# Implementation Guideline for TB/HIV Collaborative Activities in Ethiopia

*Federal Ministry of Health of Ethiopia*
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## FOREWORD

In settings where the prevalence of HIV is high, tuberculosis is often the commonest infection to develop among people living with HIV (PLHIV). Tuberculosis and HIV therefore make up a deadly synergy i.e., PLHIV are more likely to develop TB and patients suffering from TB are more likely to be PLHIV. This suggests that TB control will not make much headway in HIV prevalent countries unless HIV control is also achieved.

The synergy between TB and HIV justifies the collaboration between control programs for the two diseases. Cognizant of the need for such collaboration and in compliance with global recommendations, the Federal Ministry of Health of Ethiopia in collaboration with its development partners has been implementing TB/HIV collaborative activities across the country. To support this collaborative effort, the first version of TB/HIV implementation guideline was developed in 2005. This revision is made taking in to consideration the many developments in the field of collaboration both globally and within the country.

We hope the revised version of this guideline will be a useful companion for all those who are working to the betterment of the community in general and those infected and affected by TB and HIV/AIDS in particular.

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## ACRONYMS/ABBREVIATIONS

| | |
|---|---|
| AAU | Addis Ababa University |
| ACSM | Advocacy, Communication and Social Mobilization |
| AIDS | Acquired Immunodeficiency Syndrome |
| ALERT | All African Leprosy Education, Training and Research Center |
| ANC | Antenatal Care |
| ARI | Annual Risk of Infection |
| ART | Anti-Retroviral Treatment |
| CBOs | Community Based Organizations |
| CDC-E | Centers for Disease Control and prevention, Ethiopia |
| CU-ICAP-E | Columbia University-International Center for AIDS Care and Treatment Programs-Ethiopia |
| CT | Counselling and Testing |
| CPT | Cotrimoxazole Preventive Treatment |
| DACA | Drug Administration and Control Authority |
| DOTS | Directly Observed Treatment, Short-Course |
| DPCD | Diseases Prevention and Control Department |
| EHCL | Essential Health Commodities List |
| EHNRI | Ethiopian Health and Nutrition Research Institute |
| ETAEP | Ethiopia AIDS Emergency Plan |
| FMOH | Federal Ministry of Health |
| FHI-E | Family Health International, Ethiopia |
| GF | Global Fund |
| GFATM | Global Fund to Fight AIDS, TB and Malaria |
| GLRA | German Leprosy and TB Relief Association |
| HAART | Highly Active Anti Retroviral Treatment |
| HAPCO | HIV/AIDS Prevention and Control Office |
| HBC | Home and Community Based Care |
| HCT | HIV Counseling and Testing |
| HIV | Human Immunodeficiency Virus |
| HMIS | Health Management Information System |
| HQ | Head Quarter |
| HPPD | Health Programmes Provisional Department |
| IDU | Injection Drug Use |
| IEC | Information, Education and Communication |
| IP | Infection Prevention |
| IPT | Isoniazid Preventive Therapy |
| ISTC | International Standards for Tuberculosis Care |
| I-TECH-E | International Training and Education Center for HIV, Ethiopia |
| IRIS | Immune Reconstitution Inflammatory Syndrome |
| JHU-E | John Hopkins University, Ethiopia |
| LMIS | Logistic Management Information System |
| MDR-TB | Multi-Drug Resistant TB |
| MSH-E | Management Sciences for Health, Ethiopia |

| | |
|---|---|
| NGOs | Non-Governmental Organizations |
| OI | Opportunistic Infection |
| PAL | Practical Approach on Lung Health |
| PSA | Pharmaceutical Supply Agency |
| PHCU | Primary Health Care Unit |
| PLHIV | People Living With HIV/AIDS |
| PMTCT | Prevention of Mother-to-child transmission of HIV |
| PPM | Public-Private Mix |
| ProTEST | Promotion of HIV Test |
| RTLC | Regional TB and Leprosy Control Coordinator |
| SNNPR | Southern Nations Nationalities and Peoples Region |
| SOPs | Standard Operation Procedures |
| STIs | Sexually Transmitted Diseases |
| TB | Tuberculosis |
| TB/HIV | TB and HIV Co-infection |
| THAC | TB/HIV Advisory Committee |
| THTC | TB/HIV Technical Committee? |
| TLCP | TB and Leprosy Prevention and Control Programme |
| TLCT | TB and Leprosy Prevention and Control Team |
| TWG-TB/HIV | Technical Working Group for TB/HIV Collaboration |
| UCSD-E | University of California San Diego, Ethiopia |
| UNAIDS | The joint United Nations Programme on HIV/AIDS |
| UP | Universal Precaution |
| USAID | United States Agency for International Development |
| VCT | Voluntary Counseling and Testing |
| WCDC | Woreda Communicable Diseases Control Coordinator |
| WHO | World Health Organization |
| XDR-TB | Extensively Drug Resistant Tuberculosis |
| ZCDC | Zonal Communicable Diseases Control Coordinator |

# 1 Introduction

## 1.1 General

The human immunodeficiency virus (HIV) pandemic presents a massive challenge to the control of tuberculosis (TB) at all levels. This unprecedented scale of the epidemic of HIV-related tuberculosis demands concerted and urgent action. The synergy between TB and HIV is strong i.e., in high HIV prevalence population, TB is a leading cause of morbidity and mortality, and HIV is driving the tuberculosis epidemic in many countries, especially in sub-Saharan Africa. The spread of TB and HIV is aggravated by socio-economic factors such as poverty and low levels of literacy.

The dual epidemics have a number of impacts on the health sector. They increase TB and HIV burden, demand for care and worsen the situation of the already overstretched health care delivery system in the country. Hence, they deplete resources, worsen stress and aggravate attrition of health workers at service delivery points.

The expanded scope of the new strategy for tuberculosis control in high HIV prevalence population comprises interventions against tuberculosis (intensified case-finding, tuberculosis preventive therapy and TB infection prevention) and interventions against HIV (routine HIV testing, safe sexual practice, STI screening and treatment, Co-trimoxazole preventive therapy, antiretroviral treatment (ART) and HIV care and support). Therefore, tuberculosis and HIV Prevention and Control programmes must strengthen the general health service providers' ability to respond to the health care needs of people in high HIV prevalence population.

This guideline is intended to standardize and maintain quality of TB/HIV collaboration mainly at program management level and at health facility level. It deals with how to organize and run TB/HIV collaboration and carry out comprehensive prevention, care, treatment and support to people infected and affected by TB and HIV and the community at large.

## 1.2 Global and national burden of TB and HIV

### 1.2.1 Global burden of tuberculosis

TB is still a major cause of death worldwide, but the global epidemic is on the threshold of decline, except SSA. There were an estimated 8.8 million new TB cases in 2005, (of which 11% are under 15 children) 7.4 million in Asia and sub-Saharan Africa. A total of 1.6 million people died of TB, including 195 000 patients infected with HIV.[1]

[1] WHO Report 2007, Global Tuberculosis Control

### 1.2.2 National burden of tuberculosis:

Ethiopia stands 8th place in the global rank by estimated number of cases. The incidence of TB in Ethiopia is estimated at 152 and 341 per 100,000 populations for new smear positive pulmonary and all forms of TB respectively. The prevalence of Tuberculosis of all forms in the same period is estimated at 546 per 100,000 populations (WHO report 2007, Global Tuberculosis Control).

Data from FMoH showed that pediatric TB accounts for about 6% of the total smear positive TB cases in 2006/7, though the presentation of TB in children is predominantly EPTB.

### 1.2.3 Global burden of HIV/AIDS

Globally the number of people living with HIV (PLWH) continues to grow as does the number of deaths from HIV/AIDS. According to UNAIDS report, a total of 33.2 million people were living with HIV in 2007. This figure includes the estimated 2.1 million adults and 420,000 children who were newly infected with HIV in 2007. There were 2.1 million deaths as a result of HIV in the year 2007. Sub Saharan Africa continues to bear the burden of the global epidemic. A total of 22.5 million (67.7%) of the global people were living with HIV in 2007 in the sub-Saharan Africa and an adult prevalence of 5% is reported.

### 1.2.4 National burden of HIV/AIDS

In Ethiopia the adult prevalence of HIV is estimated to be 2.2% in 2008. The prevalence among the urban and rural populations during the same period is estimated at 7.7% and 0.9%, respectively. The total number of PLHIV in the same period is estimated to be 1,037,267 adults and 68,136 children. The number of new adult HIV infection for 2008 is estimated to be 125,147 for adults and 14 093 new pediatric infection because of vertical transmission. The number of deaths due to AIDS for the same period is estimated to be 58,290 for adults and 9,284 among children. The number of PLHIV who need to be started on ART in 2008 is estimated at 289,734 for adults and 17,274 for children under the age of 14 years. [2]

### 1.2.5 Global and national burden of TB/ HIV Co-infection

Worldwide about 11.1 million adults are co-infected with TB and HIV. Seventy per cent of co-infected people are living in sub-Saharan Africa[3], 20% in South East Asia and 4% in Latin America and the Caribbean. In Ethiopia routine data from 44 sites in the year 2005/6 showed 41% of TB patients are HIV positive. Another routine data collected in 2006/7 showed that the co-infection is 31% (FMOH).

[2] UNAIDS, December 2007 Report
[3] Single Point HIV Prevalence Estimate, FHAPCO/FMOH, June 2007
[4] Road map to TB/HIV, 4th IAS Conference on HIV pathogenesis, Rx and Prevention, July 2007

## *1.3 Impact of HIV/AIDS on TB Prevention and Control activities*

HIV increases susceptibility to infection with *M. tuberculosis*, the risk of progression to TB disease, and the incidence and prevalence of TB. The annual risk of developing TB in PLHIV who is co-infected with *M. tuberculosis* ranges from 5 to 15% as compared to a 5 to 10% life time risk for HIV negative individuals. It also increases the likelihood of re-infections and relapses of TB. In a population where HIV/TB is common, health services struggle to cope with the large and rising number of TB. HIV/AIDS has a number of impacts on prevention and control of TB. The consequence includes the following:

- Increasing numbers of TB suspects and TB patients, which in turn impacts on:
- Human and infrastructural resources in the health sector
- Services for diagnosis and case-holding
- Risk of nosocomial TB infection
- HIV related TB mortality and morbidity in health care workers, reducing staff numbers and increasing the workload of remaining staff. Which in turn compromise quality of service
- Low staff morale due to conditions of service, anxiety and powerlessness
- Increased risk of MDR & XDR-TB among health care workers
- TB becomes associated with AIDS, possibly causing TB suspects to delay accessing health services due to the stigma of HIV/AIDS
- Over diagnosis of sputum smear-negative PTB (due to difficulties in diagnosis)
- Under diagnosis of sputum smear-positive PTB (due to excess laboratory workload)
- Inadequate supervision of anti-TB chemotherapy;
- Low cure rates in advanced immunodeficiency states
- High morbidity during treatment
- High mortality rates during treatment due to other opportunistic infections
- High default rates because of adverse drug reactions;
- High rates of TB recurrence
- Increased transmission of drug-resistant strains among HIV-infected patients
- High rates of drug-drug interactions and side effects.

## *1.4 Impact of TB on HIV/AIDS*

In an individual infected with HIV, the presence of TB may affect in many ways.

- TB increases HIV replication, which leads to increased viral load. This results in more rapid progression of HIV disease.
- TB increases occurrence of other OIs.
- The management of TB and HIV co-infected individual is challenging because of:
  - Pill burden,
  - Increase adverse effect,
  - Drug to drug interaction and IRIS

## *1.5 National response against TB/HIV co-epidemics*

Based on lessons learnt from the ProTEST model WHO's project piloted and used VCT as entry point in three countries of Sub Saharan Africa (SSA) with high HIV prevalence and TB burden, WHO made a call to four countries of Sub Saharan Africa (SSA) including Ethiopia with high HIV prevalence and TB burden to introduce and implement TB/HIV collaborative activities by the end of 2001.

After an expressed commitment of FMOH of Ethiopia to WHO's Call, FMOH coordinated the establishment of a TB/HIV Advisory Committee (THAC) in 2002, which includes key stakeholders from the TLCP/FMOH and HPPD/FHAPCO (the then HIV/AIDS and STI Team), major multi- and bilateral donor organizations, research institutions, academic institutions and professional associations.

THAC has been providing technical support to HPPD of Federal HIV/AIDS Prevention and Control Office (FHAPCO) and National TBL Control Program of Federal Ministry of Health (FMOH) for the development of national TB/HIV proposal in 2002, promoted sensitization Workshop for policy makers, health program managers, health workers and community leaders, development criteria and selection of 9 TB/HIV pilot sites in 3 Regions and 1 City Administration, namely Oromia, Amhara, SNNPR and Addis Ababa respectively.

As part of capacity building activities: A national TB/HIV Coordinator supported by World Health Organization (WHO) had been recruited to work closely with both the HIV and TB programs at the FHAPCO/FMOH. TB/HIV collaborative activities in Ethiopia are supported by Round 1 Global Fund Grant. Other donors for TB/HIV in Ethiopia include in-country-USG team (CDC and USAID), WHO, UNAIDS and German Leprosy and TB Relief Association (GLRA).

Major events that happened in Ethiopia and served as an important tool for advocacy and resource mobilization that fostered the expansion of TB/HIV collaborative activities across the country were:

- TB/HIV Global Working Group (TWG) Meeting organized by WHO/HQ (September 20-21,2004, Addis Ababa)
- TB/HIV Surveillance Workshop organized by CDC Atlanta/USA (September 20-24, 2004, Addis Ababa)
- A series of International TB/HIV Managerial Courses organized by WHO/HQ and GLRA that were conducted at ALERT, Addis Ababa.
- An international symposium on treatment of latent TB infection conducted in Addis Ababa, November 2006, which generated important recommendations.

