Guidelines for the Programmatic management of TB/HIV in Myanmar

National Tuberculosis Programme

National AIDS Programme

Reprinted in March 2019

Preface

It has been 10 years since TBHIV activities have been started in 7 townships. The operational frame, implementation model and tools for monitoring and evaluation have been developed.

Although there are National Guidelines for HIV and TB that are updated regularly in accordance with WHO guidelines, there has not been a consolidated guideline for the clinical management of TB/HIV patients.

The essential knowledge such as clinical presentations of HIV related TB, differential diagnosis, diagnosis of presumptive extra-pulmonary and disseminated forms of TB, treatment of active TB patients living with HIV are included in this guideline with the contribution from experienced clinicians and skilled program staff.

The brief information about recommended TB/HIV collaborative activities, diagnosis of TB in people living with HIV with flow diagram of XPert testing, infection control, the key indicators, their definitions, and recording forms from program side will permit the attending clinicians to have orientation related to TB/HIV and programmatic management.

I am confident that this guideline will be of considerable help not only to keep the optimal quality of care but also to expand and enhance the scope and scale-up of Myanmar's TB/HIV collaborative activities. The National TB Program and National AIDS Program are thus able to monitor and evaluate the TB/HIV activities by putting the Guidelines for the Programmatic Management of TB/HIV co-infection in Myanmar.

Director (Disease Control)

Department of Public Health

Ministry of Health

The Republic of Union of Myanmar

Acknowledgement

It is to extend appreciation and thankfulness to clinicians from Department of Medical Services, Ministry of Health, Program Managers of National TB Program and National AIDS Program, the Assistance Directors from both programs, Medical Officers from both programs and WHO colleagues who contributed their time, energy and skills for the accomplishment of developing this guideline and to WHO, TB unit for their financial and logistic support.

Contents

List of tables

List of Figures

Abbreviations

3TC	Lamivudine
ART	Antiretroviral therapy
ARV	Antiretroviral drug
AZT	Zidovudine
CPT	Co-trimoxazole preventive therapy
CXR	Chest X-ray
E	Ethambutol
EFV	Efavirenz
EPTB	Extra-pulmonary tuberculosis
FTC	Emtricitabine
H	Isoniazid
HIV	Human immunodeficiency virus
IPT	Isoniazid preventive therapy
IRIS	Immune Reconstitution Inflammatory Syndrome
KS	Kaposi sarcoma
LIP	Lymphocytic interstitial pneumonia
LPV	Lopinavir
LPV/r	Ritonavir-boosted lopinavir
MDR-TB	Multidrug-resistant tuberculosis
NAP	National AIDS Programme
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NTP	National Tuberculosis Programme
PcP	*Pneumocystis jiroveci* pneumonia
PI	Protease inhibitor
PTB	Pulmonary tuberculosis
R	Rifampicin
RTV	Ritonavir
S	Streptomycin
TB	Tuberculosis
TDF	Tenofovir
TST	Tuberculin skin testing
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis
Z	Pyrazinamide

I. TB/HIV collaborative activities

Human Immunodeficiency virus (HIV) is the most powerful factor known to increase the risk of tuberculosis (TB). Persons co-infected with TB and HIV are 20 to 30 times more likely to develop active TB disease than persons without HIV. In developing countries (including Myanmar), TB is the most frequent life-threatening illness and leading cause of death among people living with HIV, including those who are taking antiretroviral therapy (ART). Though TB can occur at any point in the course of progression of HIV infection, the risk rises sharply with worsening immune status. People living with HIV are facing emerging threats of drug-resistant TB such as multidrug resistant (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB).

The goal of collaborative TB/HIV activities is to decrease the burden of TB and HIV in people at risk of or affected by both diseases, as recommended by the World Health Organization (Table 1).

The objectives are:

- To establish and strengthen the mechanisms of collaboration and joint management between the national AIDS/STD programme (NAP) and the National Tuberculosis Programme (NTP) for delivering integrated TB and HIV services preferably at the same time and location;
- To reduce the burden of TB in people living with HIV, their families and communities by ensuring the delivery of the *Three I's for HIV/TB* and the early initiation of ART;
- To reduce the burden of HIV in patients with presumptive and diagnosed TB, their families and communities by providing HIV prevention, diagnosis and treatment.

***Table 1**: WHO-recommended collaborative TB/HIV activities*

A	**Establish and strengthen the mechanisms for delivering integrated TB and HIV services**
A1	Set up and strengthen a coordinating body for collaborative TB/HIV activities functional at all levels
A2	Determine HIV prevalence among TB patients and TB prevalence among people living with HIV
A3	Carry out joint TB/HIV planning to integrate the delivery of TB and HIV services
A4	Monitor and evaluate collaborative TB/HIV activities
B	**Reduce the burden of TB in people living with HIV and initiate early antiretroviral therapy (*the Four I's for HIV/TB)*****
B1	Intensify TB case-finding and ensure high quality anti-tuberculosis treatment
B2	Initiate TB prevention with Isoniazid preventive therapy and early antiretroviral therapy
B3	Ensure control of TB Infection in health-care facilities and congregate settings
C	**Reduce the burden of HIV in patients with presumptive and diagnosed TB**
C1	Provide HIV testing and counselling to patients with presumptive and diagnosed TB
C2	Provide HIV prevention interventions for patients with presumptive and diagnosed TB
C3	Provide co-trimoxazole preventive therapy for TB patients living with HIV
C4	Ensure HIV prevention interventions, treatment and care for TB patients living with HIV
C5	Provide antiretroviral therapy for TB patients living with HIV

**Integrated Case Management (the 4th I) from Regional Strategy.

These guidelines emphasize the clinical management of HIV-related TB, i.e. on objectives B and C, as well as on monitoring and evaluation of collaborative TB/HIV activities.

II. Clinical presentation of HIV-related TB

The presentation of TB in people living with HIV depends on the degree of immune suppression and may be confused with other pulmonary or systemic infections (Table 2). TB disease in people living with HIV is more likely to be smear-negative pulmonary or extra-pulmonary compared to HIV-negative people.

***Table 2**: Differential diagnosis of TB in adults and children*

In adults	
Acute bacterial pneumonia	- Shorter history - All clients with cough should be referred to exclude TB
***Pneumocystis jiroveci* pneumonia (PcP)**	- Subacute and insidious onset - Dry cough, sputum mucoid (if any), progressive exertional dyspnoea
Kaposi sarcoma (KS)	-Typical lesions found on the skin and mucous membranes (oral cavity) - Cough, fever, haemoptysis and dyspnoea - Pleural fluid is blood-stained
In children	
Acute bacterial pneumonia	- Pulmonary TB (PTB) in infants can be acute and should be considered when there is a poor clinical response to standard antibiotics and a TB contact
Lymphocytic interstitial pneumonitis (LIP)	- Very common >2 years - Most difficult diagnosis differential in children - Clinically: symmetrical, generalized lymphadenopathy (painless and mobile), bilateral chronic non-tender enlargement, finger clubbing - Chest X-Ray (CXR): bilateral diffuse reticulonodular pattern and enlarged mediastinal/hilar lymph nodes (CXR abnormalities often unilateral with PTB)
PcP	- Common in HIV-infected children <6 months. - Acute, severe pneumonia - Severe hypoxia - CXR: diffuse interstitial infiltration and hyperinflation - Very unlikely diagnosis of persistent respiratory disease after infancy.
Bronchiectasis	- Complication of LIP or TB - Cough productive of purulent sputum, sometimes blood-stained - Finger clubbing - Halitosis

II.1. Pulmonary tuberculosis

In the early stages of HIV infection, when immunity is only partially compromised, the features are typical of post-primary pulmonary TB. As immune deficiency advances, people living with HIV present with atypical smear-negative pulmonary disease or extra-pulmonary TB (EPTB). Miliary or disseminated disease is also more common (Table 3).

***Table 3**: Clinical features of TB according to the level of immune deficiency*

	Stage of HIV infection	
	Early	**Late**
Clinical picture	Often resembles post-primary TB: Cough Sputum production Weight loss +/- fever, night sweats, loss of appetite, breathlessness, chest pain.	Often resembles primary TB: Weight loss (in presence of wasting syndrome, TB must be excluded) Fever
	Haemoptysis is less common in HIV-positive PTB patients (less cavitation, inflammation and endobronchial irritation)	
Sputum smear result	Often positive	Often negative
CXR findings	- Upper lobe infiltrates - Bilateral infiltrates - Cavitation	- Interstitial infiltrates, especially in lower zones - Hilar lymphadenopathy - No cavitation - No abnormality

***Table 4**: Differential diagnosis of chest X-ray findings often associated with PTB*

CXR finding	Differential diagnosis
Cavitation	***Infections*** Bacterial pneumonias Nocardiosis Melioidosis Paragonimiasis Lung Abscess Some fungal infections ***Non-infectious disease*** Bronchial carcinoma Connective tissue disease Occupational lung disease
Unilateral infiltration	Pneumonia Bronchial carcinoma
Bilateral infiltration	Pneumonia Connective tissue disease Occupational lung disease Sarcoidosis
Mediastinal lymphadenopathy	Lymphoma Bronchial carcinoma Sarcoidosis

Table 5*: Clinical and chest X-ray features of PcP and TB*

	Typical of PcP	Typical of TB
Symptoms	Dry cough Sputum mucoid (if any) Dyspnoea	Productive cough Purulent sputum Pleuritic chest pain Haemoptysis
Signs	May be normal Fine inspiratory crackels	Signs of consolidation Sings of pleural effusion
Chest X-ray	Bilateral diffuse interstitial shadowing May be normal	Lobar consolidation Cavitation Pleural effusion Intrathoracic lymphadenopathy

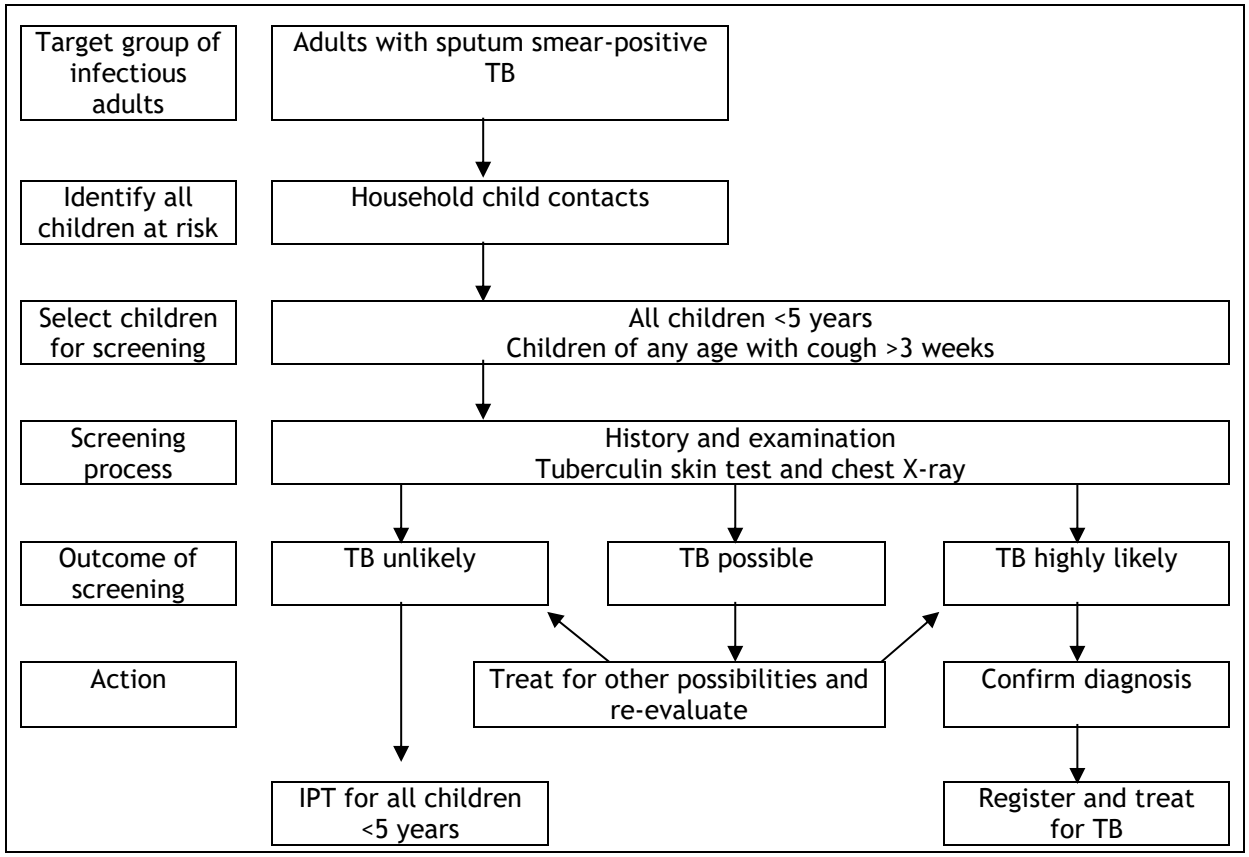
II.2. Extra-pulmonary tuberculosis

The most common forms of EPTB in people living with HIV include lymphadenitis, pleural effusion, pericardial effusion and meningitis. Presentation of EPTB in people living with HIV is generally not different from that in HIV-negative ones.

II.3. Tuberculosis in children living with HIV

The most common presenting symptoms include cough of more than two weeks duration, weight loss or failure to gain weight and fever. These symptoms are not specific to TB and may be associated with other HIV-related conditions (Table 2). Pulmonary TB is usually smear-negative. HIV-infected children may develop severe PTB (including miliary TB) at any age. Common forms of EPTB include TB meningitis, TB lymphadenitis, TB effusions and spinal TB.

Figure 1: ***How to identify and manage child contacts of infectious adults***



Role of BCG in preventing TB in HIV-infected individuals

Bacille Calmette-Guérin (BCG) is a live attenuated vaccine. The route of injection is intradermal. The usual dose is 0.05 ml in neonates and infants<3 months and 0.1 ml in older children.

