Treatment				
(From Completed HIV/TB Line-List- 1 month prior to reporting month)				
3b.1) Number of PLHIV attending ART Centre during the month (Pre ART and ART)				
3b.2) Out of above number of PLHIV screened for 4 symptoms				
3b.3) Out of above, number of PLHIV with presumptive TB (those with anyone/more symptoms out of 4S)				
3b.4) Out of above,number of PLHIV with presumptive TB referred from ART centre for TB diagnosis				
3b.5) Out of above, number of PLHIV with presumptive TB, tested for TB diagnosis				
3b.6) Out of the above number of PLHIV diagnosed as having TB :		**In Pre ART Care at time of TB diagnosis**	**Already on ART at time of TB diagnosis**	**Total**
	(i) Pulmonary TB (Bacteriologically confirmed)			0
	(ii) Pulmonary TB (Clinically diagnosed)			0
	(iii) Extra-Pulmonary TB (Bacteriologically confirmed)			0
	(iv) Extra Pulmonary (Clinically diagnosed)			0
3b.7) Total PLHIV Diagnosed with TB		0	0	0
3b.8) Out of **(3b.7),,** number of TB patients receiving RNTCP treatment				
3b.9) Out of **(3b.7),,** number of TB patients receiving Non-RNTCP treatment				
3b.10) Out of **(3b.7),** number of TB patients with RRTB (Rif Resistant TB)				
3b.11) Out of **(3b.10),** number of TB patients with RRTB (Rif Resistant TB) receiving Cat IV treatment				
3 c. Treatment of HIV in HIV TB co-infected PLHIV				
(From the HIV- TB register data -2 months prior to reporting month)				
3c.1) Total number of TB patients enrolled in HIV/TB register 2 months prior to reporting month				
3c.2) Out of **(3c.1)** number of TB patients initiated on CPT				
3c.3) Out of **(3c.1)** number of TB patients initiated on ART				
3 d. IPT Status (From Master Line List of Reporting Month)				
3d.1) Number of PLHIV newly initiated on IPT during this month				
3d.2) Number of PLHIV completed IPT during this month				

Note : Presently used in pilot sites, will be used countrywide once activities are rolled out.