Key collaborative TB/HIV activities being implemented include:

- Capacity building including training for regional TB and HIV/AIDS control program managers and health workers,
- Procurement and distribution of TB/HIV supplies,
- HIV testing of TB patients,
- Provision of Co-trimoxazole Preventive Therapy (CPT) for HIV infected TB patients,
- Referral to HIV-related care,
- TB screening and referral among HIV-infected clients receiving VCT services,
- Supportive supervision/mentoring and review meetings.

The selected 9 pilot sites have served as important testing grounds to develop training materials, recording and reporting formats, referral systems, TB/HIV Implementation Guidelines.
As part of phased expansion, TB/HIV collaborative activities are being implemented in 138 hospitals and 280 health centers and private clinics with ART services as of August 2007.

## *1.6 Overview of Tuberculosis and Leprosy Prevention and Control Programme (TLCP)*

The TB and Leprosy Diseases Prevention and Control Programme (TLCP), was reorganized in 1994 with a view to integrate TB and leprosy control activities.

The major objectives of TLCP with regard to Tuberculosis are:

- To interrupt transmission of infection
- To reduce morbidity, mortality and disability
- To prevent spread of drug resistance
- To reduce burden of TB among PLHIV and general population
- To reduce HIV incidence among TB patients.

The basic strategies to achieve these objectives includes:

- Early case detection (intensified).
- Adequate chemotherapy.
- Comprehensive patient care.
- Strong TB/HIV collaboration

There exist similar structures to coordinate prevention and control of TB and Leprosy at regional, zonal and woreda levels.

The targets and components of TBL and TB/HIV Strategic Planning and Management 2007/8-2009/10 are in line with the contents of the Stop TB Strategy, launched in 2006 by World Health Organization (WHO). The six components of the Stop TB Strategy are:

1. Pursue high quality DOTS expansion and enhancement:
    - Political commitment with increased and sustained financing
    - Case detection through quality-assured bacteriology
    - Standardized treatment, with supervision and patient support
    - An effective drug supply and management system
    - Monitoring and evaluation system, and impact measurement

2. Address TB/HIV and MDR-TB and other challenges
    - Implement collaborative TB/HIV activities
    - Prevent and control MDR-TB
    - Address prisoners, refugees and other high risk groups and situations

3. Contribute to Health System Strengthening
    - Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information system
    - Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
    - Adapt innovations from other fields

4. Engage all health care providers
    - Public-Public and Public-Private Mix (PPM) approach
    - International Standards for Tuberculosis Care (ISTC)

5. Empower people with TB and communities
    - Advocacy, communication and social mobilization
    - Community participation in TB care
    - Patients' Charter for Tuberculosis care

6. Enable and promote research
    - Program-based operational research
    - Research to develop new diagnostics, drugs and vaccine

## *1.7 Overview of the HIV Program*

Ethiopia responded to the HIV epidemic promptly by establishing a taskforce in 1985, soon after the report of the first confirmed case of HIV. Two years later, in 1987, the national taskforce was upgraded to a department level under FMOH. The department had the responsibility of coordinating the national prevention and control program. Subsequently, short-and medium-term plans were prepared and implemented in collaboration with national and international partners. However, the National AIDS Policy was issued only a decade later (1998). Further, in 1999, the Strategic Framework for the National Response against HIV was prepared. Both documents served as the basis for the expanded and multi-sectoral response against the epidemic.

Despite the prompt initial response, the national response was evaluated to be slow and interrupted. As a result, further restructuring in the response mechanism was required. In April 2000, the National AIDS Council (NAC) was established with secretariat offices from federal down to kebele levels. This further evolved into an office, the HIV/AIDS Prevention and Control Office (HAPCO), in 2002.

Following the establishment of HAPCO, both the Strategic Framework (2004-2008) and the National HIV/AIDS Policy (in 2007) have been revised. Both documents have clearly articulated guiding principles including: multi-sectoralism, shared sense of urgency, ownership and active involvement of the community, leadership commitment, partnership, gender sensitivity, public health approach, promotion and protection of human rights, greater involvement of PLHIV, best use of resources, equitable and universal access, sustainability, and coordination.

As was elsewhere, Ethiopia's initial response to the epidemic had primary focus on prevention, with little attention to treatment. With the introduction of antiretroviral therapy (ART) in resource-limited settings in early 2000's, Ethiopia was among the first few African countries to introduce ART in 2003, in selected health facilities following the issuance of the National antiretroviral drugs (ARVs) supply and use Policy in 2002. The Ethiopian free ART scheme was launched in 2005.

In recent years, HAPCO has been more strategically positioned to scale-up the health sector response against HIV/AIDS. At the moment (October 2007), the Health Programs Department (HPD) is charged with the responsibility of coordinating the health sector response against HIV/AIDS in Ethiopia. The major components of this comprehensive response include:

- HIV counseling and testing (HCT),
- prevention of parent-to-child transmission of HIV (pPTCT),
- Infection Prevention (IP),
- ART, opportunistic infection (OI) management, and
- Ensuring the quality of all activities.

# 2 TB/HIV Collaboration at programme Management Level

## 2.1 Rationale for TB/HIV collaboration

Tuberculosis and HIV Prevention and Control programs share mutual concerns: HIV prevention care and treatment should be a priority for tuberculosis control program; tuberculosis prevention and treatment should be priority concern for HIV prevention and control program.

Operational areas lead to development of new interventions in the area of TB/HIV activities. The reduced morbidity and mortality associated with Co-trimoxazole Preventive Therapy (CPT) of HIV-positive TB-patients has now been confirmed in studies from West Africa, Malawi, South Africa and Uganda. These benefits have strong implications for TB control in areas of high HIV-prevalence. On the other hand, Isoniazide Preventive Therapy (IPT) has a significant protective effect on those HIV positive clients (with out active TB) by preventing the development of TB disease.

Therefore the need for TB and HIV collaboration is justified because:

- Most of the time TB and HIV occur commonly and impact on each other.
- There is a shared benefit from the implementation of TB/HIV collaboration, that is, HIV positive clients benefit from routine TB screening and IPT, and TB patients detected HIV positive benefit from CPT, ART and chronic care linkage.
- It promotes efficient utilization of resources allocated by both programmes.

In Ethiopia though the two programs pursued their practice separately earlier, since 2002 they have initiated preparation on TB/HIV collaboration. The actual implementation of the collaborative TB/HIV activities started from May 2004. The preparations were: establishment of national TB/HIV advisory committee (THAC), TB/HIV proposal development, advocacy workshops for policy makers and program managers.

## 2.2 Objectives of TB/HIV collaboration

General objective

- To reduce the burden of TB/HIV among population affected by both diseases.

Specific objectives are to:

- Establish the mechanisms for collaboration
- Reduce the burden of TB in people living with HIV (PLHIV)
- Reduce the burden of HIV among TB patients

WHO Recommended TB/HIV Collaborative Activities

A. Establish Mechanisms for Collaboration
   - Set up a coordinating body for TB/HIV activities at all levels
   - Conduct Surveillance of HIV prevalence among Tuberculosis patients
   - Carry out joint TB/HIV planning
   - Conduct monitoring and evaluation

B. Decrease the burden of Tuberculosis in people living with HIV

- Establish intensified Tuberculosis case finding
- Introduce Isoniazid preventive therapy (IPT)
- Ensure Tuberculosis infection control in health care and congregate settings

C. Decrease the burden of HIV among TB patients

- Provide HIV testing and counselling
- Introduce HIV prevention methods
- Introduce co-trimoxazole preventive therapy
- Ensure HIV/AIDS care and support
- Introduce antiretroviral therapy

## *2.3 TB/HIV collaborative activities at program management level*

TB/HIV collaboration consists of a set of activities to be carried out at all levels of the health care delivery system. At programme management level it deals with the following activities:

### 2.3.1 Establishment of coordinating mechanism

In Ethiopian context currently there are two mechanisms for TB/HIV coordination. The first one is the Coordinating Body, which is mainly the government structure of TB and HIV programs and the second one is the technical advisory committee, which is composed of members from governmental structures as well as major partners in the area of TB and HIV.

#### 2.3.1.1 Coordinating body

Coordinating body at all program management (Federal, Regional, Zonal, Woreda and Health Facility) levels:

Roles and responsibilities of the coordinating body:

**A.1 Federal level:**

The overall national coordination of TB/HIV will be led by TLCT and HPPD/FHAPCO (with rotating chairmanship as per the TOR of THAC (Annex I.) Both TLCT and HIV/AIDS team will jointly:

- Develop TB/HIV guidelines.
- Develop plan of action (annually).
- Carryout Advocacy, Communication and Social Mobilization activities.
- Mobilize resources.
- Ensure proper implementation of TB/HIV collaborative activities.
- Facilitate and regularly follow procurement and distribution of drugs and supplies (in collaboration with PSA).
- Develop national and regional capacity with emphasis to training, motivation and retaining of health personnel.

- Establish TB/HIV surveillance system.
- Initiate and lead TB/HIV operational research.
- Promote and strengthen public-private partnership in TB/HIV collaborative activities.
- Address TB/HIV in special setups.
- Conduct monitoring and evaluation and supportive supervision.

**A.2 Intermediate level (Regional, Zonal/Sub-city, Woreda):**

- Jointly develop Plan of Action.
- Carryout Advocacy, Communication and Social Mobilization activities.
- Ensure proper implementation of TB/HIV collaboration.
- Develop capacity with emphasis to training, motivation and retaining of health personnel.
- Conduct regular supportive supervision.
- Disseminate TB/HIV national guideline and standard operation procedures (SOPs) and ensure use at facility level.
- Conduct monitoring and evaluation.
- Plan and conduct operational research
- Promote and strengthen PPM DOTS/TBHIV
- Address TB/HIV in special setups like prison, and pastoralist.

**A.3 At Health facility level:**

- Ensure TB/HIV activity is being implemented as per the implementation guideline in the health facility
- Establish multidisciplinary team
- Ensure there is regular reporting
- Analyze reports and use them for improvement of TB/HIV collaborative activities.
- Supervise TB/HIV activity at lower level

**A.4 At community level there should be:**

- A committee established and responsible to promote TB/HIV activities.
- Social mobilization activity
- Promotion of Community DOT for TB treatment

### 2.3.1.2 TB/HIV Advisory Committee

B. TB/HIV Advisory Committee (THAC) at all program management levels:

At Federal level, the Advisory Committee shall be composed of TLCT/FMoH and HPPD/FHAPCO and major partner organizations working in the area of TB and HIV/AIDS. The list of partners is subject to regular revision as indicated by the Advisory Committee. Though it is recommended to have THAC at all management levels, currently there is only one at a national level. (See annex I for the TOR of the national THAC.) At regional level it is recommended that the THAC members to be: TB program focal person, HIV focal person, Regional Pharmacy, Regional Laboratory, PLHIV, health service department and major

partners working on TB/HIV. The leadership should be TB and HIV focal person alternating on regular interval.

At national level, THAC decided to form a TB/HIV Technical Working Group (TWG) under it. The TB/HIV TWG is accountable to, overseen and supervised by THAC. The TWG is expected to work on all technical issues and matters regarding TB/HIV collaborative activities in consultation with the Secretary of THAC. (See Annex II for the TOR of the TB/HIV TWG.)

The TB/HIV advisory committee, established at all levels should give technical support to the respective levels of TB and HIV control programme offices. The TB/HIV Advisory Committee (THAC) at federal level shall provide technical support to FMoH/FHAPCO in the areas of:

- Overall planning of TB/HIV collaboration.
- Developing training strategies and materials.
- Human resource development and retaining strategies.
- TB/HIV communication strategies and material development.
- Community mobilization and participation in TB/HIV collaboration.
- Establishment and maintenance of TB/HIV surveillance system.
- Operational research
- Monitoring and evaluation

### 2.3.2 Joint planning

#### 2.3.2.1 Capacity Building including training

The success of TB/HIV collaborative activities depends largely on the adequacy (both in quantity and quality) of human resource in the system. Successful TB/HIV collaboration, therefore, calls for deployment and retaining of qualified health workers at all levels, who properly discharge responsibilities at different levels.

The following activities should be undertaken to ensure adequate deployment of human resource:

- In-service training of general health workers.
- Incorporation of TB/HIV in pre-service curricula of health care providers.
- Regular supportive supervision to maintain quality of service.
- Mentoring and on-the-site training.
- Prevent workplace exposure to HIV (training, provision of protective materials, prophylactic therapy including ART).
- Ensure sufficient capacity in health care delivery, Laboratory, drug and referral

#### 2.3.2.2 Advocacy, communication and social mobilization (ACSM)

The overall goal of advocacy, communication and social mobilization is to create awareness on TB/HIV among the community in general and those at high risk of TB/HIV in particular and mobilize them ultimately to bring about enhanced early case detection and adequate chemotherapy and ensure comprehensive patient care.

TB/HIV collaboration can be further strengthened by:

- Well-designed TB/HIV advocacy activities jointly planned to ensure coherence of messages and proper target orientation.
- Jointly developed TB/HIV communication and social mobilization strategies that address the needs of individual clients and patients and of communities affected by HIV/AIDS and tuberculosis. This has to ensure coherence in messages targeted at key stakeholders, decision makers, and program managers.
- Mainstreaming HIV components in tuberculosis communication and tuberculosis components in HIV communication.

Therefore successful TB/HIV ACSM should be able to: increase awareness on the mode of transmission, prevention and control of Tuberculosis and HIV, increase awareness of individuals, families and communities on cardinal symptoms and signs of TB and promote early health care seeking behaviour, increase awareness and skills of individuals, families and communities on prevention of HIV and bring about behaviour changes, educate, motivate and support to ensure treatment adherence, and promote awareness on the importance of proper follow-up and the dangers of defaulting treatment.

The settings for delivering health education and communication shall be the health facilities, schools, workplaces, households, religious institutions and traditional social meeting places, resorts and villages.

The details of messages to the respective target groups are described in annex III

#### 2.3.2.3 Community involvement

All stakeholders including HIV AIDS and TB programs should insure the inclusion of TB prevention and care in community based HIV prevention, care and support services. Similarly, community TB prevention and care service should also include HIV prevention, care and support activities in their services.