The benefit of BCG is in protecting young children against disseminated and severe TB, e.g. TB meningitis and miliary TB. BCG has little or no effect in reducing the number of adult cases of PTB.

It is not known if HIV infection reduced the protection conferred by BCG against TB in children. There is evidence that conversion to a positive tuberculin test after BCG is less frequent in HIV-positive children.

BCG vaccine should not be used in children who are known to be HIV-positive because of the increased risk of severe and often fatal disseminated BCG disease. BCG-induced immune reconstitution inflammatory syndrome (BCG-IRIS) is increasingly reported in infants living with HIV who have started ART early in infancy. BCG-IRIS can cause significant morbidity although - unlike disseminated BCG disease – it is rarely fatal.[1]

Guidance on implementation of BCG vaccination for HIV exposed babies

(A) Early Infant Diagnosis (either Dry Blood Spot or Viral Load Testing) is available
- BCG vaccination needs to be deferred until the result is known. If baby is infected with HIV, BCG should not be given.

(B) Early Infant Diagnosis (either Dry Blood Spot or Viral Load Testing) is not available
- BCG should not be given to the infants whose HIV infection status is unknown but who have signs or reported symptoms suggestive of HIV infection and who are born to HIV-positive mothers.
- BCG should be given to the infants whose HIV infection status is unknown but who have no signs or reported symptoms suggestive of HIV infection and who are born to HIV-positive mothers.

III. HIV testing and counselling

People access HIV treatment, care and prevention through the gateway of HIV testing and counselling. The vast majority of people living with HIV does not know their HIV status and seek health care from general service providers. HIV testing and counselling for people diagnosed with or suspected of TB disease offers an entry point for a continuum of prevention, care, support and treatment for HIV and for TB.

Provider-initiated HIV testing is recommended for all patients with suspected and diagnosed TB as well as to partners of known HIV-positive TB patients.

HIV testing and counselling should adhere to the *five C's*:

- Consent
- Confidentiality
- Counselling
- Correct test results; and
- Connections to care, treatment and prevention services.

See the guidelines for the clinical management of HIV infection in Myanmar for more information.

External Quality Assurance for HIV laboratory testing

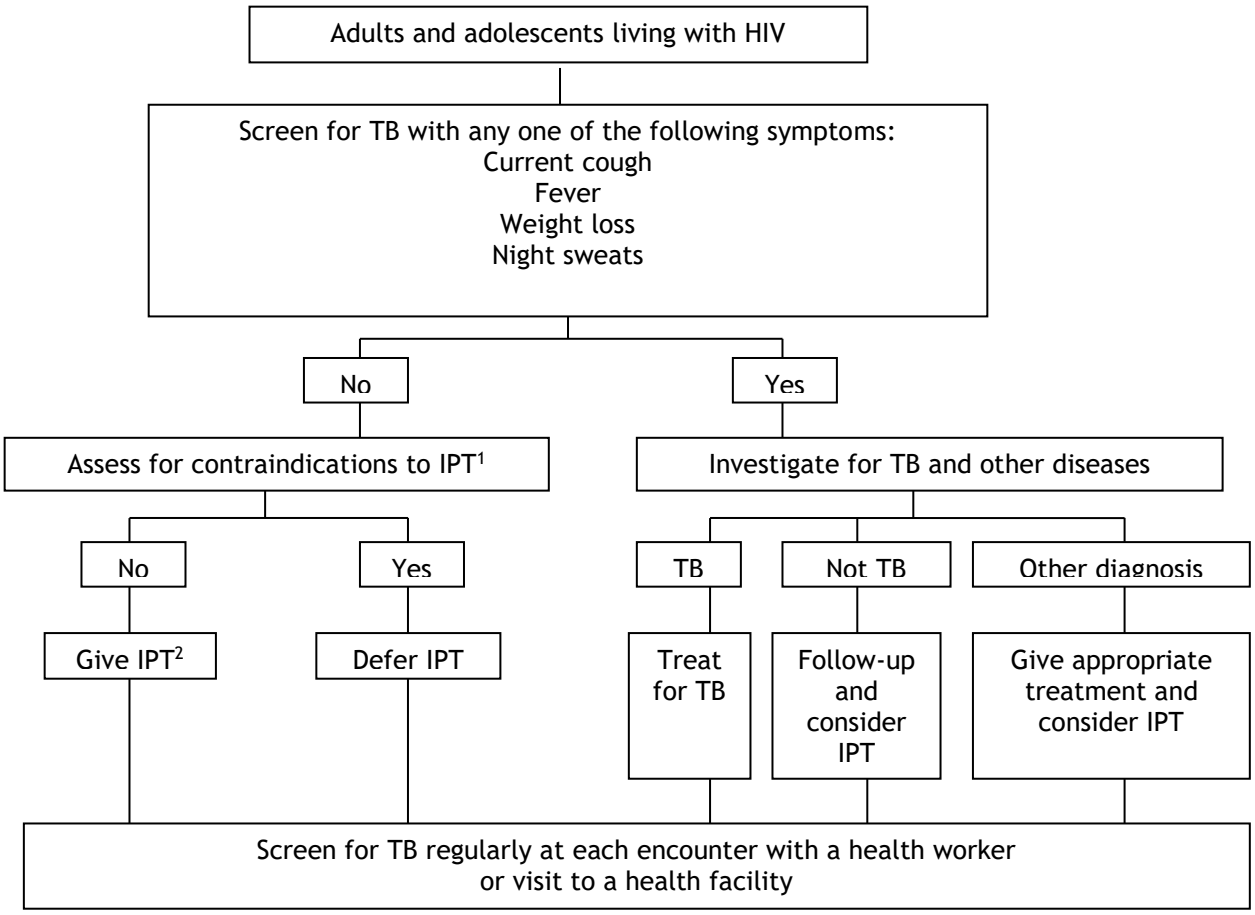
In collaboration with National Health Laboratory (NHL), all the laboratories that perform HIV testing are enrolled for External Quality Assurance. Each laboratory sends samples with test results (Panel testing) every 6 monthly and NHL provides feedback regularly.

[1] Guidance for national tuberculosis programmes on the management of tuberculosis in children, 2nd ed. Geneva, World Health Organization, 2014.

IV. TB screening in people living with HIV

All people living with HIV should be regularly screened for TB using a symptom-based algorithm consisting of current cough, fever, weight loss and night sweats (Figure 2).

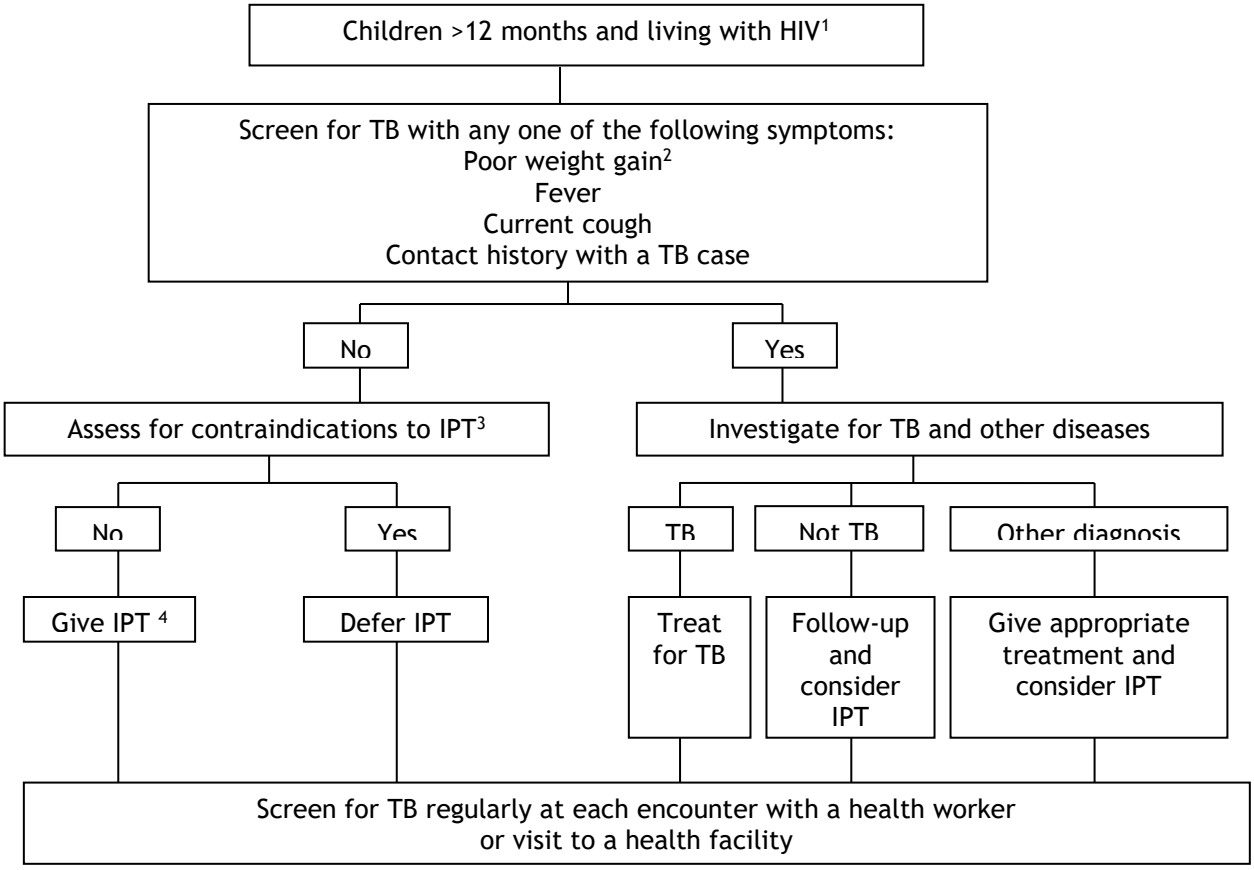
*Figure 2: **Algorithm for TB screening in adults and adolescents living with HIV***



[1] Contraindications include: active acute or chronic hepatitis, regular and heavy alcohol consumption, symptoms of peripheral neuropathy.
[2] IPT can be given regardless of prior TB treatment history. For patients with prior IPT history more than two years ago, IPT can be considered again if the patient has risk of developing TB, for example, close contact with TB cases.

In children living with HIV, the symptom-based algorithm consists of poor weight gain, fever or current cough or contact history with a TB case (Figure 3). Poor weight gain in children is defined as reported weight loss or confirmed weight loss (>5%) since the last visit or growth curve flattening or very low weight (weight for age ≤3 z score) or underweight (weight for age ≤2 z score).

Figure 3: ***Algorithm for TB screening in children more than one year of age and living with HIV***



[1] All children (including infants less than one year of age) should be provided with IPT if they have a history of household contact with a TB case.
[2] Poor weight gain is defined as reported weight loss or confirmed weight loss (>5%) since the last visit or growth curve flattening or very low weight (weight for age ≤3 z score) or underweight (weight for age ≤2 z score).
[3] Contraindications include active acute or chronic hepatitis, symptoms of peripheral neuropathy.
[4] In general, IPT is not indicated for the HIV infected children who had completed prior IPT or treated for TB. However, IPT may be considered as individual case, for those at high risk of becoming re-infected and progressing to TB disease.

Children, adolescents and adults living with HIV should be screened 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.

Role of Hospitals in TBHIV collaborative activities

Not only NAP's clinics, the general hospitals and district hospitals play a major role in HIV care component. They are the ART centres where all eligible patients are enrolled to initiate ART. The baseline investigations and follow up investigations for HIV patients are done at the laboratories of those hospitals. The clinicians of the hospital provide clinical consultations whereas NAP supports drug supply and other logistics, data captures, recording and reporting. When patients are stabilized after 6 to 12 months initiation of ART, they are transferred out to the ART decentralized sites close to the patients' residence. The ART decentralized sites which are township hospitals or township health departments provide chronic HIV care and referred back to ART centres whenever it is necessary.

ART centres and ART decentralized sites have to do TB symptom screening at each and every visit of HIV patients, implement TB prevention activities with IPT to all eligible patients. Moreover, they need to record and report the TBHIV collaborative activities of their sites in coordination with respective disease control team of the District/ State/ Region.

V. Diagnosis of TB in people living with HIV

Children, adolescents and adults living with HIV who have a positive TB screening may have active TB and should be evaluated for TB and other diseases (Figures 2 and 3). Since smear-negative pulmonary TB and EPTB are associated with poor treatment outcomes and excessive early mortality among people living with HIV, all efforts should be made to ascertain HIV status and to expedite TB diagnostic process. If extra pulmonary TB is suspected, diagnostic processes should be expedited using all available and appropriate investigations, including mycobacterial culture. [2]

Xpert MTB/RIF is recommended as the primary TB diagnostic test among people living with HIV in order to speed up TB diagnosis and to recognize MDR-TB in people living with HIV. MDR-TB is defined as TB resistant to at least isoniazid and rifampicin. Patients with both HIV and MDR-TB face complicated management, fewer treatment options and poorer treatment outcomes.

The diagnostic work-up for TB depends on the availability of Xpert MTB/RIF

[2] Improving the diagnosis and treatment of smear-negative pulmonary and extrapulmonary tuberculosis among adults and adolescents: recommendations for HIV-prevalent and resource-constrained settings. Geneva, World Health Organization, 2007.