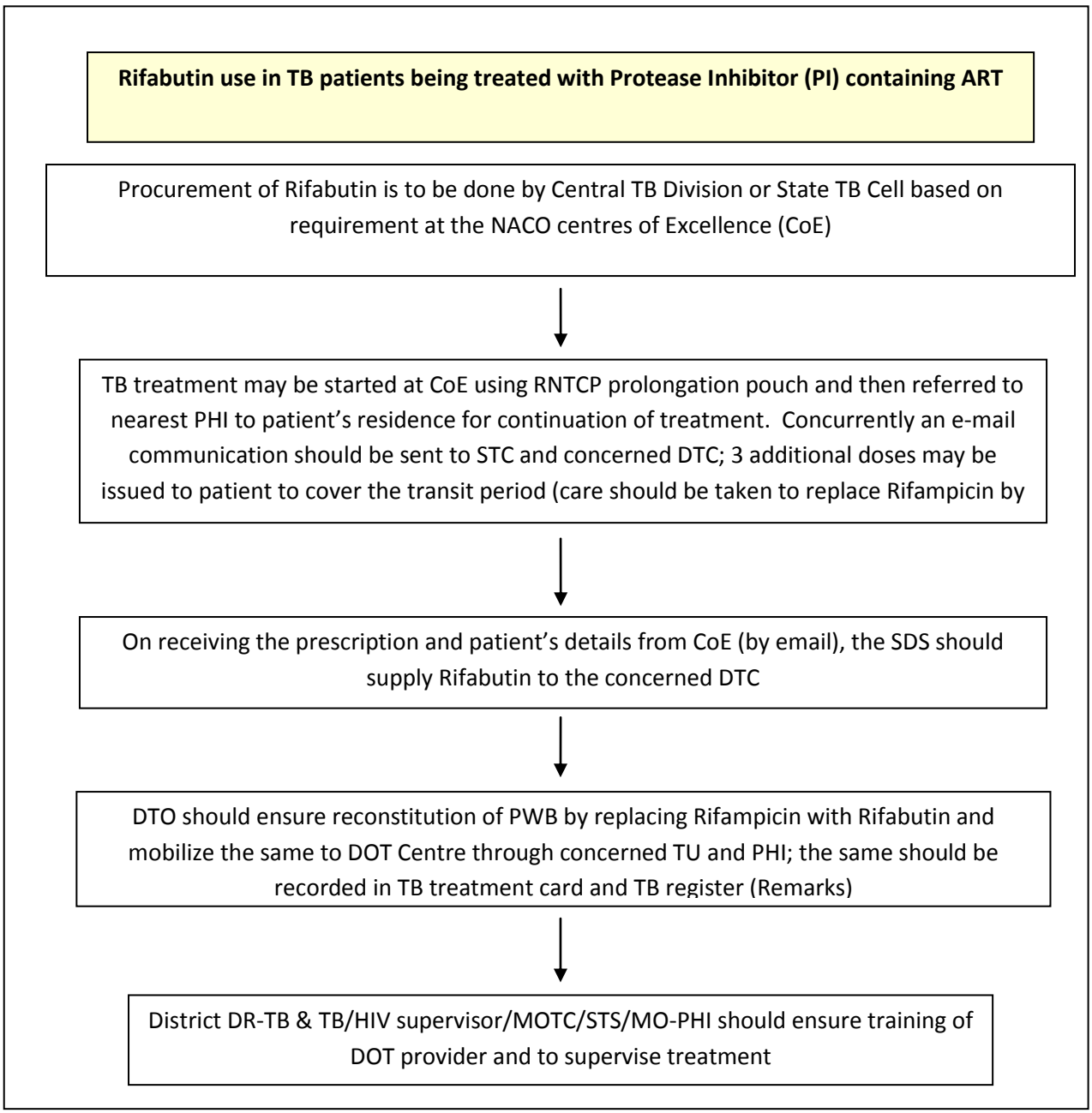
Annex : 22: HIV TB Register for ART Centres

HIV TB register for 30 IICF ART sites

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	
S. No.	Date	HIV care (Pre-ART) registration number	Complete Name	Complete Address	Age	Sex	Specify whether sputum positive TB, sputum negative TB or Extra pulmonary TB	Is the Patient initiated on RNTCP treatment ?(Yes/No)	Date of Starting Treatment	TB Number with TU and District Name	Latest CD4 Count	Date of ART Initiation	ART Registration Number	Is the patient on CPT? (Yes/ No)	TB treatment Outcome*	(Mention Rifampicine status: sen/res/NA)	Remarks

Note : Presently used in pilot sites, will be used countrywide once activities are rolled out .

Annex: 23: Management of Supplies of Rifabutin



Annex 24 A: HIV/TB variables reported in RNTCP Quarterly reports (First line and second line TB treatment)

A. HIV testing of TB patients: case finding report: Block 3 : TB / HIV Collaboration

Of all Registered TB Cases no. known to be tested for HIV before or during the TB Treatment (a)	Of (a), No. known to be HIV infected (b)

B. Linkage of HIV infected TB patients to HIV care and support and TB treatment outcome:

1) RNTCP Sputum conversion report:

Total Number of HIV-infected TB patients registered in the quarter (a)	Of (a), Number receiving CPT during TB treatment	Of (a), Number receiving ART during TB treatment

2) RNTCP Treatment Outcome report: BLOCK – B: TB treatment outcomes of HIV Positive TB Patients

Type of TB cases	**Total No. known to be HIV infected**	**Treatment outcomes**						
		Cured	**Treatment completed**	**Died**	**Treatment Failure**	**Defaulted**	**Transfer out**	**Switched over to MDR-TB treatment**
New								
Previously treated								
Total TB cases								

3. Block C: CPT and ART

Of all Registered TB cases, Number known to be tested for HIV before or during the TB treatment (a)	**Of (a), Total Number of HIV-infected TB patients identified (b)**	**Of (b), Number receiving CPT during TB treatment**	**Of (b), Number receiving ART during TB treatment**