#### 2.3.2.4 Resource mobilization

Joint proposals to solicit resources for implementing collaborative TB/HIV activities should be prepared, within the framework of the joint coordinating body, in collaboration with development partners represented in THAC.

#### 2.3.2.5 Operational Research to enhance collaborative TB/HIV activities

All stakeholders of collaborative TB/HIV activities, including both TB and HIV programs, should support and encourage TB/HIV operational research to develop the evidence base for efficient and effective implementation of collaborative TB/HIV activities. THAC/TWG should prepare broader priority area for operational research and the list of priority operational research areas for the fiscal year should be included in the annual plan of action of TLCT/FMoH and HPPD/FHAPCO at national level.

### 2.3.3 HIV surveillance among TB patient

Surveillance is essential to inform program planning and implementation. There should be HIV surveillance among TB patients. Since Ethiopia has a generalized HIV epidemic, routine HIV testing and counseling for all TB patients should form the basis of surveillance. Currently data from routine HIV testing and counseling of TB patients is weak; and it has to be strengthened to get reliable data. Complementing the routine data by periodic survey has been put as option.

# 3 TB/HIV collaborative activities at health facility level

TB/HIV collaborative activities at health facility level are an extension of the collaboration at program management level. The rationale and objectives of collaboration are basically the same.

## 3.1 Activities to decrease the burden of HIV among TB patients

### 3.1.1 Routine HIV testing and counseling for TB patients and suspects

HIV testing is an entry point for HIV care and treatment services including ART and this apply equally to TB patients. Studies show that a significant proportion of TB patients are also HIV-infected. Among TB patients who are also HIV-infected, other Opportunistic Infections (OIs) are significant causes of morbidity and mortality even with a successful treatment of tuberculosis. Hence, HIV counseling and testing should be actively promoted and routinely offered to all TB patients.

PITC offered to TB patients has several advantages.
If he/she is HIV positive, he/she will have the following benefits:

- Better diagnosis and management of other HIV-related illnesses.
- Possible use of CPT to prevent Opportunistic Infections and reduce mortality.
- Better access to ART and comprehensive HIV care
- Opportunity to access PMTCT services.
- Opportunity to counsel and test patients and families about HIV infection and its prognosis.
- Prevent the transmission of HIV to partner (s).

2. If he/she is HIV negative, he/she will have the following benefits:

- Help the patient explore ways to remain negative
- Opportunity to counsel and bring his/her partner for HIV testing

For these reasons TB patients diagnosed with HIV should be linked to HIV chronic care clinic as early as possible. The ideal recommendation is HIV testing and counseling should routinely be offered to all TB patients at TB clinic and healthcare providers at TB clinic should perform rapid test for HIV. But health facilities can adjust the place of testing according to the infrastructure and the human resource available in their set up.

### 3.1.2 Co-trimoxazole Preventive Therapy (CPT)

Co-trimoxazole is a broad spectrum and widely available antibiotic that acts on range of bacteria, fungi and protozoa that are causes of major morbidity and mortality in people living with HIV. Several clinical trails in Africa have shown the impact of CPT in reducing morbidity and mortality in PLHIV. The greatest benefit of CPT was found among persons with active TB and co-infected with HIV. Co-trimoxazole is relatively safe and widely available drug. Therefore CPT is recommended to all TB/HIV co-infected patients regardless of the CD4 Count.

#### 3.1.2.1 Placement of TB patients receiving CPT

Co-trimoxazole is to be dispensed preferably at the HIV clinic. But it can also be dispensed at TB clinic when convenient and when HIV Chronic illness clinic is not available at the site for HIV-positive TB patients. All clients receiving CPT should be registered on Unit TB register, Pre ART/ART Register and should be monitored monthly for the first two months and accordingly thereafter regardless of where the CPT is dispensed (Refer to the National Co-trimoxazole Prophylaxis Guideline for details on Co-trimoxazole Prophylaxis). (Annex IV TB Unit register, Annex V Pre- ART and Annex VI ART register).

### 3.1.3 HIV prevention services at TB clinic

#### 3.1.3.1 Comprehensive HIV prevention

TB control programs should establish a referral linkage with HIV programs to provide comprehensive HIV prevention services for their patients and families targeting sexual, parentral or vertical transmission.

#### 3.1.3.2 Reduce transmission of HIV through early detection and prompt treatment of STIs in TB patients

All clients attending tuberculosis clinics should be screened for sexually transmitted infections using a set of simple questions. Those with symptoms of sexually transmitted infections should be treated or referred to the treatment providers. (Refer to the National Guideline for the Treatment of STI Using the Syndromic Approach)

#### 3.1.3.3 Reduce occupational and nosocomial exposure to HIV infection

Tuberculosis control should implement procedures for prevention of occupational and nosocomial exposure to HIV infection in their services. Health units should be equipped with protective materials and routinely follow standard precautions to prevent HIV transmission in the health care settings.

Condoms should be made available in TB clinics. Linkage should be ensured for pregnant and non- pregnant HIV positive clients to access services for prevention of mother to child transmission.

### 3.1.4 HIV care and support

TB clinics should establish linkage with HIV programs to provide the continuum of care and support for PLHIV. These include clinical management of opportunistic infections and prophylaxis, nursing care, palliative care, home based care, counseling and psychosocial support. PLHIV who have completed their tuberculosis treatment should be provided with the continuum of care and support for HIV/AIDS support by client referral system.

### 3.1.5 Provide ART for eligible TB/HIV co-infected patients

ART should be offered to all HIV positive TB patients depending on the eligibility criteria as it is stated in the national ART guideline and on the TB/HIV co-management training module. Currently the place where ART is provided for co-infected patients is the HIV chronic care clinic, but when it is convenient a one-stop service at the TB clinic for the duration of the TB treatment is encouraged

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## *3.2 Activities to decrease the burden of TB among people living with HIV (PLHIV)*

### 3.2.1 Routine offer of TB screening for all HIV positive clients

Rates of smear-negative pulmonary and extra pulmonary tuberculosis have been rising in countries with HIV epidemics. The mortality rate among HIV-infected tuberculosis patients is higher than that of non-infected tuberculosis patients, particularly for those with smear-negative pulmonary and extra pulmonary tuberculosis. Delayed diagnosis may be an important cause of excess mortality in people living with HIV who have smear-negative pulmonary and extra pulmonary tuberculosis. In the absence of rapid, simple, and accurate diagnostic tools for smear-negative pulmonary and extra pulmonary tuberculosis, diagnostic algorithms have been recommended.

Hence tuberculosis case finding should be intensified in all HIV testing and counseling services for HIV positive clients by using a set of simple questions to identify tuberculosis suspects early before their condition deteriorates. HIV positive clients coming through HCT services should be informed the advantages of being screened for TB. Once informed the risk of developing active TB, they should undergo screening for TB and they should be further worked up using the WHO algorithm for improving the diagnosis of smear negative TB in HIV positive patients.

In early HIV disease (WHO Clinical Stage 1 and 2), most individuals are asymptomatic and the probability of active TB is very low. In this population, those who are completely without symptoms compatible with TB (cough, fever, weight loss, etc.) can be given IPT after the absence of symptoms is confirmed. Those with symptoms should be evaluated with appropriate tests, such as sputum smear and culture, and those found to have TB should be offered TB therapy. In those cases where TB is ruled out, IPT should be offered.

HIV patients with late HIV disease (WHO Clinical Stage 3 and 4) who are positive for TB symptom screen, their sputum should be examined for AFB. CXR should be requested for all HIV positive patients in WHO clinical stage 3 and 4 especially for those patients with symptom screen positive for TB if available. It would be advisable to evaluate WHO stage 3 and 4 HIV patients 3 months after start of ART for TB so as to decide on whether to put them on IPT or not.

All HIV positive clients with active TB should be referred to TB clinic for treatment. Investigation of TB suspects after screening should be either at HIV clinic or OPD as applicable. (See annex VII algorithm for diagnosis of TB in HIV positive clients and Annex VIII for TB screening questioner, Annex IX for Algorithm for IPT in Adults.)

### 3.2.2 INH preventive therapy (IPT)

HIV is the most important risk factor in the progression of latent TB to active TB. The lifetime risk for an HIV negative person infected with *Mycobacterium Tuberculosis* to develop TB is 5-10%. However, in persons with HIV, this risk can be as high as 10% per year. Compared to most other Opportunistic Infections (OIs), TB occurs earlier in the course of HIV infection even when the immune system is fairly competent. Persons living with HIV who are newly infected with *Mycobacterium Tuberculosis* are at higher risk of rapidly progressing to active TB disease with in weeks to months time. Furthermore, active TB increases viral replication, thereby accelerates the progression of HIV infection and increases the risk of the patient acquiring other opportunistic infections.

Some of the major advantages of Isoniazid Preventive Therapy (IPT) are:

- Prevention of progression of latent TB into active TB.
- Help improve quality of life
- Decrease mortality in children
- Prevention of further transmission of TB in the community, at large.

However, there are a number of concerns/issues to be looked at regarding the implementation of IPT like:

- Risk of emergence of Isoniazid resistance if active TB is not properly excluded,
- Missed cases of active disease,
- The relation of IPT to overall TB treatment programmes, and
- Drug toxicity.

These and other operational critical issues should be addressed in a separate guideline.
So far, evidences strongly favor the benefit of IPT in eligible individuals. In settings where HIV prevalence among TB patients is 5% and above, as per the WHO TB/HIV Collaborative Interim Policy, IPT intervention is part of TB/HIV comprehensive prevention and care package.

#### 3.2.2.1 Indications and dosage of IPT

Screening for exclusion of active TB in HIV infected persons, is the single most important step that should precede the decision to initiate IPT. Hence, initiating IPT depends on result of symptom screening, WHO Clinical stage of the patient and whether there is contraindication for IPT or not.

In settings where there is no CXR service, better not to start IPT for symptomatic clients (WHO Clinical stage 3 and 4). It would be advisable to evaluate WHO stage 3 and 4 HIV patients 3 months after start of ART for TB so as to decide on

whether to put them on IPT or not even if CXR is available. (See Annex IX Algorithm for IPT)
Isoniazid Preventive Therapy consists of daily, self-administered Isoniazid at a dose of 5mg/kg i.e., a maximum dose of 300mg/day for a period of six months.

*Isoniazid should be prescribed as follows:*

| Body weight (Adult) | Dosage |
|---|---|
| < 30 kg | 150 mg = half tablet |
| > 30 kg | 300 mg = one tablet |
| Body Weight (Children, 0-14Yrs) | 5-10mg/kg, maximum of 300mg. |

Pyridoxine at a fixed daily dose of 25mg is indicated in order to reduce the risk of developing INH- induced peripheral neuropathy.

### 3.2.2.2 Contraindications of IPT

Individuals with any one or more of the following conditions should *not* receive IPT:

- Active tuberculosis.
- Symptoms compatible with tuberculosis, even if the diagnosis of TB cannot be confirmed.
- Abnormal chest X-ray.
- Diagnosis and treatment of TB in the past 3 years.
- Poor prognosis (terminally ill AIDS patients).
- History of poor compliance with treatment.
- Active hepatitis (chronic or acute).
- Known or reported high daily alcohol consumption.
- Prior allergy or intolerance to isoniazid.
- History of close contact with MDR-TB patient

NB. Pregnancy is a special condition for IPT (Indication)

### 3.2.2.3 Isoniazid drug interactions

Isoniazid may interact with other drugs. The patient who is put on IPT and anyone of the following drugs should be referred to the doctor for monitoring:

- Phenytoin, warfarin, and carbamazepine (their serum levels may increase).
- Ketoconazole and diazepam (their serum levels may decrease).
- Procainamide and chlorpromazine (the half-life of isoniazid can be increased)

#### 3.2.2.4 Barriers to IPT use

Though IPT is recommended as TB/HIV prevention and care package, there are challenges not to offer to eligible clients as expected. The following points are some of the practical barriers.

- Fear of resistance development
- Fear of side effect
- Fear of re-infection
- Attitude
- Follow-up

#### 3.2.2.5 Placement of IPT clients

The most frequent entry point to care and treatment for HIV-infected persons is HCT services. After active TB is ruled out (by a physician, health officer or senior nurse) IPT should be part of a comprehensive care for PLHIV. It should be initiated and continued at the HIV care/ART clinic. The particulars of the patient should be documented in the ART and Pre-ART register for HIV positive clients without active TB who receive IPT (See annex V for Pre- ART and annex VI for ART register).

#### 3.2.2.6 Follow up of patients on IPT

Patients should be given one-month supply of Isoniazid for six consecutive months and assessed at each follow-up visit to:

- Evaluate adherence to treatment and educate the client at each visit about the importance of adherence, signs of toxicity (hepatitis), signs of active tuberculosis, and HIV-prevention.
- Evaluate for drug toxicity such as signs and symptoms of hepatitis, e.g., jaundice, anorexia, nausea, vomiting, or abdominal pain.
- Evaluate for signs and symptoms of active tuberculosis or other OIs and eligibility for ART.
- If patients develop active TB while on IPT, stop IPT and immediately start anti-TB
- Instruct the patients to return back if they develop cough, weight loss or fever during the course of therapy

Patients should be instructed to discontinue isoniazid and seek prompt medical attention if they develop jaundice and/or severe abdominal pain.

| Duration of IPT is 6 months |
| --- |

NB. To be repeated after 3 years.

It is recommended to establish strong link between ART and TB clinic in order to:

- Screen PLWH for active TB.
- Refer those with active TB to TB clinic.

*Apart from the care provided, health workers have to communicate basic information to clients/patients, family members and the community at large, based on the health network model.*

## *3.3 TB infection control in health care and congregated setting*

Each Health care and congregated setting should have a tuberculosis infection control plan supported by all stakeholders, which includes administrative, environmental and personal protection measures to reduce transmission of tuberculosis in health care and congregated settings.