Figure 4: *Diagnosis of Pulmonary TB/MDR-TB in HIV-positive patients*

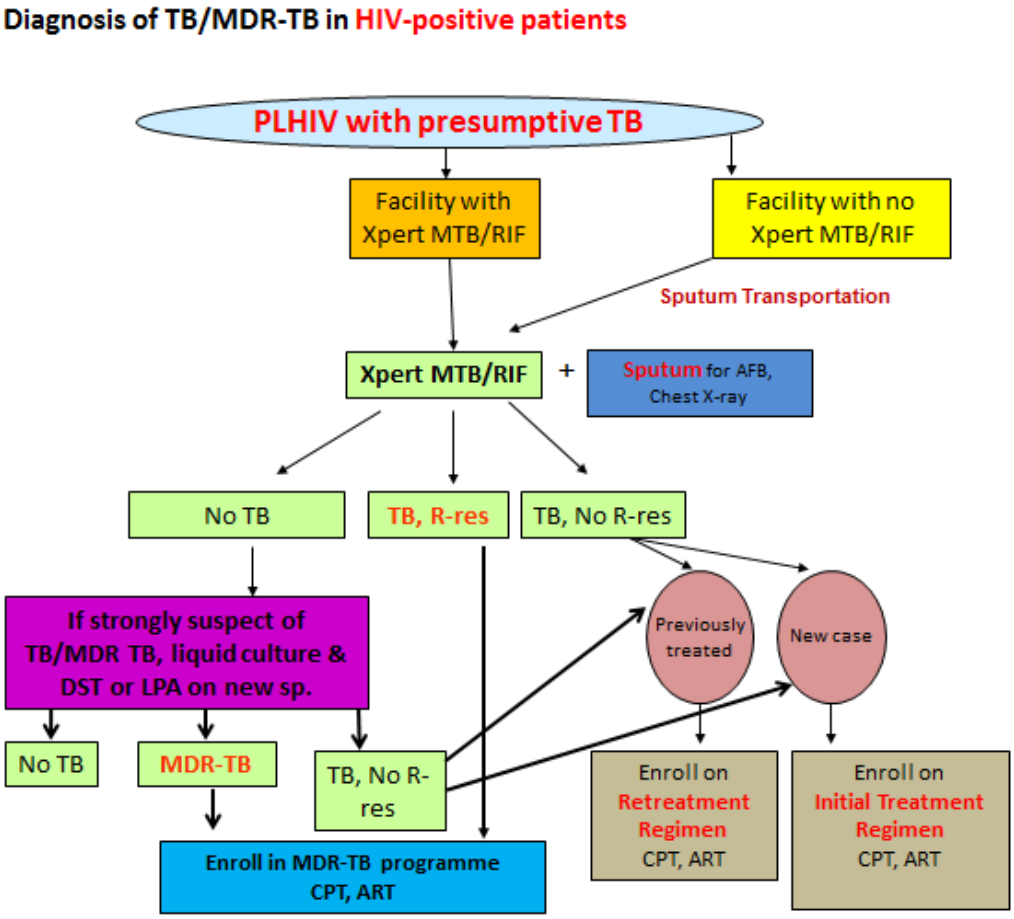
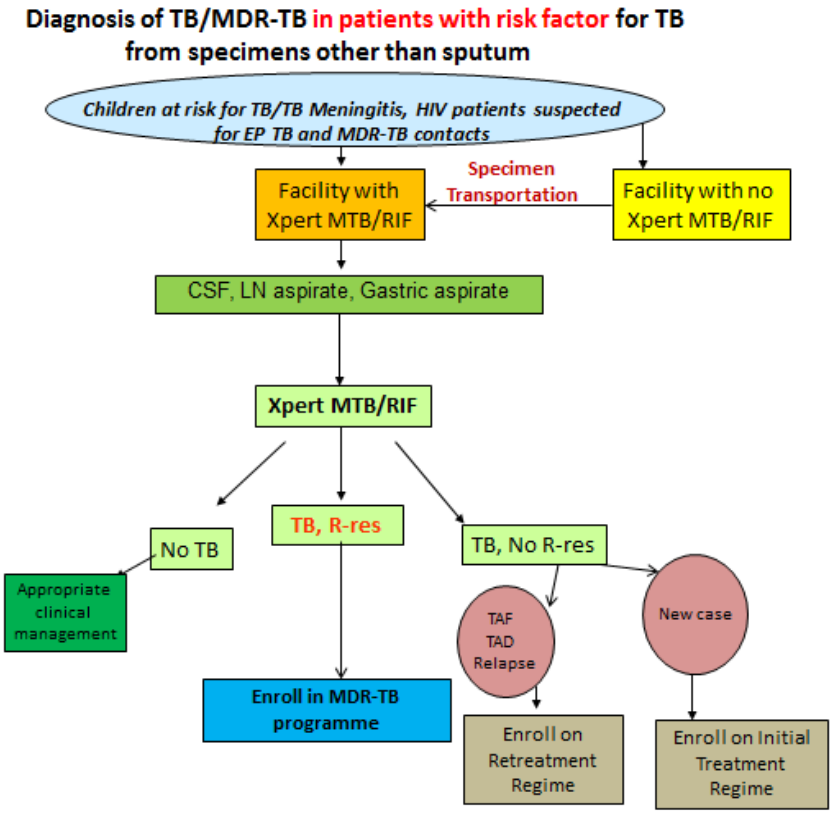


Figure 5: ***Diagnosis of Extra-pulmonary TB/MDR-TB in HIV-positive patients***



V.1. Xpert MTB/RIF or referral to Xpert MTB/RIF is available

- If Xpert MTB/RIF is positive, treat for TB.
- If resistance to rifampicin is detected, follow the algorithm of MDR-TB, treat the patient for MDR- TB (see guidelines for the management of Drug Resistant Tuberculosis (DR-TB) in Myanmar (February 2017).
- If Xpert MTB/RIF is negative, pulmonary TB is less likely. Clinical assessment and appropriate investigations which are summarized in Table 7 are important to decide whether the patient may have extra-pulmonary TB.

V.2. Xpert MTB/RIF is not available

- Specimen transportation to Xpert MTB/RIF sites
- Investigations include sputum examination, chest X-ray (CXR), sputum culture and investigations to assess EPTB (Table 7).

Patients who are not treated for TB should receive either a broad-based antibiotic (but not a fluoroquinolone) to treat bacterial infection or treatment for PcP (Table 2). Assessment of patient's response should be established in either the TB or the HIV services. For patients with immediate response to PcP or antibiotic treatment, continued vigilance is necessary to exclude superimposed TB. Those patients with an unsatisfactory response to treatment for PcP or bacterial pneumonia should be reassessed both clinically and bacteriologically for TB.

V.3. Seriously ill patients

A patient is classified as seriously ill if one or more of the following danger signs are present:

- Unable to walk unaided
- Respiratory rate >30 per minute
- Temperature >39 °C
- Heart rate >120 per minute.

The highest priority in a seriously ill patient is to provide the patient with life-sustaining supportive therapy, such as oxygen and parenteral antibiotics. If life-sustaining therapy is not available at the initial point of care, the patient should be transferred immediately to a higher level facility before further diagnostic testing.

When immediate referral is not possible, the following measures should be undertaken in the peripheral health facility:

- Immediate start with broad-spectrum parenteral antibiotics for bacterial infection and perform Xpert MTB/RIF, if available. Safe injection practices should be strictly followed. If indicated, PcP treatment should be considered (see guidelines for the clinical management of HIV infection in Myanmar).
- If the diagnosis of TB is confirmed by Xpert MTB/RIF, start anti-TB treatment. The antibiotic treatment initiated previously should be continued and completed.
- If Xpert MTB/RIF is negative, response to parenteral antibiotics should be assessed after three days into treatment. If there is no improvement, empiric TB treatment should be initiated if strong clinical suspicion of TB remains. The initial antibiotic course should be continued and completed. Patients should be referred to the next level of care to confirm the diagnosis of TB and for HIV care. If referral is not possible, TB treatment should be completed.

If referral to a higher-level facility is possible, the patient should be managed as an emergency. If Xpert MTB/RIF result is negative, additional investigations should be performed to investigate for extra-pulmonary TB and other diseases. These additional investigations may include CXR, liquid culture of sputum, lymph node aspiration for acid-fast bacilli microscopy and culture, and abdominal ultrasound. Depending on the local epidemiology, non-tuberculous mycobacterial infection should be considered in the differential diagnosis of patients who have a negative Xpert MTB/RIF but a sputum or extra-pulmonary specimen with acid-fast bacilli.

Whatever the results of TB investigations, patients should undergo HIV clinical staging and treatment assessment for co-trimoxazole preventive therapy (CPT) and ART.

V.4. Patients with multidrug-resistant tuberculosis

Rifampicin resistance is a reliable proxy for MDR-TB in high burden settings. HIV patients with resistance to rifampicin detected by Xpert MTB/RIF should therefore be started on appropriate MDR-TB treatment immediately according to guidelines for the management of Drug Resistant Tuberculosis (DR-TB) in Myanmar (February 2017).

Concomitant treatment of drug-resistant TB and HIV

ART in HIV/TB co-infected patients improves survival and slows progression to AIDS. As mentioned above, ART should be initiated in all MDR-TB/HIV patients as soon as MDR-TB treatment is tolerated. This is usually within the first two months of treatment.

If the patient is already on ART and diagnosed with MDR-TB, investigation to see if the patient may be failing ART should be done. This includes clinical evaluation, CD4 count evaluation and, whenever possible, viral load testing. If there is evidence of ART failure, a new ART regimen should be initiated.

Table 6: Special issues regarding the treatment of MDR-TB/HIV co-infection

Issue	Comment
Potential drug interactions in the treatment of drug-resistant TB and HIV	• Rifampicins lower the levels of protease inhibitors and non-nucleoside reverse transcriptase inhibitors, especially nevirapine, contributing to the development of resistance to these drugs. • ARVs increase the level of rifampicin and the risk of toxicity. • Non-enteric coated didanosine contains an aluminium/magnesium-based acid that if given together with FQs may result in decreased FQ absorption. It should be given six hours before or two hours after FQs.
Potential drug toxicity in the treatment of drug-resistant TB and HIV	• Peripheral neuropathy may be caused by stavudine, aminoglycoside, cycloserine, pyrazinamide. • Cutaneous reactions by nevirapine and cotrimoxazole are more common. • Gastrointestinal effects are more common with the higher pill burden. • Renal toxicity can be increased by the use of the injectables and tenofovir. Avoid the use of tenofovir with the injectable agent (only if AZT resistance is present should tenofovir be used, and with very close monitoring of the renal function – every 1 to 2 weeks). • Neuropsychiatric effects can be increased with cycloserine and efavirenz, but these drugs can be used together.
Immune reconstitution Inflammatory syndrome (IRIS)	• This syndrome can present as a paradoxical worsening of the patient's clinical status. • It generally presents within three months of the initiation of ART and more common with a low CD4 cell count (<50 cells/mm3). • Management of IRIS is complex and depends on the clinical status of the patient and the site and extent of involvement. Various treatment modalities have been employed, including nonsteroidal anti-inflammatory drugs (NSAIDs) in mild disease and corticosteroids in moderate to severe disease. • Most patients can be treated without interruption of ART.
Monitoring of drug-resistant TB and HIV in co-infected patients	• When treatment for MDR-TB is administered, DOT of ART should be included. • Monitoring of CXR, smears and cultures is the same as for HIV-negative patients. Monitoring of creatinine and potassium should be increased to every two weeks while on the injectable agent. • For MDR-TB patients, in the case of treatment failure both TB treatment and ART regimen should be re-evaluated.
Implications of HIV for MDR-TB infection control	• MDR-TB outbreaks have overwhelmingly involved HIV-positive populations, commonly nosocomial transmissions. Delay in recognition of MDR-TB, prolonged periods of infectiousness, crowded wards, and mixing of TB and HIV patients all contribute to MDR-TB outbreaks that affect both HIV-positive and HIV-negative patients. Hospitals must implement adequate infection control precautions significantly to reduce nosocomial transmission.

Table 7: Diagnosis of presumptive extra-pulmonary TB and disseminated forms of TB

Lymphadenitis	Pleural effusion	Pericardial effusion	Meningitis	Disseminated TB
Essential investigations				
➢ HIV test (rapid if possible) ➢ Sputum smears if coughing ➢ Needle aspirate for AFB (18 to 21 gauge)	➢ HIV test (rapid if possible) ➢ CXR ➢ Sputum smears if coughing ➢ Aspirate & inspect fluid ➢ Differential white blood cell count and protein determination (if possible) of aspirate	➢ HIV test (rapid if possible) ➢ CXR ➢ Sputum smears if coughing ➢ Cardiac ultrasound (ideally) ➢ Electrocardiogram if ultrasound not available	➢ HIV test (rapid if possible) ➢ Lumbar puncture ➢ Microscopy (Gram stain and AFB)/protein/ glucose in cerebrospinal fluid ➢ Cryptococcal antigen/stain ➢ Sputum smears if coughing	➢ HIV test (rapid if possible) ➢ CXR ➢ Malaria blood film ➢ Sputum smears if coughing ➢ Blood cultures, full blood count and cryptococcal antigen
High suspicion of tuberculosis if				
➢ 2 cm or more in size ➢ Asymmetrical/localized ➢ Painless swelling ➢ Firm/fluctuant/fistulated ➢ Cervical location ➢ Weight loss, night sweats, fever	➢ Unilateral effusion ➢ Aspirate of fluid is: -Clear and straw coloured *and* -Clots on standing in a tube without anticoagulants ➢ Weight loss, night sweats, fever ➢ Evidence for tuberculosis elsewhere	➢ Lung fields clear (but may have bilateral pleural effusion) ➢ Weight loss, night sweats, fever ➢ Evidence of tuberculosis elsewhere	➢ Weight loss, night sweats, fever ➢ Cerebrospinal fluid clear with high protein, low glucose and lymphocytes ➢ Cryptococcal antigen (or India ink and fungal culture) negative in cerebrospinal fluid ➢ Evidence of tuberculosis elsewhere	➢ Weight loss, fever and cough ➢ Abnormal CXR (which can include miliary pattern) ➢ Large spleen/liver ➢ Night sweats ➢ Anaemia

Lymphadenitis	Pleural effusion	Pericardial effusion	Meningitis	Disseminated TB
Findings that suggest a non-tuberculosis diagnosis				
➢ KS in skin or mouth (probable KS nodes) ➢ Symmetrical (probable lymphoma or HIV lymphadenopathy) ➢ Tender, inflamed, purulent (bacterial or fungal) ➢ Site other than cervical	➢ Bilateral effusion (possible heart failure or pneumonia) ➢ Clinical KS/other malignancy ➢ Aspirate of fluid is: ○ Cloudy/pus (probable empyema) ○ Fails to clot (does **not** exclude tuberculosis, but send fluid for protein and differential cell count, and consider heart failure)	➢ Streaky shadowing of lung fields and/or heart shape not symmetrical (probable heart failure) ➢ High blood pressure ➢ Electrocardiogram suggests another cause for enlarged heart (e.g. high blood pressure, valve disease, dilated cardiomyopathy) ➢ Murmur (probable valvular disease) ➢ Rigors (probable bacterial pericarditis)	➢ Cerebrospinal fluid cloudy or neutrophils on microscopy (probably bacterial) ➢ Cryptococcal tests positive ➢ Rapid onset ➢ Very high cerebrospinal fluid pressure (probably cryptococcal)	➢ Also consider Salmonella, pneumococcus, malaria, cryptococcus: ○ Rigors ○ Very breathless (respiratory rate > 30/min) ○ Severe diarrhoea ○ Blood in stool ○ Positive cryptococcal antigen, malaria smear or likely pathogen isolated from blood culture

VI. Treatment of active TB in patients living with HIV

VI.1.TB regimens

New TB patients living with HIV should receive a TB regimen on a daily schedule containing six months of rifampicin: 2HRZE/4RH [two months of isoniazid, rifampicin, pyrazinamide and ethambutol followed by four months of rifampicin and isoniazid].