C. Programme coordination and drug logistics reporting in RNTCP Programme Management Report:

1. Is there a District Coordination committee? (Yes/ No/ Not applicable)
2. If yes, did the DCC meeting take place in this quarter? (Yes/No)
3. Of the DMCs in the TU/district/state, number with co-located HIV testing services
4. Information on CPT pouches

Annex 24 B: HIV/TB reporting in programme for management of drug resistant TB (PMDT)

1) Case finding report:

Of all Registered MDR-TB cases, number known to be tested for HIV before or during the TB treatment (a)	Of (a), Total Number of HIV-infected TB patients identified (b)	Of (b), Number receiving CPT during TB treatment	Of (b), Number receiving ART during TB treatment

2) 12 month conversion report:

Number of HIV-infected MDR-TB cases registered on CAT IV regimen in the quarter	Culture results after 12 months of treatment								
	Culture Negative	Culture positive	Culture Unknown	Died	Default	Transferred Out	Treatment stopped due to adverse reactions	Treatment stopped due to other reasons	Switched to Cat-V

3) PMDT treatment outcome report:

Number of HIV-infected MDR-TB cases registered on CAT IV regimen	Cured	Treatment completed	Died	Failure	Default	Transfer out	Treatment stopped due to adverse drug reactions	Treatment stopped due to other reasons	Switched to Category V	Still on treatment	Total

Annex 25: Review Checklist For TB-HIV Activities At State Level

	State and district-level coordination	
a	Whether TB-HIV State Coordination Committee (SCC) functional at state level?	
b	No. of SCC meetings held in last 4 quarters	
c	Number of TB-HIV State Working Group meetings held in last 4 quarters	
d	Proportion of districts with at least two DCC meeting in past 4 quarters	
e	Do all ICTC counsellors attend HIV/TB monthly coordination meeting	
f	Do ART centre staff attend HIV/TB monthly coordination meeting	
g	No. of field visits made to the districts jointly by officers from SACS and STC	
	Infrastructure	
a	Total no. of stand-alone ICTCs in the state as per last month CMIS report	
b	Distribution of ICTCs as per the district category (A,B,C,D)	
c	No. of Facility integrated ICTCs in the state as per last month CMIS report	
d	No. of PPP ICTCs functional in the state as per last month CMIS report	
e	No. of ART centres in the state as per last month CMIS report	
f	No. of LAC (Link ART Centres) functional in the state as per last month CMIS report	
g	No. of Designated Microscopy Centres (DMC) in the state (latest RNTCP PMR)	
h	No. of co-located ICTC and DMC as per latest RNTCP PMR	
	Intensified TB Case Finding at ICTCs and ART Centres	
a	Proportion of ICTC reporting on ICF as per last month CMIS report	
b	Total no. of clients who attended ICTCs during the month	
c	No.(%) of ICTC clients referred to RNTCP as presumptive TB case	
d	No. (%) of the referred TB suspects from ICTCs who are diagnosed with	

	TB	
e	No.(%) of diagnosed TB patients from ICTCs who are initiated on DOTS treatment	
	Intensified TB Case Finding at ART Centres	
a	Proportion of ART centres reporting on ICF as per last month CMIS report	
b	No. (%) of ART centre attendees referred to RNTCP as presumptive TB cases	
c	No. (%) of the referred cases from ART centres diagnosed with TB	
d	No.(%) of diagnosed TB patients out of above initiated on DOTS treatment	
e	Number percentage of ART centre NOT having TB symptoms (Monthly ART centre IPT report)	
f	Number percentage of above patients assessed for eligibility for Isoniazid Preventive Treatment (IPT)	
g	Number percentage of above patients initiated on IPT	
	HIV testing of presumptive TB cases (High HIV prevalence settings)	
a	Number of presumptive TB cases tested at DMC (latest quarterly PMR)	
b	Number (%) out of above with known HIV status	
c	Number (%) out of above found HIV infected	
	HIV testing of TB patients (all states)	
a	Total Number of TB patients registered during the quarter ((latest RNTCP case finding report))	
b	Number of TB patients with known HIV status (RNTCP case finding report)	
c	Number of TB patients with known HIV status from previous quarter (RNTCP sputum conversion report)	
d	No. (%) of registered TB patients found to HIV infected (RNTCP case finding report)	
e	No. (%) of HIV infected TB patients receiving CPT in corresponding quarter last year (RNTCP results of treatment report)	
f	No. (%) of HIV infected TB patients receiving ART during TB treatment in corresponding quarter last year (RNTCP results of treatment report)	
g	No. (%) of HIV infected TB patients initiated on ART as per latest	