# 4 MANAGEMENT OF TB/HIV CO-INFECTION IN CHILDREN

Incidence of tuberculosis in HIV-infected children is a hundred times higher compared to HIV-uninfected children. The prevalence of HIV in TB- infected children ranges from 10% to 60%. Establishing the diagnosis of tuberculosis in HIV-infected children may be difficult because the manifestations of tuberculosis are similar to many HIV related infections and conditions like PCP pneumonia, lymphoid interstitial pneumonitis, viral and bacterial pneumonias. TB can coexist with lymphoid interstitial pneumonitis, broncheictasis or any other lung conditions. As a result of this there is risk of either under or over diagnosing tuberculosis. In HIV-infected children tuberculosis is often severe, progressive and likely to involve extra-pulmonary sites. The mortality rate for HIV/TB co-infected children is high particularly if there is evidence of advanced immune suppression. HIV counseling and testing should be offered to all children with diagnosis of tuberculosis and all HIV-exposed and infected children should be screened for TB using a combination of targeted history, TST if available and laboratory tests.

There is no difference in approach of diagnosing tuberculosis in HIV-infected and uninfected children.

**TB Screening Checklist for Children**

- Cough > three weeks
- Fever > two weeks (fever of > 38$^{o}$C for more than 14 days after exclusion of common causes like malaria and pneumonia)
- Documented weight loss or failure to gain weight
- Close contact with active TB case or chronically coughing person

If the child had any of the above symptoms he/she should be investigated for Tuberculosis

**Laboratory Investigations**

- Sputum for AFB in children above five years of age
- Gastric aspirate in children below five years of age
- Radiologic examination
- Mantoux test if available

Four areas of intervention need emphasis in the management of TB/HIV Co-infection

## *4.1 Anti-TB Medication:*

The principle of treatment for children with TB/HIV co-infection is similar to HIV un-infected children. Where feasible HIV-infected children should be treated with Rifampcin containing regimen the whole course of treatment. This will minimize the risk of relapse. Most HIV infected children respond well to six months anti -TB regimen.

## *4.2 Cotrimoxazole Preventive Therapy*

All children with tuberculosis have to be provided with prophylactic cotrimoxazole. It prolongs survival and decreases the incidence of respiratory tract illnesses and hospital admissions. Studies in adults have demonstrated better survival rates in patients co-infected with HIV and TB who received cotrimoxazole prophylaxis than in patients receiving no prophylaxis.

## *4.3 Antiretroviral Therapy*

In HIV-infected infants and children co-infected with tuberculosis initiation of anti-TB regimen is the priority. Children on ART and anti-TB medication need to be closely monitored as there are clinically significant drug interactions between Rifampcin and some ARV drugs (mainly NNRTIs and PIs). These drugs have similar routes of metabolism and co-administration results in sub-therapeutic antiretroviral drug levels. Rifampcin can decrease serum level of protease inhibitors by as much as 80% or more, and NNRTI by between 20%and 60%. In addition to this there is significant overlap of adverse reaction of anti-TB medications and ARVs. Close monitoring for possible drug interactions has to be carried out on regular basis.

Table 1: Shared toxicities of Antiretroviral drugs and Anti-TB medications

| Toxicity | Antituberculous therapy | Antiretroviral therapy |
|---|---|---|
| Peripheral neuropathy | Isoniazid | Stavudine, Didanosine |
| Rash | Rifampcin, Isonaizid<br>Pyrazinamide | NNRTI |
| Nausea | Pyrazinamide | Stavudine, Zidovudine<br>Protease inhibitors |
| Hepatitis | Rifampcin, Isonaizid<br>Pyrazinamide | NNRTI<br>Protease inhibitors |

The decision to start ART should take into consideration the degree of immune suppression and the child's response to anti-TB medications. Currently many experts recommend double dose Kaletra plus NRTIs as first-line option in infants and children < 3 years receiving TB treatment where NVP cannot be used because of interactions with Rifampcin. Triple NRTIs can be used as a second option. Alternatively, in children over 3 years of age a standard first-line regimen of two NRTIs + EFV (i.e. the NNRTI component) is suggested. In a study in HIV-infected adults a regimen of AZT/3TC/ABC had lower virological potency than an EFV-based regimen (79% versus 89% efficacy at

32 weeks). The current recommendations are subject to changes hence it is advisable to obtain timely updates from WHO.

Table 2: Recommendation for timing of ART following the initiation of TB treatment with Rifampcin containing regimen in HIV infected infants and children

Source*: Antiretroviral therapy of HIV infection in infants and children in resource limited settings, WHO,* 2006

| Clinical stage of the child with TB (as an event indicating need for ART) | Timing of ART following initiation of TB treatment (Rifampcin containing) [a] | Recommended ARV regimen |
|---|---|---|
| WHO pediatric clinical stage4[b] | Start ART soon after TB treatment ( between 2-8 weeks following start of TB Rx) | In children < 3 years[d]<br>▪ Double dose Kaletra plus NRTIs<br>Or<br>▪ Triple NRTIs<br><br>In children > 3 years[d]<br>▪ NRTIs+ EFV[e]<br>Or<br>▪ Triple NRTIs<br><br>-Following completion of TB Rx it is preferable to remain on the same ART regimen if well tolerated<br><br>-When ART can be delayed until after completion of TB treatment, initiation with a standard two NRTIs +NNRTI first-line regimen is recommended |
| WHO pediatric clinical stage3[c] | With clinical management alone:<br>▪ Start ART soon after TB treatment (between 2-8 weeks following start of TB Rx)<br>▪ If excellent response to TB treatment in the first 2-8 weeks of TB therapy, and the child is stable and is on CPT it may be reasonable to delay ART<br><br>If CD4 available<br>▪ Severe and advanced immunodeficiency[f] Start ART soon after TB treatment ( between 2-8 weeks following start of TB Rx)<br>▪ Mild or no immunodeficiency[f] Initiation of ART may be delayed until after completion of TB therapy. Closely monitor response to TB therapy and reassess the need for ART after TB therapy, if no improvement, consider starting ART | |

a) Administration of CPT is important in children with TB/HIV co-infection
b) All children with pediatric stage 4 should be initiated on ART regardless of CD4 criteria
c) Careful clinical monitoring with laboratory support, if available is recommended where NVP is administered concurrently with Rifampicin
d) Because of lack of data ranking of preferred or alternative ARV regimen is not possible
e) EFV is not recommended for children below 3 years of age, and should not be given to post pubertal adolescent girls who are either in the first trimester or are sexually active and not using adequate contraception
f) Refer to Table 6

Table 3: Recommendations for co-management of TB and HIV in infants and children diagnosed with TB while receiving ARV regimens

Source: *Antiretroviral therapy of HIV infection in infants and children in resource-limited settings, WHO 2006*

| Time of diagnosis in relation to ART | Underlying cause of TB | Consideration for ART following initiation of Rifampcin containing TB regimen | ART regimen |
|---|---|---|---|
| Child on standard two NRTIs and NNRTI first line regimen diagnosed with TB | TB attributable to primary infection (consider at any time during ART, depending on exposure to TB) | Continue ART but assess for need to change ART regimen- response to TB therapy should be used to evaluate need for change | Continue on standard two NRTIs + NNRTI first-line; if on NVP[b] substitute to EFV[c] if the child is >3 years<br>Substitute NNRTI to double dose of kaletra or change to triple NRTI if child is below 3 years of age |
| | TB as part of IRIS (consider in the first 6 months of ART) | | |
| | TB as a sign of treatment failure of first-line regimen (consider only after 6 months of ART) | | Consider consultation with experts for construction of second line regimen |
| Child on standard second line regimen (NRTI plus PI) diagnosed with TB | TB attributable to primary infection (consider at any time during ART, depending on exposure to TB) | Assess for need to change regimen. Response to TB therapy should be used to evaluate need for changing or stopping | Continue the same regimen, consider doubling the dose of Kaletra |
| | TB as sign of failure to second-line regimen | | Consider consultation with experts for construction of salvage regimen |

a. Administration of cotrimoxazole preventive therapy is important in children with TB/HIV co-infection
b. Careful clinical and laboratory monitoring should be ensured when Nevirapine is concurrently administered with Rifampcin
c. EFV is not recommended for children below 3 years of age, and should not be given to post pubertal adolescent girls who are either in the first trimester or are sexually active and not using adequate contraception.
d. Few data are available to guide ART recommendations; research is urgently needed

Table 4- WHO classification of HIV-associated immunodeficiency

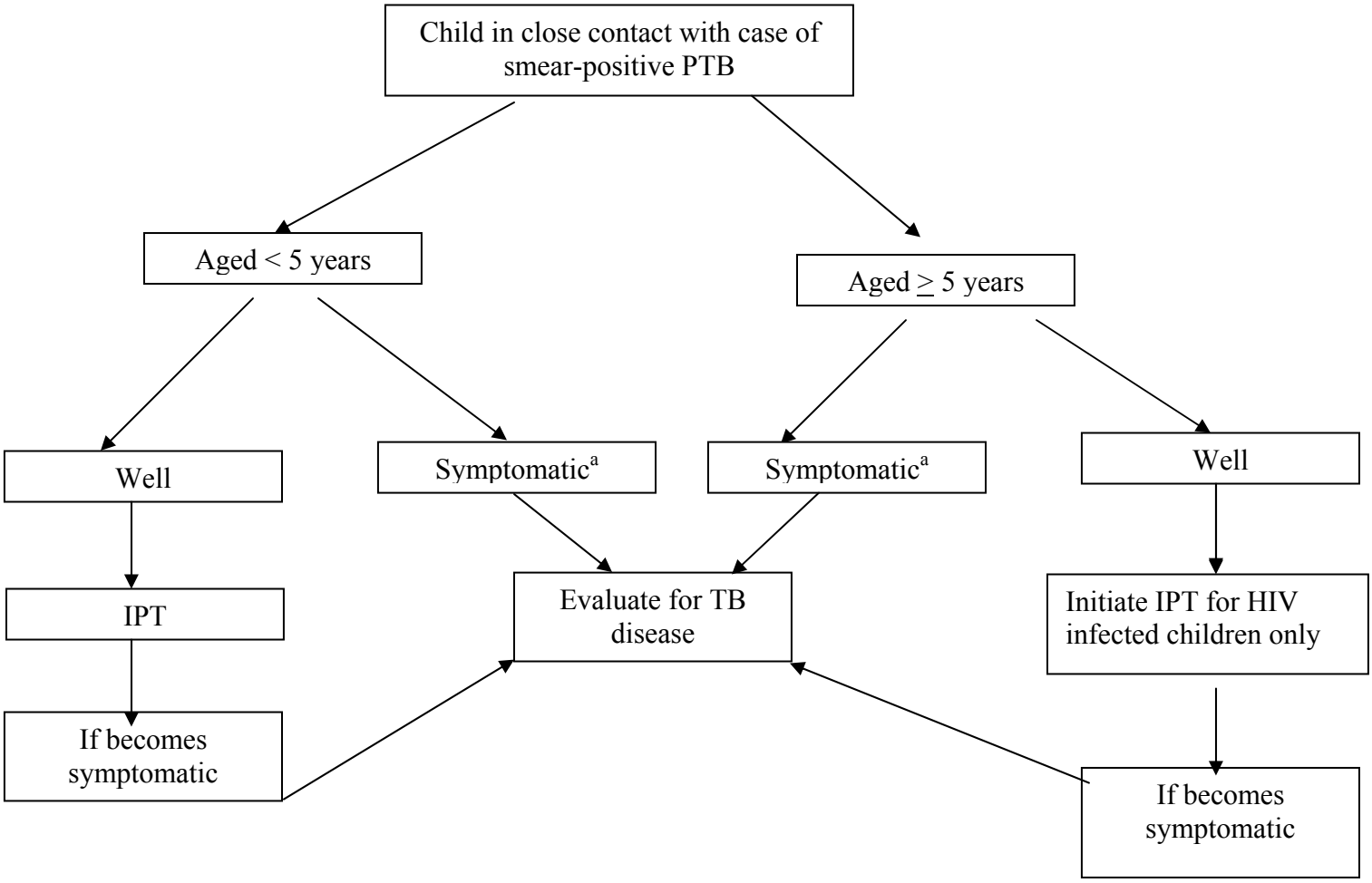
| Classification of HIV-associated immunodeficiency | Age-related CD4 values | | | |
|---|---|---|---|---|
| | **< 11 months (%)** | **12 - 35 months (%)** | **36-59 months (%)** | **≥ 5 years (cells/mm$^3$)** |
| **Not significant** | > 35 | > 30 | > 25 | > 500 |
| **Mild** | 30 - 35 | 25 - 30 | 20 - 25 | 350−499 |
| **Advanced** | 25 - 30 | 20−25 | 15−20 | 200−349 |
| **Severe** | <25 | <20 | <15 | <200 *or* <15% |

## *4.4 INH prophylaxis in children (IPT):*

TB risk assessment and INH prophylaxis (IPT) should be part of management TB/HIV co-infection. Risk assessment should focus on regular evaluation of patients based on targeted history, which includes contact history (exposure to chronically coughing person or TB patient) and annual TST for all HIV infected children beginning at one year of age. **Every effort should be made to exclude active TB before administering *IPT. (See risk assessment chart below)***

**Figure 1: Approach to contact management when chest x-ray and TST are not readily available**

Adapted from *Guidance for national tuberculosis programmes on the management of TB in children, WHO 2006*




[a] If Tb is suspected investigate as per guidelines

### 4.4.1 Who should receive preventive therapy?

Due to limited resources and high national TB prevalence, preventive therapy is only given to the most vulnerable children, those at highest risk to develop TB following *M. tuberculosis* exposure/infection. The two groups of children who qualify to benefit most from initiation of preventive therapy following *M. tuberculosis* exposure/infection are

- The very young (infants and children <5yrs of age)
- The HIV-infected children (irrespective of their age)

It is mandatory to rule out active disease (TB) prior to consideration of INH preventive therapy. Once started with IPT the child must be evaluated at least every two months. If Tuberculosis is suspected at subsequent follow up visits rescreening for active TB disease should be carried out. INH should not be given to children who have previously received INH prophylaxis, were previously treated for TB, have contraindications to INH or suspected to have active TB.