Retreatment cases who are not found to have resistance to rifampicin or isoniazid and rifampicin should be managed with a retreatment regimen containing first-line drugs: 2HRZES/1HRZE/5HRE [two months of isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin, followed by one month of isoniazid, rifampicin, pyrazinamide and ethambutol, followed by five months of rifampicin, isoniazid and ethambutol].

Retreatment TB cases who are found to have resistance to rifampicin or isoniazid and rifampicin should be enrolled in the MDR-TB programme on an MDR-TB regimen (see guidelines for the management of MDR-TB in Myanmar).

TB treatment regimen in children living with HIV depends on the TB presentation:

- 2HRZE/4HR in children with clinically diagnosed or bacteriologically confirmed PTB or peripheral TB lymphadenopathy
- 2HRZE(S)/10HR in children with clinically diagnosed or bacteriologically confirmed TB meningitis and
- 2HRZE/10HR in children with clinically diagnosed or bacteriologically confirmed osteo-articular TB.

***Table 8**: Essential first-line anti-TB drugs, side effects and interaction with ARVs*

First line anti-TB drug	Main side effects	Drug interaction with ARVs
Isoniazid	- Peripheral neuropathy - Hepatitis	- Stavudine (although not to be used anymore) also causes peripheral neuropathy
Rifampicin	- Gastro-intestinal: nausea, anorexia, vomiting, abdominal pain - Hepatitis - Coloration of all body secretions (red or orange)	- Rifampicin lowers the level of PIs and NNRTIs (especially nevirapine), contributing to the development of resistance to these drugs - ARVs increase the level of rifampicin and the risk of toxicity - Rifampicin may be replaced by rifabutin in patients on PIs, where available
Ethambutol	- Optic neuritis: decreased acuity, restricted field of vision, loss of colour discrimination	
Pyrazinamide	- Joint pains - Hepatitis	

Use of anti-TB drugs in special situations

- **Pregnancy**: streptomycin should not be given in pregnancy as it can cause permanent deafness in the baby. Second-line drugs such as fluoroquinolones, ethionamide and prothionamide are teratogenic and should not be used.
- **Renal failure**: patients with severe renal failure should receive pyridoxine with isoniazid to prevent peripheral neuropathy. Streptomycin and ethambutol should be avoided or given in reduced dosage. 2HRZ/4HR is the safest regimen

- **Liver disease**: most anti-TB drugs can give liver disease and, therefore, care is needed. Pyrazinamide should not be given as it is the most hepatotoxic. Isoniazid and rifampicin plus one or two non-hepatotoxic drugs (such as ethambutol or streptomycin) can be given for a total duration of eight months. Recommended regimens are 2SRHE/6HE or 2SHE/10HE or 2SE+FQ (Levofloxacin)/10 E+FQ (Levofloxacin).

VI.2. Antiretroviral therapy and TB treatment

ART should be started in all TB patients, including those with drug-resistant TB, irrespective of CD4 count. TB treatment should be initiated first, followed by ART as soon as possible within the first eight weeks of TB treatment. Patients with profound immunosuppression (such as CD4 counts <50 cells/mm^3) should receive ART immediately within the first two weeks of initiating TB treatment.

Similarly, ART should be started in any child living with HIV presenting active TB disease as soon as possible within eight weeks following initiation of anti-TB treatment irrespective of CD4 count and clinical stage.

Preferred nucleoside reverse transcriptase inhibitor (NRTI) backbone includes TDF/3TC (or FTC) since the combination of TDF/3TC/EFZ is available as once daily, is less frequently associated with severe adverse events and has a good virological and treatment response.

The alternative NRTI backbone is AZT/3TC. AZT is associated with anaemia which is most common in the first six months of treatment but can occur at any time. In advanced HIV disease, it may be advisable to avoid AZT.

Rifampicin is a potent inducer of liver cytochrome P_{450} system and considerably decreases almost all PIs and NVP drug levels. Therefore, EFV should be used as the preferred non-nucleoside reverse transcriptase inhibitor (NNRTI) in patients starting ART while on TB treatment.

After failure to a first-line NNRTI regimen, a boosted protease inhibitor (PI) plus two NRTIs are recommended for second-line ART. Boosted lopinavir (LPV/r) may be used in the co-administration with rifampicin. In this case, adjusted dose is necessary: LPV 800 mg + RTV 200 mg twice daily or LPV 400 mg + RTV 400 mg twice daily with close monitoring of liver function. As an alternative, rifabutin (where available) may be used at the dose of 150mg per day or 300mg thrice in a week when co-administered with standard doses of LPV/r.

***Table 9**: Preferred ART regimen in co-administration with TB treatment*

First line ART regimen	
Preferred NRTI backbone: TDF 245 mg OD + 3TC 300mg OD (or FTC 200mg OD) *Alternative NRTI backbone:* AZT 300mg BID + 3TC 300mg OD (or FTC 200mg OD)	EFV 600mg OD at night with rifampicin 600mg OD
Second line ART regimen	
If TDF used in first-line therapy: AZT 300mg BID + 3TC 300mg OD (or FTC 200mg OD) *If AZT used in first line therapy*: TDF 245 mg OD + 3TC 300mg OD (or FTC 200mg OD)	LPV/r 400mg/400mg BID or LPV/r 800mg/200mg BID with Rifampicin 600mg OD, LPV/r 400mg/100mg with Rifabutin 150mg OD

In patients on MDR-TB treatment, the preferred NRTI backbone includes AZT since the renal toxicity of TDF can increase in association with injectable drugs. If AZT resistance is present, TDF may be used with very close monitoring of the renal function. i.e. every 1 to 2 weeks.

Co-treatment in children less than three years of age with TB disease is challenging as EFV is contra-indicated in this population. Triple nucleoside-based therapy may be a suitable option to avoid interactions between rifampicin and LPV/r or NVP in young children.

***Table 10**: Summary of recommended ART regimens for children who need TB treatment*

Recommended regimens for children initiating ART while on TB treatment		
<3 years		Triple NRTI (AZT + 3TC + ABC)
3 years and older		Two NRTIs + EFV Or Triple NRTI (AZT+3TC+ABC)
Recommended regimen for children initiating TB treatment while receiving ART		
Child on a standard NNRTI-based regimen two NRTIs + EFV or NVP)	*<3 years*	Continue NVP, ensuring the dose is 200mg/m^2 Or Triple NRTI (AZT + 3TC + ABC)
	3 years and older	If the child is receiving EFV, continue the same regimen If the child is receiving NVP, substitute with EFV Or Triple NRTI (AZT + 3TC + ABC)
Child on a standard PI-based regimen (two NRTIs + LPV/r)	*< 3 years*	Triple NRTI (AZT + 3TC + ABC) Or Continue LPV/r, adding RTV to achieve the full therapeutic dose
	3 years and older	*If the child has no history of failure of an NNRTI-based regimen:* Substitute with EFV Or Triple NRTI (AZT + 3TC + ABC) Or Continue LPV/r, adding RTV to achieve the full therapeutic dose *If the child has a history of failure of an NNRTI-based regimen:* Triple NRTI (AZT + 3TC + ABC) Or Continue LPV/r, adding RTV to achieve the full therapeutic dose Consider consultation with experts for constructing a second-line regimen

ART greatly improves the survival and the quality of life of HIV-infected TB patients and prevents HIV and TB transmission among people living with HIV. It should be considered as part of HIV and TB treatment and prevention. ART is a powerful strategy to reduce TB incidence among people living with HIV across a broad range of CD4 cell-counts. All efforts should be made to timely initiate ART among eligible HIV positive patients.

ART should be offered preferably within integrated services or within TB facilities. Effective referral to HIV services remains an alternative but relies on sound referral systems and patients' ability to afford other costs such as transport and lost wages.

VI.3.Immune Reconstitution Inflammatory Syndrome

TB-associated Immune Reconstitution Inflammatory Syndrome (TB-IRIS) is a recognized complication of ART. It has two forms:

- ***Paradoxical TB-IRIS*** that occurs when patients receiving treatment for TB are put on ART and develop an immune-mediated clinical deterioration. It has been reported in 8%–43% of TB patients starting ART. A key differential diagnosis is for drug-resistant TB, which may similarly present with an initial clinical improvement followed by deterioration.
- ***Unmasking TB-IRIS*** that develops in a smaller fraction of patients not on TB treatment. Patients starting ART develop treatment-associated TB with inflammatory symptoms in the first few months. Unmasking TB-IRIS seems to be triggered by antiretroviral-induced immune recovery and may account for more than 30% of cases of TB presenting during the first months of ART.

TB-IRIS is associated with fever, enlargement of lymph nodes sometimes with liquefactive necrosis, worsening pulmonary infiltrates, pleural or pericardial effusion, expanding central nervous system tuberculomas or appearance of TB meningitis. In managing IRIS, both TB treatment and ART are continued. The excessive inflammatory response is controlled by prednisone. A double-blind placebo-controlled trial of prednisone for TB-IRIS showed that a four-week course of prednisone at the time of diagnosis of paradoxical TB-IRIS reduced the duration of hospitalization and need for procedures, without an excess of adverse events or severe infections.

Risk factors for IRIS include:

- Very low CD4 count at the start of ART
- Very high HIV viral load and very rapid fall in viral load after the start of ART
- Treatment naïve at the start of TB treatment,
- Short interval between TB treatment and ART.

However, since most episodes of TB-IRIS are self-limiting and not associated with significant mortality, the risk of TB-IRIS must be balanced against the benefit of early initiation of ART in patients with advanced immunosuppression.

VI.4. Cotrimoxazole preventive therapy and TB treatment

Pulmonary TB disease is a WHO stage 3 clinical condition (Annex 1). Therefore, routine cotrimoxazole preventive therapy (CPT) should be administered in people living with HIV with all TB diseases regardless of CD4 count.

Cotrimoxazole is a broad spectrum antimicrobial agent that prevents PcP, toxoplasmosis and a range of secondary bacterial and parasitic infections in eligible adults and children living with HIV. CPT is a simple, well-tolerated and cost-effective intervention for people living with HIV and can be administered concomitantly to ART and TB treatment.

One double-strength tablet daily of co-trimoxazole (960 mg) is recommended. Skin reaction is the most common side effect with cotrimoxazole. Erythema and maculopapular rash may be observed and treated with anti-histaminics. In case of vesiculation, mucosal ulceration and exfoliative dermatitis, CPT should be discontinued immediately and permanently, and replaced by dapsone 100 mg a day although it is less effective than CPT. Other side effects include bone marrow toxicity and hepatotoxicity. Cotrimoxazole-related adverse events are not common and typically occur within the first weeks of starting prophylaxis.

VI.5. Other HIV prevention interventions, treatment and care

Prevention of HIV includes interventions to:

- *Prevent sexual transmission* such as use of male and female condoms, male circumcision, HIV testing and counselling including couples counselling and testing, early ART and ART for serodiscordant couples. *Prevent vertical transmission of HIV* through ART initiation at least for the duration of mother-to-child transmission risk, i.e. pregnancy, delivery and breastfeeding period. Women meeting ART eligibility criteria should continue lifelong ART.
- *Prevent transmission among injecting drug users* by ensuring access to sterile injecting equipment, opioid substitution therapy and outreach services to reduce the risk of HIV transmission and other negative health effects of injecting drug use; combined with behavioural interventions and brief interventions to prevent hazardous alcohol use and use of other psychostimulants.
- *Prevent HIV transmission at the workplace* through primary prevention measures such as standard precautions, injection safety, blood safety and safe waste disposal, as well as secondary prevention measures such as occupational post-exposure prophylaxis.

A comprehensive package of diagnosis, treatment and care interventions (continuum of care) should be provided to all people living with HIV, ideally starting well before the need for ART. **Pre-ART care** includes:

- Regular assessment of the clinical and immunological stages of infection (Annex 1),
- Treatment of latent TB Infection (IPT)
- Prevention and treatment of opportunistic infections,
- Preparation for adherence to ART,
- Nutritional support, provision of safe water, sanitation and hygiene,
- Psychosocial support, and prevention and management of mental health disorders, including alcohol and other substance use.