	month ART CMIS report	
	Human Resources	
a	No. (%) of ICTCs with vacancy of ICTC counsellor (ICTC CMIS report)	
b	No. (%) of ICTCs counsellors trained in TB-HIV	
c	No. (%) of ICTCs with vacancy of Laboratory Technicians	
d	Is the 10 point counselling tool for TB available at all the ICTCs and ART centres ?	Yes/No

Source of information*: NACO CMIS/SIMS for ICTC and ART centres and RNTCP quarterly reports*

Annex 26: HIV/TB Training guideline

	Training Type	Trainees	Trainers	Level	Duration	Responsibility	Training materials
A	**Basic HIV/TB Training for ICTC and RNTCP staff**						
1	Training of trainers	SACS, STC officials, HIV/TB coordinator	CTD, NACO, WHO, NTI and NIRT	National	2 days	CTD +NACO	Combined TB-HIV module + HIV/TB module for ART centre staff
2	District programme managers	DTO / DNO (HIV-AIDS)/ DAPCU officer	State Master Trainers	State	2 days *	State TB cell +SACS	
3		MO-ICTC/MO-TC				DAPCU/SACS +DTO	Combined TB-HIV module
4	Key staff	District HIV/TB Supervisors / STS				State TB cell	Combined TB-HIV module + HIV/TB module for ART centre staff
5		District ICTC supervisors/ ICTC Counsellors				SACS	
6	Field staff	Medical Officers	DTO / DAPCU / DNO	District	1 day	DAPCU officer / DNO (DTO in their absence)	Combined TB-HIV module
7		Institutional DOT Provider			1 day		
B	**Basic HIV/TB activities for ART centre staff**						
1	Key staff	ART Centre MO	SACS CST officers /RC/NACO trainers	State	2 days	State TB cell +SACS	RNTCP module for PP + HIV-TB module for ART staff
2	Field staff	ART centre staff nurse	State Master trainers		2 days*		HIV-TB module for ART centre staff
3		ART centre counsellors, data managers	ARTC SMO/RC	District	1 Day		

C	**Data management training**						
		DEO at SACS and State TB Cell	Experts from NACO, CTD	State	1 day	State TB cell +SACS	Presentations + module reading
D	**HIV screening using Whole Blood Finger-prick test**						
1	Training of trainers	SACS, STC officials, HIV/TB coordinator	Experts from NACO, CTD	National	2 days **	NACO	WBT technical module for LT + operational guidance
2	Training of Key staff	District HIV/TB supervisor, District ICTC supervisor, STLS, ICTC counsellors	State Master trainers	State	2 days **	SACS	WBT technical module for LT + operational guidance
3	Field training	Medical Officer DMC	State Master trainers	District	1 days	SACS/DAPCU	WBT technical module +operational guidance
4		DMC LT					
5		Institutional DOT provider					
E	**PITC in presumptive TB cases**						
1	Training of trainers	SACS, STC officials, HIV/TB coordinator , /DTO/DAPCU	Experts from NACO, CTD	National	2 days **	NACO	RNTCP guideline for PITC in presumptive TB cases
2	Training of Key Staff	District HIV/TB Supervisors / ICTC supervisors/ STS /STLS	State Master trainers	State	1 days	SACS	
3	Field training	DMC LT	State Master trainers	District	1 days	SACS /DAPCU	
4		ICTC Counsellors	State Master trainers				
F	**IPT Operationalization**						
1	Training of trainers	SACS, STC officials, HIV/TB	Experts from	National	2 days **	NACO	NACO guideline on IPT

		coordinator , Regional Coordinators CST	NACO, CTD				operationalization
2	Training of Key Staff	DTO/ DAPCU officer/ District HIV/TB Supervisors / ICTC supervisors/ STS	State Master Trainers	State	1 Day	SACS	
3	Field training	ART centre SMO / MO/ Counsellors	State Master Trainers	State	2 days ***	SACS	
4		ART centre staff nurse /data managers	ARTC SMO/RC	District	1 day	DAPCU /SACS	
** Includes visit to DMC, ICTC, ART centre and DOT Centre** Includes development of micro-plan*** Includes PowerPoint presentation of supportive evidence and also development of micro-plan for implementation*							