### 4.4.2 INH dosage for infants and children

Recommended dose is INH 5mg/kg, maximum 300mg daily for 6 months. Pyridoxine should be supplemented to children with severe malnutrition, breastfeeding infants, pregnant adolescent females, and children with AIDS. Poor adherence is a serious concern and parents/care takers must be adequately counseled to encourage adherence to unsupervised preventive treatment.

# 5 Monitoring and Evaluation of TB/HIV Collaboration

Successful TB/HIV collaboration calls for not only effective, coordinated and well managed interventions but also regular monitoring and evaluation. Monitoring and evaluation (M&E) provides the means to assess quality, effectiveness and coverage of services and will promote a learning culture within programmes to ensure continued improvement. M&E plays an important role in the management of health programmes by ensuring that the resources going into the programme are being utilized, services are being accessed, activities are carried out in a timely manner, and the expected results are being achieved. This important management function ensures the most effective and efficient use of human and financial resources for the achievement of maximum health benefit for the population served.

## 5.1 Definition of Terminologies

Monitoring is the *routine* tracking of service and program performance using input, process and outcome information collected on a regular and ongoing basis from policy guidelines, routine record-keeping, regular reporting and surveillance systems, and occasional health facility observations and client surveys. This information is used to assess the extent to which a policy or program is achieving its intended activity targets on time. In a well-designed M&E system, monitoring will contribute greatly to evaluation.

Evaluation is the *episodic* assessment of results that can be attributed to program activities; it uses monitoring data and often indicators that are not collected through routine information systems. Evaluation allows exploration of the causes of failure to achieve expected results on schedule and the mid-course corrections that might be necessary.

Process evaluation assesses progress in program implementation and coverage. Outcome and impact evaluation measure the effect of program activities on the target population. M&E is generally planned and performed by staff in the TB and HIV programs or by general health service staff, but in some instances, particularly for a program evaluation or review, external consultants or experts are brought in to help.

**Monitoring and Evaluation frame work**

| CONTEXT<br>Environmental, cultural, political, and socio-economic factors external to the program |
|---|

| INPUT | PROCESS | OUTPUT | OUTCOME | IMPACT |
|---|---|---|---|---|
| Basic resources necessary<br>Policies,<br>People, money<br>Equipment | Program activities<br>Training,<br>Logistics,<br>Management,<br>IEC/BCC | Results at the program level (measure of program activities),<br>Services,<br>Service use, knowledge | Results at level of target population<br>Behaviors,<br>Safer practices | Ultimate effect of project in long term<br>TB incidence,<br>HIV prevalence,<br>morbidity,<br>mortality |

Monitoring/Process Evaluation ⟷ Outcome/Impact evaluation

*Source: A guide to M & E for TB/HIV collaboration (WHO, 2004)*

In the context of TB/HIV collaboration monitoring and evaluation encompasses:

- Health Management Information System (responsibility of PPD)
- Regular supportive supervision (responsibility of TLCP & HPPD/HAPCO at all levels and partners)
- Regular review meetings (responsibility of TLCP & HAPCO at all levels and partners)
- Review missions (external by WHO experts and other partners)

## *5.2 Core indicators for TB/HIV collaboration*

An indicator is a variable used to measure progress towards the stated goals, objectives and targets of the programme, allowing managers to assess progress towards benchmarks. It is a specific measure of programme performance that is tracked over time by the monitoring system. The value of an indicator in itself is usually of limited use but rather unexpected values or changes in the indicator suggest the need for further investigation. Indicators are usually selected and targets set during the process of programme planning. The choice of indicators will also depend on what services are being offered and the capacity of programmes to carry out M&E.

Out of 20 TB/HIV indicators recommended by WHO, seven are core indicators for monitoring collaborative TB/HIV activities. The expert group which revised this guideline strongly recommends these seven core indicators to be reported routinely though the HMIS, which is managing the health information system, has selected only two of these seven key indicators to be reported routinely for the purpose of TB/HIV M&E. See below for the description of the indictors by TB/HIV component.

**Coordinating Mechanism**

The existence of a functioning TB/HIV coordinating body at all levels of the health system (National, Regional, Zonal, Woreda and Health facility level).

**Intensified TB case finding**

- Proportion of PLHIV attending VCT or HIV care and treatment who were screened for TB symptoms. (*Any client attending VCT regardless of their HIV status should be routinely screened for TB)*
- Proportion of PLHIV attending VCT or HIV care and treatment who are newly diagnosed as TB patient during screening.

Data Source: VCT register, HIV care follow up format, Pre-ART and ART registers

During first contact to do TB screening and report, but subsequent screenings should be documented in patient file, but reporting is not required.

**Counselling and testing**

- Proportion of registered TB patients who are counselled for HIV
- Proportion of registered TB patients who are counselled and tested for HIV.

Source of Data: TB unit register

**HIV prevalence in TB patients**

- Number of all newly registered TB patients who are HIV-positive, expressed as a proportion of all newly registered TB patients who are tested for HIV.

Source of Data: TB unit register

**Isoniazid Preventive Therapy (IPT)**

- Proportion of newly diagnosed HIV-positive clients who are given IPT.

Source of Data: ART or Pre-ART register

**Co-trimoxazole Preventive Therapy (CPT)**

- Proportion of HIV-positive TB patients who receive Co-trimoxazole Preventive Therapy (CPT) during their TB treatment.

Source of Data: TB unit register, Pre-ART register, ART register

**Anti-retroviral therapy (ART)**

- Proportion of HIV-positive registered TB patients who are started on ART or continue previously initiated ART, during or at the end of TB treatment.

Source of Data: TB unit register or ART Register

| Outcomes of successful TB/HIV collaboration: |
| --- |
| Mechanism for TB/HIV collaboration established and functional. |
| Increased access to and uptake of Counseling and Testing (CT) in TB patients. |
| Increased number of TB cases detected. |
| Increased access to prevention, care and support services. |
| Increased access to highly active anti-retroviral treatment (HAART). |

For detailed description of core indicators for TB/HIV collaboration see annex X

## 5.3 Surveillance of Core Indicators for TB/HIV Collaboration

As mentioned above, out of 20 TB/HIV indicators recommended by WHO, seven are core indicators for monitoring collaborative TB/HIV activities. The National HMIS has selected two of these seven key indicators to be reported routinely for the purpose of TB/HIV M&E. To increase the use of these two indicators, it is necessary to provide support to maximize the reporting coverage from all facilities. This should be done by the facilities and respective Regional/ Zonal/ Woreda health offices following the HMIS reporting channel. Partner organizations that are engaged in TB/HIV collaborative should also assist in strengthening the reporting of these two TB/HIV indicators in the HMIS.

In addition to the above, it is essential to follow up TB/HIV collaboration and implementation with regards to all the seven Core Indicators. This should be done without affecting and creating a parallel system to the existing HMIS reporting system.

Regional health bureaus will take the lead in generating, owning and using of the information; and since this is a national system, the information from all regions should be transmitted to the Federal Ministry of Health for national level aggregation and follow up. The information on the seven Core Indicators should be raised from selected TB/HIV implementing sites only, since it requires additional burden on the facilities. Regions will select facilities that will generate the information, and once such a facility is selected, this information will need to be continuously generated, so that trend data on the performances of individual facilities can be assessed over time. Because of this, Regional Health Bureaus will limit the number of facilities they select to generate such data according to the capacity of their relevant sections.

Generation of the information on the Seven Core Indicators will be a continuous process, and Regions will be responsible for the transmission of the information to the Federal level. The information from each facility will be compiled monthly, and transmitted to the regional health bureau. The Regional Health Bureau will transmit copies of the sheets to the Federal level on continuous basis, and also make use of the information for following up their programs.

Intensive supervision and support in the generation of the seven Core Indicators in the selected sites has to be given (without compromising the quality of support given to all facilities). This is because these facilities are providing more data and also because the information from these sites will be followed over long periods of time to observe trends. It will also be necessary for the trend data from each site to be comparable over time. Thus, the procedures for generation of data (types of clients, the departments of the facilities covered in reporting, etc.) will remain constants during all periods. Details of the protocol followed in generating this information will be developed jointly by Ministry of Health and all partners involved in the field.

## *5.4 TB/HIV Management Information System*

Proper recording of TB/HIV clients and events occurring during follow-up is critical not only for effective management of individuals but also and more importantly to keep track of trends of the co-epidemics and facilitate subsequent planning.

Regular assessment has to be done at the health facility, Woreda, zonal/sub-city, regional and central levels where epidemiological and operational indicators for monitoring of the TB/HIV collaboration are compiled, analyzed and used for subsequent planning. Quarterly reports are made according to the Ethiopian fiscal year.

There are six recording and reporting forms (the VCT register annex XI, TB Unit register, annex IV, HIV care follow up format – annex XII Pre-ART register, annex V, ART register, Annex VI and the HMIS Health Center /Clinic/Hospital Quarterly Reporting Form, Annex XIII) as part of integrated reporting and recording forms to facilitate TB/HIV management information system. Though only two of the TB/HIV core indicators are meant to be reported by the HMIS system routinely, but most of the TB/HIV parameters would be captured by one of the registers mentioned above.

Other data that have an influence on TB/HIV health care provision may be available from other methods of data collection, e.g. surveys, supportive supervision, etc. While these data may be important for health sector decision-making, they are not collected through the HMIS and are not a part of the HMIS data flow.[4]

Duties and responsibilities of teams and HMIS focal persons at various levels.

A. Health facility level

I. TB/HIV HMIS at VCT

- The VCT counselor is expected to fill TB/HIV referral form for all HIV positives and all clients having cough for more than two weeks and send them to Chronic HIV care/OPD/TB clinic for TB investigation.
- Record clients who are screened and referred for TB investigation. (Annex XI VCT register)

II. TB Unit

- Record all TB patients on unit TB register. (see Annex IV for unit TB register)
- Record HIV positive TB patients who receive CPT on Unit TB register.
- Record HIV positive TB patients on ART on Unit TB register.
- Record patients referred for ART

[4] **HMIS Procedures Manual: Data Recording and Reporting Procedures**

***1 Section 4: HMIS Data flow***

***HMIS / M&E Redesign: Technical Standards Area 3***

**version 1.0**

**Federal Ministry of Health**

- Record patients referred for continuation of CPT after completion of anti TB treatment on the remark column of the Unit TB register)

Facility level HMIS focal person prepares and fills TB/HIV quarterly report. (See Annex XIII for the HMIS Health Center /Clinic/Hospital Quarterly Reporting Form, S.No B2c.1, and B2c.2)

- Record patients who are referred or transferred out to other treatment facilities

III. ART/Chronic care clinics

- Record HIV positive clients on IPT and follow adherence for therapy on Pre-ART or ART register. (See Annexes V and VI)
- Record HIV positive IPT clients who develop active TB on ART or Pre-ART register.
- Record first contact TB screening on ART or Pre-ART register.

B. Woreda HMIS focal person at Woreda Health Office

Woreda HMIS focal person receives data compiled in the `HMIS Health Center /Clinic/Hospital Quarterly Reporting Form` from facilities (MOH, NGO, Private for profit) .She/he aggregates the data by facility type and ownership in the `Woreda Health Office quarterly report form`(see Annex XIV). This Aggregation methodology is maintained through the reporting chains (See annex XV, for data flow) so that even at the federal level it is possible to disaggregate data by facility type and ownership. [5]

C. Zonal/Sub-city HMIS Focal Person

Zonal/Sub-city HMIS Focal Person collects data from Woredas

Aggregate data in the Zone or Sub-city and report to regional HMIS Focal person in the Plan and program department.

D. Regional HMIS Focal Person

Compiles the HMIS data in the region and reports to FMOH/Plan and program department.

E. National HMIS

Compiles HMIS data in which TB/HIV data are only two indicators, from all regions and prepares the national report.

*N.B. TB/HIV data report strictly follows HMIS reporting system and procedure.*

[5] **HMIS Procedures Manual: Data Recording and Reporting Procedures**

## *5.5 Supportive supervision*

Supportive supervision is a way of ensuring staff competence, effectiveness, efficiency and satisfaction through observation, discussion, record reviewing, support and guidance. Therefore, it is an important tool for proper management of health resource at all levels of health system involved in the implementation of TB/HIV collaboration activities. Supportive supervision is an essential tool to provide on-the-job training and thus it should be carried out on a regular basis.

Health workers carrying out supportive supervision at various levels are meant:

- To ensure that TB/HIV implementation guideline is properly implemented.
- To identify factors that may hinder or enhance proper implementation of the TB/HIV collaboration.
- To take remedial actions to factors that hinder implementation of TB/HIV collaboration.
- To support responsible health workers develop an action plan to improve performance.
- To provide on-the-job training.
- To motivate and support health staff and sustain a high level working morale.

In summary, the purpose of supportive supervision is to promote continuous improvement in the performance of the staff.

**Levels of supportive supervision**

Supportive supervision at all levels is the responsibility of TLCT/FMOH, HPPD/FHAPCO and partner organisations.

**I. The Federal level**

The TLCT and/or HPPD staff of FMOH in collaboration with partners working in the region should visit each region and selected sites at least once per year.

The supportive supervision is aimed at:

- Identifying problems and indicating solutions regarding TB/HIV collaborative activities implementation at regional, zonal, woreda and health facility levels.
- Developing skill needed to provide support to lower levels.
- Exchanging experience and recent developments in TB/HIV collaboration.

**II. The Regional level**

The Regional TBL and regional HAPCO (HIV focal person) are responsible for all TB/HIV supportive supervision activities in the region. The TLCT and/or regional HAPCO members should visit each TB/HIV site at least twice a year. (All Zones, selected Woredas and sites) During these visits they should assess adequacy of programme management at Zonal and Woreda levels and patient management at health facility level. In each case the teams should observe health workers while they are carrying out their work in the health units, and check supplies, records and reports.