VII. Isoniazid preventive therapy

Isoniazid is given to individuals in order to prevent progression to active disease. Exclusion of active TB is important before isoniazid preventive therapy (IPT) is started (Figures 2 and 3). All people living with HIV who have a negative screening for TB disease using the clinical symptom-based algorithm describe above, i.e. who do not report any of current cough, fever, weight loss and night sweats, are unlikely to have active TB and can be reliably initiated on IPT. IPT should be given for six months at the dose of 300 mg per day. Pyridoxine (vitamin B6) supplementation to prevent isoniazid-related peripheral neuropathy is recommended at a dose of 25 mg daily.

IPT should be given irrespective of the route of HIV transmission (including injecting drug use), of the degree of immune suppression, to those on ART, and to pregnant women. Pregnant women living with HIV are at risk for TB which can impact on maternal and perinatal outcomes. These can range from death of the mother and the new-born to prematurity and low birth weight of the new-born. The clinical algorithm should therefore be introduced into maternal services in order to prevent, diagnose and treat TB in pregnant women and women of childbearing age. Among injecting drug users, TB screening

and IPT should be combined to harm reduction services including safe needles and syringes programmes.

Children living with HIV older than 12 months of age who do not have poor weight gain, fever or current cough and have no contact with a TB case are unlikely to have active TB disease and should receive IPT for six months at the dosage of 10 mg/kg/day (Table 11). In children with HIV who are less than 12 months of age, only those who have contact with a TB case and who are evaluated for TB using investigations such as CXR should receive six months of IPT if the evaluation shows no TB disease.

***Table 11**: Isoniazid dosage according to body weight*

Weight range (kg)	Dose given (mg)	100 mg tab
<5	50	½
5 - 9.9	100	1
10 – 13.9	150	1 ½
14-19.9	200	2
20-24.9	250	2 ½
≥25	300	3

Tuberculin skin test (TST) and CXR are not a requirement for initiating IPT in people living with HIV. Providing IPT to people living with HIV does not increase the risk of developing isoniazid-resistant TB. Concerns regarding the development of INH resistance should not be a barrier to providing IPT.

Exclusion criteria to IPT include: active liver disease, peripheral neuropathy, and heavy alcoholic consumption.

VIII. Infection control

People living with HIV are at significant risk of acquiring TB in health care facilities and congregate settings. HIV promotes progression to active TB both in people with recently acquired infection or with latent *M. tuberculosis* infection.

The infection control plan of each health facility should include administrative, environmental and personal protection measures to reduce the transmission of TB and surveillance of TB disease among medical and non-medical staff (Table 12).

Health care workers, workers in congregate settings and carers living with HIV should be provided with CPT, ART and IPT if they are eligible.

Administrative controls

Administrative controls are aimed at preventing droplet nuclei from being generated and reducing exposure. The NTP/NAP should ensure that any outpatient care facilities have a system to identify persons with respiratory symptoms in waiting areas of out-patient departments and emergency units. These persons should be given priority for care in order to minimize the time spent in the health facility. Additionally, they should be instructed to cover their mouth and nose when coughing and moved to a separate waiting area, if possible. If TB is presumed, diagnostic delays should be minimized by reducing sputum turn-around time, use of rapid diagnostics, carrying out investigations in parallel rather than in sequence, and by using smear-negative algorithms.

A person with presumed MDR-TB in need of other medical tests or procedures should be accompanied to other departments, and not be left in a waiting area. The person should wear a surgical mask or cover mouth and nose with a tissue. For patients diagnosed with TB, prompt initiation of treatment should be ensured.

Each health facility should have an infection control plan or a set of standard operation procedures which (i) includes the health staff responsible for identifying persons with respiratory symptoms; and (ii) outlines the procedures to be followed to ensure separation, cough hygiene, and fast-tracking.

Triage & Separate

- **Identify people with respiratory symptoms**

Administrative controls

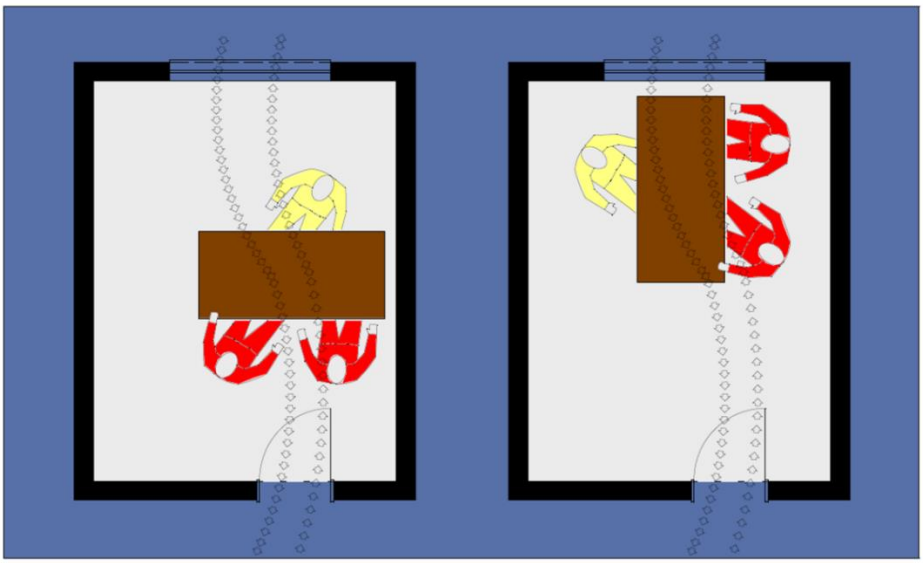
Estimated number of bacilli liberated by:

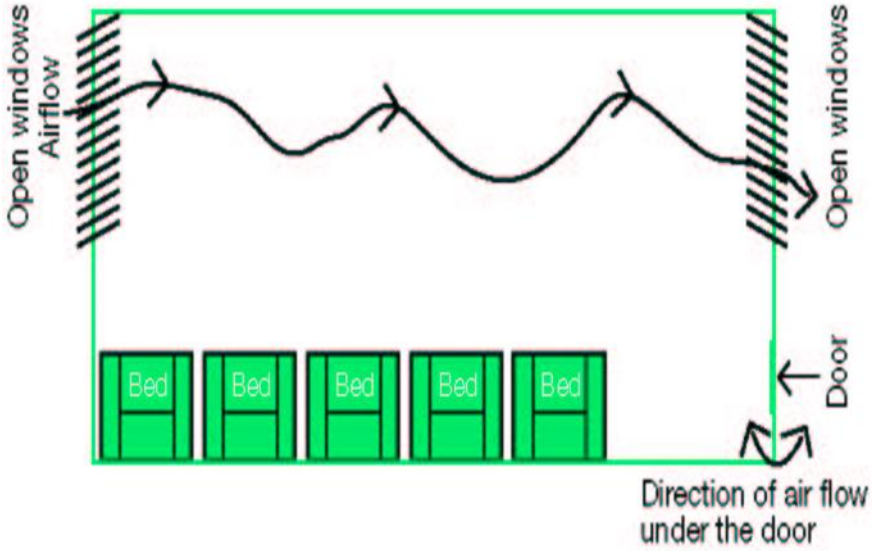
- **Talking: 0-200**
- **Coughing: 0-3,500**
- **Sneezing: 4,500-1,000,000**

(Wells 1934, Duguid 1945, Wells/Riley 1953 et.al)

Environmental controls

Environmental controls include methods to reduce the concentration of infectious respiratory aerosols (i.e. droplet nuclei) in the air; and methods to control the direction of infectious air. A variety of simple to complex environmental controls can be used to reduce the number of aerosolized infectious droplet nuclei in the work environment. The simplest and least expensive technique is to remove and dilute the air from TB patient areas away from patients without TB by maximizing natural ventilation through open windows and doors. More complex and costly methods involve the use of mechanical ventilation (e.g. window fans, exhaust ventilation systems) in isolation rooms or wards to produce negative pressure and prevent contaminated air from escaping into hallways and other surrounding areas. Additional complex and costly methods include air filtration to remove infectious particles and ultraviolet germicidal irradiation to kill *M. tuberculosis* organisms. Given that Myanmar has a tropical climate in most parts of the country and for most time of the year, it is possible to take advantage of natural ventilation, e.g. utilizing wind to provide air exchanges and reduce the concentration of droplet nuclei. When constructing or renovating space, consideration should be given to placing windows and openings on opposite walls to enhance cross-ventilation, as well as to the prevailing wind direction. Natural ventilation can be enhanced with the use of exhaust fans, if necessary.





Personal protective equipment

Personal protective equipment (particulate respirators) should be used together with administrative and environmental controls in situations where there is an increased risk of transmission Respirators that meet standards N95, FFP2 or higher and are properly used may provide health workers with additional protection from TB. Prioritization will be given to MDR-TB wards and centres, reference laboratories, and high volume diagnostic centres, e.g. at the State/Regional level.

***Table 12**: Key actions for infection control in health care facilities and congregate settings*

Measure	Key actions
Administrative (facility-level infection control committee and protocols)	- A triage system to identify people suspected of having TB - Separate people with suspected or confirmed TB - Cough etiquette and respiratory hygiene - Rapid diagnosis with Xpert MTB/RIF (with prompt treatment of active TB)
Environmental	- Ventilation (natural) - Ventilation (mechanical) - Upper-room ultraviolet germicidal irradiation, where present
Personal	- Spend as much time as possible outside - Cough etiquette - Sleep alone while smear-positive - Avoid congregate settings and public transport while smear-positive - Use of surgical mask by TB patient
Health workers and carers	- Surveillance and information - Package of care for HIV-positive workers (ART and IPT) - Protective equipment (particulate respirator masks that meet or exceed N95 standards) - Relocation for health care workers living with HIV to a lower-risk area of TB transmission

IX. Monitoring and evaluation

Monitoring and evaluation provides the means to assess the delivery, coverage, quality and effectiveness of collaborative TB/HIV activities. It involves collaboration between NAP and NTP, between Medical Care and Public Health, Laboratory and all partners involved in TB/HIV collaborative activities. It deals with the development of referral linkages between the different services and organizations, and joint supervision.

Indicators for TB/HIV collaborative activities are summarized in Table 13. They are collected using TB registers and pre-ART and ART registers based on the WHO Three Interlinked Systems.

TBHIV committee meetings

TBHIV committee meetings at townships level are organized quarterly in order to monitor the activities and to overcome the barriers for the effective implementation of TBHIV collaborative activities. Focal persons from Regional/ district level disease control team (NTP and NAP) participate in those meeting and guide the township team.

***Table 13**: TB/HIV indicators and data sources*

Indicator and definition	Data source
To be reported by NAP	
percentage of estimated HIV positive incident TB cases that received treatment for TB and HIV.	ART register
Number of adults and children enrolled in HIV care who had their TB status assessed and recorded during their last visit among all adults and children enrolled in HIV care in the reporting period.	Pre-ART register ART registers
Number of adult and children newly enrolled in HIV care who are started on treatment for latent TB infection, isoniazid preventive therapy, expressed as a proportion of the total number of adults and children newly enrolled in HIV care during the reporting period.	Pre-ART register (all newly enrolled should be registered on pre-ART register)
Number of facilities providing ART services for people living with HIV with demonstrable infection control practices that include TB control, expressed as a proportion of the total number of facilities providing ART services. *Demonstrable infection control measures include a written infection control plan, a person responsible for implementing TB infection control, a well-ventilated waiting area, identification and separation of TB suspects on arrival and monitoring of TB cases among health care workers.*	Facility visits as part of regular supervision or external review
Indicators to be reported by the NTP	
Number of TB patients registered during the reporting period who had an HIV test result recorded in the TB register, expressed as a proportion of the total number of TB patients registered during the reporting period. *It includes TB patients who were known to be HIV-positive before being diagnosed with TB as well as TB patients with a negative HIV result from previous testing that was acceptable to the clinician (e.g. done in the last 3-6 months in a reliable laboratory).*	TB register
Number of registered TB patients with a documented HIV status on TB register who were HIV-positive, expressed as a proportion of all registered TB patients with documented HIV status over the reporting period.	TB register
Number of HIV positive TB patients who were started on or continued previously initiated CPT, during TB treatment, expressed as a proportion of all HIV-positive TB patients registered over the reporting period.	TB register
Number of HIV positive TB patients who were started on or continued previously initiated ART during their TB treatment, expressed as a proportion of all HIV positive TB patients registered over the reporting period. *This figure should be equivalent to the one reported by the NAP and entail reconciliation of data between the two programmes.*	TB register

Annex 1

WHO clinical staging of HIV disease in adults, adolescents and children

Adult	Children
Clinical stage 1	
- Asymptomatic - Persistent generalized lymphadenopathy	- Asymptomatic - Persistent generalized lymphadenopathy
Clinical stage 2	
- Moderate unexplained weight loss (<10% of presumed or measured body weight) - Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) - Herpes Zoster - Angular cheilitis - Recurrent oral ulceration - Papular pruritic eruption - Fungal nail infections - Seborrheic dermatitis	- Unexplained persistent hepatosplenomegaly - Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis) - Herpes Zoster - Linear gingival erythema - Papular pruritic eruption - Fungal nail infections - Extensive wart virus infection - Extensive molluscum contagiosum - Unexplained persistent parotid enlargement
Clinical stage 3	
- Severe unexplained weight loss (>10% of presumed or measured body weight) - Unexplained chronic diarrhoea for >1 month - Unexplained persistent fever (intermittent or constant for >1 month) - Persistent oral candidiasis - Oral hairy leukoplakia - Pulmonary tuberculosis - Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia) - Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis - Unexplained anaemia <8g/dl, neutropenia (<0.5 G/l) and/or chronic thrombocytopenia (<50 G/l)	- Unexplained moderate malnutrition not adequately responding to standard therapy - Unexplained persistent diarrhoea (≥14 days) - Unexplained persistent fever (above 37.5 °C, intermittent or constant, >1 month) - Persistent oral candidiasis (after first six weeks of life) - Oral hairy leukoplakia - Lymph node tuberculosis - Pulmonary tuberculosis - Severe recurrent bacterial pneumonia - Acute necrotizing ulcerative gingivitis or periodontitis - Unexplained anaemia <8g/dl, neutropenia (<0.5 G/l) and/or chronic thrombocytopenia (<50 G/l) - Symptomatic lymphoid interstitial pneumonitis - Chronic HIV-associated ling disease, including bronchectiasis