Annex27: Notification of TB Cases

Z-28015/2/2012-TB
Government of India
Ministry of Health and Family Welfare

Nirman Bhavan, New Delhi
Dated: 7th May 2012

Notification of TB cases

TB continues to be a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of TB is the corner-stone of TB prevention and control strategy. Inappropriate diagnosis and irregular/incomplete treatment with anti-TB drugs may contribute to complications, disease spread and emergence of Drug Resistant TB.

In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence and spread of Drug Resistant-TB, it is essential to have complete information of all TB cases. Therefore, the healthcare providers shall notify every TB case to local authorities i.e. District Health Officer / Chief Medical Officer of a district and Municipal health Officer of a Municipal Corporation / Municipality every month in a given format (attached).

For the purpose of case notification, a TB case is defined as follows:

- A patient diagnosed with at least one sputum specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP endorsed Rapid Diagnostic molecular test positive for tuberculosis

OR

- A patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and initiated on anti-TB drugs.

For the purpose of this notification, healthcare providers will include clinical establishments run or managed by the Government (including local authorities), private or NGO sectors and/or individual practitioners.

For more detailed information, the concerned State TB Officers / District TB Officers, whose details are available on www.tbcindia.nic.in, may be contacted.

Encl: As mentioned

(Manoj Sinha)
Under Secretary to the Government of India

Copy for immediate further necessary action, to:

1) All Principal Secretaries / Secretaries of Health of States / UTs
2) All Directors of Health Services of States / UTs
3) All State TB Officers of States / UTs

With the request to kindly immediately bring this order to the notice of all concerned for compliance, in their respective State / UT

Annex 28: Ban on Serological test kits for TB in India The Gazette of India - 7th June 2012

रजिस्ट्री सं० डी० एल०-33004/99

REGD. NO. D. L.-33004/99

सत्यमेव जयते

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 265] नई दिल्ली, बृहस्पतिवार, जून 7, 2012/ज्येष्ठ 17, 1934
No. 265] NEW DELHI, THURSDAY, JUNE 7, 2012/JYAISTHA 17, 1934

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 7 जून, 2012

सा.का.नि. 433(अ).—जबकि केन्द्र सरकार इस बात से संतुष्ट है कि क्षयरोग के निदान के लिए सीरियोडायग्नोस्टिक परीक्षण किटों के प्रयोग से असंगत और संदिग्ध परिणाम मिल रहे हैं जिससे गलत निदान हो रहा है और उनके प्रयोग से लोगों को खतरा होने की संभावना है और जबकि इनके सुरक्षित विकल्प उपलब्ध हैं;

और जबकि केन्द्र सरकार इस बात से संतुष्ट है कि लोक हित में उक्त परीक्षण किटों के आयात को वर्जित करना आवश्यक और समीचीन है;

अतः, अब, औषध एवं प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 10क के द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए केन्द्र सरकार एतद्द्वारा स्वास्थ्य एवं परिवार कल्याण मंत्रालय के दिनांक 23 जुलाई, 1983 की सं. सा.का.नि. 577 (अ) में भारत सरकार की अधिसूचना में निम्नलिखित संशोधन करती है, अर्थात्:—

उक्त अधिसूचना में संलग्न सारणी, क्रमांक 10 के पश्चात् और इससे संबंधित प्रविष्टि में निम्नलिखित क्रमांक और प्रविष्टि निवेशित की जाएगी, अर्थात्:—

"11. क्षयरोग के निदान के लिए सीरियोडायग्नोस्टिक परीक्षण किटें"

[फा. सं. एक्स-11014/13/2011-डीएफक्यूसी (2)]