The teams should discuss their findings with the Heads of the respective office (Zonal, Woreda, Health Facility), congratulate them on good performance, clearly discuss deficiencies and propose remedial action.

**III. The Zonal level**

The Zonal TBL and HIV/AIDS experts are responsible for all supportive supervision activities in their zone. Where they are not assigned, the ZCDCs serve the same purpose. They supervise the Woreda TBL and HIV/AIDS or WCDC experts and ensure proper implementation of the TB/HIV collaboration. It is recommended to carry out supervision on quarterly basis.

During these visits the experts should assess the performance of the Woreda and health facility TB/HIV collaboration. This should be done by observing them carrying out their work in the health units and by checking supplies, records and reports. At the end of the supportive supervision the experts should discuss their findings with the Head of the Woreda Health Office in the presence of the Woreda TBL and HIV/AIDS experts i.e., congratulate them on good performance, clearly discuss deficiencies and propose remedial action.

**IV. The Woreda level**

The Woreda TBL and HIV/AIDS or WCDC experts are the key persons for supervision of the general health staff. They should supervise and assist the general health staff in the implementation of TB/HIV collaborative activities. The WCDC should visit all health facilities implementing TB/HIV collaboration on quarterly basis. The staff of the health facilities to be supervised should be informed before hand.

During the supportive supervision the Woreda TBL and HIV/AIDS or WCDC experts should observe the staff carrying out the work, do the supervision by use of the supervision checklist and also do client interview when ever applicable. All deficiencies identified during the visit should be discussed with the head of the health facility in the presence of the responsible staff. The supervising team should be able to demonstrate to them the skills that need improvement. The team should congratulate the health worker for all achievements.

In general, when TB/HIV collaboration is introduced into an area for the first time visits should be made at least monthly during the initial phase, and gradually it can be done less frequently (quarterly basis).

**V. Facility level (Hospitals and Health centers)**

Facility management team conducts regular supervision on day-to-day activities of TB/HIV services and provide constructive feedback to maintain quality of service to clients/patients.

The team closely works with Woreda CDC/TBL/HIV focal person to monitor the services and motivate staff working in TB/HIV units.

### 5.5.1 Supervisory checklist

Supervision should be done in a systematic manner by using checklists (annex XVI.) This checklist contains major TB/HIV collaborative activities that should be implemented at all levels of the health care delivery system.

The supervision checklist can be modified depending on the purpose and level of supervision. Before each visit the supervisor should review reports of assessment made during the last visit, corrective action already taken and identify features that should receive special attention during the forthcoming visit.

At the end of every supportive supervision, it is advisable to ensure that:

- Major problems are identified, discussed and solutions proposed.
- Visited facility received immediate feedback (annex XVII).
- Findings of the visit are discussed in the presence of heads of the respective offices and concerned health workers.
- Comprehensive report is written and forwarded to the level higher up.

## *5.6 Review Meetings*

Review meetings are important tool for monitoring and evaluation of TB/HIV collaboration. Regular semi-annual and annual review meetings should be organized at all levels in order to assess performance of the various activities, share experiences and adopt best practices. Such review meetings should be jointly organized by TLCT, HPPD/FHAPCO and implementing partners.

Recommended frequency of review meetings

| Level | Frequency |
|---|---|
| National | Twice /year |
| Regional | Twice/year |
| Zonal | Twice/year |
| Woreda | Quarterly |

Minutes of the proceedings must be recorded and reported.

## 6 TB/HIV Logistic Management

Good logistic management system is crucial for the successful implementation of TB/HIV collaboration. It is very important to ensure that every health unit involved in the TB/HIV collaboration has an adequate supply of drugs and supplies needed for comprehensive care and support of TB/HIV patients IEC materials, recording & reporting formats and registers. The selected TB/HIV supplies includes:

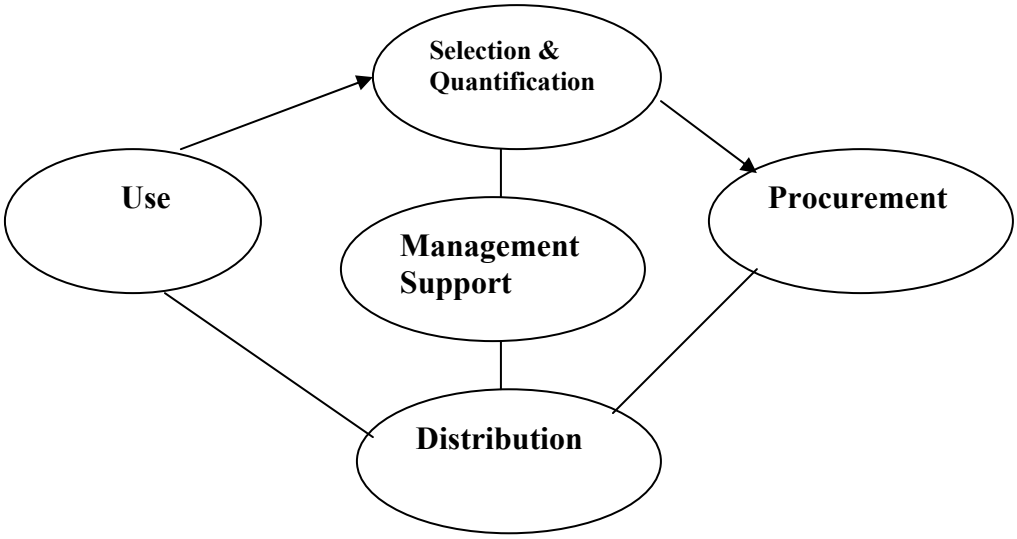
- INH & other anti-TB drugs,
- Pyridoxine,
- AFB reagents,
- Co-trimoxazole,
- ARV drugs,
- HIV test kits,
- Protective materials,
- TB quarterly reporting format,
- TB unit register,
- HCT register and other consumables.

Availability and rational use of TB/HIV supplies is crucial for effective TB/HIV collaboration. Irregular and inadequate supplies, on the other hand could damage credibility of the TB/HIV collaboration.

### 6.1 Procurement, storage, distribution and use of drugs and other supplies

Proper logistic management system ensures adequacy of drugs and other supplies at various levels of the health system and health facilities.

Drug Supply Management Cycle



### 6.1.1 Selection and quantification

The TB/HIV supplies that PSA procures and distributes will be from the approved Essential Health Commodities List (EHCL). This list is to be developed utilizing the Ethiopian Essential Health Services Package and the Standard Treatment Guidelines, in order to match products to the primary health care program.

PSA will develop state-of-the-art management information systems, which will include the logistic management information system (LMIS) to be implemented in the public health sector. The data from this LMIS is the basis for fore casting / quantification results for the essential health commodities of the public sector system. When the system is operational, facility specific, consumption-based forecasting for the key products is possible.

### 6.1.2 Procurement

PSA will take over the procurement activities of the Ministry's PSLD Department, using a 2 or 3 year rolling procurement plan, prepared in collaboration with FMOH, program departments, Regions/Cities, and donors. Procurement will be made according to procurement legislation and procedures.

TB/HIV supplies procurement is the responsibility of Pharmaceutical Supply Agency, PSA (formerly known as Pharmid) of FMOH. Need estimation of INH and Cotrimoxazole is the joint responsibility of TLCT and FHAPCO and procurement is effected by Pharmaceutical Supply Agency upon request. Health Program Provisional Department of FHAPCO is responsible for the quantification of HIV test kits, reagents, anti-fungals and other consumables. However, before new procurement procedures start, the stock available at all levels should be determined.

The quantity of TB/HIV drugs and supplies required for a given period is determined based on:

- The total client/patient load reported or estimated from Annual Risk of Infection (ARI).
- The forecasted additional number of PLHIV with latent infection and TB (due to increasing HIV prevalence).
- Budget allocated for TB/HIV drugs and supplies.
- The current stock available.
- The consideration of contingency for depletion of buffer stocks.

Pharmaceutical Supply Agency or PSA (former Pharmid)
PSA is designed to focus its operations on ensuring that vital and essential drugs and health commodities are available in public sector health facilities. It will do so this by providing efficient distribution from a series of hub warehouses, with suppliers delivering commodities to ware houses.

### 6.1.3 Distribution (Storage and Transport)

The PSA distribution design emphasizes that there should be adequate warehouses/hubs at selected regional level. These regional Hubs will play significant role in storage and distribution to facilities as per the new PSA master plan.

This new system is in favour of strengthening the regional capacity, minimizing the storage capacity and its subsequent challenges at central level. All issues related to Logistic management are handled and addressed in the new Logistic Master Plan of FMoH, 2007.

## *6.2 Shelf life of drugs*

The shelf life of the TB/HIV drugs and supplies in general and HIV test kits in particular is limited. After new supplies have arrived, in the health facilities the pharmacy unit should make sure that the old supplies are distributed before the new ones.

If there is excess of drugs and supplies which is unlikely to be consumed in the immediate future, complete information should be passed to the next higher level so that arrangements can be made for redistribution to other places.

Health Facility level
Strictly adheres to the FIFO/ FEFO systems of stock rotation.

## *6.3 HMIS formats and registers*

The following formats and registers should be available in all facilities implementing TB/HIV collaboration.

- All government vouchers used for ordering, receiving and issuing.
- Stock cards and bin cards.
- Inventory sheets.
- Pre-Art register
- ART Register
- HMIS facility level formats
- HMIS Woreda level data aggregation format
- HMIS Woreda level reporting format
- VCT Register
- Unit TB Register

FMOH and RHBs supply these formats and registers to the respective lower levels.
Proper TB/HIV logistic management system:

- Keeps sufficient stock of supplies.
- Orders new supplies in time.
- Safe-guard timely distribution.
- Strictly adheres to FIFO/FEFO system of disbursement.
- Keep an up-to-date record of supplies received and distributed.
- Builds capacity for and promotes rational prescribing, dispensing and use of TB/HIV drugs and supplies.

## Annex

I. TOR of THAC
II. TOR of TWG
III. Messages to the patient, family and community
IV. TB Unit Register
V. Pre-ART Register
VI. ART Register
VII. Algorithm to diagnose TB in HIV positive patients
VIII. TB screening questionnaire
IX. IPT algorithm for adults
X. TB/HIV indicators
XI. VCT Register
XII. HIV care follow-up
XIII. HMIS H/Center/ Clinic/Hospital quarterly reporting format
XIV. Woreda Health Office quarterly reporting format
XV. HMIS data flow
XVI. Supervisory Checklist
XVII. Supervision Immediate feedback form

*** Interim Period Health Facility, Woreda, Zone and Region Quarterly Reporting forms**

# ANNEX I - Terms of Reference (TOR) of TB/HIV Advisory Committees

**Purpose of TB/HIV Advisory Committee (THAC):** The purpose of the THAC is to coordinate efforts against TB and HIV/AIDS co-epidemics and provide guidance towards successful implementation of collaborative activities.

**Composition of THAC:** The Advisory Committee shall be composed of major partner organizations working in the area of TB and HIV/AIDS and the list of partner is subjected to regular revision as indicated by the Advisory Committee. To keep the committee manageable the maximum number of partners is limited to 15.

**Modalities of Operation:** THAC has right to establish or propose establishment of Task Forces or Technical Working Groups to address any issue (s) related to TB/HIV collaborative activities. The Advisory Committee can also invite experts within or outside of the Federal Ministry of Health to make presentations, share experiences and contribute to development of relevant documents.

**Relation with Technical Working Groups:** THAC is the highest body with regard to all technical matters in the area of TB/HIV collaborative activities and works in harmony with all technical working groups jointly working with TBL and HIV/AIDS and other STIs Prevention and Control Teams under the DPCD of FMOH.

The TB/HIV Advisory Committee (THAC) shall provide guidance and broker technical support to FMOH:

1. On planning and management of TB/HIV collaborative activities with special emphasis to capacity building. The issues to be addressed include:
    - 1.1 Proposal development and soliciting fund for training on TB/HIV collaborative activities.
    - 1.2 Ensuring uninterrupted TB/HIV supplies
    - 1.3 Setting up a coordinating body for TB/HIV collaborative activities at all levels
    - 1.4 Support in the area of TB/HIV operational researches
    - 1.5 Conducting supportive supervision, monitoring and evaluation of TB/HIV

collaborative activities

2. In the area of Communication and Social Mobilization (CSM) regarding TB/HIV. The support should contribute significantly to strengthening the health care delivery system to ensure social mobilization that generates public will and secures broad consensus and social commitment among all stakeholders in order to mitigate stigma and prevent TB and HIV, as well as encourage participation in TB/HIV collaborative activities.

3. In order to enhance community involvement in TB/HIV collaborative activities through successful implementation of Health Service Extension Program (HSEP).

**Governing rules:**

1. Rotating chairmanship: chairmanship should rotate between TLCT and APCT teams every year.

2. Frequency of THAC meeting: THAC meets once in three months on regular basis. Extraordinary meetings can be called as deemed necessary.