Adult	Children
Clinical stage 4	
- HIV wasting syndrome - *PcP* - Recurrent severe bacterial pneumonia - Chronic herpes simplex infection (orolabial, genital or anorectal of >1 month's duration or visceral at any site) - Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) - Extra-pulmonary tuberculosis - Kaposi sarcoma - Cytomegalovirus infection (retinitis or infection of other organs) - Central nervous system toxoplasmosis - HIV encephalopathy - Extra-pulmonary cryptococcosis, including meningitis - Disseminated nontuberculous mycobacterial infection - Progressive multifocal leukoencephalopathy - Chronic cryptosporidiosis - Chronic isosporiosis - Disseminated mycosis (extra-pulmonary histoplasmosis, coccidioidomycosis) - Lymphoma (cerebral or B-cell non Hodgkin) - Symptomatic HIV-associated nephropathy or cardiomyopathy - Recurrent septicaemia (including nontyphoidal Salmonella) - Invasive cervical carcinoma - Atypical disseminated leishmaniasis	- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy - *PcP* - Recurrent severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) - Chronic herpes simplex infection (orolabial or cutaneous of >1 month's duration or visceral at any site) - Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) - Extra-pulmonary tuberculosis - Kaposi sarcoma - Cytomegalovirus infection (retinitis or infection of other organs with onset of age >1 month) - Central nervous system toxoplasmosis (after the neonatal period) - HIV encephalopathy - Extra-pulmonary cryptococcosis, including meningitis - Disseminated nontuberculous mycobacterial infection - Progressive multifocal leukoencephalopathy - Chronic cryptosporidiosis (with diarrhoea) - Chronic isosporiosis - Disseminated endemic mycosis (extra-pulmonary histoplasmosis, coccidioidomycosis, penicilliosis) - Cerebral or B-cell non-Hodgkin lymphoma - HIV-associated nephropathy or cardiomyopathy

Annex 2: TB Registers and Reporting forms

Annex 2.1: Request for examination of biological specimen for TB (TB-05)

Request for examination of biological specimen for TB (TB - 05)

Treatment unit: _____ Date of request: _____

Patient name: _____

Age (years): _____ Date of birth: _____ Sex: ☐ Male ☐ Female

Patient address: _____

_____ Telephone: _____

Previously treated for TB: ☐ Yes ☐ No ☐ Unknown

HIV Status: ☐ Positive ☐ Negative ☐ Unknown

Reason for examination: _____

☐ Diagnosis Presumptive TB Reg. / OPD No. _____

☐ Follow-up Township TB No/MDR-TB No. _____ Month of treatment (___)

Specimen type: ☐ Sputum ☐ Other (specify): _____

Test(s) requested: ☐ Microscopy ☐ Xpert MTB/RIF

☐ Culture ☐ Drug susceptibility ☐ Line probe assay

Requested by Signature: _____

Name: _____

Designation: _____

Contact phone no. : _____

Microscopy results (to be completed in laboratory) ☐ Auramin ☐ ZN

Date of specimen received	Laboratory serial number (s)	Specimen type	Visual appearance (blood-stained, mucopurulent or saliva)	Result (tick one)				
				Negative	Scanty	+	++	+++

Examined by Signature: _____

Name: _____

Designation: _____

Date of result: _____

Annex 2.2: Laboratory register for smear microscopy and X-pert MTB/RIF (TB-04)

Laboratory register for smear microscopy and X-pert MTB/RIF (TB - 04)

Lab No.	Date	Patient's name	Sex M/F	Age	Patient Address Phone No.	Treatment unit	OPD No. (or) TB No. (or) DR No.	HIV Status (Pos/ Neg/ Unk)	Previously treated for TB (Y/N/Unk)	Examination type		Examination results			Remarks
				Date of birth						Dx	F- u (Mth)	Smear microscopy 1	Smear microscopy 2	Xpert result Lab. No	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	
				.....										.....	

Annex 2.3: Laboratory register for culture, X-pert MTB/RIF and Drug susceptibility testing

Laboratory register for culture, Xpert MTB/RIF and Drug susceptibility testing

Lab Serial No.	MGIT Serial No.	Date of Specimen received	Patient's Name	Sex	Age	Patient Address	Treatment Unit	TB Registered No/DR-TB Suspect No	HIV Status (Pos/ Neg/ Unk)	Patient prreviously treated for TB (Yes/ No/Unk)	Date of Specimen collected	Date of Specimen inoculated	Reason	
					Date of Birth								Dx	F-U Mth

Laboratory register for culture, X-pert MTB/RIF and Drug susceptibility testing (continued)

Smear		GXP[a]	Culture[b]				Identification	Results of drug susceptibility testing(DST)										LPA					Date Results reported	Remarks
		GXP Lab No.	Solid		Liquid													Mutation			No Mutation	NTM		
A	B	T/RR/TI/N/I	A	B	A	B		H	R	E	S	AMK	KM	CM	FQ			HR	H	R				

Annex 2.4: TB treatment card (TB-01)

TUBERCULOSIS TREATMENT CARD (TB - 01)

Township TB No.: _____
Health facility: _____

Name _____ Phone No._____
Complete address (Permanent) _____
(Temporary) _____
Sex M☐ F☐ Age _____ Date of Birth _____
Name and address of 1. DOT Provider _____
2. DOT Supervisor _____
3. Contact Person _____

Disease site
Pulmonary☐ Extra Pulmonary ☐
(Specify) _____

Types of TB patient
New ☐ Treatment after failure ☐
Relapse ☐ Treatment after LFU ☐
Transfer in ☐ Others (previously treated) ☐
Unknown previous treatment ☐

INTENSIVE PHASE - Prescribed regimen and dosages

☐ **Initial Regimen** — All new TB cases
☐ **Retreatment Regimen** — All Previously Treated TB Cases
☐ **Childhood Regimen** — All TB case<15 Yrs

Referred by
☐ Health Staff (**HS**)
☐ Private Practitioner (**PP**)
☐ Community (**C**)
☐ Other (specify) _ _ _ _ _ _ _

☐ (HRZE) (HR) Z S(E)
☐ (HRZE) (HR) Z E S
☐ (HRZE) (HRZ) (HR) Z

(HR) = isoniazid and rifampicin Z = pyrazinamide E= ethambutol
S = streptomycin (HRZE) = 4FDC (HRZ) = 3FDC

Month	Results of Examination		Result of Culture and DST						Weight (kg)
	Smear Result	Xpert Result	Culture result	DST			LPA		
	Lab No.	Date. / Lab No.	Date. / Lab No.	H	R	S	E	H	R	

Culture result: (**Pos** = positive, **Neg** = Negative, **Con** = Contaminated)
DST result: **S** = Sensitive, **R** = Resistant, **C** = Contaminated
Xpert result: **N**= No MTB, **I** = Invalid/ No result , **T**= MTB detected, **RR**= Rif resistant, **TI**= MTB (+) / Rif resistant is invalid or No result

Tick appropriate box after the drugs have been administered

Month \ Day	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	Number doses this month	Total doses of IP given

Please turn over for continuation phase

TB treatment card (TB-01) (continued)

II. CONTINUATION PHASE - Prescribed regimen and dosages

☐ **Initial Regimen** ☐☐ **(4 months)** **(HR)**

☐ **Retreatment Regimen** ☐☐☐ **(5 months)** **(HRE) (HR) E**

☐ **Childhood Regimen** ☐☐ **(4 months)** **(HR)**

Day / Month	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	Number doses this month	Total number doses given

Enter (✔) on day of directly observed treatment. For a self-administered regimen, enter (X) on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (--------) through the number of days' supply given.

Observations: eg. CXR findings, side effect, any action by BHS, other co-morbidities, pregnancy, etc.:

_____

_____

_____

TB/HIV Activities	Status			Date
HIV tested	☐ Positive	☐ Negative	☐ Unknown	
CPT received				
ART received				

Treatment outcomes

Date of decision _____

Cured ☐
Treatment completed ☐
Treatment failure ☐
Died ☐
Loss to follow up ☐
Not evaluated ☐
Move to SLD treatment ☐

Annex 2.5: Township TB register (TB-03)

Township TB Register (TB - 03)

Date	Township TB No.	Name	Sex M/F	Age / DOB	Address Phone No.	Health Facility / Refered from (HS/PP/C/Oth)	Type of Patients						Transfer in (T)	TB Site
							New (N)	Previously treated patient				Previous treatment history unknown (Unk)		P/ EP
								Relapse (R)	Treatment after failure (F)	Treatment after loss to follow-up (LFU)	Others previously treated (O)			

Township TB register (TB-03) (continued)

Township TB Register (TB - 03)

Treatment regimens (choose one enter started date)			TB/HIV Activities		Smear (S), Xpert MTB/RIF (X) results or Culture (C)											Treatment outcomes (Choose one with Decision Date)							Remarks
					At the time of TB diagnosis					Month 2 or 3		Month 5		End of treatment										
Initial regimen	Retreat-ment regimen	Childhood regimen	CPT Date	ART Date	HIV Status (Pos/ Neg/ Unk)	S	X	C		S	C	S	C	S	C	DST	Cured	Treat-ment Complete	Treat-ment failure	Died	Lost to follow-up	Not Evaluated	Moved to second-line treat-ment register	
						Lab No.					Lab No.		Lab No.		Lab No.									

Annex 2.6: Quarterly report on TB case registration (TB-07)

National Tuberculosis Programme
Quarterly Report on TB Case Registration (TB - 07)

Name of townships/code no. _____ Region/State: _____ Name of Township TB coordinator _____	Patients registered during _____ quarter of _____	Date of completion of this form: _____
Area population _____ CNR (Bacteriologically confirmed) = Block(1), Row (1+3) x 100,000 (Per 100000 pop.) Population CNR (All TB cases) = Block (1), Row (1+2+3+4) x 100,000 (Per 100,000 pop.) Population		

Block 1: All TB cases registered during the quarter except Transfer in patients

Type of disease \ Type of patient	New		Re-treatment Cases: Relapse		Previously treated (excluding relapse)		Unknown previous treatment history		Total		Grand Total
	M	F	M	F	M	F	M	F	M	F	
Pulmonary, bacteriologically confirmed											
Pulmonary, clinically diagnosed											
Extra pulmonary, bacteriologically confirmed											
Extra pulmonary clinically diagnosed											
Total TB Case											

Block 2: All new and relapse cases (bacteriologically confirmed or clinically diagnosed) registered during the quarter by age group and sex

Type \ Age / Sex	0-4		5-9		10-14		15-24		25-34		35-44		45-54		55-64		≥ 65		Total		Grand Total
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	
New																					
Relapse																					
Total																					

Childhood TB Meningitis by Age group and Sex

0 – 4		5 – 9		10 – 14		Total		Grand Total
M	F	M	F	M	F	M	F	

Block 3: Laboratory diagnostic and follow-up activity

	NTP		MMA		PSI		Total	
	S	X	S	X	S	X	S	X
(a)Patients with presumptive TB for Diagnosis (Dx)								
(b)Number of Patients with positive bacteriological results out of Diagnosis (Dx)								
(c)Number of patients examined for follow-up								
(d)Number of positive patients out of follow-up								

Block 4: TB/HIV activities (all TB cases registered during the quarter)

Number of patients tested for HIV or/and known HIV status (Pos / Neg) at the time of Diagnosis registered in the Township TB register	No. of HIV-positive TB patients	HIV-positive TB patients Start CPT and ongoing CPT	No. of HIV + TB patients Start ART and ongoing ART

Remarks - IR ( ) cases RR ( ) cases CR ( ) cases Total ( ) cases

Countersigned by:

Signature: _____ Signature: _____

Name: _____ Name: _____

Designation: _____ Designation: _____

Annex 2.7: Quarterly report on the outcome of TB patients registered 12-15 months earlier (TB-08)

Quarterly report on the outcome of TB patient registered 12-15 months earlier (TB - 08)

Name of township _____ Township code no. _____ Name of Township TB coordinator _____	Patients registered during _____ quarter of _____	Date of completion of this form: _____ signature _____

TB patient type	No. of cases registered	Treatment outcomes						
		Cured	Treatment completed	Failed	Died	Lost to follow-up	Not evaluated	Moved to second-line drug
Block 1(A). All TB cases registered during the quarter of the previous year								
1. Bacteriologically confirmed new cases								
2. Bacteriologically confirmed relapse cases								
3. Clinically diagnosed, new and relapse								
4. Retreatment (excluding relapse)								
Block 1(B). All HIV positive TB cases registered during the quarter of the previous year								
1. Bacteriologically confirmed new cases								
2. Bacteriologically confirmed relapse cases								
3. Clinically diagnosed, new and relapse								
4. Retreatment (excluding relapse)								
Block 1(C). All childhood cases registered during the quarter of the previous year								
All childhood TB cases (< 15 Yrs)								

Block 2: TB/HIV activities (all TB cases registered during the quarter of the previous year)

HIV-positive TB patients	HIV-positive TB patients on CPT	HIV-positive TB patients on ART

Countersigned by:

Signature: _____

Name: _____

Designation: _____

Annex 3: HIV registers and forms

Annex 3.1: TB Screening and IPT Evaluation Register

Township …… Quarter ……..