अरुण के. पण्डा, संयुक्त सचिव

पाद टिप्पणी : प्रधान अधिसूचना को दिनांक 11-12-2009 की सं. सा.का.नि. 884(अ) के तहत भारत के राजपत्र में प्रकाशित किया गया।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th June, 2012

G.S.R. 433(E).—Whereas the Central Government is satisfied that the use of the serodiagnostic test kits of diagnosis of tuberculosis are giving inconsistent and imprecise results leading to wrong diagnosis and their use is likely to involve risk to human beings and whereas safer alternatives are available;

And whereas the Central Government is satisfied that it is necessary and expedient to prohibit the import of the said test kits in public interest;

Now, therefore, in exercise of the powers conferred by Section 10A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment in the notification of the Government of India in the Ministry of Health and Family Welfare number G.S.R. 577 (E), dated the 23rd July, 1983, namely :—

In the Table appended to the said notification, after serial number 10 and the entry relating thereto, the following serial number and entry shall be inserted, namely :—

"11. Serodiagnostic test kits for diagnosis of tuberculosis."

[F. No. X-11014/13/2011-DFQC (2)]

ARUN K. PANDA, Jt. Secy.

Foot Note : The principal notification was published in the Gazette of India *vide* No. G.S.R. 884(E), dated 11-12-2009.

2053 GI/2012

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Annexure 29: Integrated 10 Points counselling Tool on TB/Drug Resistant TB

INTEGRATED 10 POINTS COUNSELLING TOOL ON TB/DRUG RESISTANT TB

1. Tuberculosis (TB) is the most common opportunistic Infection in people living with HIV (PLHIV) and leading cause of death in PLHIV.
2. Tuberculosis is an infectious disease caused predominantly by Mycobacterium Tuberculosis. The infection occurs most commonly through droplet nuclei generatedby coughing, sneezing etc., inhaled via the respiratory route. TB usually affects the lungs, but may affect other parts of the body as well.
   - ***An HIV* negative person infected with TB has a 10% life-time risk of developing TB disease.**
   - **HIV increases the risk of progression from TB infection to TB disease and PLHIVs have a 60% lifetime risk of developing TB disease.**
3. Persons having cough of 2 weeks or more, with or without other symptoms, are referred to as pulmonary TB suspect (Presumptive TB case). They should have 2 sputum samples examined at Designated Microscopy Centre (DMC).
4. A person with extra-pulmonary TB may have symptoms related to the organs affected along with symptoms like enlarged cervical lymph nodes, Chest pain, Pain and swelling of the joints etc. Extra-pulmonary TB can be confirmed by other investigations.
5. All people living with HIV should be regularly screened for TB using a clinical symptom-based algorithm consisting with any one of the symptoms of Cough of any duration, Fever, Weight loss or Night sweats at the time of initial presentation for HIV care and at every visit to a health facility or contact with a health-care worker afterwards.
6. Diagnosis and treatment services for TB are available free of cost through the Revised National TB Control Programme (RNTCP)
   - 2 sputum smear examinations are necessary for the diagnosis of pulmonary TB. During the course of treatment the progress is monitored by means of follow up sputum examinations.
   - Anti TB drugs are provided in patient-wise drug boxes, which ensure that the full course oftreatment is available at the start of treatment. Treatment is provided by "DOT provider "at a place near the patient's home.
   - Cure from TB can only be ensured by taking complete and regular treatment. Without correct and complete treatment, a patient can become very ill or develop Drug resistant TB.
7. PLHIV diagnosed with TB should be linked to ART services at earliest, irrespective of CD4Count. Co-trimoxazole preventive therapy should be provided to all HIV-TB co-infected patients to prevent opportunistic infection.
8. An HIV/ TB co-infected patient should be referred to nearest RNTCP certified Culture and Drug sensitivity laboratory facility /CBNAAT facility for diagnosis of Drug resistant TB.
9. The client's information is to be kept confidential and this information is not furnished under any circumstances to any other person except 'Shared confidentiality' with the treating physician and public health system DOT provider for better case management & to get benefit of prophylactic/ treatment options available for him.
10. All TB/ Drug resistant TB patients should maintain cough hygiene (putting a cloth onnose & mouth while coughing or sneezing) to prevent transmission of TB/DRTB.