# ANNEX II - Terms of Reference for the TB/HIV Technical Working Group

## 1. *TB/HIV collaborative Activities*

### *1.1 Magnitude of the problem*

The HIV pandemic presents a massive challenge to the control of TB at all levels. These two diseases are inextricably linked. There is an unprecedented scale of epidemic of HIV-related tuberculosis that demands effective and urgent action. TB is the leading cause of death among People Living with HIV/AIDS (PLWHAS) and HIV, through immunosuppression, fuels the TB epidemic. Currently, the most powerful risk factor for developing TB disease is HIV. After TB infection, a person with HIV have 10% annual risk and 60% life-time risk of developing TB disease, compared with a 10% life-time risk for person`s without HIV. The HIV epidemic, therefore, create a large pool of persons at high risk of developing TB and, as a result, increases the pool of persons who will ultimately develops TB and transmit TB to HIV-infected and HIV-uninfected persons. HIV-infected patients can develop TB at any level of immune-suppression. In HIV-infected patient with relatively intact immune systems, the presentation of TB is similar to patients without HIV infection. As immune-suppression increases, patients are most likely to manifest TB in atypical ways. They tend to develop sputum smear –ve pulmonary TB and Extra Pulmonary TB. This causes a big challenge on the diagnosis of TB in HIV-infected individuals. Which make the HIV-infected persons to remain undiagnosed for a longer period, which increases the possibility that they could transmit TB to others, that they could die from untreated TB, or they could develop drug resistance when they are treated for other diseases with antimicrobial agents. The TB-HIV co-infection rate (the prevalence of HIV infection among TB patients) in Ethiopia is 41%[i]. Thus HIV prevention and care must be a priority concern for TB Prevention and Control Programmers and TB care and prevention should be a priority concern for HIV/AIDS Prevention and Control programmers.

### *1.2 Rational for TB/HIV collaboration*

Collaborative TB/HIV activities aim to decrease the burden of TB and HIV in a population affected by both diseases through collaboration between programs. This approach aims to provide integrated and comprehensive tuberculosis and HIV prevention, treatment and care service as close to the client as possible, maintaining existing tuberculosis and HIV program

management structure rather than combining them or creating a third TB/HIV program. The other rational for TB/HIV collaboration is, more than anytime before there is increased opportunity for joint working with clearer policy guidance and availability of more resource. In addition there is a big need to promote efficient utilization of resource allocated by both programmers. Lastly there is a common need to increase access to comprehensive services to achieve the millennium development goals (MDG) for HIV and tuberculosis.

### *2. Objectives of the TB/HIV collaborative activities*

There are three objectives of the TB/HIV collaborative activities:

1. Reducing HIV incidence among TB patients.
2. Reducing TB incidence among PLWHAS.
3. Improve care of people for people who are co-infected with TB and HIV.[ii]

To achieve these objective there are a number of strategies in place by the FMOH/TLCT. The actual TB/HIV activities at a service delivery points and also at other levels currently in Ethiopia is still in its infancy. The TB/HIV TWG is expected to contribute a lot in the improvement of TB/HIV collaborative activities and help in the implementation of the TB/HIV strategies at all levels.

In a meeting conducted on 17.04. 2007 in Addis Ababa, the TB/HIV Advisory Committee (THAC) noted that the implementation of TB/HIV collaborative efforts was not realized up to the expected standard. As part of a remedial action to revitalize TB/HIV collaborative efforts in Ethiopia and upon the recommendation of the TB/HIV advisory committee (THAC), a national TB/HIV technical working group (TWG) was formed.

### *3. Purpose of the TWG*

To provide technical assistant to issues related to the collaborative TB/HIV activities that require expert input in order to ensure effective implementation of the intended activities.

## *4. Composition and operational rules*

The TB/HIV TWG which is selected by THAC is composed of experts from the FMOH which are TLCT, HPPD/HAPCO, and EHNRI, WHO, CDC, ICAP and USAID. The TWG shall work under direct guidance of the THAC and in close consultation with the Secretary of THAC.

### *4.1 Chairmanship*

The chairman of the TWG shall be either from the TLCT or HPPD/FHAPCO on a yearly rotation basis. If the chairman is from TLCT the vice chairman would from HPPD/FHAPCO and vice versa. In the absence of the chairman the vice-chairman will assume the role of the chairman.

The roles of a chairman are:

- Chairing TWG meetings
- Calling meetings
- Decide on extraordinary meetings
- Represent the TWG in THAC or in other relevant forums

### *4.2 Secretary*

The secretary of the TWG shall be from one of the partner members of the TWG. Each member organization will serve as secretary for 6 months and that will rotate between the members. The secretary will work closely with the chairman of the TWG.

The roles of secretary are:

- Facilitates the TWG meetings.
- Takes minutes.
- Circulates documents and minutes
- Organizes venues for the TWG meetings and
- Facilitates related activities.

### *4.3 Meetings and Meeting formality*

- The TWG shall meet every month. Extraordinary meetings can be called as deemed necessary

- More than fifty percent of the members should be present to make a decision or to proceed with a meeting by TB/HIV TWG (more than 4 out of the 8 members).
- It is essential to have either the chairman or the vice chairman to proceed with a TB/HIV TWG meeting.
- The TB/HIV TWG can delegate a smaller number of the members (less than fifty percent) to carry out a specific assignment.

### *5. Responsibilities of the Technical Working Group*

The TWG is expected to work on all technical issues and matters regarding TB/HIV collaborative efforts in consultation with the THAC.

Specific responsibilities include:

The TB/HIV TWG will actively contribute to:

- Planning, coordinating, organizing, conducting and facilitating consultative meetings on revision of TB/HIV implementation guidelines after endorsement by THAC.
- Designing, developing and production of TB/HIV and related proposals, projects and plans and presenting them to THAC.
- Assist in planning, coordinating, organizing, conducting and facilitating consultative meetings for standardization of TB/HIV training strategies, tools and materials after approval by THAC,
- Planning, coordinating, organizing, conducting and facilitation of the adaptation of TB Recording and Reporting (R&R) registers and forms, in which HIV variables are captured, to Ethiopian context.
- Participate in the training and dissemination of the revised recording and reporting tools and further monitoring their use.
- Planning, coordinating, organizing, conducting and facilitating series of consultative meetings for adaptation of TB, Leprosy and TB/HIV Prevention and Control Manual, IPT, CPT, PIHCT, ART, TB infection control guideline and other /related guidelines and/or manuals after endorsement by THAC.

- Assist in devising innovate ways/mechanisms to strengthen laboratory services to improve diagnostic capacity for Sputum Smear Negative Pulmonary TB and Extra Pulmonary TB in the country in consultation with EHNRI and AHRI.
- Perform periodic site visits to do supportive supervision.
- Participate in biannual TB/HIV review meetings as well as any other TB/HIV relevant forums organized by TLCT and HPPD/HAPCO.
- Participate in annual TB/HIV programme evaluation.
- Develop TB/HIV provider support tools and IEC materials appropriate to the local context.
- Advice the THAC, TLCT and HPPD/FHPCO on matter related TB/HIV
- Advice THAC to provide guidance to TLCT, HPPD/FHAPCO or other units involved in procurement and distribution of supplies, on TB/HIV logistic management.
- Other technical activities as assigned by the THAC.
- For urgent matters the chair or co-chair of the TWG in consultation with the chair of the THAC can make decisions.

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[i] WHO Report 2007, Global Tuberculosis Control
Surveillance, Planning, Financing , Page 97
[ii] Tuberculosis , Leprosy and TB/HIV Prevention and Control Programme
Manual, 3rd edition, Federal Ministry of health, Ethiopia, 2005

## ANNEX III - MESSAGES TO PATIENTS, FAMILIES AND THE COMMUNITY

**What a client/patient should know at the diagnosis of TB and/or HIV:**

- Both TB and HIV are infectious diseases caused by bacilli and virus, respectively (not by a curse or witchcraft).
- TB passes from diseased to healthy persons during coughing and sneezing.
- The patient should encourage his/her household HIV –ve adult with contacts to undergo screening for TB (if they develop persistent cough). Children under 5 and HIV + adult house hold contacts should undergo HIV test even though they are not symptomatic.
- Counsel the patient on the modes of HIV transmission
- Counsel on the benefits of HIV testing.
- Educate and counsel HIV positive clients to practise safe sex and encourage his/her partner to be counselled and tested for HIV.
- Explain available treatment and care for HIV including Cotrimoxazole prophylaxis, regular follow-up and support, treatment for infections, ARV therapy, Interventions to prevent transmission from mothers to their infant Counselling to make informed decisions about future pregnancies and family planning advice. Support and counselling, Support for disclosure.

- The indication, dosage and usefulness of IPT in preventing TB disease, side effects and importance of follow-up (for HIV positive clients without active TB).
- The indication, dosage and usefulness of CPT in reducing mortality due to opportunistic infections, side effects and importance of follow-up (for HIV positive patients with active TB).
- Never share your drugs with anyone.

**What the family members should know at diagnosis of TB and/or HIV:**

The health education given to individual patients and their immediate family members is very important. The understanding and support of the family will largely determine the success of the

patient's treatment. The examination of the household contacts in case of TB and partners in case of HIV should be adequate and comprehensive as this may:

- Reveal other patients with early TB and HIV status.
- Provide the necessary information and education for other family members and partners who may pick/develop TB and/or HIV.

The contents of the information should be basically the same as that given to the client/patient.

**What the community should know about TB/HIV:**

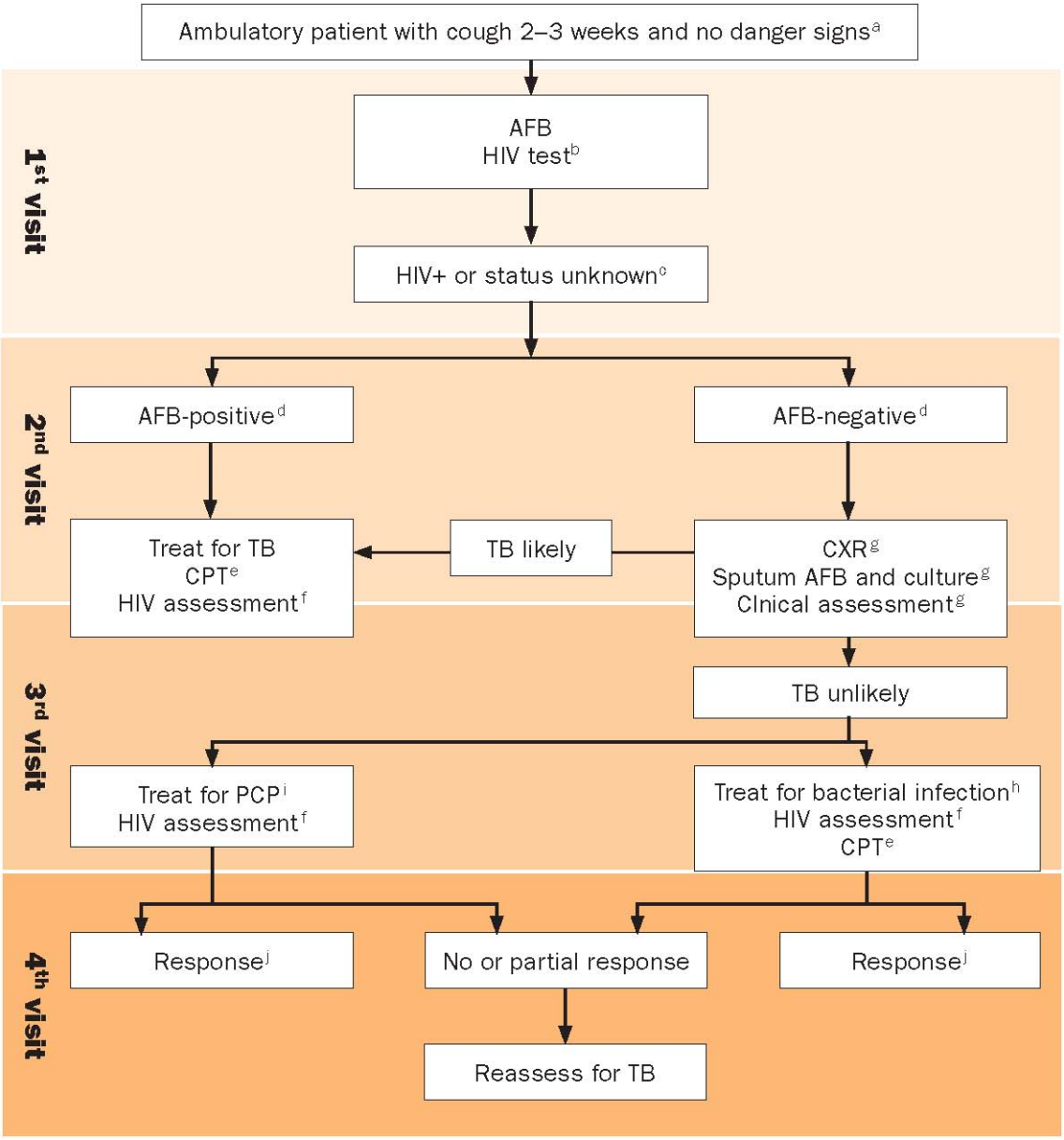
TB/HIV Advocacy, Communication and Social Mobilization (ACS) should ensure the mainstreaming of HIV components in TB communication and TB components in HIV communication and has to enhance community involvement in collaborative activities.

In order to encourage all the stakeholders and the members of the community to be actively involved in the prevention and control of these dual epidemics, the community should regularly receive appropriate health messages. The contents should be basically the same as outlined above.

TB/HIV ACS should enable the community:

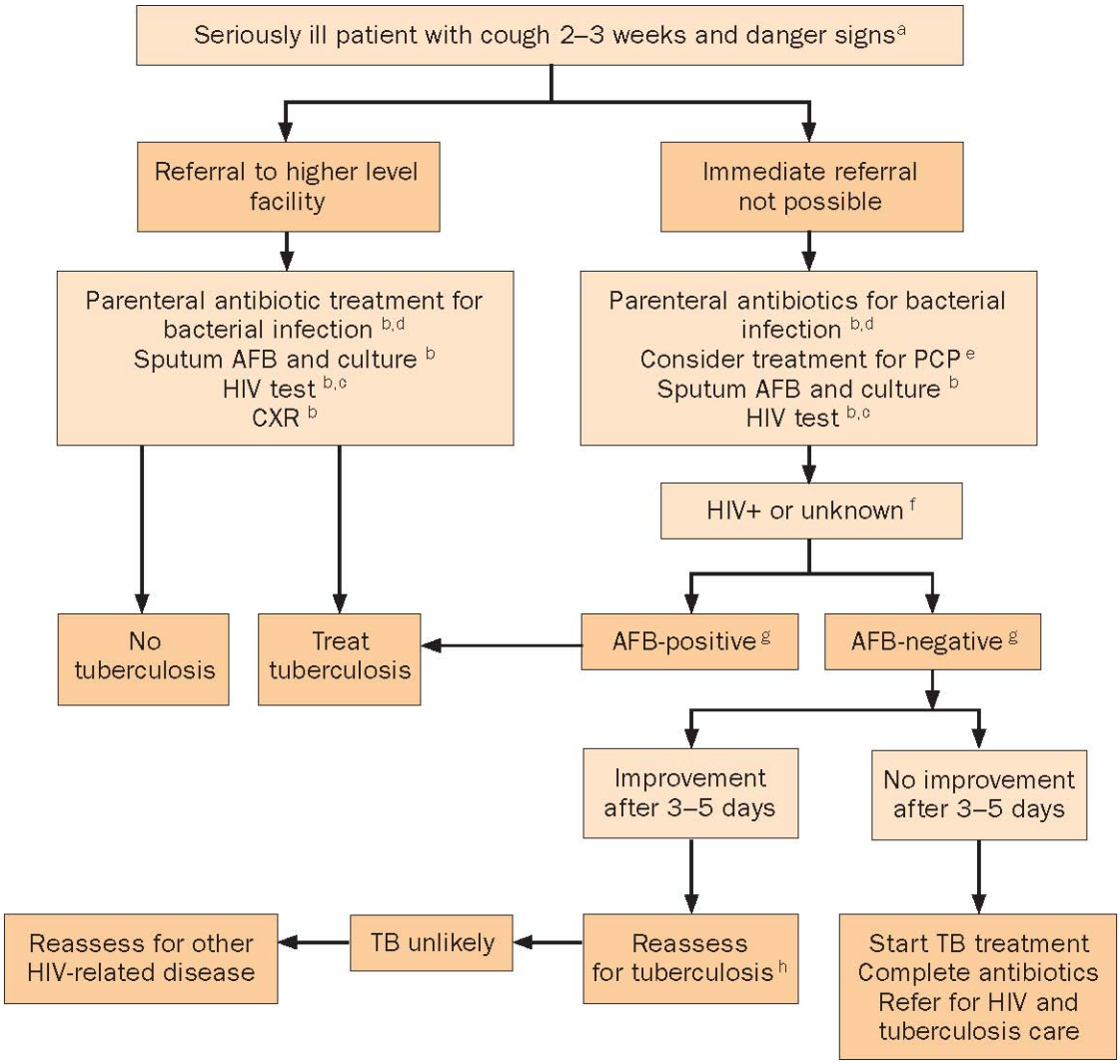
- To develop awareness on prevention of TB and HIV.
- To adopt positive behavioural change to prevent transmission of TB and HIV.
- To support intensified case finding by identifying and referring suspected cases.
- To support patients adhere to treatment.
- To provide care and support to PLWHA and TB patients.
- To fight stigma and discrimination against PLWHA and TB patients.

## ANNEX VII - Diagnosis of tuberculosis in ambulatory HIV-positive patient




The danger signs include any one of: respiratory rate >30/minute, fever >39 °C, pulse rate >120/min and unable to walk unaided. [b] For countries with adult HIV prevalence rate ≥1% or prevalence rate of HIV among tuberculosis patients ≥5%. [c] In the absence of HIV testing, classifying HIV status unknown ias HIV-positive depends on clinical assessment or national and/or local policy. [d] AFB-positive is defined at least one positive and AFB-negative as two or more negative smears. [e] CPT = Co-trimoxazole preventive therapy. [f] HIV assessment includes HIV clinical staging, determination of CD4 count if available and referral for HIV care. [g] The investigations within the box should be done at the same time wherever possible in order to decrease the number of visits and speed up the diagnosis. [h] Antibiotics (except fluoroquinolones) to cover both typical and atypical bacteria should be considered. [i] PCP: *Pneumocystis carinii* pneumonia, also known as *Pneumocystis jirovecii* pneumonia. [j] Advise to return for reassessment if symptoms recur.

## Algorithm for the diagnosis of tuberculosis in seriously ill HIV-positive patient

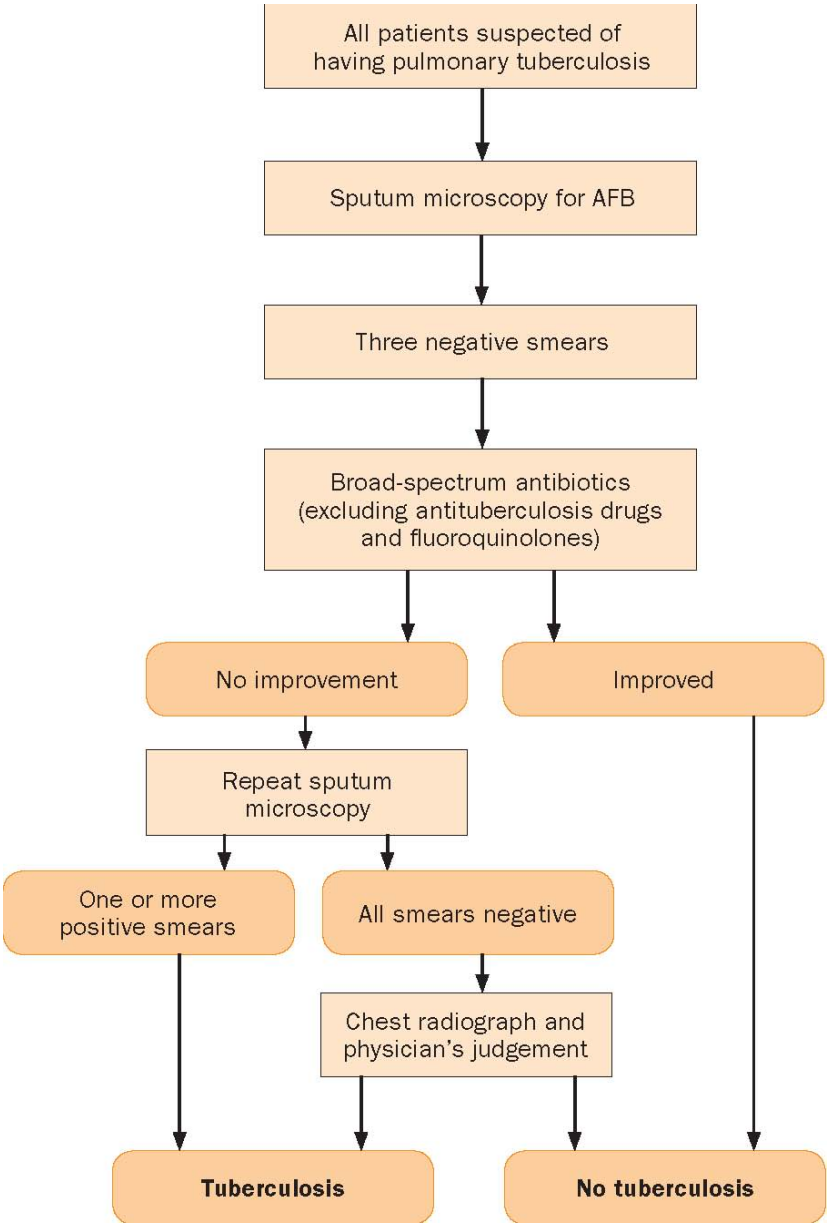



[a] The danger signs include any one of: respiratory rate >30/min, fever >39 °C, pulse rate >120/min and unable to walk unaided.

[b] The investigations within the box should be done at the same time wherever possible in order to decrease the number of visits and speed up the diagnosis. For countries with adult HIV prevalence rate ≥1% or prevalence rate of HIV among tuberculosis patients ≥5%. Antibiotics (except fluoroquinolones) to cover both typical and atypical bacteria should be considered. PCP: *Pneumocystis carinii* pneumonia, also known as *Pneumocystis jirovecii* pneumonia. In the absence of HIV testing, classify HIV status unknown into HIV-positive depends on clinical assessment or

National and/or local policy. [g]AFB-positive is defined as at least one positive and AFB-negative as two or more negative smears. [h] Reassessment for tuberculosis includes AFB examination and clinical assessment.

**Algorithm for the diagnosis of tuberculosis in HIV-negative patients**
(*International standards for tuberculosis care, 2006*)



## *ANNEX VIII: TB SCREENING QUESTIONS*

1. Has the individual had cough for >2 weeks?
2. Has the individual had fever for > 2 weeks?
3. Has the individual had weight loss ≥3kg in the last 4 weeks?
4. Has the individual had night sweats for > 2 weeks?
5. History of TB contact in the past one year?

*INTERPRETATION OF THE RESULT*

If YES to Question 1

Or

If NO to question 1 but YES to 2 or more of other questions = Positive TB screen [P] => Evaluate for TB

If NO to all questions = Negative TB screen [N]

*START INH PREVENTIVE THERAPY (IPT)* and

* Repeat Evaluation at Every Follow up Visit

# ANNEX X - Core TB/HIV collaboration Indicators

| *Indicator and definition* | What to measure | Data sources |
|---|---|---|
| *Indicator B.1.1 Number of PLWHA, attending for HIV testing and counselling or HIV treatment and care services, who were screened for TB symptoms expressed as a proportion of all PLWHA attending for HIV testing and counselling or HIV treatment and care services* | *Numerator:* Number of PLWHA attending for HIV testing and counselling or HIV treatment and care services who were screened for TB symptoms, over a given time period<br>*Denominator:* Total number of PLWHA attending for HIV testing and counselling or HIV treatment and care services, over the same given time period | HIV testing and counselling facility registers and HIV care and support registers |
| *Indicator B.1.2 Number of cases of newly diagnosed TB identified in PLWHA attending for HIV testing and counselling or HIV treatment and care services (who were screened for TB symptoms), expressed as a proportion of all PLWHA attending for HIV testing and counselling services and HIV treatment and care services (who were screened for TB symptoms)* | *Numerator:* Number of cases of newly diagnosed TB identified in PLWHA attending HIV testing and counselling or HIV treatment and care services (who were screened for TB symptoms), over a given time period<br>*Denominator:* Total number of PLWHA attending for HIV testing and counselling or HIV treatment and care services (who were screened for TB symptoms), over the same given time period | Modified HIV treatment and care register, HIV counselling and testing register, TB register or TB/HIV register |
| *Indicator B.2.1 Number of newly diagnosed HIV-positive clients who are given treatment for latent TB infection, expressed as a proportion of the total number of newly diagnosed HIV-positive people* | *Numerator:* Total number of newly diagnosed HIV-positive clients who start (given at least the first dose) treatment for latent TB infection<br>*Denominator:* Total number of newly diagnosed HIV-positive clients | Modified HIV testing register, HIV care register or TB preventive therapy register |
| *Indicator C.1.1 Number of registered TB patients who are tested for HIV (after giving consent) expressed as a proportion of the total number of all registered TB cases* | *Numerator*: Total number of TB patients, registered over a given time period, who are tested for HIV (after giving consent) during their TB treatment.<br>*Denominator:* Total number of TB patients registered over the same given time period | Modified TB register, modified HIV counselling and testing register or TB/HIV register |
| *Indicator C.1.2 Number of registered TB patients who are tested for HIV (after giving consent), and who test HIV-positive, expressed as a proportion of the total number of all registered TB patients who are tested for HIV* | *Numerator*: Total number of all TB patients registered over a given time period who test HIV-positive (after giving consent) during their TB treatment *Denominator*: Total number of TB patients registered over the same given time period who are tested for HIV (after giving consent) | Modified TB register, modified HIV counselling and testing register or TB/HIV register |

| Indicator and definition | What to measure | Data sources | I |
|---|---|---|---|
| Indicator C.3.1 Number of HIV-positive TB patients who receive (at least one dose of) co-trimoxazole preventive therapy (CPT) during their TB treatment, expressed as a proportion of the total number of HIV-positive TB patients | *Numerator:* Number of HIV-positive TB patients, registered over a given time period, who receive (at least one dose of) CPT during their TB treatment<br>*Denominator:* Total number of HIV-positive TB patients registered over the same given time period | Modified TB register or separate TB/HIV register | N r c f |
| Indicator C.5.1 Number of HIV-positive registered TB patients who are started on ART or continue previously initiated ART, during or at the end of TB treatment, expressed as a proportion of all HIV-positive registered TB patients | *Numerator:* All HIV-positive TB patients, registered over a given time period, who receive ART (are started on or continue previously initiated ART)<br>*Denominator:* All HIV-positive TB patients registered over the same given time period | Modified TB register, TB/HIV register or modified HIV care register | N r c f |

**HMIS / TB/HIV M&E Indicator Definitions** :

There are 2 HMIS indicators related to TB/HIV co infection; both are analyzed monthly/quarterly.

*Proportion of registered TB patients who are tested for HIV:*

| | |
|---|---|
| definition | The proportion of TB patients enrolled in DOTS who are tested for HIV. |
| interpretation | This indicator suggests the effectiveness of Provider Initiated HIV Counseling and Testing (PIHCT) in promoting screening for HIV/AIDS among patients enrolled in the DOTS program. |
| formula | The *proportion of registered TB patients who are tested for HIV* is calculated as the number of TB patients enrolled in DOTS who are tested in a specified period divided by the total number of TB patients enrolled during the same period. |
| numerator / denominator | $\% \text{ TB patients tested for HIV} = \frac{\text{No. of TB patients enrolled in DOTS tested for HIV}}{\text{Total no. of new TB cases enrolled in the same period}} x100$ |
| sources | TB program records |

| frequency of collection and reporting | | HP | HC | Hospital | WorHO / Subcity | Region / Zone | FMOH |
|---|---|---|---|---|---|---|---|
| | **collected** | | quarterly report | quarterly report | quarterly report | quarterly report | quarterly report |
| | **reported** | | quarterly | quarterly | quarterly | quarterly | annually |