No	HIV Reg No.	Name	< 15 yrs		≥ 15 yrs		Newly enrolled	1st visit		TB screening					TB Contact History (Age<5yrs)	Refer for TB Diagnosis (Date) *	IPT evaluation **			IPT Decision		Remark
			Male	Female	Male	Female		Calendar Year	Current Quarter	Cough (any)	Fever	Weight loss / Failure to thrive	Night sweats	Lymph node enlarged			Prior or Current Anti-TB treatment	Prior or Current IPT	Chronic liver D/s or Alcohol use	Yes/ No	Date	
1																						
2																						
3																						
4																						
5																						
6																						
7																						
8																						
9																						
10																						
11																						
12																						
13																						
14																						
15																						
16																						
17																						
18																						
19																						
20																						

* In the column "**Refer for TB diagnosis**", if refer, please fill the referral date.
** In IPT decision, If yes, please fill *IPT started date*, and if no, please fill (a: Not eligible, b: Provider / Doctor decision, c: Patient decision, d: others)

Annex 3.2: pre-ART register

PRE-ART REGISTER page 1 (left)

	1	2	3	4	5	6	7			8				9				10	11	12
	Date 1st visit at the clinic	Registration number	Name and address	Age	Sex: M/F	Status at enrolment*	Fill when applicable			Clinical stage				Pregnancy (Y/N)				Risk factor code 10 **	Date medically eligible for ART	ART start date. (transfer to ART register)
							CTX Start month/year	INH start month/year	TB Rx start: month/year started and TB reg no.	1	2	3	4	If yes, record EDD, ANC No. and HIV – exposed infant No.						
														Preg 1	Preg 2	Preg 3	Preg 4			
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
12																				

* Status at enrolment (Pregnant; Post Partum; TB Rx; Other). If pre-ART transfer in patient, write TI.
* Entry point: 1-VCT; 2-PMTCT; 3-STI; 4-TB; 5-Outpatient; 6-Inpatient; 7-Private; 8-NGO; 9-Self referred; 10-Drug Treatment Unit; 11– Others-Write code TR if the patient was transferred in on ART
**Risk factor for HIV; 1-Heterosexual; 2-Men who have sex with men; 3-Sex work; 4-Injecting drug use (IDU); 5-Blood transfusion; 6-Mother to child; 7-Unknown

PRE-ART REGISTER page 2 (right)

Quarterly follow—up status																							
Year				Year				Year				Year				Year				Year			
Q1 Jan-Mar	Q2 Apr-Jun	Q3 Jul-Sep	Q4 Oct-Dec	Q1 Jan-Mar	Q2 Apr-Jun	Q3 Jul-Sep	Q4 Oct-Dec	Q1 Jan-Mar	Q2 Apr-Jun	Q3 Jul-Sep	Q4 Oct-Dec	Q1 Jan-Mar	Q2 Apr-Jun	Q3 Jul-Sep	Q4 Oct-Dec	Q1 Jan-Mar	Q2 Apr-Jun	Q3 Jul-Sep	Q4 Oct-Dec	Q1 Jan-Mar	Q2 Apr-Jun	Q3 Jul-Sep	Q4 Oct-Dec
Total TB status Y																							
Seen at least once in Y																							

Top row: record follow-up status at end of each quarter

CD4-record last CD4 in quarter
→ - Did not have visit scheduled for that quarter
Lost— not seen in the last quarter, but scheduled for a visit
TO– transferred out (record to when)
DEAD– record date

Bottom row: Record TB status

Yes/No—TB status completed at last visit in last quarter

Annex 3.3: ART register

ART REGISTER (1)

Month: **Year:**

1	2	3	4	5		6	7	8	9	10	11	12	13	14	15		16	17	18		
			Age	Sex				**Status at start of ART**			**Fill in when applicable**			**PMTCT**					Treatment substituted within 1st line drugs		
Date of Start of ART	Registration number	Name		M	F	Patients Address and Contact number	Treatment Supporter's name and contact number	Weight	WHO Clinical Stage	CD4	CPT Starting date	IPT Starting date	TB Rx Starting date and TB reg No.	Preg 1	Preg 2	Preg 3	Preg 4 >	ART Regimen Started	Date substituted	Reason **	New Regimen

**Reasons for substitution within first line treatment: 1-toxicity or side effects; 2-pregnancy; 3-newly diagnosed TB; 4-new drug available; 5-drug out of stock; 6-others.

*** Reasons for switching to second line treatment: 1-toxicity; 2-pregnancy; 3-newly diagnosed TB; 4-new drug available; 5-drug out of stock; 6-clincial treatment failure; 7-others; 8-immunological failure; 9-virological failure.

Reasons for stopping ART: 1- toxicity side effects; 2-pregnancy; 3-treatment failure; 4-poor adherence; 5-illness hospitalisation; 6-drug out of stock; 7-patient's decision to stop; 8- planned interruption; 9 others.

19			20	21																									22
Treatment Switched to 2nd line			Cause of end of follow up	**Monthly visits: • 1st row:** write patient outcome: on treatment record current regimen code if patient picked up ART drugs; stopped **(ST)** if ART was stopped by the doctor; missing (MIS) if the patient missed the scheduled visit; lost to follow-up **(LFU)** if the patient is missing for 2-3 months; restart (RS) if ART was restarted after an interruption; transferred out (TR); dead (D); if the patient was not scheduled to visit this month **(NA)**. **Bottom, 2nd row:** Record TB status at last visit in last quarter																									
Switched	Reason**	Regimen	Death/LFU /Transfer out	Week 2	mo.1	mo.2	mo.3	mo.4	mo.5	mo. (6)	mo. 7	mo. 8	mo. 9	mo. 10	mo. 11	mo. (12)	mo.15	mo.18	mo.21	mo. (24)	mo.27	mo.30	mo.33	mo. (36)	mo.39	mo.42	mo.45	mo. (48)	Remark
			D/L/T							CD4						CD4				CD4				CD4				CD4	
			...../..../.......																										
			D/L/T																										
			...../..../.......																										
			D/L/T																										
			...../..../.......																										
			D/L/T																										
			...../..../.......																										
			D/L/T																										
			...../..../.......																										
			D/L/T																										
			...../..../.......																										

Page 2

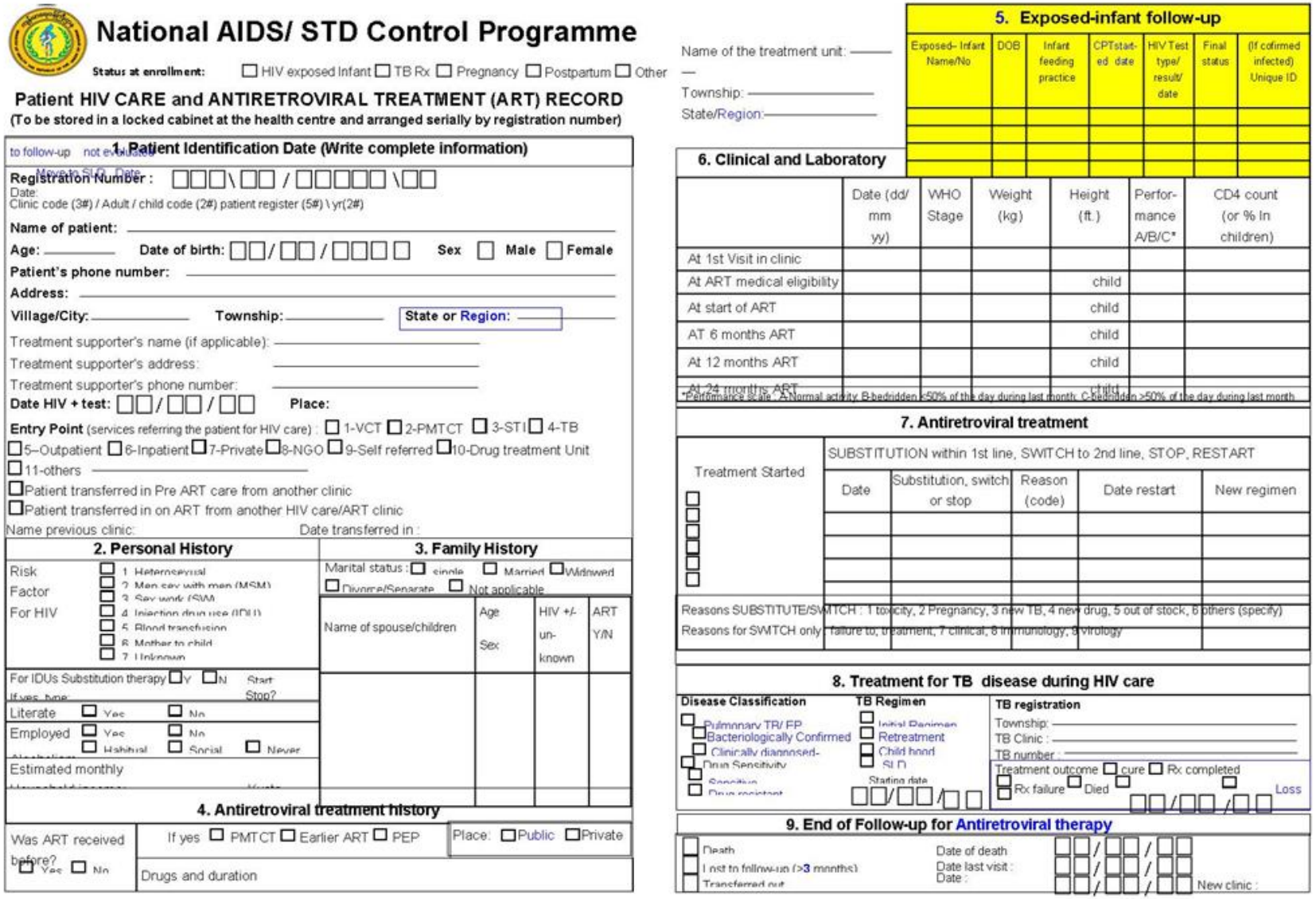
D - Death
L - Lost to follow up
T - Transfer out

Adult 1st - line re
1a = AZT-3TC-EFV
1b = AZT-3TC-NVI
1C=TDF-3TC-EFV
1d = TDF-3TC-NV

Child 1st - line regimens
4a = AZT-3TC-EFV
4b = AZT-3TC-NVP
4c = ABC-3TC-EFV
4d = ABC-3TC-NVP

Adult 2nd - line regimens
2a = AZT-3TC-LPV/r
2b = AZT-3TC-ATV/r
2c = TDF-3TC-LPV/r
2d = TDF-3TC-ATV/r
2e = ...
2fe = ...

Annex 3.4.1 ART treatment card



National AIDS/ STD Control Programme

Status at enrollment: ☐ HIV exposed Infant ☐ TB Rx ☐ Pregnancy ☐ Postpartum ☐ Other

Patient HIV CARE and ANTIRETROVIRAL TREATMENT (ART) RECORD

(To be stored in a locked cabinet at the health centre and arranged serially by registration number)

1. Patient Identification Date (Write complete information)

to follow-up not evaluated

Never in SLD Date

Registration Number : ☐☐☐\☐☐ / ☐☐☐☐☐ \☐☐

Date:

Clinic code (3#) / Adult / child code (2#) patient register (5#) \ yr(2#)

Name of patient: _____

Age: _____ **Date of birth:** ☐☐/☐☐/☐☐☐☐ **Sex** ☐ **Male** ☐ **Female**

Patient's phone number: _____

Address: _____

Village/City: _____ **Township:** _____ **State or Region:** _____

Treatment supporter's name (if applicable): _____

Treatment supporter's address: _____

Treatment supporter's phone number: _____

Date HIV + test: ☐☐/☐☐/☐☐ **Place:**

Entry Point (services referring the patient for HIV care) : ☐ 1-VCT ☐ 2-PMTCT ☐ 3-STI ☐ 4-TB

☐ 5–Outpatient ☐ 6-Inpatient ☐ 7-Private ☐ 8-NGO ☐ 9-Self referred ☐ 10-Drug treatment Unit

☐ 11-others _____

☐ Patient transferred in Pre ART care from another clinic

☐ Patient transferred in on ART from another HIV care/ART clinic

Name previous clinic: Date transferred in :

2. Personal History

Risk Factor For HIV

☐ 1 Heterosexual
☐ 2 Men sex with men (MSM)
☐ 3 Sex work (SW)
☐ 4 Injection drug use (IDU)
☐ 5 Blood transfusion
☐ 6 Mother to child
☐ 7 Unknown

For IDUs Substitution therapy ☐ Y ☐ N Start Stop?

If yes, type:

Literate ☐ Yes ☐ No

Employed ☐ Yes ☐ No

☐ Habitual ☐ Social ☐ Never

Estimated monthly

3. Family History

Marital status : ☐ single ☐ Married ☐ Widowed ☐ Divorce/Separate ☐ Not applicable

Name of spouse/children	Age Sex	HIV +/- un-known	ART Y/N

4. Antiretroviral treatment history

Was ART received before? ☐ Yes ☐ No

If yes ☐ PMTCT ☐ Earlier ART ☐ PEP Place: ☐ Public ☐ Private

Drugs and duration

Name of the treatment unit: _____

Township: _____

State/Region: _____

5. Exposed-infant follow-up

Exposed- Infant Name/No	DOB	Infant feeding practice	CPTstart-ed date	HIV Test type/ result/ date	Final status	(If cofirmed infected) Unique ID

6. Clinical and Laboratory

	Date (dd/ mm yy)	WHO Stage	Weight (kg)	Height (ft.)	Perfor-mance A/B/C*	CD4 count (or % In children)
At 1st Visit in clinic						
At ART medical eligibility				child		
At start of ART				child		
AT 6 months ART				child		
At 12 months ART				child		
At 24 months ART				child		

*Performance scale : A-Normal activity; B-bedridden <50% of the day during last month; C-bedridden >50% of the day during last month

7. Antiretroviral treatment

Treatment Started	SUBSTITUTION within 1st line, SWITCH to 2nd line, STOP, RESTART				
	Date	Substitution, switch or stop	Reason (code)	Date restart	New regimen
☐					
☐					
☐					
☐					
☐					

Reasons SUBSTITUTE/SWITCH : 1 toxicity, 2 Pregnancy, 3 new TB, 4 new drug, 5 out of stock, 6 others (specify)

Reasons for SWITCH only : 7 failure to; treatment, 7 clinical, 8 immunology, 9 virology

8. Treatment for TB disease during HIV care

Disease Classification

☐ Pulmonary TB/ EP
☐ Bacteriologically Confirmed
☐ Clinically diagnosed-
☐ Drug Sensitivity
☐ Sensitive
☐ Drug resistant

TB Regimen

☐ Initial Regimen
☐ Retreatment
☐ Child hood
☐ SLD

Starting date ☐☐/☐☐/☐☐

TB registration

Township: _____

TB Clinic : _____

TB number : _____

Treatment outcome ☐ cure ☐ Rx completed ☐ Rx failure ☐ Died ☐ Loss ☐☐/☐☐/☐☐

9. End of Follow-up for Antiretroviral therapy

☐ Death Date of death ☐☐/☐☐/☐☐

☐ Lost to follow-up (>3 months) Date last visit : ☐☐/☐☐/☐☐

☐ Transferred out Date : ☐☐/☐☐/☐☐ New clinic :

Annex 3.4.2 ART treatment card

10 . Patient HIV care & Antiretroviral treatment Follow - up													
Date of visit*	Date next visit	Weight (kg) and Height	WHO stage	Pregnancy (Y/N, EDD) or FP/BS method	Opportunistic infections-code* If child, nutritional problems	CPT	TB status	IPT	Anti-retroviral drugs and dose prescribed	Adherence to ART* >95%, 80-95% , <80%	ART side effects-code*	Lab results when available	Referred to CoC

* **Instructions and codes:**

Date: Write the date of actual visit starting rom the 1st visit for HIV care. ALL DATES ; DD/MM/YY

FP: Family planning ; 1 condoms. 2 oral contraceptive pills, 3 injectable/implantable hormones, 4 diaphram/ cervical cap, 5 intrauterine device, 6 vasectomy/tubal ligation/hysterectomy

TB status: No signs = no signs or symptoms of TB

Presumptive TB = TB refer or sputums sent (Record sputum sent & results in lab column; record referral in Refer col)

Not done (ND) = not assessed for whatever reason

Opportunistic infection: Enter one or more codes—Tuberculosis (TB); Candidiasis(C); Diarrhoea (D); Cryptococcal meningitis (M) ; Pneumocystis jerovici pneumonia (PCP) ; Cytomegalovirus disease (CMV) ; Penicilliosis (P) ; Herpes Zoster (Z) ; Genital herpes (H) ; Toxoplasmosis (T) ; Other—specify

Adherence: Check adherence by asking the patient if he/she has missed any doses. Also check the bottle/blister packet. Write the estimated level of adherence is (e.g. > 95% - <3% does missed in a period of 30 days; 80-95% - 3 to 12 doses missed in a period of 30 days; <80%=>12 doses missed in a period of 30 days for 60 tablets/ 30 days)

Side effects: Enter one or more codes—S=Skin rash; Nau=nausea; V=Vomiting; D= Diarrhea; N= Neuropathy; J=Jaundice; A=Anaemia; F=Fatigue; H=Headache; F=Fever; H/S=Hypersensitivity; Dep=Depression; P=Pancreatitis; L=Lipodyatrophy;

Annex 4: IPT registers and forms

Annex 4.1: IPT register

IPT. Reg. No.	Clinic Reg. No. (ART No.)	Name (in full)	Age	Sex (M/F)	Address	IPT registration date (DD/MM/YY)	Dose	Date of monthly drug issue						IPT discontinuation date (DD/MM/YY)	Outcome †	Remarks
								Month 1	2	3	4	5	6			

Page Summary for quarterly report	Treatment Registration		Treatment Outcomes (to be reported 1 year after registration)		
	Adults ≥15 years	Children <15 years	Completed for 6 months	Incomplete (Discontinue due to side effect, by patient, Died)	TB Disease
Respective township					
Other township					

† For TB Prophylactic Treatment Outcome Definitions

Completed Tx – completed treatment for 6 months
Incomplete Tx – Discontinue due to side effect, by patient, Died
TB Disease – diagnosed as TB disease while on IPT

Annex 4.2: IPT card

ISONIAZID PREVENTIVE THERAPY CARD FOR CHILDREN AND ADULT

Health Facility _____ Township _____District _____Region/State _____

Name _____ Age _____ Sex _____Address _____

Father's name_____ Contact Township TB Number_____ IPT Sr. No._____

IPT starting date: ___/___/____ daily dose _____Expected stop date ___/____/____

Completion date of Isoniazid Preventive Therapy ____/____/____

Month	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	Doses	Wt in Kg	Remarks

Annex 5: Cross referral forms

Annex 5.1 Three inter link referral form

3 Interlinked Patient Monitoring System
Department of Health
Referral Form

Name _____ Age _____ Sex _____
Referred from _____ to _____
Registration No _____(If depart / organization has registration No)
Referral No _____ Date of referral __/ __/ _____
Background history (Any relevant Medical history + risk factor)
.....
.....
Reason for referral

1. HIV testing / HCT	☐	6. PMCT	☐
2. CD4 testing	☐	7. OI & STI treatment	☐
3. Viral Load testing	☐	8. IPT	☐
4. Laboratory investigations (other than CD4 & VL	☐	9. TB (diagnosis & treatment)	☐
5. Antiretroviral therapy (ART)	☐	10. Transfer of ART patients*	☐

**(Please send old records. This referral should only be done after discussion and agreement from the center where patient is transferred to)*

11. Others- please provide detail

-

-

Official seal

Signature ----------
Name ----------
Designation ----------
Department / organization----------

-

Action taken for referral (to be provided by place where referred)

Name of Department/Organization _____
Registration No (if any) _____(Referred center registration No)
Date of referral received __/ __/ ___ Date of feedback: __/__/___
Action taken ----------

Official seal

Signature ----------
Name ----------
Designation ----------
Department / organization: ----------

Referral form to be filled in duplicate (using carbon less copy). Record of in and out referrals should be maintained by both for proper follow up, while keeping it confidential.

Annex 5.2: TB/HIV cross referral form

TB-HIV Cross Referral Form

Township .....

Patient's Name ..... Age ..... Sex .....

Referred from NAP/NTP to NAP/NTP Referral No: .....

Registration No: ..... Date of referral .....

Reasons for Referral

☐	Diagnosis and Treatment of TB	☐	Cotri prophylaxis
☐	HIV Testing and Counselling (HTC)	☐	IPT intiation
☐	Assessment & Enrollment for ART	☐	CoC
☐	Treatment for Ols	☐	others

Remarks:

Signature

Name

Designation

✂==========

TB-HIV Cross Referral Feedback Form

Township .....

Patient's Name ..... Age ..... Sex .....

Feedback from NAP/NTP to NAP/NTP Referral No: .....

Registration No: ..... Date of received .....

Action(s) taken for Referred case

Diagnosis of TB: sputum ex:	☐	CXR	☐	Provide anti TB	☐
				Started date:	
HTC: Testing	☐	Counselling	☐		
Enrolled for ART	☐	started ART	☐	started date:	
Treatment for Ols	☐				
Provide Cotri prophylaxis	☐				
Provide IPT	☐				
others (specify)	☐	Started date:			
others (specify)	☐				

Signature Remarks:

Name

Designation

Annex 6: Reporting forms for TB/HIV activities

Annex 6.1: Quarterly Reporting Format for TB/HIV Activities to be reported by NTP

Block B: Reporting for TB team					
	Number				Data Source
	0-14		≥15		
	M	F	M	F	
Number of TB patients (New+ replase) registered during the reporting period					Township TB register
Number of TB patients (New+ replase) registered during the reporting period who had an HIV test result recorded in the TB register					Township TB register
Number of TB patients (New+ replase) registered during the reporting period with documented HIV-positive status					Township TB register
Number of HIV-positive TB patients (New+ relapse), registered during the reporting period, starting or continuing CPT treatment during their TB treatment					Township TB register
Number of HIV-positive TB patients (New+ relapse), registered during the reporting period, who are stared on or continue previously initiated ART during TB treatment					Township TB register

Signature …….

Name ……

Designation ……

Program ……

Signature …….

Name ……

Designation ……

Program ……

* Total number of incident TB cases (New+replase) of a reporting unit for a defined reporting period will be equal to the total number of patients of **Block 2 of TB 07** of the corresponding reporting period.

Annex 6.2. Quarterly Report for TB/HIV collaborative activities

Quarterly Report for TB/HIV collaborative activity

AIDS/STD team/ HIV clinic ----------

Quarter_____

TB team ----------

Year _____

Township/District ----------

Block A: Reporting for AIDS/STD team/ HIV clinic	Newly enrolled				1st visit for calender year				Head count in current quarter			
	0-14		≥ 15		0-14		≥ 15		0-14		≥ 15	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Number of PLHIV attended HIV care during the reporting period												
Number of PLHIV screened for TB during reporting period												
Number of PLHIV referred for TB diagnostic evaluation												
Number of PLHIV diagnosed with active TB diasease and registered for TB treatment												
Number of PLHIV received IPT evaluation												
Number of PLHIV who were eligible for IPT												
Number of PLHIV who were given IPT in reporting period												

IPT outcome reporting for patient registered in IPT during the same quarter, one year earlier	Total Number registered during same quarter, one year earlier	Completed ≥ 6 months	Incomplete (Discontinue due to side effects, lost to follow-up)	TB disease while on IPT
Patients registered during: Quarter ..... of Year.....				

Block B: Reporting for TB team	New and relapsed TB patients				Data Source
	0-14		≥ 15		
	Male	Female	Male	Female	
Number of TB patients registered during the reporting period					Township TB register
Number of TB patients registered during the reporting period who had an HIV test result recorded in the TB register					Township TB register
Number of TB patients registered over the reporting period with documented HIV-positive status					Township TB register
Number of HIV-positive TB patients registered over the reporting period, starting or continuing CPT treatment during their TB treatment					Township TB register
Number of HIV-positive TB patients who are already on ART or started ART during TB treatment					Pre-ART, ART, TB register

Signature ----------

Name ----------

Designation ----------

Programme ----------

Signature ----------

Name ----------

Designation ----------

Programme ----------

Annex 7. Supervision Check Lists

Annex 7.1 Supervision Check List for TB/HIV collaborative Activities in TB Centres/ Clinics

Township Profile related to TBHIV

Township population –

Total registered TB patients in previous year (minimum estimated number for Determine/yr)–

HIV positive rate in last year (for estimated number for Uni-gold and Stat Pak /yr)–-

Infection Control

Space and ventilation status of waiting area, TB consultation room and laboratory

Vinyl for cough Hygiene displaying at OPD

Surgical masks for all TB patients

N95 for Health care workers

Human Resource and capacity building

Appointed staff versus number of staff mobilized at the TB center

Number of staff received TBHIV training among appointed staff

Recording

Recording status of TBHIV data in TB 03 (HIV status and test dates, GXP result, CPT, ART dates for TBHIV patients)

Recording status of TBHIV data in TB 04 and Township TB code

Reporting and data analysis

Consistency of TB 03, TB 07 and quarterly TBHIV activity report

Trends of proportion of known HIV status, proportion of HIV positive cases, proportion of TBHIV patients on CPT and ART for 4 Quarters

Outcomes data of TBHIV patients TB 08 and its trends for 4 Quarters

Referral and linkage system

Mapping of service delivery points for HIV care services (ART centers and ART decentralized sites)

Filing system of referral register and feedback form

Logistics, store and stock management

Store condition (temperature chart, pallets, and bin card)

Estimated monthly consumption versus stock in hand and expire dates for all test kits

Annex 7.2 Supervision Check List for TB/HIV collaborative Activities in ART Centers/ ART DC site/AIDS-STD team

Township Profile related to TBHIV

Township population (Census)

Total No of PLHIV on ART (NAP + IPs data)

Total No of PLHIV enrolled for HIV care during this month

No of HIV +ve TB patients who received both ART and TB treatment during this month

No of PLHIVs who were given IPT in reporting period

Infection Control

Space and ventilation status of waiting area, HIV consultation room and laboratory

Surgical masks for open cases

N95 for Health care workers

Human Resource and capacity building

Appointed staff versus number of staff supposed to be at the center

Number of staff received TBHIV training among appointed staff

Recording

Pre ART care register (HIV enrollment register)

ART register

HIV care and Antiretroviral treatment record card (White card)

OPD TB screening register

IPT register

ART monthly report

Reporting and data analysis

Consistency of TB screening register, HIV care register and quarterly TBHIV activity report

Quality of service and outcomes data from TB/HIV activity report

Referral and linkage system

Mapping of service delivery points for HIV care services (ART centers and ART decentralized sites)

Filing system of referral register and feedback record.

Proper filling of referral and in referral record

Logistics, store and stock management

Store condition (temperature chart, pallets, and bin card)

Estimated monthly consumption versus stock in hand and expire dates for drugs.

Annex 8. Quarterly Consumption Report and Request for HIV Tests

National TB Program

Quarterly Consumption Report and Request for HIV Tests

Reporting period: _____ Quarter, _____ Year.

State/Region: _____ TBHIV project township _____ Date of completion of report _____

HIV Test	Basic Unit	Opening balance	Qty received	Qty used/issued	Closing balance	Average monthly consumption	Maximum Stock Qty	Qty needed for next quarter
		A	B	C	D=(A+B-C)	E=C/3	F=Ex3	G=F-D
Determin	Test							
Uni-gold	Test							
Stat-pak	Test							

Monthly Consumption

HIV Test	Basic Unit	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Determin	Test												
Uni-gold	Test												
Stat-pak	Test												

* The formulas are given for the reporting period of 3 months.

Prepared by:

Signature:

Name:

Designation:

Date: