Collaborative TB/HIV Services

Standard Operating Procedures for Implementation of TB Activities at HIV/AIDS Service Delivery Sites

Family Health International
October 2009

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Introduction

Tuberculosis (TB) is widely acknowledged as both one of the most common and potentially treatable life-threatening infections worldwide. When combined with HIV infection, TB constitutes an even deadlier threat. A synergistic relationship exists between TB and HIV: HIV infection is a risk factor for reactivation of latent TB infection; HIV infection causes rapid progression to active TB disease in newly acquired TB; further, HIV-infected individuals with active TB disease tend to have higher HIV viral loads and progress faster to AIDS. In people infected with HIV/AIDS, the morbidity and mortality rates related to TB infection are staggering.

As these two diseases are inextricably linked, so too should be their care and treatment. As separate clinics, TB and HIV/AIDS service delivery points have demonstrated effective mechanisms of implementing evidence-based protocols and procedures that facilitate access to quality care and treatment of both diseases. Despite current treatment of co-infected people through referral mechanisms between TB and HIV/AIDS clinics, there is a need for combined services of both TB and HIV/AIDS in one setting, whether at a facility-based, primary care, or community-based healthcare site. The burden of TB in HIV-infected people is too high for this epidemic to be handled by TB and HIV clinics in parallel systems; patients need "one-stop-shopping" for their TB and HIV care.

Standard operating procedures (SOPs) have been developed and proven effective as a resource in the HIV care and treatment community. Based on this success, these SOPs were developed to provide direction in providing combined TB and HIV/AIDS services at the HIV care site. The synergy found in treating these diseases concurrently is what distinguishes these SOPs from other TB or HIV-specific guidelines. These SOPs are essential to providing equity of care, patient safety, and standardization of service provision for this at-risk population. They address, among other priority topics:

- TB infection control measures to prevent further transmission of TB
- Intensified case finding
- TB screening for all infants, children, and adults with HIV
- TB (isoniazid) and cotrimoxazole preventive therapy
- Treatment and management of drug-resistant TB

SOPs describe processes and provide instructions to optimize TB and HIV service delivery in accordance with national guidelines. They guide clinicians in providing TB and HIV clinical care and treatment to people living with both diseases and in evaluating clinical performance, thereby serving as a quality assurance tool for management. These SOPs are generic in format and designed for adaptation to specific national contexts. Given the ongoing improvements and changes to clinical care and treatment of TB and HIV co-infected individuals, the SOPs should be viewed as working documents to be adapted and updated to incorporate new or revised procedures to ensure quality TB and HIV service delivery. The SOPs should be updated as new information impacting TB and HIV clinical care is introduced at the local, national and international level.

Who will use the SOPs for TB activities at HIV/AIDS service delivery sites?

This SOP series targets a range of professionals working in TB and HIV/AIDS, from clinical doctors to community-based volunteers, including:

- Medical doctors
- Registered clinical officers
- Nurses
- Adherence counselors
- Health facility management
- Registration/records staff
- Quality assurance staff
- Community-based volunteers
- People living with HIV/AIDS and TB

Each clinician must rely on his/her experience and clinical judgment when providing care to patients.

The document presumes that clients are already diagnosed with HIV infection. As SOPs exist for monitoring the care and treatment of HIV-infected individuals at the community level (e.g., HIV testing, PMTCT, HIV care and support, ART) these focus on care and treatment of an HIV-infected individual co-infected with TB in resource-limited settings. There will be country-specific variations in TB drug regimens and the management of patients taking antiretroviral medications (ARVs) in accordance with National TB Programs and HIV/AIDS National Guidelines.

What are the objectives of the SOPs for TB activities at HIV/AIDS service delivery sites?

The primary objective of the SOPs is to describe procedures to effectively integrate TB activities into HIV/AIDS service delivery sites practicing in tertiary level facilities, the primary health care level and the community-based level of care.

Further, these SOPs:

- Provide clinical staff with operational information to deliver TB and HIV care and treatment in a healthcare setting
- Ensure that care and treatment service delivery procedures are performed consistently to maintain quality
- Ensure that procedures comply with site standards and national guidelines
- Serve as training documents to prepare new staff in TB and HIV service delivery and reinforce standards for existing staff needing additional training
- Serve as a quality assurance tool for management to evaluate service delivery and reinforce performance in accordance with site standards and national guidelines
- Promote a “family-centered care” approach; age-specific care–the care of adults, adolescents and children–is specifically indicated throughout

How are the SOPs organized?

The SOPs are organized into four parts. Part 1 describes essential administrative elements for the provision of care and treatment of HIV and TB co-infected individuals in low-resource settings. Parts 2, 3, and 4 focus on the procedures directly related to care and treatment of HIV and TB co-infected individuals and are broken up into three levels of care: community-based care (Part 2); primary care (Part 3); and facility-based care (Part 4). Health workers using Parts 2, 3, and 4 should adapt relevant SOPs from their respective Part as well as Part 1 to meet specific needs and available resources while maintaining a standard of care that ensures patient and staff safety.

Part 1: Describes essential elements required to incorporate TB into HIV care and treatment at a basic management unit (BMU)

- Defines a BMU as an HIV care and treatment site
- Addresses overall issues for implementing TB activities in a BMU unit providing HIV care and treatment at one of the three levels of care targeted in Parts 2, 3, and 4
- Is designed to be adapted to the needs and resources of the HIV care and treatment site
- Lists key practitioners and essential items for a site to provide HIV and TB care and treatment

- Outlines procedures for managing a BMU, including those for monitoring and evaluating (M&E) a site's program, addressing cost issues, and providing referral mechanisms both within a large facility and to another site for complementary care services
- Includes standard precautions and other procedures for preventing disease transmission at a BMU
- Provides generic forms for adaptation: "standard" forms 101 and 103 target primary healthcare sites, and "expanded" forms 109–111 target facility-based care

Part 2: Provides direction in conducting standard TB and HIV activities at the community-based care level

- Lists key practitioners at the community level
- Describes symptoms and signs of adult and pediatric TB disease, explains the significance of household contact with smear-positive source cases, and outlines procedures for identifying contacts of newly diagnosed source cases
- Offers guidance for working at the primary healthcare level and with the national TB program (NTP) to provide care and treatment, make referrals, and follow up on referrals

Translating these guidelines into local languages is recommended to reach as many trained community sites as possible.

Part 3: Focuses on TB and HIV care delivered at the primary healthcare (PHC) level

- Identifies staff members at the PHC level
- Outlines responsibilities of the PHC level, including the diagnosis, treatment, and care of pulmonary TB; and coordinating with facility- and community-based care teams, and the NTP
- Presumes that most clinicians are trained to, at minimum, perform tuberculin skin testing (TST) and interpret chest X-rays (CXRs)
- Reviews procedures to diagnose *M. tuberculosis* infection and TB disease by taking a history, performing a physical examination and interpreting specific tests
- Advises referral of cases of suspected smear-negative TB, cases of severe or complicated TB, and patients with moderate to severe side-effects

While primary-level clinicians refer complex co-infected patients to secondary and tertiary facilities, the seriousness of TB/HIV co-infection demands expertise in both diseases on the part of HIV clinicians at the primary- and community-based level of care for standard care and treatment.

Part 4: Offers direction in providing complex, clinical TB activities for HIV-infected individuals at the facility-based care level

- Indicates regional, national, and district-level hospitals
- Refers to "facility" or "clinic" throughout the document, as a patient could be hospitalized or treated as an outpatient by a facility-based outpatient clinic
- Advises that the facility has on staff someone with expertise in managing complicated TB and HIV cases
- Describes the specialized roles often found in this setting, as well as the need for staff flexibility as tasks are shifted to alternative clinicians or staff, pending appropriate staff training to meet patient needs
- Outlines clinicians' diagnostic and managerial roles in handling complicated TB cases
- Describes the advisory and collaborative relationship with the NTP on the management of complicated TB cases
- Advises collaboration with the PHC to refer the patient back to the first level of care for continued treatment and follow-up
- Recommends consultation with a specialist in TB and HIV if the prescribing clinician is inexperienced in providing advanced TB care in HIV-infected individuals; this is a requirement in the treatment of drug-resistant TB

Abbreviations

AFB	Acid-fast bacilli
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral drugs
AZT	Zidovudine
BMU	Basic management unit
BMI	Body mass index
CBO	Community-based organization
CDC	US Centers for Disease Control and Prevention
CHW	Community health worker
CNS	Central nervous system
CO	Clinical officer
CPT	Cotrimoxazole preventive therapy
CSF	Cerebral spinal fluid
CTX	Cotrimoxazole
CTU	Care and treatment unit
D4T	Stavudine, Zerit
DOT	Directly observed therapy
DR	Drug resistant
DST	Drug susceptibility testing
DU	Drug user
EFV	Efavirenz
EMB	Ethambutol
EP	Extrapulmonary (TB)
FB	Facility-based
FBC	Full blood count
FHI	Family Health International
G/GM	Gram
HAART	Highly active antiretroviral therapy
HBC	Home-based care
HCW	Healthcare worker
HIV	Human immunodeficiency virus
IDU	Injection drug user
IDV	Indinavir
IEC	Information, education and communication
INH	Isoniazid
IPT	Isoniazid preventive therapy
IRIS	Immune reconstruction inflammatory sydrome
IV	Intravenous
KG	Kilogram
3TC	Lamivudine
LFT	Liver function test

LPV	Lopinavir
MD	Medical doctor
MDR-TB	Multi-drug resistant tuberculosis
M&E	Monitoring and evaluation
MG	Milligram
MOH	Ministry of Health
MTCT	Mother-to-child transmission
NGO	Nongovernmental organization
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NSAIDS	Nonsteroidal anti-inflammatory drugs
NTP	National tuberculosis program
NVP	Nevirapine
OI	Opportunistic infection
OPD	Outpatient department
OVC	Orphans and vulnerable children
PEP	Post-exposure prophylaxis
PI	Protease inhibitor
PLHA	People living with HIV/AIDS
PMTCT	Preventing mother-to-child transmission
PPD	Purified protein derivative
PTB	Pulmonary tuberculosis
PZA	Pyrazinamide
RN	Registered nurse
RFT	Renal function test
RIF	Rifampicin
RTV	Ritonavir
SARS	Severe acute respiratory syndrome
SOP	Standard operating procedure
SQV	Saquinavir
STI	Sexually transmitted infection
TB	Tuberculosis
TDF	Tenofovir
TLC	Total lymphocyte count
TST	Tuberculin skin test
USAID	US Agency for International Development
VCT	Voluntary counseling and testing
WHO	World Health Organization
XDR	Extremely drug resistant tuberculosis
ZDV	Zidovudine

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Part 1. Overview SOPs for Collaborative TB/HIV Services

Forms

SOP 101: Organization of TB Activities in HIV/AIDS Basic Management Unit

These SOPs are general and should be adapted to suit the resources and services available at the particular level of care in which they are used: the community-based site, the primary healthcare site, or the healthcare facility.

I. Key Concepts:

- **Basic management unit (BMU):** a service delivery site where HIV care and treatment is provided, with additional capacity to offer TB screening/testing, care, and treatment

II. Objectives of the BMU:

A. The BMU **ensures that TB diagnosis, care and treatment are integrated into the following core elements**, and as defined by the national TB and HIV/AIDS program and policy guidelines, include at least the following:

1. **Basic education** and counseling regarding HIV infection, TB infection, disease progression of both TB and HIV, and how TB and HIV are interrelated, including:
    a. How to reduce the transmission of TB and HIV
    b. Actions that can delay disease progression and reduce co-morbidities
    c. The importance of nutrition, food safety, and clean water
    d. Family planning and reproductive health
    e. Life-long disease management and prevention
2. **Screening/testing for TB** in HIV-infected individuals
   When diagnosed at the HIV/ART BMU, TB treatment may be arranged differently according to disease severity and resources of the particular level of care. For example, PHC BMUs refer smear-negative PTB patients for treatment at the facility-level BMU)
3. **Orientation** to the TB and HIV co-treatment program and the national TB program
4. **Prophylaxis** for TB and opportunistic infections (OIs), according to national guidelines
5. **Routine** clinical **care** and **nutritional assistance**
6. **Clinical management** of **OIs** and other HIV-related developments and co-morbidities
7. **Management of pain** and other distressing symptoms
8. **Monitoring patients** on anti-TB medication or on TB/ART, and providing **adherence** education and counseling
9. **Recording and reporting** TB and other OIs according to national TB and HIV/AIDS program guidelines and the local established system
10. **Providing referrals** to other complementary services

III. Core services of the BMU:

A. **Minimum requirements:**

1. **Patient registration**
2. **Triage** (Registration and triage can be performed by one staff member, based on staffing and patient volume.)
3. **Clinical consultation**
4. **TB infection control implementation plan,** which ideally includes four levels of control: managerial, administrative, environmental, and respiratory
5. **Disease transmission prevention procedures**, including standard precautions
6. **Directly observed therapy (DOT) for TB patients**
7. **Adherence** counseling
8. **Medical record keeping,** including standardized register and forms required by the national TB program (NTP)
9. **Patient education**, and distribution of information, education and communication (IEC) materials

10. **Referrals** within a health facility, and outside to other services such as radiology or home-based care
11. **Quality assurance** and quality improvement
12. **Pharmacy** services (or link) to dispense drugs such as anti-TB medications, ART, OI prophylaxis (e.g., cotrimoxazole), and other HIV-related medications and palliation
13. **Laboratory** services (or link)

IV. Infrastructure:

A. **Dedicated space** for the BMU
   1. Patient waiting area
   2. Registration and triage area
   3. Consultation room with auditory and visual privacy; base the number of rooms on patient volume and number of clinic days per week
   4. Counseling room with auditory and visual **privacy;** one per clinical consultation room
   5. **Confidential** counseling area
   6. **Well-ventilated sputum collection** area
   7. **Ventilated area for suspected TB patients, separate from general waiting room**
   8. Disease containment **supplies**
      a. Facemasks, cloths, and tissues
      b. Garbage container with cover for everyone–patients, staff, clinicians, and family members–to discard sputum (spit) and used tissues

B. **Pharmacy** with:
   1. Secure drug storage area for:
      a. Anti-TB medications
      b. Basic OI prophylaxis and treatment medications
      c. ART
   2. Drug counseling and dispensing room for TB and ART medications

C. **Laboratory** services
   1. Ideally, a dedicated room for drawing blood on-site with services available to transport hazardous materials to the laboratory
   2. If not on-site, laboratory services available by referral to consistently complete requested laboratory investigations and report results to ordering clinician in a timely way
   3. Routine laboratory tests
      a. FBC, LFTs, RFTs
      b. Sputum smear microscopy
      c. Rapid HIV antibody test, CD4
      d. Pregnancy test
   4. Recommended additional laboratory tests offered on-site or by referral
      a. Mycobacterial culture
      b. Confirmatory HIV antibody test
      c. HIV viral load
      d. Full serum chemistry
      e. Urine culture and sensitivity
   5. Other laboratory tests
      a. Biopsy (e.g., lymph node) results
      b. **Drug resistance testing** for TB, HIV (could be referred to national or international laboratory)

Routine and recommended laboratory tests at the BMU will be adapted to the primary or facility-based level of care based on resource availability.

D. **Radiology** onsite or available by referral to consistently complete requested images and report results to ordering clinician in a timely way:

1. Chest X-ray
2. CT scan

Radiology requests will be adapted to the primary or facility-based level of care based on resource availability.

E. Consistent **electricity** supply
   1. Back-up generator
   2. Sufficient generator fuel

F. **Clean, running water** throughout BMU, including in:
   1. Patient consultation rooms
   2. Toilets
   3. Pharmacy
   4. Laboratory

V. Staffing

A. Base the number of staff on patient volume and number of clinic days.

B. Required personnel:
   1. Registration clerk/triage nurse
      a. Registers patients, directs clinic and patient flow
      b. Can also assume responsibilities of data clerk
   2. Medical officer (MO), clinical officer (CO), or medical assistant (MA)
      a. Assesses clinical status, prescribes medications
      b. Assesses "complicated" patients referred by lower level healthcare workers (HCWs)
   3. Clinical care nurse or adherence nurse counselor
      a. Provides clinical care
      b. Leads patient education and medication adherence counseling
      c. Can also assume responsibilities of referral and BMU coordinator

C. Recommended optional staff:
   1. Nutritionist
   2. Data Clerk
   3. Referral coordinator
   4. BMU coordinator

D. Provide a **multidisciplinary TB-HIV team**
   1. Create a unified team from BMU, pharmacy, and laboratory staff; include treatment supporters, staff, and others as appropriate
   2. **Institute regularly scheduled (e.g., weekly, monthly) meetings** to review:
      a. Patient case consultation
      b. M&E report: enrollment, clinic attendance, defaulters, deaths
      c. Pharmacy report of drug and reagent stock supplies
      d. Laboratory report on requested laboratory results, processing, and communication
      e. Referrals to and within the health facility and community-based services
      f. Challenges and successes in overall TB-HIV service delivery
      g. Ways to support team members, encourage collaboration, and avoid job burn-out
   3. **Dedicate monthly meetings** to include other services in the referral network in order to address issues pertaining to the identification and treatment of TB-HIV co-infected individuals, including:
      a. Counseling and testing (CT)
      b. Prevention of mother-to-child transmission (PMTCT)
      c. Inpatient wards

SOP 102: TB-HIV Care and Treatment Operational Overview

I. Key Concepts:

- **Care and treatment** of HIV-infected individuals includes regular screening, testing, and management of TB.
- If an HIV-infected person is found to have developed TB, monitor the patient's HIV and TB clinical status and provide HIV and TB care and treatment throughout the entire TB treatment.

II. Procedures:

A. Once **trained** in TB and HIV co-management, **clinicians and staff in a community- or facility-based site provide holistic, comprehensive care services** directly or by referral to TB and HIV care points.

B. **Members** of the **comprehensive** TB-HIV care team will vary according to level of care (facility, primary healthcare site, or community-based care site), but could include any of the following to create a diverse care team:

1. Medical doctors (MDs)
2. Clinical officers (COs)
3. Nurses (RNs)
4. Nurse assistants
5. Pharmacists
6. Nutritionists
7. Laboratory technicians
8. Adherence counselors
9. Home-based care workers or volunteers
10. Treatment supporters
11. Clinic staff
12. Other trained health workers

C. **Responsibilities** of each care provider are determined by the level of care and resources available to the site or facility, by site-specific guidelines, and by national guidelines.

D. Once an HIV-infected individual is found to have TB disease, **the following sequence of care is required to ensure the patient safe, quality care and treatment** whether by direct care provision or coordinated referral:

1. **Triage.** Responsible team member: RN or other designated, trained staff member
    a. Occurs at the patient's baseline visit and every follow-up visit
    b. Includes:
    c. Registration
    d. Taking the patient's history
    e. Taking the patient's vital signs
    f. Fast-tracking acute cases and TB suspects
    g. Documenting findings in the medical chart
    h. Prioritizing patients in order of appointment time as well as clinical status
2. **General assessment.** Responsible team members: RN, MD/CO
    a. Includes:
        (1) Vital signs
        (2) Clinical review of signs and symptoms
        (3) Medication review (including prophylaxis)
        (4) Adherence (RN)

(5) Medication side effects
(6) Complications
(7) Functional status (RN)
(8) Clinical staging (MD/CO)

b. **Check for TB in all patients at every visit (Text Box 1).**
c. Specifically monitor TB-related symptoms and treatment side effects.
d. Repeat clinical staging (MD/CO)
(1) If new signs of clinical stage 4 disease occur
(2) If patient is losing weight
e. If on ART, monitor for signs/symptoms of IRIS, other OIs and medication side effects.

Text Box 1: TB Assessment

1. Assess for TB at every clinic visit or acute care appointment.
2. Rule out whether a patient is:
   a. TB suspect
   b. TB disease
   c. TB exposed
   d. Latent TB
3. For TB disease
   a. Determine disease site, TB type, TB treatment category, TB-ART co-treatment plan, family status and HIV status of partner(s) and children.
   b. Decide TB or TB-ART treatment plan.
   c. Prepare TB treatment card, update HIV care card and medical record.
   d. Educate patient and family on TB and HIV.
   e. Prescribe and give preventive therapy.
      - Cotrimoxazole
      - INH to TB household contacts including children < 5
      - BCG to TB contacts < 2 years
4. Prepare for and support treatment plan adherence.
   - Prepare for self-management.
   - Determine treatment supporter and DOT plan.

   a. Support patient throughout entire TB treatment, including treatment interruptions.
      - DOT
      - Manage side-effects
      - Continue TB-HIV education
   b. Monitor TB and ART treatment.
   c. Determine TB treatment outcome.

** Adapted from WHO "Tuberculosis Care with TB-HIV Co-management" 2007*

3. **Education and support.** Responsible team members: entire clinical team at every visit or patient interaction
   a. Give ongoing support and praise for participating in treatment.
   b. Discuss disease disclosure issues.
   c. Explain treatment and follow-up care.
   d. Support chronic HIV care needs.
   e. Assess and support adherence to care, prophylaxis, and ART.
   f. Provide positive prevention messages and education.
4. **Family-centered care.** Responsible team members: RN, MD/CO, other designated team members (Text Box 2)
   a. Assess family status.
      (1) Ask about the health of other household members.
      (2) Assess and treat household friends and family (infants, children, and adults).
   b. Assess pregnancy status of patients and household members.
   c. Discuss family planning.
   d. Assess the HIV status of children in the patient's household.
5. **Clinical care.** Responsible team members: RN, MD/CO
   a. Provide on a regular monthly schedule.
   b. Include interval acute care and symptom management.

Text Box 2: Providing family-centered care

- Clinic team meets weekly to discuss the health status and needs of treated family members.
- Team develops strategies to care for and support the family during weekly meeting.
- Team informs family members about the family-centered care approach during initial registration in the HIV care unit.
- A designated team member (e.g., case manager, nurse) documents care and support interventions in the medical records of both pediatric and adult family members treated in the clinic.
- Family centered-care allows for intensified case-finding of TB.

6. **Prophylaxis monitoring**. Responsible team members: RN, MD/CO
    a. Cotrimoxazole preventive therapy (Parts 3 and 4, SOP 106)
    b. Isoniazid preventive therapy (Parts 3 and 4, SOP 107)
    c. Fluconazole prophylaxis (if indicated, e.g., following cryptococcal meningitis acute infection)
7. **ART**. Responsible team members: RN, MD/CO
    a. Assess eligibility according to national guidelines. (MD/CO)
    b. Consult or refer to district clinician per site protocol.
    c. Assess for other OIs that may need treatment prior to ART initiation.
        (1) Assess mental health status.
        (2) Assess substance use status.
    d. Provide the correct education card to match the prescribed ART. (RN)
    e. Monitor clinical signs and symptoms of ART.
    f. Provide medication adherence support. (RN)
8. **Chronic problem management.** Responsible team members**:** RN, MD/CO
    a. Check for persistent diarrhea, fever, weight loss, injecting drug use, and drug substitution therapy.
    b. Attend to palliative care needs.
9. **Coordination of care.** Responsible team members**:** RN, MD/CO
    a. Dispense and record prescribed medications for both TB and ART. (MD/CO)
    b. Link with community services regarding home-based care needs. (RN)
    c. Update TB Treatment Card, HIV Care/ART Card, and medical record.
    d. Make home visits and trace patients who do not follow-up. (RN)
10. **Prevention for positives.** Responsible team members: RN and others as designated
    a. Offer methods for the prevention of HIV transmission
        (1) Safer sex, condoms
        (2) Disclosure support
        (3) Household and caregiver precautions
        (4) Reproductive health options and family planning
        (5) PMTCT
        (6) Positive living, such as nutrition support and exercise
        (7) Harm reduction plans for substance users, IDUs and others at risk
11. **Once TB treatment is completed, make sure that HIV-infected individual continues to receive comprehensive HIV care and treatment.**
    a. Consider starting a new patient treatment card.
    b. Update medical record.
    c. Consider approaches to adherence support following mandated TB DOT.

SOP 103: Preparing a TB Treatment and HIV/ART Care Form

I. Key Concepts:

- Prepare a TB Treatment Card and update the HIV Care/ART Card for every co-infected patient, active or latent.
- Prepare an IPT card for every patient on isoniazid preventive therapy.
- Update each card at every clinic visit and when patient results (e.g., laboratory, radiology) are received.
- Keep cards in the patient's medical/ART record file.
- Preparing and updating forms such as the TB Register every time the BMU provides TB patients with TB treatment helps in the preparation of TB case summaries and treatment outcome reports, as required by national TB control policy and guidelines (SOP 110).

II. Materials: Patient's medical record, TB Treatment Card, HIV Care/ART Card, TB Register (Forms 101, 102, and 103)

III. Procedures:

A. At **every clinic visit**, update the:
   1. TB Treatment Card (or IPT Card)
   2. TB Register
   3. HIV Care/ART Card
   4. Pre-ART or ART Register, depending on whether the patient is on both TB and ART

B. **Documentation** on TB Treatment Card (Form 101)
   1. **General** patient information:
      a. Name, sex, age, address, map, other contact information (enough to trace treatment defaulters)
      b. Identification number: assigned district TB register number and registration date
      c. Name of health facility or clinic responsible for treatment supervision
      d. Community treatment supporter, if appropriate: name of person responsible for treatment supervision, if on CB-DOTS
      e. Referral: indicate who referred the patient for TB diagnosis or treatment
      f. Patient's informed consent for DOT and default tracing (e.g., home visit, telephone contact, letter)
   2. **Clinical** information:
      a. TB disease site and patient type
      b. Sputum smear microscopy:
         (1) Microscopy when treatment started (month 0) or month during treatment
         (2) Date sputum taken
         (3) Laboratory number
         (4) Result, using standardized grading
      c. Patient's weight at treatment initiation and each clinical care visit until treatment completion
      d. Culture results, if available
      e. TB treatment category
      f. TB regimen
         (1) Record TB initial phase drug regimen on the front of the TB Treatment Card.
         (2) Record the TB continuation phase drug regimen on the back of the TB Treatment Card.

(3) Record the number of (FDC) tablets, or "g" if using streptomycin, under the Drug Combination section.

g. On the back of the TB Treatment Card, record:
   (1) X-ray results, if sputum-smear negative
   (2) The patient's HIV care registration number
   (3) Most recent CD4 count when TB treatment started
   (4) ART eligibility (date assessed or ART register number)

C. **Documentation** on HIV Care/ART Card (Form 102)

This form was developed for the initial assessment of HIV/ART care and treatment and can be adapted according to national guidelines and site standards.

1. Document "B.1" above and according to clinic standard, but **include in the medical chart** at least points B.2 and B.3 regarding **HIV care and treatment as related to TB** care and treatment.
2. **Clinical** information
   a. Date and result of HIV test(s)
   b. Date and result of negative TB screening and/or sputum microscopy examinations
   c. Date when first dose of cotrimoxazole preventative treatment (CPT) was given
      (1) Enter "P" (for previous) if CPT was started before TB diagnosis and is continuing.
      (2) If the patient is not eligible for CPT, document reason why.
   d. Date when ART first started
   e. Date when TB medications started and completed (or stopped for default)
3. **Document follow-up HIV/ART care during the TB care and treatment** phases.
   a. Use follow-up form per unit standards.
   b. This form can be adapted for follow-up HIV/ART care and treatment as needed.

D. **Referrals**
1. If a referral is needed for radiology, laboratory investigations, advanced HIV care, palliative care, support groups, or other services, complete the appropriate referral form per unit standard (SOPs 107 and 108) and document referral on the appropriate treatment card and the medical record.
2. If you refer the patient or the patient is transferring TB care to another BMU, follow procedures suggested in SOP 106 to complete the TB Treatment Referral/Transfer Form (Form 104) and document referral on the appropriate treatment card and the medical record.

SOP 104: Special Adherence Support

I. Key Concepts:

- Some co-infected individuals may require extra adherence support strategies to avoid treatment failure.
- If individuals at risk of TB treatment failure are identified early in the treatment course, poor outcomes may be avoided, leading to better patient outcomes.

II. Materials: Patient's medical record, TB Treatment Card, educational aids

III. Procedures:

A. The entire team, led by the **nurse and treatment supporter, works together** to identify those needing extra support for adhering to TB and ART co-regimens.

B. Patients potentially needing extra or special adherence support:
   1. Patients with **complex care and treatment issues**
      a. New TB and ART treatment patients
      b. Patients on second-line ART
      c. Drug-resistant TB patients
      d. Those experiencing severe or adverse treatment side effects
      e. Those with other medical diagnoses
         (1) Hepatitis C infection
         (2) Diabetes
         (3) Hypertension
      f. Those with psychiatric illness
         (1) Depression
         (2) Bipolar disease
      g. Those with substance use issues
         (1) Injection drug users
         (2) Alcohol users
         (3) Other illicit or non-prescribed drug use
   2. Patients with **complex social situations**
      a. Those without stable living situation, such as migrants or homeless patients
      b. Children, adolescents, and adults who lack full understanding of their disease
      c. Those who live far from the clinic or facility
      d. Orphans or vulnerable children
      e. Prisoners

C. Once these patients are identified, the entire clinical team works together to offer enhanced adherence support based on individual patient needs and available resources, through all phases of the patient's clinic appointment.
   1. **Cater** adherence support strategies to identified patient needs.

Potential adherence barrier	Suggested adherence support
Patient refuses home visit and home-based DOT due to stigma; patient is shunned by community and perceived as contagious.	• Discuss with patient to determine alternative to ensure treatment adherence. • If home-based DOT is not possible, make appointment for patient to visit clinic more frequently. • Discuss with community leader and perform campaign for better understanding about TB throughout the entire community (e.g., that patients who take anti-TB pills will not transmit TB to others and therefore should be accepted by community, not shunned).
Patient shows signs/symptoms of depression.	• Offer intensified counseling and support. • Refer patient to peer support group(s).
Patient has inconsistent schedule and misses scheduled appointments.	• Offer drop-in hours for people unable to make scheduled appointments.
Patient does not demonstrate full understanding of disease during appointments.	• Ensure that educational aids such as pillboxes and medication information cards are available in the local language. • Refer to peer support group(s) specific to patient's medical and social demographics.
Patient reports difficulty traveling to facility for DOT and appointments.	• Provide or raise transportation funds if possible. • Schedule monthly outreach to isolated populations such as those in rural areas and prisons.
Documented substance use does not stop, or patient becomes addicted to alcohol, injection drugs, illicit drugs, or other non-prescribed drugs (e.g., benzodiazepines).	• Explain that alcohol reduces anti-TB drug absorption and may reduce treatment efficacy. • Create a clinic environment in which patients feel safe, and can access health services and information without stigma, harassment, or legal intervention. • Refer patient to substance use/addiction counseling and support. • Offer or refer patient for drug substitution therapy or a needle-exchange program. • Refer to peer support groups targeted to the patient's need(s).
Patient has kidney failure, is on dialysis, and has frequent appointments at the tertiary facility.	• Meet patient at dialysis center to give DOT.

2. If a successful trend in addressing a barrier is noticed, consider developing and implementing a protocol for the intervention to ensure quality and standardization of effective intervention elements.

D. Support the clinicians and treatment supporters caring for patients with special needs, in order to prevent provider burnout.
   1. Provide incentives or rewards for those healthcare workers who achieve high adherence rates and low default rates, and who participate in or organize community-based activities or events.
   2. Offer continuing education opportunities, sharing case studies and experiences that demonstrate how other staff members cope with feelings and symptoms of burnout.

SOP 105: Standard Precautions for Disease Prevention

I. Key Concepts:

- This SOP describes how health care workers and others working in a healthcare site can minimize exposure to blood and body fluids and thereby reduce the risk of transmitting blood-borne and other pathogens to patients, to themselves, and to others.
- If an occupational exposure to blood or body fluid (saliva, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, semen, or vaginal secretions) occurs percutaneously, through a mucous membrane, non-intact skin, or bite, refer to *FHI Standard Operating Procedures for Post-Exposure Prophylaxis (PEP)* or other reference guide (national guidelines, site protocol) to determine next steps.
- Some countries or settings may have national infection control policies. These SOPs are meant to supplement such existing policies.

II. Procedures:

A. **Hand hygiene. Wash hands to reduce contamination with microorganisms, regardless of exposure to** blood, body fluids, secretions or excretions such as saliva, nasal secretions, breast milk, amniotic fluid, wound drainage, urine, feces, vomit, vaginal fluids, semen, pericardial fluid, cerebrospinal fluid, pleural fluid, or synovial fluid.

1. **When to wash hands**
   a. **Before** any patient contact
   b. **After** handling any blood, body fluids, liquid or solid waste
   c. **Immediately after** each patient encounter
   d. **Between clinical tasks for the same patient** (e.g., after drawing blood and before a chest exam, wash hands and change gloves)
   e. **Immediately after removing gloves and before touching anything else**, such as a telephone, pen, mobile telephone, patient record
2. **How to wash hands**
   a. Keep nails short and clean.
   b. Roll up sleeves; remove jewelry and watches.
   c. Use soap or an antimicrobial agent such as waterless antiseptic, if available.
   d. Wet hands with continuous and free-flowing water.
   e. Rub hands together vigorously with soap and lather well, including web spaces between fingers, for a minimum of 15 seconds.
   f. Avoid splashing clothing or the floor.
   g. Rinse both hands carefully under free-flowing water; hold hands down to rinse.
   h. Pat hands dry with a clean paper towel (preferred) or clean cloth towel (if clean paper towel is unavailable).
   i. If the water is from a faucet, turn the faucet off with the paper or cloth towel.
   j. Dispose paper towel in general medical waste and cloth towel in laundry.

B. **Personal protective equipment**. Use gloves, caps, masks, gowns, aprons, protective eyewear, and other personal protective equipment when coming into direct contact with blood or other body fluids.

1. **Gloves**
   a. **When to wear gloves**
      (1) Wear when coming in contact with non-intact skin or mucous membranes (e.g., examining the inside of the mouth).
      (2) Use a new pair of gloves for each exam or procedure.
      (3) Avoid direct patient contact and contact with contaminated equipment if you have open or weeping lesions or cuts on the hands.
   b. **Applying gloves**
      (1) Select gloves to fit the caregiver's hand size.

(2) Check gloves for punctures before use. Throw away gloves with visible holes or punctures.
(3) Place fingers into glove holding the glove at the cuff.
(4) Pull the glove's cuff all the way to the wrist.

c. **Removing gloves**
(1) Remove gloves before other protective equipment such as gowns and masks.
(2) Hold the cuff with one hand while easing out fingers, turning the glove inside out during the process. Repeat process to remove the second glove.
(3) Discard gloves in an appropriate container. Avoid hand contamination by handling the inside part of the glove.
(4) Wash hands with soap and free-flowing water immediately after removing gloves and before touching anything else.
(5) **Do not reuse exam glove**s. Do not wash, disinfect or prepare gloves for reuse.

2. **Caps**
a. **When to wear a cap**
(1) When splashes of blood, body fluid, secretions, or excretions might touch the hair
(2) For each possible exposure to blood and/or body fluid

b. **Applying and removing a cap**
(1) Place cap on head, covering hair completely.
(2) Discard the cap in an appropriate container.
(3) Wash hands with soap and free-flowing water after removing the cap.

3. **Masks**
a. **When to wear a surgical splash-proof mask**
(1) To cover the nose and mouth when splashes or sprays of blood, body fluids, secretions or excretions might happen

b. **Applying a mask**
(1) Wash hands with soap and free-flowing water, then dry.
(2) Place and fit new mask securely on face, covering the nose and mouth.
(3) If wearing glasses, make upper edge of mask fit underneath glasses.

c. **Removing a mask**
(1) Remove mask using only the strings.
(2) Discard mask in an appropriate container.
(3) Wash hands after removing cap and before touching anything else.

4. **Gowns**
a. **When to wear a disposable gown**
(1) To cover the body when splashes of blood, body fluid, secretions or excretions are expected during patient care
(2) Use clean, cotton gowns with a plastic apron underneath only if disposable gowns are not available.

b. **Applying a gown**
(1) Wash hands with soap and free-flowing water and dry.
(2) Slide arms and hands inside the sleeves.
(3) Fasten ties at neck and waistband.

c. **Removing a gown**
(1) Remove gown after removing gloves.
(2) Avoid contact with the outside of the gown.
(3) Turn gown inside out and discard in an appropriate container.
(4) Wash hands immediately after removal and before touching anything else.

d. **How to clean a gown**
(1) Machine-wash (or steam sterilize) reusable gowns using soap and hot water, followed by a clean water rinse.
(2) **Use personal protective equipment when washing dirty items by hand** if a washing machine is not available.
(3) Dry the gown in the sun or in a clothes dryer, if available.

(4) Be careful of repeated washing of reusable gowns, which may break down the fabric and eventually reduce the gown's barrier strength.

5. **Aprons**
   a. **When to wear a disposable, water-repellent apron**
      (1) To cover the body when splashes of blood, body fluids, secretions or excretions are expected
      (2) Use reusable, plastic aprons only when disposable aprons are not available.
   b. **Applying an apron**
      (1) Wash hands with soap and free-flowing water, then dry.
      (2) **Apply the apron** over uniform and tie around waist in the back.
   c. **Removing an apron**
      (1) **Untie the apron**, avoiding contact with the outside of the apron.
      (2) Turn the apron inside out and throw away in an appropriate container.
      (3) Wash hands immediately and before touching anything else.
   d. **Clean a reusable, plastic apron** by washing with soap and water after each patient encounter.
6. **Protective eyewear**
   a. **When to wear protective eyewear**, such as disposable goggles or face shields
      (1) When splashes of blood, body fluid, secretions or excretions onto caregiver's face and eyes may occur
      (2) When providers' glasses do **not** provide sufficient protection
   b. **Applying and removing** protective eyewear
      (1) Place goggles over the bridge of the nose and over the mask.
      (2) Place goggles over prescription glasses.
      (3) Remove goggles and discard or place in an appropriate container for decontamination.

C. **Aseptic technique.** Use when performing an invasive, sterile medical or surgical procedure.
1. **Wash hands with anti-microbial soap and water using the following hygienic hand washing technique:**
   a. Roll up sleeves, removing jewelry and watches.
   b. Wet hands under continuous and free-flowing water.
   c. For at least one minute with anti-microbial soap and water:
      (1) Rub palms together, right palm over left top and left palm over right top.
      (2) Rub palms together with fingers and backs of fingers interlaced.
      (3) Then, rub backs of fingers to opposite palms of fingers interlocked.
      (4) Then, rub the right thumb around in left palm and the left thumb around in right palm.
      (5) Rotationally rub backwards and forwards clasping fingers of right hand and in the left palm and vice versa.
   d. Do not splash clothing or the floor.
   e. Rinse both hands carefully under free-flowing water, holding hands down.
   f. Pat both hands dry with a clean paper towel or a clean cloth towel.
   g. Turn off faucet with the towel. Dispose of the paper towel in general waste disposal or dispose of the cloth towel in the laundry.
2. Apply sterile exam gloves.
3. **Always notify the patient** that you plan to administer an injection.
4. **Use antiseptic and sterile gauze to disinfect the target areas of skin immediately prior to any clinical procedure that will puncture the skin.**
   a. Consider any of the following antiseptics:
      (1) 70-80 percent w/w ethanol
      (2) 60-70 percent v/v isopropanol
      (3) 10 percent w/v aqueous or alcoholic povidone-iodine (1 percent w/v available iodine) such as betadine

(4) Chlorhexidine in aqueous formulations (0.5-4 percent w/v) or in alcoholic formulations with chlorhexidine (0.5 to 1 percent w/v) in 60-70 percent isopropanol or ethanol (for example, Hibiclens)
(5) Solutions containing 1 percent w/v diphenyl ether (triclosan)

5. Do not use cotton balls stored wet in a multi-use container.
6. Once clean, allow the area of skin to dry before the procedure.
7. Do not touch or allow any other object to touch the skin area before the procedure.
8. Perform procedure.
9. When using scalpel blades in a procedure, always use forceps to hold the blade.
10. When transferring blood from a syringe into a test tube:
    a. Make sure the test tube is in a test tube holder.
    b. Use only one hand to insert the needle into test tube.
11. Once finished, dispose of all blades, needles and other "sharps" in a designated, leak-proof, puncture-proof sharps container (see Section "J").

D. **Injection administration**

1. **Always notify the patient** that you plan to administer an injection.
2. **Pre-procedure**
    a. Prepare each injection in a separate, clean area without body fluids and blood.
    b. Use a new, single-use, disposable needle and syringe for every injection administered and to reconstitute every medication unit.
    c. Inspect syringe and needle packaging.
        (1) Ensure it is not torn, punctured, or damaged.
        (2) Discard if damage is found.
        (3) Discard needles that had contact with non-sterile areas such as countertops.
    d. Use single-dose vials to prepare medication.
        (1) If this is not possible, always clean the top of the multi-dose vial with available antiseptic, then puncture the septum of the multi-dose vial with a clean, sterile needle.
        (2) Do not leave needles in the septum of the vial.
        (3) Do not remove or manipulate the needle from the syringe prior to disposal.
    e. Avoid ampules that require a metal file to open.
        (1) If this is not possible, protect hands while opening the ampule.
        (2) Protect fingers with a clean gauze pad or other clean barrier.
        (3) Discard medications with evidence of tampering or expiration (cracks, tears, broken seals).
3. **How to perform an injection**
    a. Wash hands prior to administration of the injection.
    b. Avoid giving injections to patients with poor skin integrity, such as flaky skin or a painful rash.
    c. Wear single-use, disposable gloves if bleeding is anticipated.
    d. Clean the area of skin to be injected.
        (1) Remove visible dirt with soap and clean water.
        (2) Use an antiseptic (clean, single-use swab) to disinfect the target area of skin immediately prior to injection.
        (3) An antiseptic is preferred, but is not required if the skin has been cleaned with soap and clean water.
        (4) Do not use cotton balls stored wet in a multi-use container.
        (5) Allow the area of skin to dry prior to injection.
    e. Be aware of and avoid sudden or jerking movements of the patient during and after injection administration.
    f. Do not recap needle after use and prior to disposal.
    g. Immediately dispose of contaminated needle and syringe in sharps container.
    h. Remove gloves, wash hands with soap and free-flowing water, and dry.

E. **Cleaning of patient-care rooms. Includes instrument processing area and laboratory; excludes waiting areas**

1. **At the start of each day:**
    a. Use a damp cloth to remove dust from examination tables, trolleys, lamps and other office furniture.
    b. Use a damp mop to remove excess dust from the floors.
2. **Between patients:**
    a. Clean examination tables, counters, lamps, blood pressure cuffs and other patient care equipment, and other surfaces at risk for contamination.
    b. First, clean with soap and water, then dry.
    c. Then, use a disinfectant solution such as JIK (sodium hypochloride), permanganate de potassium, Dakin, or any 1-2 percent sodium hypochlorite or 70 percent alcohol solution, on a damp cloth and wipe off the dirty item.
    d. Do the same thing to clean floors, ceiling and walls if contaminated.
    e. If areas are soiled with blood or body fluids, see section "E" below.
3. **At the end of each day:**
    a. Use a disinfectant solution such as JIK, permanganate de potassium, or Dakin to clean all counters, floors, tables, sinks, lights, door handles, walls, blood pressure cuffs and other patient-care equipment.
    b. For facilities with toilets/commodes, clean the seat and other areas with warm water and soap using cleaning cloth or sponge, and then dry.
    c. Then use the disinfectant solution and dry again.
4. **Weekly:**
    a. Use a mop or other appropriate tool dampened with a disinfectant solution (JIK, permanganate de potassium, or Dakin) to clean ceilings in patient consultation areas, if soiled.

F. **Spills of blood or body fluids**

1. **Smaller spills** (less than 10cm in diameter)
    a. Use standard precautions and personal protective equipment as described in this SOP as appropriate. Use heavy-duty or utility gloves when addressing spills and cleaning surfaces.
    b. Apply dry, absorbent paper towels or a cloth saturated with a disinfectant solution directly to contain the fluid spill.
    c. Dispose of the paper towels or cloth by following the procedures for infectious, non-sharps, clinical waste disposal as outlined in Sections "I" and "J" below.
    d. Immediately clean with soap and water to remove surface dirt and contaminants within the spill.
    e. Use a disinfectant such as bleach or 0.5 percent chlorine solution after cleaning with soap and water when:
        (1) Spills are contaminated with blood or body fluids.
        (2) There is risk of bare skin contact with the spill area.
        (3) Cleaning is difficult.
    f. Wash hands with soap and free-flowing water.
2. **Larger spills (more than 10cm in diameter)**
    a. Use standard precautions and personal protective equipment described in Sections "A" and "B" above.
    b. Wear disposable cleaning, heavy-duty, or utility gloves when cleaning spills and surfaces.
    c. Coat the area with a disinfectant (0.5 percent chlorine) solution.
    d. Wipe spill with dry, absorbent paper towels, a damp cloth, sponge or a mop to contain the majority of the spill.
    e. Immediately clean area with water and soap using absorbent paper towels, a cleaning cloth, sponge or mop.

f. Disinfect the area with at least 0.5 percent chlorine solution and allow to dry completely.
g. Dispose of all paper towels, damp cloths or mops using procedures for infectious, non-sharps, clinical waste disposal described in Section "J" below.
h. Wash hands with soap and free-flowing water.

G. **Linen and examination room item handling**

1. **How to handle linens**
   a. Use paper or protective liners, if available, to keep bed and exam table linen clean.
   b. If protective liner is unavailable, remove used linen from exam tables after each patient encounter and store for cleaning in a labeled bag or container.
   c. Wear gloves when removing and placing dirty linen in marked, leak-proof biohazard bags if linen is contaminated with blood or other body fluids.
   d. Separate blood-contaminated linen from other items, then clean using soap and bleach.
   e. Separate and clean all used and soiled linens away from patient consultation areas.
   f. Wash used or soiled linens with laundry soap and water heated to approximately 75 degrees C, for at least 25 minutes.
   g. Items may dry in the sun.
   h. Keep fresh, clean linen in a separate clean linen area to avoid contamination.
2. **How to handle exam room items**
   a. Wipe examination tables, mattresses, and pillows that have plastic covers, with soap and water after each patient encounter.
   b. Steam-clean mattresses without plastic covers when exposed to body fluids.
      (1) If steam-cleaning is unavailable, wash mattress manually with soap and hot water while wearing personal protective equipment.
      (2) Alternatively, the contaminated mattresses may be thrown away.
   c. If contaminated with body fluids, pillows without plastic covers should be dry-cleaned.
      (1) If dry-cleaning is unavailable, wash manually with soap and hot water while wearing personal protective equipment.
      (2) Alternatively, the contaminated pillow may be thrown away.
   d. Clean curtains when there is visible dirt, using technique described immediately above.

H. **Instrument processing. Includes reusable items such as speculas, containers, and glass bottles**

1. **Prior to processing**
   a. Avoid hand-to-hand transfer of sharp, reusable instruments.
   b. Place reusable items or instruments in marked containers immediately after use.
   c. Transport equipment to designated area for processing.
   d. Use a designated room or bench space to keep clean and dirty equipment separate.
2. **How to process instruments**
   a. Wear heavy-duty or utility gloves, protective eyewear and a mask.
   b. Disassemble instruments in non-patient care areas.
   c. Use warm water in a dedicated instrument-processing sink to rinse instruments and remove any blood or body fluids.
   d. Thoroughly wash and clean the instruments in free-flowing water with a mild alkaline soap (ph 8.0-10.8) using a soft brush or non-abrasive scouring pad.
   e. Keep the brush and utility gloves in a clean and serviceable condition.
   f. Carefully rinse and wash instruments under free-flowing warm or hot water.
      (1) Remove all soap.
      (2) Dry instruments prior to **disinfection or sterilization procedures** (removal or inactivation of all microorganisms).

g. Use steam sterilization, high-level disinfection, or low temperature automated chemical sterilant systems to clean instruments that contact intact mucous membranes. Refer to facility for potential resources and capabilities.
h. Instruments that puncture sterile tissue, enter the vascular system, or are otherwise contaminated with blood or body fluids should undergo steam, chemical, or dry-heat sterilization to remove all microorganisms. Choose the sterilization process based on the intended use of the equipment.
   (1) Steam (autoclave): moist heat under pressure
   (2) Chemical: low-temperature chemical sterilant or ethylene oxide sterilization
   (3) Dry-heat (electric oven): high heat for a fixed time period
i. Store instruments in a dry, clean, dust-free, and covered space until next use.

I. **Syringes**
1. Do not reuse or sterilize syringes or needles after use.
2. Each injection or blood draw should occur with a **new, disposable** syringe and needle.

J. **Clinical waste disposal – sharps.** Includes waste created during examination, diagnosis, preventative, and curative patient treatments, such as syringes, needles, and scalpel blades
1. **Where to first dispose of sharps**
   a. Immediately after use place all sharps, including syringes, needles, scalpel blades, and other items for disposal, in **leak-proof, puncture-proof sharps containers**, regardless of whether or not they are contaminated.
   b. Keep sharps containers as close as possible to clinical use area.
2. **How to dispose of sharps**
   a. Place uncapped, used syringe directly into the nearest leak-proof, puncture-proof sharps container.
   b. Do not remove or manipulate the needle from the syringe prior to disposal.
   c. Do not hand the contaminated sharp to another person for disposal; the person who uses the sharp object throws it away.
   d. Do not try to recap the needle or syringe prior to disposal.
3. **Making a sharps container**
   a. Make the container from metal or high-density plastic and fit with a cover.
   b. Use a dense cardboard safety box if metal or plastic is unavailable.
   c. Seal the puncture-proof, leak-proof container when it is three-quarters full.
   d. Do not reopen or empty the sharps disposal container once it has been sealed.
4. **Where to finally dispose of sharps**
   a. Place filled, sealed sharps disposal container in disposal bag.
   b. Label or color-code bag “Highly Infectious Waste” before removal from clinical use area.
   c. Options for final sharps disposal:
      (1) On-site incineration, if possible
      (2) Transporting of labeled disposal bags to a distant, appropriate facility
      (3) Burial, per WHO recommendations (WHO, December 2004)

K. **Clinical waste disposal – non-sharps**
1. **Place non-infectious waste in general garbage disposal stream**
2. Put **highly infectious, non-sharps material** (items containing blood, vomit, urine, body fluids, soiled or used wound dressings**) in leak-proof, biohazard** bags.
3. Color-code and label waste disposal bags by waste category (WHO, 1999):
   a. Yellow and marked “Hazardous” for non-sharp infectious waste
   b. Yellow and marked “Highly Infectious” for highly infectious non-sharp waste
   c. Yellow and marked “Sharps” for sharps

4. **Tightly seal all** waste disposal bags when three-quarters full.
    a. Light gauge bags may be tied at the neck.
    b. Seal heavier bags with a plastic, self-locking sealing tag.
    c. Do not staple bags.
5. **Do not reopen any closed or sealed biohazard** bags or containers.
6. **Mark** all designated biohazard areas. Keep all bagged, biohazardous material in an area protected from public access, including scavengers and children.
7. **Consider burning or burying waste as designated by the facility or clinic site protocol** if clinical disposal is not taken to a designated place on a regular basis.

SOP 106: Transferring or Referring TB Treatment

I. Key Concepts:

- **Referral**: the process of sending a patient to receive care or start treatment at another site or facility
- **Transfer**: the process of moving a TB patient registered in one site's TB register to continue treatment in another area with a different TB register

II. Key personnel: RN, MD/CO, designated site staff

III. Materials: TB Treatment Card, TB Treatment Referral/Transfer Form, TB Register, medical record; HIV Care/ART Card and other forms as required by site protocols

IV. Procedures:

A. At each monthly clinic visit, the RN or MD/CO **assesses the patient** to see whether the patient needs to be referred or transferred to another TB (and HIV) clinic site.
   1. Reasons for referring a patient include:
      a. Clinical status: The patient requires further diagnostic work-up, emergent, or acute care beyond the scope of the site.
   2. Reasons for transferring a patient include:
      a. Clinical status: The patient requires chronic care (e.g., treating MDR TB) beyond the scope of the site.
      b. Social situation: The patient reports that they are moving.
         (1) Whether a permanent or semi-permanent (longer than 2 months) move, find out where the patient is moving and identify a site providing co-treatment of TB and HIV (if available). At minimum, determine the nearest TB center and HIV clinic and coordinate referrals.
         (2) If the patient has been lost to follow-up, is found during patient tracing, and at that time indicates a permanent move, coordinate referrals for TB and HIV co-treatment in the new location.

B. Once a site appropriate to the patient's needs has been identified, **contact the site** to make them aware of the patient referral or transfer.

C. **Discuss** the referral or transfer plan with the patient.
   1. **Determine a date and time** for the patient to report to the referral or transfer site and make sure the patient is aware of the need to report for the appointment.
   2. **Provide enough medications** for the patient to have during travel time if this is a transfer of care and treatment.
      a. If transferring care and treatment, also provide transfer information for HIV care, treatment, and ART (if applicable) per site protocol for Transfer Out.
      b. Indicate Transfer Out procedures in the patient's medical record and HIV care form.

D. **Complete Form 104**: Tuberculosis Treatment Referral/Transfer and make three copies of the form:
   1. Give one copy to the patient and tell the patient to present it to the new clinic/facility upon arrival.
   2. Keep one copy in the patient's file.
   3. Send one copy to the district TB coordinator.

E. **If referring or transferring many people**, use separate forms for referral and transfer, and a specific referral register as needed.

F. **After transfer or referral procedures above have been completed**, contact the referral/transfer site to check if the patient completed the referral/transfer.
   1. The site receiving a "referred" patient is responsible to inform the “referring” site about the care provided to the referred/transferred patient, including:
      a. Date patient arrives for continuing treatment
      b. Final treatment outcome
   2. For patients permanently “transferred out,” the original “transferring-out” site reports the treatment outcome after getting the information from the site completing the treatment, and documents it in the patient’s medical record.

SOP 107: Referral Management: Internal Referrals by the Basic Management Unit

I. Key Concepts

- This SOP pertains mainly to facility-based TB/HIV care and treatment sites making referrals to other specialized services within the same health facility network or building.

II. Key Personnel: RN, MD/CO, designated staff

III. Procedures

A. Clinical facility staff members refer co-infected patients to the following **services within the health facility for specialized management:**

1. Inpatient department
2. Maternal health center
3. Antenatal health center
4. Specialty departments (e.g., TB, infectious disease, gynecology)
5. Laboratory
6. Radiology
7. Facility-based community outreach department (e.g., DOTS, palliative care, home-based care)

B. The nurse **arranges the details of the referral** as ordered by the MD/MO.

C. Within 24 hours, the nurse **contacts the inpatient department or specialty department to which the patient was referred** to assure that the patient receives the services ordered.

D. The nurse **documents the referral** in the **Clinical Care/ART: Adult Follow-Up Visit Form** (or other designated form per facility standard), or documents the referral in the patient's medical record and maintains the form there.

E. The nurse includes **documentation received from the referral site about the patient** in the patient's medical record.

SOP 108: Referral Management: External Referrals by the Basic Management Unit

I. Key Concepts:

- Provide community-based service referrals for TB/HIV co-infected patients and their family members who desire assistance with and access to resources to maintain positive health status and effectively manage the multiple dimensions of TB/HIV disease.
- This SOP pertains to both facility and community-based TB/HIV care and treatment units (BMUs), as both refer patients for services outside the scope of their BMUs scope of care and service provision

II. Key Personnel: RN, MD/CO, administrative staff, volunteers, PLHA and other designated members

III. Procedures:

A. **Confidentiality**. Maintain confidentiality about each patient and protect the confidentiality of patient records.

B. **Designated staff**
   1. The **nurse** assists the patient in determining needs and how to best meet those needs.
   2. If **PLHA organization members** volunteer at the site, they can also assist patients with referral arrangements for: needed services, as well as patient education and support.

C. **Service areas.** The referral staff will **assist the patient in determining needs and how to best meet those needs** in the following areas:
   1. Health care, including preventing viral transmission
   2. Nutrition
   3. Housing
   4. Home-based care
   5. Economic support/employment
   6. Activities of daily living
   7. Mental health
   8. PLHA association support
   9. Social relationships
   10. Recreation and leisure
   11. Transportation
   12. Legal assistance
   13. Spiritual support

D. **Referral process**
   1. The referral staff and the patient jointly **develop a service plan** that defines the patient's needs and the steps to meet those needs. Update the plan according to the patient's needs.
   2. The referral staff **makes referrals** and coordinates delivery of services to meet the patient's needs.
   3. The referral staff **tracks referral requests** and follows up to assure patient needs are met.
   4. The referral staff maintains a record of meetings with the patient, the referrals made for the patient, and outcomes of the referrals. **Maintain this documentation in the patient's medical record.**

E. **Community-level referrals to facility**

1. Community-site staff refer co-infected patients to the following **services within the health facility for specialized management:**
    a. Inpatient department
    b. Maternal health center
    c. Antenatal health center
    d. Specialty departments (e.g., TB, infectious disease, gynecology)
    e. Laboratory
    f. Radiology
2. The nurse or other designated staff member **arranges the details of the referral** as ordered by the MD/MO using the appropriate referral form.
3. Within 24 hours, the nurse or other designated staff member **contacts the specific department or service to which the patient was referred** to confirm the patient receives the needed care, treatment or support.
4. The nurse **documents the referral** in the **Clinical Care/ART: Adult Follow-Up Visit Form** (or other designated form per clinic standard), or documents the referral in the patient's medical record. Form is maintained in the patient's medical record.
5. Include **documentation received from the referral site about the patient** in the patient's medical record.

SOP 109: Record Keeping

I. Procedures:

A. Create a **medical record on file** for each patient seen at the site or facility. For patients with a pre-existing record at the site/facility, integrate the old file into the new one.

B. **Maintain** the following **forms in the patient's medical record**:
   1. Triage Nurse Assessment Form (use unit standard form)
   2. Clinical Care: Initial Adult/Pediatric Assessment Form (use unit standard form)
   3. Tuberculosis Treatment Card (Form 101 or Form 110)
   4. HIV Care/ART Card (Form 102)
   5. TB Register (Form 103 or Form 111)
   6. Clinical Care/Antiretroviral Therapy: Adult Follow-Up Form (use unit standard form)
   7. Pre-Start Counseling Form (use unit standard form)
   8. Adherence Monitoring Form (Forms 106, 107)
   9. Laboratory Investigation Result Forms (use unit standard form)
   10. Laboratory Register (use unit standard form)
   11. All referral forms (Forms 104 and unit standard)

C. The **registration clerk** in the BMU registration and records department will:
   1. **Facilitate the patient's attendance** for treatment and clinical review in the TB/HIV program. Ensure that the patient's medical record is available for each patient visit and that the appropriate forms are included in the file.
   2. **Review the clinical management form after the patient's visit to assure its completion.** Return forms to the appropriate clinician (i.e., MD/CO, adherence counselor, triage nurse) for completion if data is missing from the form.

D. The **clinician** in the BMU using the form will complete the form during the patient visit.
   1. **Ensure key HIV/AIDS data is recorded in the TB Register**.
   2. Ensure TB data is recorded in the HIV Care/ART Card.

E. Timely record keeping by the BMU staff and clinicians facilitates accurate monitoring and evaluation of the services provided.

SOP 110: Monitoring and Evaluation

I. Key Concepts:

- Monitoring and evaluation includes: tracking data on an individual patient basis in the medical chart at both the site and facility levels; collecting data for district/provincial and country-level reports; clinical monitoring and mentoring to improve patient care, enhance provider education and evaluate quality of care and service coverage.

II. Procedures:

A. Monitoring
   1. **All BMU staff members** who provide patient care or have access to patient charts are responsible for **maintaining current, continuous data on TB and ART management as well as HIV comprehensive care**. Staff members include: MD/CO, RN, pharmacist, registration clerk.
   2. Each staff member documents in the patient's medical record during and immediately after working on particular patient issues such as registration, clinical care, prescriptions, referrals, and appointments.

B. Clinical monitoring and mentoring
   1. Organize a **Clinical Care Committee** to meet weekly and review difficult patient cases.
   2. The **site Multidisciplinary Care Team** will meet weekly to share insights, discuss issues pertaining to patient care, discuss ways to improve patient care, and participate in brief care updates on topics of interest.
   3. All care staff will be invited to these meetings, including MDs, COs, nurses, adherence counselors, nutritionists, pharmacy staff, and laboratory staff.
   4. Monthly or quarterly continuing education refresher trainings can be scheduled or added on to these meetings.

C. Care indicators for monitoring and evaluation
   1. **On a monthly basis**, an identified data clerk collects and reports data on defined indicators in accordance with the ministry of health's monitoring and evaluation (M&E) plan.
   2. On a quarterly basis the clerk organizes the data and completes a report in accordance with the NTP and national guidelines (Form 108: Quarterly Report on TB Treatment Outcome and TB/HIV Activities in BMU).
   3. Changes to clinic practice to improve patient care and site function can be supported by this data and discussed in a dedicated, regularly scheduled meeting (e.g., on a monthly or quarterly basis after the reporting in C.1 and 2 above is complete).
   4. Examples of process indicators reported for each quarter:
      - Number of patients identified with active TB
      - Number of patients who started taking ARVs and TB meds
      - Number of patients whose ARV regimen was changed
      - Number of patients on TB meds lost to follow-up
      - Number of patients on TB/ART who received adherence counseling

D. **Evaluating patient satisfaction**
   1. Develop or modify a **Patient Satisfaction Survey** and make it available for completion by patients receiving TB/HIV care.
   2. Encourage the patient and family members to fill out the form to provide feedback about the care received, including suggestions for improvement and additional concerns.
   3. **Appoint a designated site staff member, such as the** registration clerk or data manager, to collect, tally, and analyze the survey data on a regular basis.

4. Use the data and comments to improve or change site practice as needed, as well as to commend staff if feedback is positive.
5. Report or present to patients (for example, in a poster or newsletter) ways in which their feedback was used by the site.

SOP 111: Cost Issues

I. BMU policy:

A. The BMU will offer TB testing, care, and treatment free of charge according to the national TB program.
B. The BMU will apply existing cost-sharing policies to TB and HIV co-infected persons who are unable to pay for needed treatments.
C. The BMU will provide waivers and exemptions for those patients unable to meet the cost of treatment, including required laboratory tests.

II. Procedures:

A. BMU administration of **cost-sharing**
   1. A cost-sharing fee, as determined by the BMU, will be charged for clinical consultations, treatment, drugs and routine laboratory and other monitoring tests.
   2. Fees and rates will be determined by BMU policy and approved by the Ministry of Health.
   3. Adapt or revise this policy according to existing site policy as well as in consideration of local funding opportunities.

B. Providing **BMU cost-sharing programs to the patient**
   1. During the registration process, the BMU staff (e.g., registration clerk, RN, MD/CO) will identify patients who are unable to pay for needed services and treatments.
   2. Once identified, the BMU registration staff member will ask those patients to complete a waiver request form.
      a. The waiver form will indicate:
         (1) Needed services, treatments and/or drugs
         (2) How much, if any, the patient can contribute toward the cost of the needed services
   3. The registration staff member processes the waiver request using the existing mechanism that involves the site or facility social worker or administration staff.
   4. Upon approval of this waiver request, which also indicates the length of waiver validity, the patient receives requested services and drugs without charge. The designated staff member follows up on the waiver to ensure that the patient receives the needed treatment in a timely fashion.
   5. A patient who is able to pay will be charged for the services and drugs according to existing cost-sharing rates.
   6. The patient and his or her sponsor, together with the site's designated financial staff, will decide on the payment schedule and method.

Forms

Form	Source
101: Tuberculosis Treatment Card – *Standard*	World Health Organization. *Tuberculosis care with TB-HIV Co-management. Integrated management of adolescent and adult illness (IMAI). April 2007*. Geneva, World Health Organization, 2007
102: HIV Care/ART Card	World Health Organization. *HIV Care/ART Card. Accessed June 2009*. http://www.who.int/hiv/pub/imai/primary_artcard/en/print.html
103: TB Register	World Health Organization. *Tuberculosis care with TB-HIV Co-management. Integrated management of adolescent and adult illness (IMAI). April 2007*. Geneva, World Health Organization, 2007
104: Tuberculosis Treatment Referral/Transfer Form	World Health Organization. *Revised TB recording and reporting forms and registers – version 2006*. Geneva, World Health Organization, 2006.
105: Request for Sputum Smear Microscopy Examination Form – *Standard*	World Health Organization. *Tuberculosis care with TB-HIV Co-management. Integrated management of adolescent and adult illness (IMAI). April 2007*. Geneva, World Health Organization, 2007
106: TB/HIV Medication Adherence Monitoring Record	Family Health International. *SOPs for ART Adherence Counseling. 2005.*
107: Adherence Monitoring Record	Family Health International. *SOPs for ART Adherence Counseling. 2005.*
108: Quarterly Report on TB Treatment Outcome and TB/HIV Activities in BMU	World Health Organization. *Revised TB recording and reporting forms and registers – version 2006.* Geneva, World Health Organization, 2006.
109: Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test	World Health Organization. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006.
110: TB Treatment Card – *Expanded*	World Health Organization. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006.
111: TB Register in Basic Management Unit Using Routine Culture and Drug Sensitivity Test	World Health Organization. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006.

Form 101: Tuberculosis Treatment Card - Standard

Tuberculosis Treatment Card

BMU TB Register No._____

Name: _____

Sex: ☐ M ☐ F Date of registration: _____

Age: _____ Health facility: _____

Address: _____

_____

Name / address of community treatment supporter (if applicable)

_____

I. INITIAL PHASE - prescribed regimen and dosages

CAT (I, II , III): ☐

Number of tablets per dose and dosage of S:

(RHZE)	S

Cotrimoxazole	ARV	Other

Referral by :

☐ Self-referral
☐ Community member
☐ Public facility
☐ Private facility/provider
☐ Other, specify
_____

Disease site (check one)

☐ Pulmonary ☐ Extrapulmonary, specify _____

Type of patient (check one)

☐ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other, specify _____

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0				

TB/HIV		
	Date	Result*
HIV test		
CPT start		
ART start		

* *(Pos) Positive; (Neg) Negative; (I) Indeterminate; (ND) Not Done/unknown*

Tick appropriate box after the drugs have been administered

Daily supply: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (——●) through the number of days supplied. Ø = drugs not taken

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

II. CONTINUATION PHASE

Number of tablets per dose

(RH)	(RHE)	Other

Daily supply: enter ☞ . Periodic supply, enter X on day when drugs are collected and draw a horizontal line (——●) through the number of days supplied. Ø = drugs not taken

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

X-ray (at start)
Date:
Results *(-), (+), ND*

HIV care	
Pre ART Register No.	
CD4 result	
ART eligibility *(Y/N/Unknown)*	
Date eligibility assessed	
ART Register No.	

Comments: _____

_____

_____

_____

_____

Treatment outcome
Date of decision ____
☐ Cure
☐ Treatment completed
☐ Died
☐ Treatment failure
☐ Default
☐ Transfer out

_____

_____

_____

_____

_____

_____

Name and address of contact person: _____

Form 102: HIV Care/ART Card

Unique # ☐☐☐☐☐☐

HIV CARE/ART CARD ____

District_____Health Unit_____ District clinician/team_____

Name_____Pt Clinic No._____
Sex: M ☐ F☐ Age ____DOB_____Marital status_____
Address_____
_____
Phone(whose):

Prior ART: ☐Transfer in with records ☐PMTCT only
☐ Earlier ARV, not transfer In ☐ None

Care entry point: PMTCT Medical Outpatient Under5 TB STI Private/Co Inpatient IDU Adol Sex Outreach Self-refer CBO Other:

Treatment supporter/med pick-up if ill:_____
Address_____
Phone:
Home-based care provided by:

Names of family members also in care	Age	HIV status	Unique No.

ART treatment interruptions			
Stop Lost (circle)	**Date**	**Why**	**Date if Restart:**
Stop Lost			
Stop Lost			
Stop Lost			
Stop Lost			

Date

_____ Confirmed HIV+ test Where_____ HIV 1 2 Ab / PCR if < 18 mo

_____ Enrolled in HIV care

ARV Therapy

COHORT:

_____ Medically eligible Clinical stage_____
Why eligible: ☐Clinical only ☐ CD4 #/%_____ ☐ TLC_____

_____ Medically eligible and ready for ART

_____ Transferred in from _____ART started_____

1st- line

_____**Start ART first-line– initial regimen:**_____

At start ART: Weight _____Function ___ Clinical stage___

_____ **Substitute within first-line:**

_____ New regimen_____ Why___

_____ New _____ Why___

2nd-line

Switch to 2nd line (or Substitute within 2nd line):

_____ New regimen_____Why____

_____ New_____Why___

_____ New_____Why___

_____ **Dead**

_____ **Transferred out** To where:_____

Why STOP codes:
1 Toxicity/side effects
2 Pregnancy
3 Treatment failure
4 Poor adherence
5 Illness, hospitalization
6 Drugs out of stock
7 Patient lack finances
8 Other patient decision
9 Planned Rx interruption
10 Other

Why SUBSTITUTE or SWITCH codes:
1 Toxicity/ side effects
2 Pregnancy
3 Risk of pregnancy
4 Due to new TB
5 New drug available
6 Drug out of Stock
7 0ther reason (specify)
Reasons for **SWITCH** to 2nd-Line Regimen only:
8 Clinical treatment failure
9 Immunologic failure
10 Virologic failure

Unique # ☐☐☐☐☐☐ **HIV CARE/ART CARD** ____ **Name**_____

Date Check if scheduled. Write in alternate pick-up if ill	Follow-up Date	Duration since last starting ART/ since starting current regimen	Wt	Pregnant PMTCT? Due date or FP— no FP/ yes: Methods___ If child: Height	Func-tion Work Amb Bed	WHO Clinical Stage	TB Status	Potential SIDE EFFECTS	New OI, Other PROBLEMS	Cotrimoxazole Adhere /Dispense		Other meds dispensed	ARV drugs Adherance	Dispense	CD4	Hgb, RPR, TLC, other lab	Refer or consult or link/ provide Hospital days- no.
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Basic Management Unit TB Register– Left side of the register book

Date of registration	BMU TB No.	Name	Sex M/F	Age	Address	Health facility[1]	Date treatment started	Treatment category[2]	Site P / EP	Type of patient[3]					
										N	**R**	**F**	**D**	**T**	**O**

Footnotes appearing on first page of the register only.

1 Facility where patient's treatment card is kept. In case several copies are kept, the most peripheral facility should be entered. Use standardized type of health facilities according to block 2 of the *Yearly Report on Programme Management in BMU*. Health facility is defined as any health institution with health care providers formally engaged in any of the following TB control functions (DOTS): referring TB suspects/cases, laboratory diagnosis, TB treatment and patient support during treatment.

2 Enter the treatment category:

CAT I: New case of sputum smear microscopy (+), severe sputum smear microscopy (-)PTB & EPTB e.g. 2(RHZE)/4(RH)
CAT II: Re-treatment e.g. 2(RHZE)S/1(RHZE)/5(RHE)
CAT III: New sputum smear microscopy negative PTB and EPTB e.g. 2(RHZE)/4(RH)

3 Tick only one column:

N=New – A patient who has never had treatment for TB or who has taken antituberculosis drugs for less than 1 month.
R=Relapse – A patient previously treated for TB, declared cured or treatment completed, and who is diagnosed with bacteriological (+) TB (sputum smear microscopy or culture).
F=Treatment after failure – A patient who is started on a re-treatment regimen after having failed previous treatment.
D=Treatment after default – A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 or more consecutive months.
T=Transfer in – A patient who has been transferred from another TB register to continue treatment. This group is excluded from the *Quarterly Reports on TB Case Registration and on Treatment Outcome*.
O=Other previously treated– All cases that do not fit the above definitions. This group includes sputum smear microscopy positive cases with unknown history or unknown outcome of previous treatment, previously treated sputum smear microscopy negative, previously treated EP, and chronic case (i.e. a patient who is sputum smear microscopy positive at the end of a re-treatment regimen)

Results of sputum smear microscopy and other examination										Treatment outcome & date							TB/HIV activities		Remarks
Before treatment				2 or 3 months [1]		5 months		End of treatment		Date	Outcome [5]						ART Y/N Start date	CPT Y/N Start date	
Sputum smear micros-copy result [2]	Date/ Lab. No.	HIV result [3] Date	X-ray Result [4]	Sputum smear micros-copy result [2]	Date/ Lab. No.	Sputum smear micros-copy result [2]	Date/ Lab. No.	Sputum smear micros-copy result [2]	Date/ Lab. No.		Cure	Treatment Complete	Treatment Failure	Died	Default	Transfer			

Footnotes appearing on first page of the register only

1 CAT I patients have follow-up sputum smear microscopy examination at 2 months; CAT II patients have follow-up sputum smear microscopy examination at 3 months. CAT I patients with initial phase of treatment extended to 3 months have follow-up sputum examinations at 2 AND 3 months with results registered in the same box.

2 (ND): Not done; (NEG): 0 AFB/100 fields; (1-9): exact number if 1 to 9 AFB/100 fields; (+): 10-99 AFB/100 fields; (++): 1-10 AFB/ field; (+++): > 10 AFB/ field

3 (Pos): Positive; (Neg): Negative; (I): Indeterminate; (ND): Not Done / unknown. Documented evidence of HIV test performed during or before TB treatment is reported here. Measures to improve confidentiality should accompany recording of HIV status in the TB patient record or registers

4 (Pos): Suggestive of TB, (Neg): Not suggestive of TB; (ND): Not Done.

5 **Tick only one column for each patient:**

Cure: Sputum smear microscopy positive patient who was sputum negative in the last month of treatment and on at least one previous occasion.
Treatment completed: Patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure.
Treatment failure: New patient who is sputum smear microscopy positive at 5 months or later during treatment, or who is switched to Category IV treatment because sputum turned out to be MDRTB. Previously-treated patient who is sputum smear microscopy positive at the end of his re-treatment or who is switched to Category IV treatment because sputum turned out to be MDRTB.
Died: Patient who dies from any cause during the course of treatment.
Default: Patient whose treatment was interrupted for 2 consecutive months or more.
Transfer out: Patient who has been transferred to a health facility in another BMU and for whom treatment outcome is not known.

Form 104: TB-HIV Treatment Referral/Transfer Form

Tuberculosis Treatment Referral/Transfer

(Complete top part in triplicate)

Tick for this referral or transfer: ☐ Referral[1] or ☐ Transfer[2] Date of referral/ transfer _____

Name/address of referring/transferring facility
From sending facility: _____ Sending BMU _____
To receiving facility: _____ Receiving BMU _____

Name of patient _____ Age _____ Sex: ☐ M ☐ F
Address of patient (if moving, future address): _____
_____

Diagnosis:_____

(For Transfer) BMU TB Register No. _____ Date TB treatment started: _____

*CAT I, II, III ☐ Other (CPT, ART etc) : ☐

Drugs patient is receiving _____
_____

Remarks (e.g., side-effects observed): _____

Name / signature of person sending the patient _____
Documented evidence of HIV tests (and results) during or before TB treatment should be reported.

For use by facility receiving referred / transferred patient

BMU _____ Facility _____

BMU TB Register No. _____ Name of patient _____

The above patient reported at this facility on _____ (date)

Name / signature of person receiving the patient _____ Date _____

Return this part to facility sending referred / transferred patient as soon as patient has reported.

[1] **Referral** is the process of moving a TB patient **prior to registration in a *BMU TB Register*** for the purpose of start of treatment (treatment closer to patient's home). The BMU receiving a "referred" patient is responsible to inform the facility sending the patient about the care provided.

[2] **Transfer** is the process of moving **a TB patient registered in a *BMU TB Register*** to continue his treatment in another area with a different *BMU TB Register*. The BMU 'transferring-out' a patient is responsible to report the treatment outcome, after getting the information from the BMU completing the treatment. The BMU receiving a patient 'transferred-in' is responsible for informing the BMU sending the patient 1) of the arrival of the patient, and 2) at the end of the treatment, of the treatment outcome.

Note: A facility referring or transferring large numbers of patients such as large hospitals may use separate forms for referral and transfer and may have a specific register for referrals.

Form 105: Request for Sputum Smear Microscopy Examination Form

Request for Sputum Smear Microscopy Examination

The completed form with results should be sent promptly by laboratory to the referring facility

Referring facility[1] _____ Date _____

Name of patient _____ Age _____ Sex: ☐ M ☐ F

Complete address _____

_____

Reason for sputum smear microscopy examination:

☐ Diagnosis

OR ☐ Follow-up Number of month of treatment: _____ BMU TB Register No. [2] _____

Name and signature of person requesting examination _____

1. Including all public and private health facility/providers
2. Be sure to enter the patient's BMU TB Register No. for follow-up of patients on chemotherapy

RESULTS (to be completed in the laboratory)

Laboratory Serial No. _____

Date collected [3]	Sputum Specimen	Visual appearance [4]	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
	1						
	2						
	3						

3. To be completed by the person collecting the sputum
4. Blood-stained, muco-purulent, saliva

Examined by _____

Date _____ Signature _____

Form 106: TB/HIV Medication Adherence Monitoring Record

TB/HIV Medication Adherence Monitoring Record

Patient name:_____ Registration No. (TB or ART):_____

Counselor's name:_____ Visit date: _____

1. Patient Adherence Report

It can be hard to always take your pills. Since your last visit, have you missed one or more doses of any of your pills? ❑ Yes ❑ No	When did you last miss a dose? ❑ Yesterday ❑ Within the last three days ❑ Within the last week ❑ Within the last month
If yes, how many doses did you miss? ❑ 1 – 2 ❑ 3 – 5 ❑ 5 – 10 ❑ > 10	Did you miss: ❑ One of your pills ❑ Two of your pills ❑ All of your pills

2. Adherence Assessment Methods *(Tick all that apply)*

✓	**Method**
	DOTS/DAART
	Patient verbal self-report
	Pill count: number of pills missed____
	Pharmacy refill records: *Are drug refills on time?* Yes___ No___
	Patient diary
	Other: _____

3. What are the reasons for not taking your pills? *(Tick all that apply)*

- ❑ None
- ❑ Forgot to take
- ❑ Too many pills
- ❑ Too busy to take
- ❑ Felt sick/ill
- ❑ Unable to pay
- ❑ To avoid side effect
- ❑ Ran out of pills
- ❑ Felt depressed/anxious
- ❑ Didn't want to take them
- ❑ Felt well
- ❑ Shared pills with others

4. Have you had any side effects from the pills? *(Tick all that apply)*

- ❑ None
- ❑ Nausea/vomiting
- ❑ Diarrhea
- ❑ Rash
- ❑ Headache
- ❑ Dizziness
- ❑ Fatigue/loss of energy
- ❑ Pain/tingling/numbness in hands or feet
- ❑ Abdominal/back pain
- ❑ Persistent muscle pain/weakness
- ❑ Chills/fever
- ❑ Insomnia
- ❑ Anxiety/depression
- ❑ Other: _____
- ❑ Other: _____

5. Suggest strategies to help adherence

- ❑ Identify reminder aide (e.g., calendar checklist; link to routine activity)
- ❑ Recommend help from family member/friend/"buddy"
- ❑ Provide support
- ❑ Schedule return visit for follow-up counseling in 72 hours
- ❑ Other: _____
- ❑ Other: _____

6. If < than 95% adherence, specify if TB, ART or both missed and report to MO; Report date: _____

7. Notes: *(Continue writing on back of this page if more space is needed.)*

_____

Form 107: Adherence Monitoring Record

Patient name: _____ Registration number: _____

Visit date	Patient or caregiver report	Missed one or more doses	Dose type	# of doses missed	When was last missed dose	# of pills missed	Adherence methods	Reasons for missing doses	Side effects experienced	Strategies suggested	Referrals to MD/CO	Counselor initials
	1=patient report, 2=treatment supporter, 3=caregiver (for child) list name and relationship	1=yes, 2=no	1=TB, 2=ART, 3=both	1=1-2, 2=3-5, 3=5-10, 4=>10	1=yesterday, 2=in last 3 days, 3=in last week, 4=in last month	1=1, 2=2, 3=all	1= DOTS/ DAART, 2= pt verbal report, 3=pill count, 4= diary	1=none, 2=forgot, 3=too many pills, 4=too busy, 5=felt sick, 6=payment, 7=side effects, 8= anxiety or depression, 9=didn't want to take, 10=felt well, 11=shared pills, 12=child refused	1=none, 2=nausea or vomiting, 3=diarrhea, 4=rash, 5=headache, 6=dizzy, 7=fatigue, 8=pain, tingling/numb hands or feet, 9=abd/back pain, 10=muscle pain or weakness, 11=chills/fever, 12=insomnia, 13= anxiety, depression, 14=vision change, 15=decrease hearing, 16=jaundice	1=reminder aide, 2=buddy, 3=provide support, 4=return visit in 72 hours	Refer if <95% adherent or SE manage-ment 1=yes, 2=no	

** Adapted from Family Health International: "SOPs for ART Adherence Counseling" 2005*

Form 108: Quarterly Report on TB Treatment Outcomes and TB/HIV Activities in BMU

Quarterly Report on TB Treatment Outcomes and TB/HIV Activities in BMU

Name of BMU: _____ Facility:_____ Name of TB Coordinator:_____ Signature: _____	**Patients registered during**[1] _____ quarter of year_____ Date of completion of this form: _____

Block 1: TB treatment outcomes

Type of case	Total number of patients registered during quarter *	Treatment outcomes						Total number evaluated for outcomes: (sum of 1 to 6)
		Cure (1)	Treatment completed (2)	Died (3)	Treatment failure [2] (4)	Default (5)	Transfer out (6)	
New sputum smear microscopy positive								
New sputum smear microscopy negative								
New sputum smear microscopy not done								
New extrapulmonary								
Relapse								
Treatment after failure								
Treatment after default								
Other previously treated [3]								

* These numbers are transferred from the *Quarterly Report on TB Case Registration* for the above quarter. Specify any exclusion. _____

Block 2: TB treatment outcomes of HIV-positive patients

Type of case	Total number of HIV-positive TB patients Block 3, Column (a)*	Treatment outcomes						Total number evaluated for outcomes: (sum of 1 to 6)
		Cure (1)	Treatment completed (2)	Died (3)	Treatment failure [2] (4)	Default (5)	Transfer out (6)	
All TB cases								
New sputum smear microscopy pos. TB								

* Of these TB/HIV patients, _____ *(number), specify any exclusion:* _____

Block 3: TB/HIV activities (same quarter analysed as Block 1)

	No. patients tested for HIV 4	No. patients HIV-positive(a) 4	No. patients on CPT 5	No. patients on ART 6
All TB cases				
New sputum smear microscopy positive TB				

1 Quarter: This form applies to patients registered (recorded in the *BMU TB Register*) in the quarter that ended 12 months ago. For example, if completing this form at the close of the second quarter then record data on patients registered in the 2nd quarter of the previous year.
2 Include patients switched to Cat IV because sputum sample taken at start of treatment turned out to be MDRTB.
3 Include pulmonary cases with unknown result of previous treatment, previously treated sputum smear microscopy negative pulmonary cases, or previously treated sputum smear microscopy not done pulmonary cases and previously treated extrapulmonary cases.
4 Documented evidence of HIV tests (and results) performed in any recognized facility before TB diagnosis or during TB treatment (until last day of TB treatment) should be reported here.
5 Includes TB patients continuing on CPT started before TB diagnosis or those started during TB treatment (until last day of TB treatment).
6 Includes TB patients continuing on ART started before TB diagnosis AND those started during TB treatment (until last day of TB treatment).

Form 109: Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test

Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test

The completed form with results should be sent promptly by the laboratory to the referring facility.

Referring facility [1]: _____ Date _____
Name of patient _____ Age _____ Sex: ☐ M ☐ F
Complete patient's address _____
_____

Test(s) requested (check any that are needed):

☐ Smear microscopy ☐ Culture ☐ Drug susceptibility testing

Reason for sputum smear microscopy examination (check one):

☐ Diagnosis

☐ Follow-up Number of month of treatment _____ BMU TB Register number[2]_____

Reason for culture examination: _____
_____

Reason for DST:

_____
_____

Name and signature of person requesting examination:_____

[1] *Including all public and private health facilities/providers*
[2] *Be sure to enter the patient's BMU TB Register No. for follow-up of patients on chemotherapy*

SPUT**U**M SMEAR MICROSCOPY RESULTS (to be completed in laboratory)

Date collected[3]	Sputum specimen	Laboratory serial No.	Visual appearance[4]	Result (check one)				
				NEG	1- 9	(+)	(++)	(+++)
	1							
	2							
	3							

Date _____ Examined by (name and signature) _____

[3] *To be completed by the person collecting the sputum*
[4] *Blood-stained, muco-purulent, saliva*

CULTURE RESULTS (to be completed in laboratory)

Date collected	Specimen	Laboratory serial No.	Result (check one)					Contam-inated
			Neg	(1–9)	(+)	(++)	(+++)	
	1							
	2							

No. growth reported	Neg
Fewer than 10 colonies	Exact number
10 -100 colonies	(+)
More than 100 colonies	(++)
Innumerable or confluent growth	(+++)

Date _____ Examined by (name and signature) _____

DST RESULTS (to be completed in laboratory)

Date collected	Specimen	Laboratory serial No.	S	H	R	E	Z	Km	Am	Cm	Ofx	Pto/ Eto	Other
	1												
	2												

R: Resistant; S: Susceptible; C: Contaminated; ND: Not done

Date _____ Examined by (name and signature) _____

Form 110: TB Treatment Card – Expanded (blue circles indicate expanded section from standard form)

Tuberculosis Treatment Card

BMU TB Register No. _____

Name: _____ _____

Sex: ☐ M ☐ F Date of registration: _____

Age: _____ Health facility: _____

Address: _____

Name / address of community treatment supporter (if applicable)

_____

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0				

Referral by :

☐ Self-referral
☐ Community member
☐ Public facility
☐ Private facility/provider
☐ Other, specify_____

Disease site (check one)

☐ Pulmonary ☐ Extrapulmonary, specify _____

Type of patient (check one)

☐ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other, specify _____

Culture		
Date result	Result *(Neg),(Pos),Nd, contaminated*	Lab No.

DST	
Date:	
Result *(R, S, Nd, contaminated)*	
H	
R	
E	
S	

I. INITIAL PHASE - prescribed regimen and dosages

CAT (I, II , III): ☐

Number of tablets per dose and dosage of S:

(RHZE)	S	Other	Cotrimoxazole	ARV

TB/HIV		
	Date	Result*
HIV test		
CPT start		
ART start		

**(Pos) Positive; (Neg) Negative; (I) Indeterminate; (ND) Not Done / unknown*

Tick appropriate box after the drugs have been administered

Daily supply: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (——●) through the number of days supplied. Ø = drugs not taken

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

II. CONTINUATION PHASE

Number of tablets per dose

(RH)	(RHE)	Other

Daily supply: enter ✓ . Periodic supply, enter X on day when drugs are collected and draw a horizontal line ( ) through the number of days supplied. Ø = drugs not taken

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

X-ray (at start)
Date:
Results *(-), (+), ND*

HIV care	
Pre ART Register No.	
CD4 result	
ART eligibility *(Y/N/Unknown)*	
Date eligibility assessed	
ART Register No.	

Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Treatment outcome
Date of decision ____
☐ Cure
☐ Treatment completed
☐ Died
☐ Treatment failure
☐ Default
☐ Transfer out

Name and address of contact person: _____

Form 111: TB Register in Basic Management Unit using Routine Culture and DST– Expanded (blue circles indicate expanded section from standard form)

TB Register in Basic Management Unit using Routine Culture and DST – Left side of the register book

Date of registration	BMU TB No.	Name	Sex M/F	Age	Address	Health facility[1]	Community support [2]		Date treatment started	Treatment category[3]	Site P / EP	Type of patient [4]					
							Referral for diagnosis	For treat-ment				N	R	F	D	T	O

Footnotes appearing on first page of the register only

1 Facility where patient's treatment card is kept. In case several copies are kept, the most peripheral facility should be entered. Use standardized type of health facilities according to block 2 of the *Yearly Report on Programme Management in BMU*. Health facility is defined as any health institution with health care providers formally engaged in any of the following TB control functions (DOTS): referring TB suspects/cases, laboratory diagnosis, TB treatment and patient support during treatment.

2 Community support is help provided by trained and supervised informal practitioners, a community worker/volunteer, family members, or friends providing services outside of a health institution.

3 Enter the treatment category:

CAT I: New case
CAT II: Re-treatment, e.g., 2(RHZE)S/1(RHZE)/5(RHE)
CAT III: New sputum smear microscopy negative PTB and EPTB e.g., 2(RHZE)/4(RH)

4 Tick only one column:

N=New – A patient who has never had treatment for TB or who has taken antituberculosis drugs for less than 1 month.

R=Relapse – A patient previously treated for TB, declared cured or treatment completed, and who is diagnosed with bacteriological positive TB (sputum smear microscopy positive or culture positive).

F=Treatment after failure – A patient who is started on a re-treatment regimen after having failed previous treatment.

D=Treatment after default – A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 or more consecutive months.

T=Transfer in – A patient who has been transferred from another *TB Register* to continue treatment. This group is excluded from the *Quarterly Reports on TB Case Registration and on Treatment Outcome.*

O=Other previously treated – All cases that do not fit the above definitions. This group includes sputum smear microscopy positive cases with unknown history or unknown outcome of previous treatment, previously treated sputum smear microscopy negative cases, previously treated EP and chronic case (i.e. a patient who is sputum smear microscopy positive at the end of a re-treatment regimen).

TB Register in Basic Management Unit using Routine Culture and DST – Right side of the register book

Results of sputum smear microscopy and other examinations											Treatment outcome & date		TB/HIV activities		Remarks
Before treatment					2 or 3 months [1]		5 months		End of treatment						
Sputum smear micros-copy date/No/ Result[2]	HIV result[3]/ Date	X-ray Result[4]/ date	Culture date/No/ Result [5]	DST date/No/ Result [6]	Sputum smear micros-copy No./ Result[2]	Culture No./ Result[5]	Sputum smear micros-copy No./ Result[2]	Culture No./ Result[5]	Sputum smear micros-copy No./ Result[2]	Culture No./ Result[5]	Date	Outcome in text [7]	ART Y/N Start date	CPT Y/N Start date	

Footnotes appearing on first page of the register only

1 CAT I patients have follow-up sputum smear microscopy examination at 2 months; CAT II patients have follow-up sputum smear microscopy examination at 3 months. CAT I patients with initial phase of treatment extended to 3 months have follow-up sputum smear microscopy examinations at 2 AND 3 months with results registered in the same box.

2 (ND): Not done; (NEG): 0 AFB/100 fields; (1-9): Exact number if 1 to 9 AFB/100 fields; (+): 10-99 AFB/100 fields; (++): 1-10 AFB/ field; (+++): > 10 AFB/ field

3 (Pos):Positive; (Neg):Negative; (I):Indeterminate; (ND):Not Done / unknown. Documented evidence of HIV test performed during or before TB treatment is reported here. Measures to improve confidentiality should accompany recording of HIV status.

4 (Pos): Suggestive of TB; (Neg): Not suggestive of TB; (ND): Not Done.

5 (Pos): Positive; (Neg): Negative; (ND): Not Done.

6 (ResistR): Resistant to Rifampicin; (ResistH): Resistant to Isoniazid; (ResistE): Resistant to Ethambutol; (ResistStrept): Resistant to Streptomycin; (ResistRH): Resistant to Rifampicin and Isoniazid; (Suscept): Susceptible; (ND): Not Done.

7 Write clearly ONE of the following outcomes per patient:

Cure: Patient with culture or sputum smear microscopy positive at the beginning of the treatment who was culture or sputum smear microscopy negative in the last month of treatment and on at least one previous occasion.
Treatment completed: Patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure.
Treatment failure: New patient who is culture or sputum smear microscopy positive at 5 months or later during treatment, or who is switched to Category IV treatment because sputum smear microscopy turned out to be MDRTB. Previously-treated patient who is culture or sputum smear microscopy positive at the end of his re-treatment or who is switched to Category IV treatment because sputum turned out to be MDRTB.
Died: Patient who dies from any cause during the course of treatment.
Default: Patient whose treatment was interrupted for 2 consecutive months or more.
Transfer out: Patient who has been transferred to a health facility in another BMU and for whom treatment outcome is not known.

Part 2. Standard Operating Procedures for Collaborative TB/HIV Care Delivery *(Community-based Guidelines)*

Appendices

SOP 201: TB Infection Control

I. Key Concepts:

- **The community-based health worker has a unique opportunity to help prevent the spread of TB by teaching and monitoring proper implementation of infection control measures practiced in the home during home visits.**
- **Infection control (IC) goal**: to **minimize the risk of TB transmission** by detecting patients with TB disease early, isolating them promptly, and treating people with TB disease quickly to prevent spread of TB to others
- Implement IC along with universal or standard precautions (Part I SOP 105).
- Any pulmonary TB (PTB) patient during the first two weeks of treatment is considered infectious**; PTB patients may spread TB to others via airborne transmission.**
- HIV-infected healthcare workers (HCW) are at increased risk of TB infection and active disease due to frequent exposures to TB suspects and undiagnosed individuals with TB disease.
- A TB patient is considered non-infectious after
  - having 2-3 consecutive negative sputum smears on 2 different days
  - completing at least two weeks of anti-TB therapy
  - completing a diagnostic evaluation or full TB treatment course
- The reference to "TB" in this and other SOPs refers to the spread of *Mycobacterium tuberculosis*, or TB bacilli, that the recommended TB IC measures mean to prevent.

II. Key Personnel: Community health workers (CHWs), RN, patient, family members, administrative staff

III. Materials: Paper tissues, disposable cloth scraps, container with lid, face masks (if available)

IV. Procedures:

A. **Managerial** control measures for administrative staff and all CHWs

1. **Develop a TBIC committee.**
   a. Identify a person with expertise in IC to lead the committee at the community-based site.
   b. Carry out a risk assessment to identify risk of TB transmission to PLHA at the site.
   c. Develop a TBIC implementation plan based on findings from the risk assessment. Include clinic management and staff in creating the IC plan.
2. Develop policies and procedures to ensure proper implementation of plan.
   a. Rethink the use of available spaces and consider renovation of health site.
      (1) Design waiting areas and examination rooms with the most natural ventilation possible.
      (2) Place educational posters about IC measures in outpatient waiting areas, as well as in procedure rooms and other areas where they can be seen and easily read by patients and staff.
   b. Work with local coordinating bodies.
   c. Participate in research efforts.
3. Monitor the TBIC implementation plan.
   a. The lead IC team member regularly supervises and monitors the IC plan; the TBIC steering committee meets annually to assess the plan.
   b. Include civil society involvement, behavioral change campaigns, and reinforcement of a positive message for health workers, patients, and visitors.

4. Schedule annual all-staff training about TB, TB infection control, and the clinic's TBIC implementation plan.

B. **Administrative** control measures for administrative staff and all CHWs
   1. **Promptly identify potential and known infectious cases of TB; separate and treat them with minimal delay.**
      a. Explain to patients that **safety without stigma** is the goal of IC, and that screening for and prevention of TB transmission is part of providing quality care.
      b. At the site, the community-based site RN screens all patients in a well-ventilated area and **identifies people with a cough lasting > 2 weeks** as soon as possible upon arrival to the site.
      c. **If symptomatic, initiate TBIC measures.**
         (1) If face mask is available, give to TB suspect to wear over their mouth and nose.
         (2) Place the person in a separate, well-ventilated area well away from other HIV-infected patients.
         (3) Refer patient immediately for TB testing at the primary health clinic (PHC).
   2. Offer a rapid screening referral mechanism for potential contacts of TB suspects, such as symptomatic patients and visitors accompanying TB suspects.
   3. **Encourage proper cough hygiene.**
      a. Talk with TB suspects and people diagnosed with active TB disease about how they can adhere to proper cough hygiene and etiquette.
      b. Ask the coughing person to **cover their mouth when they cough or sneeze** and practice **handwashing**.
      c. **Provide tissues or disposable cloth scraps**, and instruct patient to cover their mouth and nose when coughing or sneezing.
   4. Encourage safe management of sputum.
      a. Instruct patient to **not clear their throat** and then **spit on the street** or on the ground.
      b. Give patient a container with a lid for receiving sputum, if available, and instruct patient to spit sputum only into the container provided.
      c. If a plastic bag is used to receive sputum, always tie the opening.
      d. Dispose of sputum in a toilet or burn it.
   5. If possible, encourage the TB patient to sleep in a separate bedroom from other family members, especially during the first 2-3 weeks of TB treatment while the cough is present.
   6. Promote proper eating hygiene
      a. Encourage family to use serving spoons during a meal with family and friends.
      b. Ask patient to not share drinking glasses with others.
   7. **Provide all staff intensified screening for TB.**
      a. Periodically screen staff for symptoms of active TB disease.
      b. Schedule all-staff TB testing twice a year (e.g., TST, CXR) in high TB and HIV-prevalence areas.
      c. Document results in the staff member's occupational file.
   8. **In high-burden TB and HIV settings, test all HCWs for HIV in addition to TB.**
      a. Offer staff voluntary, confidential HIV counseling/testing, and annual repeat testing if HIV-negative on previous occasions.
      b. Refer for assessment of and preferential access to ART.
   9. If possible, **do not assign HIV-infected CHWs** to work in high-prevalent TB settings, including
      a. Where patients are assessed for but not yet diagnosed with TB (e.g, health site waiting area)
      b. Performing sputum collection procedures

C. **Environmental** control measures for all CHWs
   1. **Environmental control measures combined with patient practices further reduce TB transmission**.

2. Remind patients that **sunlight is a free anti-bacterial disinfectant.**
    a. Advise patients and household members to open the doors and windows to their bedrooms, allowing the sun to reach inside.
    b. Encourage patient and household members to regularly
        (1) Wash pillowcases and bed sheets and dry them in the sunlight.
        (2) Place their mattresses in the sun.
3. Work with the family to lower the concentration of TB particles in room air, or to move air in the home and replace it with air from outside.
        (1) **Natural ventilation**
            (a) Keep doors and windows on opposite sides of the home open to bring in air from the outside.
        (2) **Mechanical ventilation**
            (a) Use propeller fans, if available, mounted in ceilings or in a window opening to distribute and direct airflow.
            (b) Ensure that the air flows past household members first, then past the coughing patient and out the opposite window.

D. **Respiratory** control measures for administrative staff and all CHWs
    1. **Do not use a face mask** as a TB prevention method when working with TB suspects.
        a. Face masks only reduce transmission from symptomatic persons to others.
        b. The best prevention of TB transmission occurs when TB suspects are diagnosed promptly with TB and started immediately on the correct TB drugs, and when the drugs are taken by patients exactly as prescribed. In these cases, patients usually become non-infectious in a week or two.

SOP 202: TB Symptom Assessment in HIV-infected Individuals

I. Key Concepts:

- TB is the most frequent opportunistic infection (OI) of HIV-infected persons.
- TB demands routine and symptom-based TB screening and testing in HIV-infected individuals.
- Regular TB symptom assessment can lead to early detection of TB.
- Always consider TB in an HIV-infected patient with a cough, or even in the absence of a cough if other symptoms are present.
- **The home-based health worker can detect early signs of TB infection in the household and refer suspects for treatment during home visits.**

II. Key Personnel: Home-based health workers, volunteers, patient, family members

III. Materials: Patient Treatment Card, Patient Referral Form (site standard forms)

IV. Procedures:

A. The home health worker assesses all HIV-infected infants, children, adolescents, and adults for TB at each home visit. Note and record all findings on the Patient Treatment Card.

Infants and children

1. **Evaluate** for **TB symptoms and signs**.
   a. Chronic, progressive cough > 3 weeks
   b. Fever
   c. Night sweats
   d. Weight loss
   e. Failure to thrive
   f. Spinal mass
   g. Distended stomach without stomach pain
   h. Light sensitivity, neck stiffness, bulging fontanelle
   i. Non-painful enlarged joint
   j. **Reported weight loss or failure to gain weight**, especially following nutritional rehabilitation treatment
2. **Assess history.**
   a. **Contacts**
      (1) Ask if the child has had close contact with active or suspected TB patients:
         i. "Is anyone at home ill and what are the symptoms?"
         ii. "Does anyone in the household or someone in regular contact with the child have a chronic cough or other symptoms suspicious of TB?"
         iii. "Does anyone in the home have TB?"
      (2) Ask about the general health of friends, family, caretaker, and specifically the mother if the TB suspect is an infant.

Adults and adolescents

1. **Evaluate** for **TB symptoms**.
   a. **Cough**
      (1) Assess if **≥ 2 weeks**
      (2) Ask if cough is **productive**. If so, ask **if sputum is blood-tinged**.
      (3) Ask if cough wakes patient up at night, occurs more in the morning, or occurs commonly with exercise.

b. Difficulty breathing, chest pain
c. Persistent fever
d. Unexplained weight loss
e. Severe malnutrition
f. Night sweats

2. **Assess history**.
   a. Social history
      (1) Any TB contacts
      (2) General health of friends, family
      (3) Current living situation (e.g., group home, homeless, prison)

B. If the **HIV-infected patient has symptoms of TB**, or **has had contact** with someone with active TB:
   1. Refer patient immediately to the primary health clinic or facility using the Patient Referral Form.
   2. Follow procedures in Part 3 SOP 304 to assist in diagnosis of TB suspect, as needed.

C. If the **HIV-infected patient does not have signs or symptoms of TB**, or contacts with individuals with active TB disease:
   1. Document negative TB assessment **on the Patient Treatment Card.**
   2. Continue TB symptom assessment during each clinical evaluation of HIV-infected individuals, especially if in high-burden TB and HIV areas.

SOP 203: Assisting TB Diagnosis in HIV-infected Individuals

I. Key Concepts:

- Immediate diagnostic action is needed for TB-symptomatic patients.
- Documentation of TB symptom assessment and referral for TB testing is important in the care of HIV-infected individuals.
- **The community-based health worker can help TB suspects complete diagnostic testing procedures in a correct, safe, and timely way.**

II. Key Personnel: Home-based health workers, volunteers, patient, family members

III. Materials: Patient Treatment Card (site standard form), Patient Referral Form (site standard form), Request for Sputum Smear Microscopy Examination Form (Part 1 Form 105), specimen cup, plastic bag, label

IV. Procedures:

A. **The community health worker** assesses HIV-infected infants, children, adolescents, and adults for TB at each home visit (SOP 202).

B. If patient is **symptomatic**, or history is suspicious of TB (e.g., HIV-infected individual has had contact with someone with active TB):
   1. **Initiate** and explain to patient and family TBIC measures (SOP 201).
   2. Refer TB suspect to the nearest primary health center for a diagnostic evaluation.
   3. Identify TB suspect's contacts and refer them for TB screening and diagnosis at the primary health center.
   4. Document outcome of referral on the **Patient Treatment Card**.
   5. Follow up with the household and make sure the referral was completed.

C. **Assist in collecting a sputum specimen**, as trained and requested by health clinic staff.
   1. The TB suspect will need to provide three consecutive sputum specimens; two are collected in the clinic.
   2. If observing or assisting the patient to collect the second specimen in the home:
      a. Collect specimen in a well-ventilated area.
      b. Perform this procedure early in the morning, before the patient eats a morning meal.
      c. Instruct the patient to rinse her mouth with water before producing the specimen.
      d. Instruct the patient to take a deep breath, hold the breath for a few seconds and then exhale slowly; repeat two times.
      e. After the third inhale, instruct the patient to forcefully blow the air out.
      f. Ask the patient to hold the sputum container close to the lips, then breathe in a fourth time, then cough; this should produce sputum from deep in the lungs.
      g. Ask patient to spit sputum gently into the container after the productive cough.
      h. If the sputum coughed up is not enough to send for the test, ask the patient to cough again until a good specimen is in the container.
      i. If the patient cannot bring up sputum from a cough, consider the container used and safely dispose of it.
   3. If successful, once collected in the container:
      a. Cover tightly with the lid.
      b. Clean off any sputum left on the container.

    c. Put the container in a plastic bag and tie the opening tightly. Mark the container and bag with the patient's identification information.
4. Wash hands following this procedure.
5. Complete the Request for Sputum Smear Microscopy Examination Form and keep it with the sputum specimen.
6. Bring the sample and completed Form 105 to the clinic or send the sample and completed form to the lab immediately.
    a. If you cannot send the specimen right away, put the bag in the regular chamber of the refrigerator, not the freezer, of the clinic.
    b. Send the specimen within the week.
    c. Do not keep specimens for longer than one week.
7. Document collection and transfer of sputum to the laboratory on the Patient Treatment Card.

SOP 204: TB and HIV Prevention Education

I. Key Concepts:

- Prevention education for the HIV-infected individual and household members improves quality of life, decreases disease transmission to other household and community members, and decreases stigma surrounding both TB and HIV.
- **The community-based health worker can offer TB and HIV prevention in the household and refer people for treatments or HIV testing during home visits**.

II. Key Personnel: Community-based health workers, volunteers, patient, family members

III. Materials: Patient Treatment Card (site standard form), IEC materials, treatment aids (e.g., Appendix 1 and 2, calendars, pillboxes)

IV. Procedures:

A. Provide education for all HIV-infected infants, children, adolescents, and adults in the household
   1. At each home- or clinic-based visit
   2. Any time a patient, family member, household member, treatment supporter, or other person asks a question about TB and HIV
   3. During events in the community, such as health education promotions and peer support group sessions

B. In all interactions, use a thoughtful, non-stigmatizing communication style to present messages about TB and HIV **co-infection to patients, family members and other household and community members.**
   1. Ensure effective two-way communication between the provider and the patient.
   2. Use a non-judgmental tone when speaking during patient interactions.
   3. Give the patient 100% of your attention during appointments.
   4. When discussing questions related to TB and HIV, show a caring and respectful attitude.
   5. **Praise and encourage** the patient for asking questions and completing milestones throughout the treatment, including:
      a. Completing the initial TB medication phase
      b. Adhering to a TB-HIV medication regimen
      c. Managing mild to moderate side effects of medications and the disease process

C. When discussing TB and HIV in the household, ask questions to **assess the current level of education** about disease among your audience.
   1. First, ask questions to **assess the current level of education about disease**. Provide messages based on the respondent's answers. Following are questions that could be asked by healthcare workers or by patients, and their suggested answers:

      Q: What do you think tuberculosis is? What do you think may have caused you to get TB?

      ***A**: Tuberculosis, or TB, is an illness caused by a germ that is breathed into the lungs. The TB germs can settle anywhere in the body, but most often land and stay in the lungs. When TB hurts or damages the lungs, a person coughs up sputum from the lungs and cannot breathe well. Without the correct medication, a person can die from TB.*

Q: Have you ever known anyone with TB?
What happened to that person?
Do you know that TB can be cured?

***A**: TB can be cured with the correct medication treatment. A patient must take every recommended drug for the entire treatment time to be cured.*
TB drugs are free of charge. Patients do not have to pay for their anti-TB medications.
You can take your TB medications without changing your daily routine or work schedule.

Q: How do you think TB is spread?

***A**: TB spreads from one person to another when an infected person coughs or sneezes and sprays TB germs into the air. When that happens, other people breathe in the germs and may become infected.*
Germs pass easily to family and other household members when many people live together in a close space.
Generally, the TB bacteria is killed in 5 minutes after direct exposure to sunlight and UV light, but it can survive for up to one year in a dark, moist and poorly ventilated area.
Anyone can get TB, but not everyone infected with TB will become sick.

Q: Why do some people, such as HIV-infected people, easily develop TB disease once they are infected with TB?

***A**: HIV infection is the strongest risk factor that makes TB infection progress into TB disease. People with advanced HIV-infection (AIDS) are most at risk for TB disease.*

Q: How can someone avoid spreading TB?

***A:** Take prescribed anti-TB medications on a regular basis (daily, every other day) to become cured of TB.*
Cover the mouth and nose when coughing or sneezing.
Open windows and doors to allow fresh air through the home; use a fan if available.
Use sunlight; dry clothes outside during the morning hours.
Use UV lights, if available.
There is no need to eat special foods if infected with TB and taking anti-TB medications; eat balanced meals.
There is no need to use separate plates, dishes or household items when a family member is on TB treatment.
Do not spit on the ground in the home, outside the home, in the general workplace, or in the community.
Patient should spit sputum into a disposable paper, tissue, or old cloth and discard (e.g., burn, bury, place in toilet or covered garbage receptacle if available).

Q: How many people live with you, and what ages are they?
Does anyone else in your household have a cough? If so, who?

***A**: All children under 5 years of age living in the household should be evaluated for TB symptoms. Children this age are at risk of severe forms of TB. Young children may need preventive medications or referral to a specialist for evaluation.*
Other household members, especially if HIV-infected, need to be tested for TB, especially if they have cough.

Q: Can you explain why it is important that somebody else observes and supports me to swallow my TB and HIV medications?

***A**: A good TB health service should make sure that a patient takes every medicine dose without problems.*
A health worker must watch you swallow all your prescribed TB and HIV drugs according to the prescribed schedule. This will ensure that you take the correct drugs for the correct period of time. If you need to take injections to cure TB, they will be given safely. When a

health worker sees you on a regular basis, the health worker will see if you have side effects or other problems from the drugs and/or disease.
If you do not take all of your prescribed drugs, you will continue to spread TB to others in your family and community, and your TB will not be cured. It is dangerous to stop or take a break from treatment. If you do this, the disease may never be cured. With direct observed therapy, the health worker will know if you miss a dose and will quickly figure out the problem.
If you must travel or move away, tell the health worker so plans can be made to continue your treatment without taking any breaks.

Q: How long should I take anti-TB drugs? Where and how frequent are my clinic visits?

***A**: **Explain** the medication and clinic visit schedule individualized for each patient: **treatment length, visit frequency, where to go for treatment**.*
If preassembled drug boxes are used, explain that all the drugs needed to treat TB (and HIV, if applicable) are kept in a box with the patient's name on it so the clinic will never run out of medications.

Q: What should someone expect when taking the drugs? What should they do next?

***A**: If the patient is **taking rifampicin**, explain that their urine may turn orange/red because of taking the drug. This **color is expected and is not harmful**. If they feel nauseous from the drugs, they should bring a bit of food to eat at the time they take their next dose.*
TB and HIV treatment does not have to interrupt normal life and work.
Be sure that the patient knows exactly where and when to go for the next treatment visit. Ask questions to be sure the patient can make the next scheduled visit and that the patient is committed to return to the clinic.
Remind the patient to bring family, friends, and other close contacts for TB testing.

*Adapted from WHO "Tuberculosis Care with TB-HIV Co-management" 2007

1. Offer motivational statements throughout TB treatment duration (see Text Box 1).
2. Review issues related to HIV and TB.
   a. How TB and HIV are transmitted
   b. How TB and HIV care are interrelated
3. **Support disclosure** of TB and HIV status.
   a. Discuss advantages.
   b. Discuss concerns of disclosure to partner, family members, children, and friends.
      (1) If patient has not disclosed yet, assess readiness to disclose disease status.
      (2) Assess social network; encourage disclosure to the most trustworthy person first.
      (3) Assess social support and needs.
      (4) Reassure that you will keep results confidential.
      (5) Offer another appointment if needed; offer more help as needed, such as peer counselors.

Text Box 1:
Motivational Statements

TB can be cured if you keep coming for the medicine, and then you will not have to worry about it any more.

You only have __ more doses to take every day. After that, you will come less often.

These are the safest, most effective drugs available to treat TB anywhere in the world.

Almost all patients who take their medicines as recommended are cured.

If you keep taking your medicine, you will not spread TB to your family.

Taking only some of the drugs, or taking them irregularly, is dangerous and can make the disease difficult or impossible to cure.

* Adapted from WHO "Tuberculosis Care with TB-HIV Co-management" 2007

4. After finishing the question and answer session, **ask review questions** to make sure the patient fully understood the information discussed.
    a. Make sure the patient knows what to do before leaving the household.
    b. Reinforce earlier messages and give more information as needed.
5. Always ask the patient if she/he has any further questions before completing the appointment.

D. **Document all educational sessions** in the **Patient Treatment Card**.

SOP 205: Making a Referral

I. Key Concepts:

- Early referrals to primary or facility-level health care can improve health outcomes as well as protect other community members from exposure to infectious TB.
- **The home-based health worker can refer any HIV-infected patient or family/household member with early signs of TB infection**.

II. Key Personnel: Home-based health workers, volunteers, patient, family members

III. Materials: Patient Treatment Card (site standard form), Patient Referral Form (site standard form), Request for Sputum Smear Microscopy Examination Form (Part 1 Form 105)

IV. Procedures:

A. **When making any referral, maintain confidentiality** about each patient and protect the confidentiality of the patient's records.

B. Referral process

1. Assist the patient in determining needs and how to best meet those needs.
2. Refer a patient for services based on needs assessed, such as:
   - Acute health care (primary or facility-care level)
   - Education (e.g., preventing TB and HIV transmission)
   - Nutrition
   - Housing
   - Home-based care
   - Economic support/employment
   - Activities of daily living
   - Mental health
   - PLHA association support
   - Social relationships
   - Recreation and leisure
   - Transportation
   - Legal assistance
   - Spiritual support
3. **Make a referral using the appropriate form** and help coordinate delivery of services to meet the patient's needs.
4. **Track referral requests** and follow up to ensure that the patient's needs are met.
5. Maintain a record of meetings with the patient, the referrals made for the patient, and the outcomes of the referrals. Keep this documentation in the patient's record.

C. Specific referral examples

1. When referring patients for care based on clinical symptoms:
   a. Explain the reason for making the referral, such as the noted signs or symptoms of TB or HIV-associated disease.
   b. Make sure the patient understands the urgency level of the referral, which depends on the severity of symptoms. Either:
      (1) Patient needs to go immediately; or
      (2) Patient can go in a few days.

c. Complete a Patient Referral Form and provide a copy to the patient to bring to the referred clinical site.
d. Ensure that the patient knows where to go to complete the referral.
e. Make sure the patient has the means (e.g., transportation) to complete the referral. If not, work with the PHC or other community-based organizations on ways to arrange rides in case of patient emergencies.

2. Laboratory referrals
   a. If a patient has been requested to have labs drawn at the local level:
      (1) Remind the patient to report to the laboratory usually one week before the clinic appointment.
      (2) Ensure that the patient knows how to get to the lab.
   b. If collecting sputum for TB diagnosis or treatment monitoring:
      (1) Follow procedures outlined in SOP 203.
      (2) Complete a Request for Sputum Smear Microscopy Examination Form.
      (3) Bring or send it with the specimen to the lab.
      (4) Follow up with the laboratory for results.
      (5) Document process in the patient's record.

SOP 206: Treatment Follow-up

I. Key Concepts:

- Scheduled follow-up at the community level is essential and can be coordinated together with both the primary and facility-level of healthcare.
- **The community health worker follows up on HIV-infected patients with active TB disease when the patient is treated at the community level on a regular basis**.

II. Key Personnel: Community-based health workers, RNs, MD/CO, volunteers

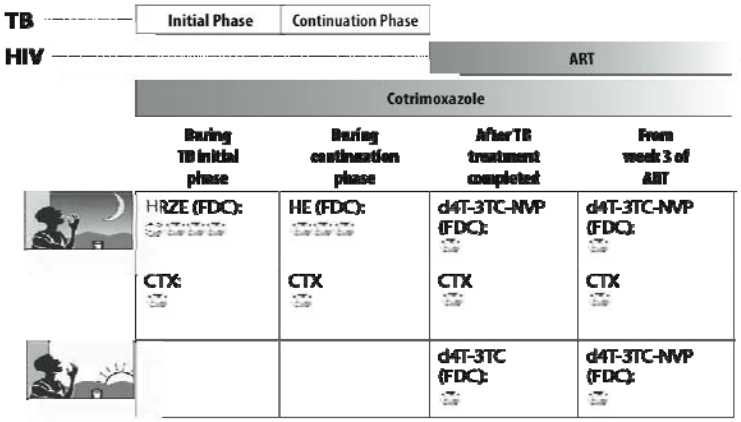
III. Materials: Patient Treatment Card (site standard form), Patient Referral Form (site standard form), Tuberculosis Treatment Card (Part 1 Form 101), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106), Adherence Monitoring Record (Part 1 Form 107)

IV. Procedures:

A. Monitoring **TB regimen** adherence

1. Treatment supporter or clinic/site staff member providing DOT, once determined, meets with the patient to arrange a specific time and place to take medications. Locations could include the home, workplace, or health clinic.
2. Arrive at the designated place on time; **do not make the patient wait.**
3. **When the patient arrives**, or upon meeting the patient:
   a. First, check to make sure the drugs are correct.
   b. Next, observe the patient swallow all the drugs.

Example 1*: When ART starts after TB treatment is complete



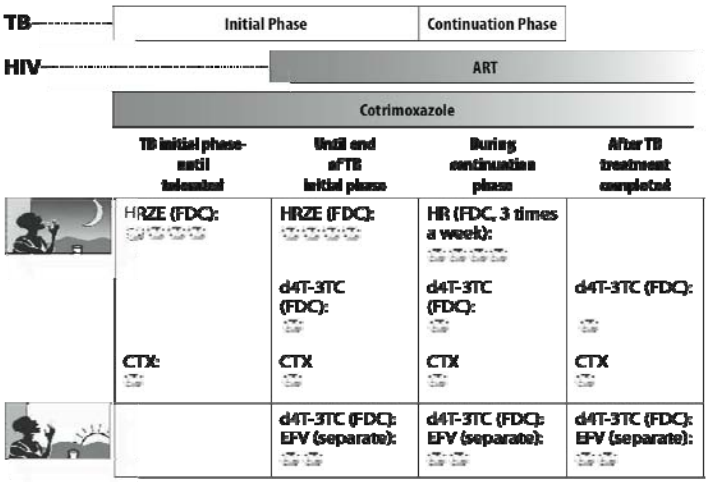
*Source: WHO "Tuberculosis Care with TB-HIV Co-management" 2007

   c. If needed and trained to do so, give the prescribed injection according to protocol.
   d. Document on the treatment card that the patient took the drugs.
4. Ask the patient about clinical symptoms and medication side effects (SOP 207).
5. **If no major symptoms are present, encourage** the patient to continue treatment exactly as prescribed. Praise the patient for completing doses, managing mild to moderate side effects, and keeping scheduled appointments.

6. **If providing DOT at home or workplace**, schedule a time to collect a monthly supply of drugs each month with the site staff RN.
    a. If possible, ask the patient to come to the clinic or schedule the patient's monthly clinic appointment the same day.
    b. Show the RN the treatment card each month when picking up medications.
    c. Review with the RN the patient's adherence and troubleshoot any problems from the past month.
7. **If providing DOT at the clinic site**, schedule time with the RN and patient at the patient's monthly clinic appointment.
    a. Review the treatment card with the RN and patient, if present.
    b. Review the adherence pattern together and troubleshoot any problems from the past month.
8. Document treatment on the Tuberculosis Treatment Card and Adherence Monitoring Record as discussed with the TB treatment-prescribing site RN.
9. Follow up with the TB treatment-prescribing site on a monthly basis to review the patient's adherence with the site's designated RN. Bring the TB Treatment Card and Adherence Monitoring Record for reference.

B. Monitoring **TB/ART** medication regimen adherence
    1. Ensure DOT for **all** infants, children, and adolescents.
    2. DOT is ideal for adults throughout TB treatment period.
    3. The same procedures in Section IV.B above apply to TB/ART adherence monitoring.

Example 2*: Monitoring co-treatment started as soon as TB treatment is tolerated

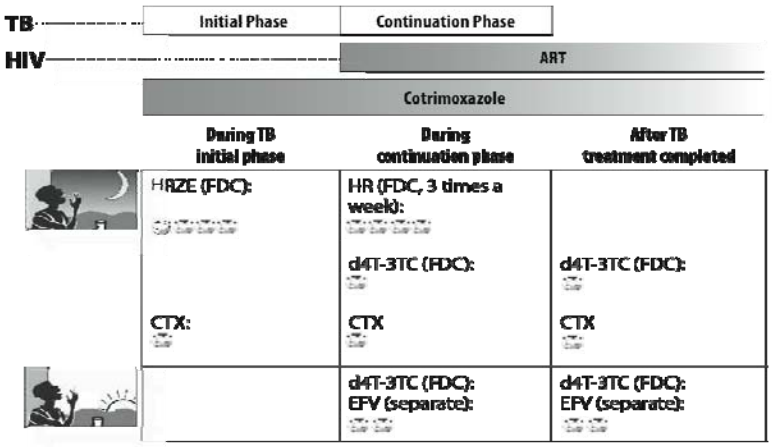


*Source: WHO "Tuberculosis Care with TB-HIV Co-management" 2007

4. Co-treatment may begin:
    a. During the initial phase of TB treatment (Example 2), approximately 2 weeks after the initial phase started so the patient has time to get used to the regimen before starting more medications
    b. After the initial phase is completed, ART can start along with the TB continuation phase regimen (Example 3).
5. DOT may not be sustainable after the end of TB treatment for lifelong ART.
6. **Make your approach with the patient flexible and individualized.**
    a. Observe the patient receiving ART at different intervals, depending on the patient's individual needs:
        (1) Once a week
        (2) Several times a week
        (3) Daily or twice daily

7. **Combine the daily observation of TB treatment with the one ART dose**, preferably in the morning if possible.
    a. Remind the patient about the next unobserved dose(s) of ART and help as able to ensure adherence with ART.
        (1) Lay out the pills.
        (2) Discuss ways that help the specific patient.
        (3) The next day, check whether the patient took the other ART doses.

Example 3*: Monitoring ART started after initial phase of TB treatment



*Source: WHO "Tuberculosis Care with TB-HIV Co-management" 2007

C. **Be aware of the patient's appointments and laboratory schedule** for either TB or TB/ART treatment.
    1. Patient's clinic appointments should be at least monthly, and more frequent depending on other clinical issues or emergent needs.
    2. **If a pulmonary TB patien**t, the patient will need to go to the site, lab, or facility (depending on site resources) for **repeat sputum smear exams. These are usually scheduled three times:** at the end of the initial treatment phase, after 5 months of treatment, and after the last month of treatment.
    3. Make sure the patient goes to the site (or laboratory, per site standard) to have labs checked (e.g., blood or sputum collection) at least a week before the clinic appointment, so that results will be available for MD/CO evaluation.
    4. Attend the patient's clinical and adherence appointments as discussed with the patient and the prescribing site's RN.

D. **Consider travel schedule of both the patient and treatment provider; arrange continued TB or TB/ART treatment.**
    1. Review travel plans at every clinic visit.
    2. If the treatment supporter or patient **travels out of town for a few days**:
        a. Inform each other of travel plans at least 1 week in advance.
        b. Make arrangements for the patient to have exactly enough drugs to self-administer medication for only one week.
        c. **If travel will be longer than one week**, meet with the clinic team to make a plan.
            (1) Reinforce with the patient that treatment cannot stop or pause once started but needs to continue until the end.
            (2) Perhaps consider transferring the patient to a site near the patient's destination if travel will be longer than a few weeks.

d. **Reinforce instructions and drugs** for how to self medicate for a short time.
   (1) Instruct the patient to:
      - Swallow the drugs at the same time each day.
      - Swallow pills with water.
      - Swallow all of the drugs for the day together.
   (2) Point out the number and color of the drugs in each day's packet.
   (3) If patient does not read, arrange for a traveling companion to come to the clinic visit and help with adherence support, if possible.

e. **Ask checking questions** to make sure that the patient understands when and how to take the drugs.

f. If necessary, provide drug supply that lasts up to 2 weeks.

g. **If the patient's drugs are not pre-packaged,** prepare a separate packet of drugs for each day the patient will be gone.

h. **On the patient's Tuberculosis Treatment Card,** mark a tick when you observe treatment. Then draw a line through the days on which the patient will self-administer the drugs.

E. **Missed doses**

1. If the **patient misses one dose**:
   a. **Respond immediately**.
   b. If a patient **takes medication at home or work**:
      (1) Return the next day and ask the reason for the missed dose; problem solve so doses are not missed again in the future.
      (2) Give the next scheduled dose.
      (3) Extend the treatment by the missed dose day.
      (4) If unable to find the patient or the patient refuses the medication, contact the clinic site the same day for help.
   c. If this is a patient who **takes medication at the clinical site**:
      (1) Visit the patient's home within 24 hours.
      (2) Ask the reason for the missed dose.
      (3) Give the next scheduled dose.
      (4) If unable to find the patient or the patient refuses the medication, make an urgent appointment for the patient to see the MD/CO in the clinic for further support and evaluation.
2. **If a patient misses doses or appointments, work with the RN to schedule a home visit** to find out barriers to proper TB/HIV care and treatment.
   a. Do **not** give an extra dose on any day.
   b. **Ask specific questions** about adherence in a non-judgmental way (e.g., avoid "why" questions):
      (1) What happened that you missed your appointment?
      (2) What happened that you missed taking your medication?
   c. **Listen to the patient's answers** to figure out the barriers to treatment adherence.
      (1) Attitudes of the health clinic staff
      (2) Waiting time at the health clinic
      (3) Transportation
      (4) Work or family commitments
      (5) Side-effects of treatment
      (6) Other health problems
   d. Work together to solve identified problems:

Example reasons for missed doses:	Possible solutions:
Coming to the health facility is inconvenient.	• Identify a convenient community TB treatment supporter.
Patient dislikes coming to the health facility because of the long queue.	• Make arrangements so that TB patients do not have to wait in a queue. For example, let them enter through a back or side door.
Supervisor at work kept the patient late.	• Offer to talk with the supervisor and explain the importance of the treatment, or identify a community TB treatment supporter at work.
Patient had troublesome side-effects.	• Give appropriate advice or remedies for side-effects (Appendix 4, 5); refer the patient if necessary.
Patient had difficulty swallowing because of pain (this could be oral thrush).	• Use IMAI Acute Care or IMAI Palliative Care to classify and provide treatment or to refer patient as necessary.
Patient cannot leave small children at home and is tired of bringing them to the health facility.	• Discuss with the patient other childcare solutions (e.g., support group members, church members). • Remind family members/neighbors that the patient must continue treatment to protect their health, particularly the health of the children. • If possible, identify a community TB treatment supporter closer to the patient's home.

F. Work **with the patient, treatment supporter, family, friends, and household members to motivate** the patient during conversations.
   1. **Use correct statements*** about taking prescribed treatment:
      a. "TB can be cured if you keep coming for the medicine, and then you will not have to worry about it any more."
      b. "You only have __ more doses to take every day. After that, you will come less often."
      c. "These are the safest, most effective drugs available to treat TB anywhere in the world."
      d. "Almost all patients who take their medicines as recommended are cured."
      e. "If you keep taking your medicine, you will not spread TB to your family."
      f. "Taking only some of the drugs, or taking them irregularly, is dangerous and can make the disease difficult or impossible to cure."

      ** Adapted from WHO "Tuberculosis Care with TB-HIV Co-management" 2007*

   2. Show photos (if available and permission provided) of patients with TB and HIV co-infection before and after TB treatment. Photos show that despite HIV infection, TB is curable and these patients – despite difficulties – were cured

G. If a patient **misses doses or appointments for longer than a month, attempt to find the patient**.
   1. **First**, find their location using family members, friends or other community resources.
   2. **Once the patient is traced** and contacted, work with the RN to meet **immediately with the patient** in the clinic, if possible.
   3. The RN ensures the patient's health status is stable, then arranges with the MD/CO to collect 2-3 sputum samples (SOP 203).
   4. Together, discuss the reason the patient stopped treatment.
   5. As a team, **determine the cause of the treatment interruption** and work together with the patient to find ways to prevent future treatment interruption. If found that the **patient plans to move to another place permanently or for a prolonged period of time**, work with clinic staff to help the transition of care.

6. If **treatment interruption has been for 1-2 months**:
    a. The MD/CO restarts the patient's TB treatment and provides prescriptions for other medications, as needed, while waiting for sputum results.
    b. Assist with sputum collection, as needed (SOP 203).
7. **If the treatment interruption has been 2 months or longer**, the patient is considered a treatment defaulter. Wait for return of sputum results to restart treatment regimen.

H. Monitoring **IPT** medication adherence
1. IPT does not require daily medication monitoring.
2. Monitor medication adherence, clinical status, and medication side effects at regularly scheduled visit,
    a. Refer to Appendix 2 for monitoring of isoniazid-related side effects,
    b. Document findings on Patient Treatment Card,

SOP 207: Monitoring Treatment in TB- and HIV-infected Individuals

I. Key Concepts:

- The follow-up schedule discussed in SOP 206 ensures monitoring of medication adherence, early clinical symptoms related to TB and HIV disease, and side effects from anti-TB and HIV treatments.
- **The community health worker not only observes medication adherence in HIV-infected patients with active TB disease in the home, but also identifies early warning signs, which improves patient outcomes.**

II. Key Personnel: Home-based health workers, RN, MD/CO, volunteers, patient, family members

III. Materials: Patient Treatment Card (site standard form), Patient Referral Form (site standard form), Tuberculosis Treatment Card (Part 1 Form 101)

IV. Procedures:

A. Monitoring medication side effects of TB

Infants and children on anti-TB therapy

1. If present, document onset, duration, and severity, and refer immediately. Children typically have fewer adverse reactions than adults to anti-TB therapy.

Sign/symptom	Management
Abdominal tenderness Yellowing of the eyes (jaundice)	• Instruct child/parent to stop all hepatotoxic medications. • Refer child immediately to facility-level care.
Burning pain in the feet and/or hands (peripheral neuropathy)	• Refer patient to primary health level for pyridoxine prescription.

2. Document side effect, referral, and response in the **Patient Treatment Card**, the **Tuberculosis Treatment Card** and the **Patient Referral Form**.

Adults and adolescents on anti-TB therapy

1. **For major side effects:**
   a. If you are the DOT caregiver, do not give the TB medication if any of the following symptoms occur:
      - **Skin rash, itching**
      - **Hearing loss, deafness** (after starting TB drugs)
      - **New dizziness, balance loss, vertigo**
      - **Shaking/wobbling of eyes**
      - **Yellowing of the eyes**
      - **Continued vomiting**
      - **Confusion**
      - **Visual changes** (other causes excluded)
      - **Red or purple marks on the skin** that do not disappear when pressure is applied
   b. Tell the patient the anti-TB drugs will be stopped for evaluation.
   c. Immediately refer patient to facility-level care for an emergency appointment.
   d. Document referral on the Patient Treatment Card and Patient Referral Form.

2. For minor side effects:
   a. Continue anti-TB drugs.
   b. Observe whether patient is taking the correct drug dose.
   c. Encourage patient to report all minor symptoms but continue home-based management (see table).

Symptom	Management
Loss of appetite, nausea, stomach pain	• Encourage patient to eat a small snack with the tablets. • For patients who do not have food to eat, refer to NGO or welfare service for food support. • Suggest taking the drugs at bedtime. • If nausea continues, refer the patient for an clinic appointment. • Document referral on the treatment card.
Joint pains	• Give aspirin.
Burning pain in hand/feet	• Make sure patient takes prescribed pyridoxine 100 mg daily. • If patient is not prescribed pyridoxine, refer patient to the site for the soonest appointment.
Orange/red urine	• Reassure patient. • Explain that this is a normal finding when taking Rifampicin.

   d. Document response to home-based management on the **Patient Treatment Card.**

B. **Monitoring** of HIV-infected patients of all ages taking **both TB treatment and ART**
   1. Evaluate onset, duration, and severity of each specific symptom.
   2. Determine if presentation requires home management or referral to primary- or facility-level health care.

Symptom	Management
Fatigue	• Inform patient that symptom can last 4-6 weeks then go away. • **Refer patient to facility if fatigue is severe** and lasts longer than 4-6 weeks.
Burning pain in hands/feet	• Make sure patient takes prescribed pyridoxine 100 mg daily. • If **pain is unrelieved, refer patient to primary health care level.**
Yellowing of eyes	• **Do not** administer TB/ART. • Instruct patient to stop all drugs. • Refer immediately to facility-level care.
Diarrhea with abdominal pain	• Offer symptomatic treatment, if mild (Appendix 1). • Make sure patient tolerates fluids. • Instruct patient to try a bland diet. • If just started ART, encourage patient that diarrhea may stop in a few more days. • **Refer patient to primary healthcare level (PHC) if symptom persists and patient becomes dehydrated.**
Skin rash (Usually an early side effect)	• If rash is **peeling** or **all over the body, refer patient immediately** to facility. • If rash is **wet or persists, refer patient to PHC** level for assessment. • If mild, offer symptomatic treatment (Appendix 1).
Anxiety, nightmares	• Usually unrelated to TB medications • If on EFV, ensure EFV is given at night. • Explain that these symptoms usually end 3 weeks after starting EFV. • If patient shows signs of **severe depression, suicidal thoughts, or psychosis, ensure the patient's safety** and **refer immediately to facility.**

Balance loss, dizziness (Early or late side effect) Change in pallor with weakness and fatigue (Usually an early side effect) Fever Worsened cough, difficulty breathing New, swollen lymph nodes Persistent vomiting	**Refer to facility-level care**

3. For symptomatic management of moderate medication-related symptoms that can be managed from the home, monitor and manage closely (e.g., daily, or weekly).
4. **Document** the **home-based management and response** on the Patient Treatment Card and Tuberculosis Treatment Card.
5. **If a referral for primary- or facility-level care is made**, document on the Patient Treatment Card and Patient Referral Form and follow up to make sure the referral was completed and issues were addressed.

SOP 208: Recording and Reporting

I. Key Concepts:

- The quality of patient care and program effectiveness are measured by the recording and reporting process.
- Recording and reporting data on forms documents the patient's health status and adherence with medications, clinic visits, referrals, and laboratory requests.
- National programs and funding agencies can review and summarize reporting forms to measure the quality of an organization's service provision to community members.
- **The community health worker records data from clinic or home visits on required forms and submits them on a regular basis**.

II. Key Personnel: Community-based health workers, RN, volunteers, data management staff

III. Materials: Patient Treatment Card (site standard form), Patient Referral Form (site standard form), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106), Adherence Monitoring Record (Part 1 Form 107)

IV. Procedures:

A. Record data collected during each interaction with the patient, using the appropriate form.
   1. Patient Treatment Card
   2. TB/HIV Medication Adherence Monitoring Record, Adherence Monitoring Record
   3. Patient Referral Form

B. Submit completed forms on a monthly basis to the data management staff member or RN to keep in the patient's main record.

C. Ensure confidentiality of patient information captured on forms at the community-based site.
   1. Use filing cabinets that lock, if available.
   2. Keep all data in a room that locks; limit access to the key.
   3. If computers are used, install data management programs with high security.

D. The community-based site appoints someone to collect and review forms on a monthly basis.
   1. Discuss and reconcile any noted discrepancy with the individual who completed the form.
   2. Prepare report on a monthly or quarterly basis.
   3. Share results of report with community-based organization staff.

E. Report TB-related activities to NTP representative as coordinated with the TB medication-prescribing site.

Appendices

Appendix 1: Mild Symptom Management Educational Aid

Mild side effects: Monitor and manage at each clinical visit; encourage home-based management.

Symptom	Strategies to Manage
Headache	o Give aspirin, paracetamol, NSAIDS. o Assess for signs/symptoms of meningitis (e.g., neck stiffness, sensitivity to light). If suspected, refer patient to facility for evaluation and treatment. o If meningitis is ruled out, and patient is on AZT or EFV, encourage patient to continue treatment until the common side effect stops. o Provide supportive care and continue follow-up. o Have patient decrease activity and rest in a quiet, dark room with eyes closed. o Place cold moist cloth over patient's eyes. o Encourage patient to stay out of the sun and decrease exposure to light. o Encourage patient to stay hydrated: drink boiled water; avoid caffeine (coffee, tea, carbonated soft drinks) and alcohol. o Have patient avoid foods and other stimuli that trigger headaches.
Nausea, vomiting, or loss of appetite	o Give INH at bedtime. o Have patient take medicine with food (except if taking DDI, IDV). o If on AZT, encourage patient to continue until this common side effect stops. o Encourage patient to stay hydrated: drink boiled water, and peppermint or ginger tea. o Encourage patient to eat small, bland snacks throughout the day, such as bananas, white rice, toast, applesauce, porridge, and potatoes. o Avoid foods and smells that trigger nausea/vomiting or decrease appetite, such as spicy, greasy, or acidic foods (oranges, tomatoes). o For nausea/vomiting: Drape a comfortably warm moist towel around the neck until the nausea/vomiting subsides.
Diarrhea	o Stay hydrated: drink boiled water or weak tea. o Don't stop eating, but avoid foods and fluids that can increase diarrhea, such as fruits, vegetables, milk products, high fat foods, and very sweet foods. o Eat bland foods, such as white rice and porridge. o Maintain good hygiene: Wash hands after going to the bathroom, before and after eating, before and after handling any food. o *Gently* clean skin around rectal area after each episode of loose stool.
Mild tingling, burning, or pain in hands or feet	o Give pyridoxine 100mg daily. o Call for advice if pyridoxine fails. o Wear loose-fitting shoes or sandals. o Walk around to help blood circulation to the feet, but not too much. o Soak hands or feet in the coldest water that can be tolerated. o Gently massage hands or feet. o Keep hands and feet uncovered in bed.
Insomnia	o Reduce noise and light: sleep in a quiet, dark room. o Avoid exercise and other energetic activity several hours before bedtime. o Avoid eating a large meal 3-4 hours before bedtime. o Avoid drinking fluids with caffeine at least four hours before going to bed (coffee, tea, carbonated soft drinks). o Avoid drinking alcohol. o Consciously relax muscles, especially in shoulders, arms and legs. o Perform quiet activities that usually make you sleepy, such as listening to soft music.
Dizziness	o Change positions very slowly (for example, from lying down to sitting). o Use nearby furniture and walls for support if dizziness occurs when walking. o Ask family members and friends for support if intense dizziness occurs when walking. o Stay hydrated: drink boiled water and fluids without caffeine. o Avoid alcohol.
Bad dreams	o Talk about your dreams with a family member or friend. o Recognize that dreams are imagination and are not real.

Symptom	Strategies to Manage
Confusion/difficulty concentrating	o Talk about your feelings of confusion or difficulty concentrating with a family member or friend. o Ask a family member or friend to clarify what confuses you. o Focus on one activity or thought at a time.
Mild rash	o Bathe with unscented mild soap (for example, oatmeal). o Avoid bathing in extra hot water. o Protect the skin from sun exposure. o Don't scratch your skin.
Joint pains	o Give aspirin, paracetamol, NSAIDS.
Blue/black nails	o This is unrelated to TB medications. o Explain that this is a normal finding for people taking AZT.
Changes in body fat	o This is unrelated to TB medications. o Explain that this is a normal finding. o Discuss whether patient can accept this body image change.

Appendix 2: TB Drug Information and Monitoring Guide

TB Drug Information and Monitoring Guide

Drug	Dose	Use	Side Effects for Patient Monitoring	Side Effects for Referral to Secondary or Tertiary Facility
Pyrazinamide (PZA)	o Active TB (induction): 20-25mg/kg (max 2gm) daily o DOT dose changes for 2x/week and 3x/week dosing o If CD4 < 100, dose DOT 3x/week	o New TB: smear (+), smear (-), EP, smear (-) relapse o TB smear (+) retreatment: treatment failure, treatment after default, smear (+) relapse o MDR-TB	o Joint pain o Nausea, vomiting o Stomach discomfort	o Severe stomach pain o Severe joint pain o Persistent vomiting o Yellowing of eyes
Rifampicin (RIF)	o Active and latent: 10 mg/kg (max 600mg) daily o DOT: 600mg 2-3x/week o If CD4 < 100, dose DOT 3x/week o With LPV/r: LPV/r 400/100mg (3 caps) + RIF 300mg bid o With EFV: EFV 800mg + RIF 600mg daily	o TB treatment o Latent TB o Contraindicated with all PIs except LPV/r	o Orange discoloration of urine, tears, sweat o Nausea, vomiting o Stomach discomfort o Signs/symptoms of hepatitis in first month o Flu-like symptoms (fever, chills dizziness, bone pain, generalized itching)	o Hypersensitivity o Bleeds easily o Change in pallor o Headache o Dizziness o Yellowing of eyes
Isoniazid (INH) *Co-administer with pyridoxine 50mg/day or 100mg 2x/week to prevent neuropathy*	o Active and latent: 5 mg/kg (max 300mg) daily o DOT: 15mg/kg (max 900mg) 2-3x/week o If CD4 < 100, dose DOT 3x/week o Give drug 1 hour before or 2 hours after meals	o Active TB treatment o Latent TB	o Nausea, vomiting, diarrhea o Stomach discomfort o Burning sensation in hands and feet o Joint pain	o Hypersensitivity o Signs/symptoms of hepatitis o Bone marrow suppression o Fever o Vision changes o Rash, exfoliative dermatitis, itching, swelling o Psychosis o Jaundice
Ethambutol (EMB)	o 15-20 mg/kg (max 2 grams) daily o DOT: 50 mg/kg 2x/week (max 4 grams) or 25-30 mg/kg 3x/week (max 2.4 grams) o If CD4 < 100, dose DOT 3x/week	o New TB: smear (+), smear (-), EP, smear (-) relapse o TB smear (+) retreatment: treatment failure, treatment after default, smear (+) relapse o MDR-TB	o Anorexia o Nausea, vomiting o Stomach discomfort o Vision changes: decreased acuity, decreased color vision, constricted visual fields, blind spots	o Bleeds easily o Neutropenia o Swollen lymph nodes o Burning sensation in hands and feet o Confusion o Dizziness o Rash, itching, dermatitis, exfoliative dermatitis o Acute gout
Streptomycin	o 15 mg/kg (usually 1 gram) intramuscular (IM) injection daily o If > 50 years old, 10 mg/kg (usually 750mg) daily o DOT: 25-30 mg/kg IM 2-3x/week o If CD4 < 100, dose DOT 3x/week	o Second-line treatment o Added during TB smear (+) retreatment: treatment failure, treatment after default, smear (+) relapse o MDR-TB	o Rare	o Low urine output o Vision changes: decreased acuity, decreased color vision, constricted visual fields, blind spots o Hearing changes o Neuromuscular blockade o Changes in mental status

Source: WHO ""Treatment of Tuberculosis: Guidelines for National Programmes Third Edition" 2003; Johns Hopkins University Antibiotic Guide accessed online http://prod.hopkins-abxguide.org/antibiotics 2009; WHO: Guidelines for the programmatic management of drug-resistant tuberculosis Emergency update 2008. 2008.

Appendix 3: Common Antiretroviral Drug Guide

Drug	Dose	Formulation	Comments
Zidovudine (AZT)	o 300 mg bid	o Syrup: 10 mg/ml o Capsules: 100 mg; 250 mg o Tablet: 300 mg	o Large volume syrup not well tolerated in older children o Needs storage in glass jars; is light sensitive o Can give with food o Do not give with d4T. o Dose = 600 mg/m^2 bid in HIV encephalopathy
Stavudine (d4T)	o > 60 kg: 40 mg bid o < 60 kg: 30 mg bid	o Oral solution: 1 mg/ml o Capsules: 15 mg, 20 mg, 30 mg, 40 mg	o Large volume solution o Keep solution refrigerated; stable for 30 days o Must shake well before administration o Store in glass bottles. o Can open capsules and mix with food – well tolerated (stable in solution for 24 hours if kept refrigerated) o Do not use with AZT.
Lamivudine (3TC)	o 150 mg bid	o Oral solution: 10 mg/ml o Tablet: 150 mg	o Well tolerated o Can give with food o Store solution at room temperature (use within one month of opening). o Tablet can be washed, mixed with a small amount of water or food, and taken immediately.
Abacavir (ABC)	o 300 mg bid	o Oral solution: 20 mg/ml o Tablet: 300 mg	o Syrup well tolerated or can crush tablet o Can give with food o WARN patient about hypersensitivity reaction. o Stop and never restart if patient experienced hypersensitivity reaction to ABC.
Tenofovir (TDF)	o 300 mg daily	o Tablet: 300 mg	o Well tolerated o Can take with or without food
Efavirenz (EFV)	o Capsule (liquid) dose for > 3 years: 10-15 kg: 200 mg (270 mg = 9 ml) once daily o 15-20 kg: 250 mg o (300 mg = 10 ml) once daily o 20-25 kg: 300 mg (360 mg = 12 ml) once daily o 25-33 kg: 350 mg (450 mg = 15 ml) once daily o 33-40 kg: 400 mg (510 mg = 17 ml) once daily o Maximum dose: >40 kg: 600 mg daily	o Syrup: 30 mg/ml (note: syrup requires higher doses than capsules) o Capsules: 50 mg, 100 mg, 200 mg	o Capsules may be opened and added to food by have very peppery taste; however can mix with sweet foods or jam or disguise taste. o Can give with food but avoid high-fat meals which increase absorption by 50%. o Best if given at bedtime, especially for the first 2 weeks of administration. o Watch for drug interactions. o Only for children > 3 years

Drug	Dose	Formulation	Comments
Nevirapine (NVP)	o 15-30 days: 5 mg/kg once daily for 2 weeks, then 120 mg/m^2 bid for 2 weeks, then 200 mg/m^2 bid o > 30 days to 13 years: 120 mg/m^2 once daily for 2 weeks, then 120-200 mg/m^2 bid o Maximum dose: >13 years: 200 mg daily for 14 days, then 200 mg bid	o Oral suspension: 10 mg/ml o Tablet: 200 mg	o Avoid co-administration with Rifampicin. o Store suspension at room temperature; shake well. o Can give with food. o MUST warn about rash; do not escalate dose if rash occurs. o Drug interactions exist.
Nelfinavir (NFV)	o <1 year: 40-50 mg/kg tid or 75 mg/kg bid o >1 year to < 13 years: 55 to 65 mg/kg bid o Maximum dose: 1250 mg bid	o Powder for oral suspension (mix with liquid): 200 mg per level 5 ml teaspoon (50 mg per 1.25 ml scoop) o Tablet: 250 mg (tablets can be halved; can be crushed and added to food or dissolved in water)	o Powder is hard to dissolve; must be reconstituted immediately prior to administration in water, milk, formula, pudding, etc. Do not use acidic food or juice (increases bitter taste). o Because of difficulties using powder, crushed tablets are preferred (even for infants) if appropriate dose can be given. o Powder and tablets can be stored at room temperature. o Take with food. o Drug interactions exist (less than with the RTV-containing PIs).
Lopinavir / Ritonavir	o >6 months to 13 years: 225mg/m^2 LPV/57.5 mg/m^2 RTV bid o or weight-based dosing: o 7-15 kg: 12 mg/kg LPV 3 mg/kg RTV bid o 15-40 kg: 10 mg/kg LPV 2-5 mg/kg RTV bid o Capsules o Maximum dose >40 kg: 400 mg LPV/100 mg RTV (3 capsules or 5 ml) bid o Tablets o Treatment-naïve 2 tablets bid (400/100 mg bid) regardless of co-administration with EFV or NVP o Treatment-experienced: 3 tablets bid (600/150 mg bid) when combined with EFV or NVP	o Oral solution: 80 mg/ml LPV plus 20 mg/ml RTV o Capsules: 133.3 mg LPV plus 33.3 mg RTV o Tablet: 200 mg LPV plus 50 mg RTV	o Preferably oral solution should be refrigerated, however can store at room temperature for up to 25 C (77 F) for 2 months. o Heat stable tablets can be stored at room temperature. o Liquid formulation has low volume but bitter taste. o Capsules are large. o Take with food. o Drug interactions exist.

Drug	Dose	Formulation	Comments
Indinavir / Ritonavir (IDV/r)	o 800 mg/100 mg bid o Other doses include: 800/200 mg bid, or 400/100 mg bid	o Capsule: 200 mg IDV, 400 mg IDV (RTV separate)	o Take with water. o Drink plenty of fluid throughout the day while on this medication, preferably 6 8-ounce glasses a day to prevent kidney stones. o Can take with or without food (light meal preferred) o Avoid taking medicine at the same time as eating any foods high in fat, calories or protein.

Source: WHO "TB/HIV: A Clinical Manual, Second Edition" 2004.

Part 3: Standard Operating Procedures for Collaborative TB/HIV Care Delivery *Primary Healthcare Level Guidelines*

Appendices

SOP 301: TB Infection Control

I. Key Concepts:

- The TB infection control (IC) goal **is to** minimize the risk of TB transmission by **detecting patients with TB disease early, isolating them promptly, and treating them quickly to prevent the spread of TB to others.**
- Every health center should **have or develop an IC implementation plan** that describes appropriate activities and measures for the health center, including four control levels: managerial, administrative, environmental, and respiratory.
- Implement IC along with universal or standard precautions (Part I SOP 105).
- HIV-infected healthcare workers (HCW) and support staff are at increased risk of TB infection and active disease because of frequent exposure to TB suspects and undiagnosed individuals with TB disease in the workplace.
- Any pulmonary TB (PTB) patient during the first two weeks of treatment is considered infectious**; PTB patients may spread TB to others via airborne transmission.**
- The reference to "TB" in this and other SOPs refers to the transmission or spread of *Mycobacterium tuberculosis*, or TB bacilli, that the recommended TBIC measures mean to prevent.
- A TB patient is considered non-infectious after:
  - having 2-3 consecutive negative sputum smears on two different days while on TB treatment
  - completing at least two weeks of correct anti-TB therapy
  - completing a diagnostic evaluation or full TB treatment course

II. Key Personnel: MD, CO, RN, patient, family members, health workers

III. Materials:

- Face/surgical masks: Help prevent TB transmission from the patient wearing the mask to others by capturing the large wet particles near the mouth and nose
- Paper tissues: Less costly; lower stigma as tissue use does not readily mark one as a TB suspect; less likely to be used correctly

IV. Procedures:

A. **Managerial** control measures

1. **Develop a TBIC Steering Committee**.
   a. Identify a person with expertise in IC, planning, architecture, and engineering to lead the team.
   b. Carry out a risk assessment to identify risk of TB transmission to PLHA in the clinic.
2. Develop policies and procedures to ensure proper implementation of controls.
   a. Rethink the use of available spaces and consider renovation of the health center, as able, to optimize the implementation of IC measures.
   b. Design waiting areas and examination rooms with the most natural ventilation possible.
   c. Develop a TBIC Implementation Plan based on findings from the risk assessment.
   d. Include clinic management and staff in creating a feasible IC plan. A sample plan is presented as an Annex in the Addendum to *WHO Guidelines for the Prevention of Tuberculosis in Health Care Facilities in Resource-Limited Settings, 1999.*
   e. Work with local coordinating bodies (including human resources) in the development and implementation of TBIC.
   f. Participate in research efforts to improve the TBIC plan.

3. Monitor the TBIC implementation plan.
    a. The lead IC team member regularly supervises and monitors the IC plan; the TBIC steering committee meets annually to assess the plan.
    b. Include civil society involvement, behavioral change campaigns, and reinforcement of positive messages for health workers, patients, and visitors.
4. Schedule annual all-staff training about TB, TB infection control, and the clinic's TBIC implementation plan.

B. **Administrative** control measures for administrative staff and all HCWs
    1. **Promptly identify potential and known infectious cases of TB; separate and treat them with minimal delay**.
    2. **Triage and screening**
        a. Promote **safety without stigma**.
            (1) Educate patients and health workers on proper cough etiquette and cough hygiene.
            (2) Place educational posters about IC measures in outpatient waiting areas, as well as in procedure rooms and other areas where they can be seen and easily read by patients and staff.
        b. The triage RN screens all patients in a well-ventilated area and **identifies people with a cough lasting > two weeks** as soon as possible upon arrival to the clinic.
        c. Explain to patients that **safety without stigma** is the goal of IC, and that screening for and prevention of TB transmission is part of providing quality care.
        d. **If patient is symptomatic, initiate TBIC measures**.
    3. **Encourage proper cough hygiene**.
        a. Work together to help patients adhere to proper cough hygiene and etiquette.
        b. Ask the coughing person to **cover their mouth when they cough or sneeze** and to practice **handwashing**.
        c. **Provide face masks, tissues, or disposable cloth scraps** to cough suspects for immediate use.
            (1) If face mask is available, give to TB suspect to wear over their mouth and nose until they leave the clinic.
            (2) If tissues or cloth scraps are available, instruct TB suspect to cover their mouth and nose when coughing or sneezing.
    4. **Place TB suspects in a separate or designated area.**
        a. Follow diagnostic protocols (SOPs 303 and 304) in an outpatient setting whenever possible.
        b. Place the person in a separate, well-ventilated area or room well away from other HIV-infected patients.
        c. **Expedite** the patient's receipt of **outpatient clinic services**; if possible, the RN should fast-track TB suspects to receive care and attention from the MD/CO.
            (1) **Move suspects to the front of the queue** for whatever services they require (e.g., medication refills, medical evaluation).
            (2) When the RN or lab staff collects sputum samples for TB, **collect the specimen outside in a designated procedure room or an open environment**, away from other people.
                (a) Do not collect sputum samples in enclosed spaces such as small rooms, bathrooms, or toilets.
        d. **Wash hands** between each patient interaction (Part 1 SOP 105).
    5. Ensure **rapid diagnosis process and initiation of treatment**.
        a. Follow up on sputum smear and culture results from laboratory daily. Turnaround time for sputum acid-fast bacilli (AFB) is no longer than 24 hours.
        b. Evaluate chest X-ray (CXR) results as soon as they are available.
        c. Monitor TB suspect frequently for symptomatic improvement.
        d. Provide diagnosis and treatment plan to patient and family.
        e. Implement daily directly observed therapy (DOT).

f. **Initiate isoniazid preventive therapy** (IPT) in HIV-infected individuals who definitively **do not have active TB disease** (SOP 307).

6. Offer a rapid screening mechanism for potential contacts of TB suspect, such as symptomatic patients or visitors accompanying the TB suspect.
7. **Provide all staff with intensified screening for TB.**
   a. Periodically screen staff in each area of the health facility: HIV clinic, TB clinic, PMTCT clinic, ART clinic and pediatric ward, for symptoms of active TB disease.
   b. Schedule all-staff TB testing twice a year in high TB and HIV-prevalence areas.
   c. Document results in the staff member's occupational file.
8. **In high-burden TB and HIV settings, test all HCWs for HIV in addition to TB.**
   a. Offer staff voluntary, confidential HIV counseling/testing, and annual repeat testing if HIV-negative on previous occasions.
   b. Refer staff members for assessment of and preferential access to ART.
   c. Provide cotrimoxazole preventive therapy (CPT) for co-infected HCWs.
   d. Provide IPT as indicated (SOP 307).
9. **Do not assign HIV-infected HCWs** to work in high-prevalent TB settings, if possible.
10. **Prevent HIV-infected HCWs from coming in contact with**:
    a. Patients assessed for but not yet diagnosed with TB, such as in outpatient department (OPD) waiting rooms
    b. Sputum collection procedures

C. **Environmental** control measures
   1. **Use environmental control measures together with the recommended clinic practices to reduce the transmission of TB bacilli.**
   2. Dilute the concentration of TB particles in room air or move the air in a building and replace it with air from outside.
   3. **Tailor environmental controls to local climatic and socioeconomic conditions**.
      a. **Natural ventilation**
         (1) Use in outpatient clinic waiting rooms, and rooms used for sputum collection and cough-inducing procedures.
         (2) Weather permitting, arrange for sputum collection outdoors.
         (3) In warm climates, use an open-air shelter with a roof to protect patients from sun and rain.
         (4) If indoors, keep clinic doors and windows on opposite sides of the area open to bring in air from the outside.
      b. **Mechanical ventilation**
         (1) Use propeller fans mounted in ceilings or in a window opening to distribute and direct airflow.
         (2) Ensure that the air flows across the room if used in a high-risk area. For example, place the fan behind the healthcare worker, directing air past the HCW, past the TB suspect, and out the opposite window.

D. **Respiratory** control measures for all HCWs and administrative staff
   1. **Do not use a face mask** as a TB prevention method when working with TB suspects. Face masks only reduce transmission from symptomatic person(s) to others.
   2. The best prevention of TB transmission occurs when TB suspects are diagnosed promptly and started immediately on the correct TB drugs, and when the drugs are taken by patients exactly as prescribed. Patients usually become non-infectious in a week or two.

SOP 302: Screening for TB in HIV-infected Individuals

I. Key Concepts:

- TB is the most frequent opportunistic infection (OI) of HIV-infected persons, demanding routine and symptom-based TB screening and testing in HIV-infected individuals.
- Regular TB screening can lead to early detection of TB; screening facilitates provision of TB preventive therapy.
- Always consider TB in a patient with a cough, or even in the absence of a cough but with other symptoms.
- When screening for TB, use purified protein derivative (PPD) if available and if staff is trained to administer and evaluate the results of a tuberculin skin test (TST) (SOP 303).

II. Key Personnel: MD, CO, RN, trained health worker

III. Materials: Stethoscope, thermometer, scale, medical record, specimen cups, area to isolate TB suspects, face mask for TB suspects (if available), SOP 301: TB Infection Control; BMI chart

IV. Procedures:

A. **The RN triages HIV-infected patients as they present to the clinic.**

1. **Assess all patients for serious medical conditions:** Does the patient have any of the following signs and symptoms?
   a. Labored breathing/shortness of breath
   b. Chest pain
   c. Moderate to severe abdominal pain
   d. Persistent vomiting (> 3 days)
   e. Persistent diarrhea +/- blood (> 3 days)
   f. Moderate to severe dehydration
   g. Severe headache with neck stiffness
   h. Seizures
   i. Profound weakness (patient unable to stand/walk)
   j. Suicidal thoughts/severe depression
2. **If the patient has any of the above, immediately refer them to the secondary or tertiary healthcare level.**
   a. **Notify the facility** that the referral has been made.
   b. **If the patient is on ART,** notify the ART initiation site or prescriber that the referral has been made.

B. If no serious medical conditions are present during triage, continue to **screen HIV-infected infants, children, adolescents, and adults for TB whether it is an acute or scheduled chronic HIV care visit**.

Infants and children

1. Check **vital signs.** (RN or designated, trained staff member) Note and record all findings in medical record.
   a. Weight
   b. Length/height
   c. Respiration rate
      (1) Recount if fast (for children 5-12 years old: fast = 30/minute, very fast ≥ 40/minute)
   d. Temperature
   e. Heart rate

f. Blood pressure
g. Nutritional status; look for failure to thrive on the Road-to-Health Chart (weight-for-age chart)

2. **Assess history**. (RN, MD/CO)
   a. **Contacts**
      (1) Determine whether the child has had close contact with active or suspected TB patients. Ask:
         i) "Is anyone at home ill and if so, what are the symptoms?"
         ii) "Does anyone in the household or someone in regular contact with the child have a chronic cough or other symptoms suggestive of TB?"
         iii) "Does anyone in the home have TB?"
      (2) Ask about the general health of friends, family, caretakers, and specifically the mother if the TB suspect is an infant.
   b. **Current/past medical history** (RN, MD/CO)
      (1) Prior TB exposures, especially persons with sputum-positive pulmonary TB
      (2) Prior TB treatments
      (3) History of pulmonary disease or infection (e.g., asthma, pneumonia); heart failure
      (4) History of previous clinical presentations of recurrent lung disease(s)
3. **Evaluate** for **TB symptoms**. (RN, MD/CO)
   a. Chronic, progressive cough > 3 weeks; does not improve on broad-spectrum antibiotics
   b. Fever
   c. Night sweats
   d. Weight loss
   e. Failure to thrive
4. Perform thorough "head-to-toe" **physical exam.** (MD/CO)
   a. Always examine the respiratory and cardiac systems.
   b. Presentation of auxiliary lymphadenopathy on the same side as the BCG should alert clinician to rule out BCG disease.
5. **Evaluate** for **physical signs of TB**. (MD/CO)
   a. Signs/symptoms commonly suggestive of pulmonary TB (PTB) in HIV-infected children:
      (1) Chronic, progressive cough unrelieved by course of broad-spectrum antibiotics (more common in children > 3 years old)
      (2) Can present as acute pneumonia in HIV-infected children
      (3) Respiratory exam findings are focal, marked, and persistent in an ambulatory child not in respiratory distress.
   b. **Documented weight loss or failure to gain weight**, especially following nutritional rehabilitation treatment
   c. Signs **highly** suggestive of **extrapulmonary TB** (EPTB):
      (1) Non-painful, asymmetrical lymphadenopathy (TB adenitis)
      (2) Spinal mass (gibbus), especially of recent onset (spinal TB)
      (3) Distended abdomen with painless ascites (peritoneal TB)
   d. Other **physical signs suggestive** of EPTB:
      (1) Meningitis (e.g., light sensitivity, neck stiffness, bulging fontanelle) unresponsive to antibiotic treatment; can have subacute onset or raised intracranial pressure
      (2) Pleural effusion (e.g., diminished lung sounds)
      (3) Pericardial effusion
      (4) Non-painful enlarged lymph nodes without fistula formation
      (5) Non-painful enlarged joint
      (6) Signs of tuberculin hypersensitivity (e.g., phlyctenular conjunctivitis, erythema nodosum)

Adults and adolescents

1. **Check vital signs.** (RN or designated, trained staff member)
    a. Temperature
    b. Weight, BMI
    c. Respiration rate
        (1) Recount if fast (> 20/minute = fast, > 30/minute = very fast)
    d. Heart rate
    e. Blood pressure
2. **Evaluate** for **TB symptoms**. (RN, MD/CO)
    a. **Cough**
        (1) Assess if **≥ 2 weeks.**
        (2) Ask if cough is **productive. If so, ask if sputum is blood-tinged**.
        (3) Ask if cough wakes patient up at night, happens more in the morning, or happens more with exercise.
    b. Difficulty breathing, chest pain
    c. Persistent fever
    d. Unexplained weight loss
    e. Severe malnutrition
    f. Suspicious lymph nodes (> 2 cm)
    g. Night sweats
3. **Assess history**. (RN, MD/CO)
    a. Social history
        (1) Any TB contacts
        (2) General health of friends, family
        (3) Current living situation (e.g., group home, homeless, prison)
    b. Current/past medical history
        (1) History of TB
        (2) Family history of TB
        (3) History of asthma, bronchitis or COPD, heart failure
        (4) Ask if patient is a smoker.
4. **Perform** thorough "head-to-toe" **physical exam.** (MD/CO) Carefully examine the respiratory and cardiac systems.

Adults, adolescents, infants, and children

B. If patient is **symptomatic** and history is suspicious of TB:
    1. **Initiate** and explain to patient and family the TBIC measures (SOP 301).
    2. Determine the severity of the disease. (MD/CO)
        a. **Severe** (e.g., very fast breathing, pulse > 120, fever ≥ 39 C)
            (1) Begin treatment with supplemental oxygen (as needed and available) and antibiotics (SOP 303).
            (2) **Refer** immediately to secondary or tertiary facility.
        b. Symptomatic but stable
            (1) Start diagnosis protocol for TB (SOPs 303 and 304).
    3. **For infants and children only**, perform a TST (SOP 303).
    4. **Document screening procedures and all investigation results** in patient's medical record.

C. If HIV-infected patient is **asymptomatic**:
    1. Document negative TB screening results in medical record.
    2. If **baseline** visit for an adult or adolescent, perform a TST (SOP 303).
        a. Repeat TST **every six months** if in a high-burden TB area.
        b. Document results in patient's medical record.
    3. In children < 5 years old, offer isoniazid preventive therapy (IPT) if child was exposed to a TB-infected individual (SOP 307).
    4. In adults and adolescents in high-prevalence HIV areas, offer IPT (SOP 307).

SOP 303: Performing a Tuberculin Skin Test in HIV-infected Individuals

I. Key Concepts:

- The tuberculin skin test (TST) can provide important information when assessing a child with suspected TB.
- The TST is an intradermal injection of a combination of mycobacterial antigens; it is also known as a PPD (purified protein derivative).
- Once injected under the skin, the PPD creates an immune response, represented by induration and measured in millimeters.
- The Mantoux method is a standard way of evaluating a TST to identify TB infected people.
- HIV-infection can cause false-negative TST results; BCG vaccination can cause false-positive TST results.

II. Key Personnel: RN, MD, trained health worker

III. Materials: sterile, short bevel (¼- to ½-inch) 27-gauge needle; single dose tuberculin syringe; 5 tuberculin units (TU) of tuberculin PPD-S per patient; alternative to 5 TU of tuberculin PPD-S is 2 TU of tuberculin PPD RT2 3; single use exam gloves; clear, flexible ruler

IV. Procedures:

A. **Explain reason for TST** and the steps involved to the patient.

B. Gather needed materials.
   1. Check expiration date on vial.
   2. Ensure vial contains tuberculin PPD-S (5 TU per 0.1 ml).

C. **Wash hands** thoroughly and dry; **put on a clean set of exam gloves.**

D. **Examine** the patient's forearm.
   1. Choose an injection site on the inner aspect of the forearm, 5–10 cm (2–4 inches) below elbow joint.
   2. Avoid areas with a rash, scar or broken skin.

E. **Prepare** the injection site.
   1. Place forearm palm-side up on a firm, well-lit surface.
   2. Clean the area with an alcohol swab.

F. Prepare and **perform TST.**
   1. Fill (or draw up) the syringe with 0.1 ml tuberculin PPD.
   2. Insert the needle slowly, bevel up, at an angle of 5–15 ° from the patient's forearm.
   3. Ensure needle bevel is visible just below skin surface.
   4. Inject the PPD, forming a flat intradermal wheal of 8-10 mm diameter.
   5. Withdraw the needle and dispose according to Standard Precautions.
   6. Inspect the injection site; if wheal is not visible, repeat the injection (using a new needle and syringe) at a site at least 5 cm (2 inches) away from the original site.
   7. Remove gloves and wash hands thoroughly after disposing of needle.
   8. If possible, mark area around the wheal with a pen to indicate location of PPD.

G. Document TST. Record in medical chart the date and time of test administration, injection site location, and lot number of tuberculin.

H. Evaluate TST results.

1. Schedule with the patient a time to examine the TST site between 48 and 72 hours after placing the PPD. Reschedule and repeat TST if patient does not return within 72 hours following PPD placement for evaluation.
2. Inspect the injection site visually under good light.
3. Measure the extent of induration (thickening of the skin) rather than erythema (reddening of the skin).
4. Use fingertips to find induration margins and for marking widest edges of induration across the forearm.
    a. Measure the diameter of induration using a clear, flexible ruler.
    b. Place "0" of ruler line on the inside-left edge of the induration.
    c. Read ruler line on the inside-right edge of the induration (use lower measurement if between two gradations on mm scale).
5. Record diameter of induration.
    a. Do not record as "positive" or "negative."
    b. Only record measurement in millimeters.
    c. If no induration, record as 0 mm.

I. **Interpret TST results.**

1. Base interpretation on diameter of induration, person's risk of being infected with TB, and risk of progression to disease if infected.
2. Diameter of induration indicates TB infection.
    a. Infants and children
        (1) ≥5 mm is considered significant or positive if the child is HIV-infected or severely malnourished.
        (2) ≥10 mm diameter of induration when read 48-72 hours after administration irrespective of BCG immunization
    b. HIV-infected adults
        (1) ≥5 mm diameter of induration when read 48-72 hours after administration

SOP 304: Diagnosing TB in HIV-infected Individuals

I. Key Concepts:

- Evaluate TB suspects in an outpatient setting whenever possible (SOP 301).
- In patients with advanced HIV infection, atypical TB presentation is more common (e.g., non-cavitary, lower- and mid-lobe involvement, extrapulmonary disease) alongside other clinical symptoms such as prolonged fevers and low BMI.
- The highest risk of extrapulmonary disease is in advanced HIV disease (e.g., when CD4 < 50 cells/mm^3); TB meningitis is fatal if untreated; if suspected, diagnose and treat immediately.
- Diagnosing TB in HIV-infected children is difficult; recognizing signs and symptoms, along with determining the exposure source, often prove more definitive than sputum sample, TST, and CXR results.
- Bacteriological confirmation is especially important for HIV-infected children; pulmonary TB (PTB) in HIV-infected children is often smear-negative.
- Base TB diagnosis on clinical assessment and test results (smear microscopy, CXR, TB culture).
- Specialized tests such as computerized chest tomography and bronchoscopy are not recommended for the routine diagnosis of pulmonary TB.
- When diagnosing TB in HIV-infected individuals, always define the disease classification (site), the type of patient, and their HIV clinical status as recommended in national guidelines.

II. Key Personnel: MD, CO, RN, radiologist, laboratory staff

III. Materials: Sterile needles, sterile PPD vials, medical record

IV. Procedures:

Infants and children

A. **If the infant or child is not severely ill** (e.g., is ambulatory), **but** is clinically **symptomatic and highly suspicious of TB:**
   1. Continue TBIC.
      a. Register the child ahead of other persons waiting in line to decrease time spent in the clinic.
      b. **Place the child in a separate, well-ventilated waiting area**.
   2. **Begin broad spectrum antibiotics; avoid use of fluoroquinolones**.
   3. **Order a chest X-ray (CXR).**
      a. While preparing for CXR, review the history carefully for positive TB contact or symptoms.
      b. Review the clinical examination, including growth assessment.
      c. MD/CO or radiologist evaluates the CXR.
      d. **CXR findings in pediatric TB-HIV may indicate PTB or miliary TB:**

Findings…		**…indicate PTB**	**Findings…**		**…indicate miliary TB**
• Cavitation (unusual in young children; more common in older children and adolescents) • Persistent opacification • Enlarged perihilar lymph nodes • Focal abnormalities	→		• Diffuse, bilateral, micronodular, evenly distributed small miliary shadows (differentiate from LIP)	→	

e. Use CXR to diagnose TB in HIV-infected children, which is complicated by other HIV-related lung diseases such as LIP (lymphocytic interstitial pneumonia), bacterial/PCP/viral pneumonia, or concurrent respiratory infections.

4. Order and begin collection of sputum specimens (Section C below).
5. Monitor TST site (SOP 303).

B. **To rule out pulmonary TB, send specimen(s) for AFB smear microscopy and mycobacterial culture (if available) evaluation** using one of the following methods:

1. **Expectorated sputum**
   a. **Obtain any expectorated sputum sample** outside, or in **a well-ventilated area.**
   b. **Obtain three sputum specimens** in children able to produce a specimen.
      (1) An "on-the-spot" specimen (at first evaluation)
      (2) An early morning specimen (the next day)
      (3) A final "on-the-spot" specimen (at third follow-up visit, or 8 hours after the second specimen)
   c. **Instruct child (and parent/family member** monitoring child) on how to vigorously cough up a specimen into the specimen cup (Text Box 1). Perform **this procedure early in the morning, before the patient eats a morning meal.**
   d. If successful, once collected in the container:
      (1) Cover tightly with the lid.
      (2) Clean off any sputum left on the container.
      (3) Put the container in a plastic bag and tie the opening tightly, mark the container and bag with the patient's identification information.
   e. **Wash hands** following this procedure.
   f. **Send the sample** to the lab **immediately**.
      (1) If you cannot send the specimen right away, put the bag in the regular chamber of a refrigerator, not the freezer, of the clinic.
      (2) Send the specimen within the week.
      (3) Do not keep specimens for longer than one week.
   g. Encourage the child during this procedure; many children cannot produce sputum from deep in the lungs after only a few minutes; it may take a few tries.
   h. Give the child enough time to produce an expectorated sample everyone feels is produced by the deep cough.
   i. Once obtained, the **RN** (or other designated, trained staff member) **labels and sends specimen to lab with** Form 105 "Request for Sputum Smear Microscopy Examination."

Text Box 1
Procedure: Expectorated Sputum

1. Explain the reason for collecting sputum.
2. Instruct the patient to rinse her mouth with water before producing the specimen.
3. Instruct the patient to take a deep breath, hold the breath for a few seconds and then exhale slowly; repeat two times.
4. After the third inhale, instruct the patient to forcefully blow the air out.
5. Ask the patient to hold the sputum container close to the lips, then breathe in a fourth time, then cough; this should produce sputum from deep in the lungs.
6. Ask patient to spit sputum gently into the container after the productive cough.
7. If the sputum coughed up is not enough to send for the test, ask the patient to cough again until a good specimen is in the container.
8. If the patient cannot bring up sputum from a cough, consider the container used and safely dispose of it.

Source: WHO: Guidance for national tuberculosis programmes on the management of tuberculosis in children, Annex 2. 2006

2. **Gastric aspiration**
   a. Collect a gastric aspirate sample from a young child **unable or unwilling to expectorate sputum**.
   b. Perform this procedure first thing in the morning as an outpatient and refer to Part 4, SOP 403 for procedures, if supplies are available.
3. Consider using results of the presumed source case (e.g., household member) to guide diagnosis and treatment of the HIV-infected child.

4. **Refer to district doctor or medical officer if child is not producing sputum or if nodes are present**.

Adults and Adolescents

C. **If patient is not severely ill, but is clinically symptomatic and highly suspicious of TB**:
   1. **Continue TBIC** measures (SOP 301).
   2. **Begin broad spectrum antibiotics; avoid the use of fluoroquinolones.**
   3. **Order chest X-ray.**
      a. While preparing for CXR, review the history carefully for positive TB contact or symptoms; review the clinical examination, including weight.
      b. MD/CO or radiologist evaluates radiographic exam, and confirms TB results (Text Box 2).

Text Box 2:
Chest x-ray findings in HIV-infected adult with PTB

Mild HIV-disease:
- Cavitation
- Upper lobe infiltrates

Advanced HIV-disease: "Atypical"
- Interstitial infiltrates especially in lower zones
- Intrathoracic lymphadenopathy
- Lack of cavitation
- No abnormalities
- Pleural + pericardial involvement

Source: WHO "TB/HIV: A Clinical Manual, Second Edition" 2004

D. **To rule out pulmonary TB**, collect, send, and interpret sputum results for AFB smear and culture (if available).
   1. **Collect two or three consecutive (e.g., 8 hours apart) expectorated sputum specimens, according to national guidelines, site protocols and HIV prevalence of particular setting** (refer to Text Box 1 for sputum collection procedures).
      a. First "spot" specimen; produced in well-ventilated area
      b. Second specimen: one early morning specimen; can be brought to clinic
      c. Third specimen: a "spot" specimen at least 8 hours from second sputum specimen
   2. The nurse obtains the specimen or works with trained facility staff to transport specimens to the laboratory with **Form 105** "Request for Sputum Smear Microscopy Examination."
   3. Send one sputum specimen for TB culture, if laboratory resource is available.
   4. Follow up on and document sputum results in medical record and **Form 105.**
   5. If patient **coughs but does not produce sputum** for evaluation, or **if nodes are present**, continue to section "H – I" below.

Infants, children, adolescents and adults

D. **Interpret POSITIVE sputum sample** results.
   1. Diagnose HIV-infected **infants and children** with smear-positive, infectious pulmonary TB:
      a. If two or more initial sputum smear exams are AFB positive**, or**
      b. One sputum smear exam is AFB positive, plus clinician decides that CXR abnormalities are consistent with active PTB, **or**
      c. One sputum smear exam is AFB positive, plus sputum culture is positive for *M. tuberculosis*
   2. Diagnose HIV-infected **adults and adolescents** with smear-positive (infectious pulmonary) TB if one AFB smear sample is positive.
   3. Always attempt to confirm PTB diagnosis based on sputum smear-positive results with culture-positive results for *Mycobacterium tuberculosis.*
   4. Stage HIV-positive patients diagnosed with smear-positive pulmonary TB as WHO HIV clinical stage 3.
   5. Start TB treatment (SOP 305).
   6. Continue TB infection control and educate patient and family about infection control measures at home.

E. Interpret **NEGATIVE sputum results (MD/CO)**
   1. If all sputum samples are negative, HIV-infected person may or may not have TB; sputum smear microscopy is generally negative in a person with severe immune suppression.
   2. **If patient's symptoms improve on broad-spectrum antibiotics**, sputum results are negative, and CXR does not indicate TB disease, do not diagnose patient with TB.
      a. **Continue treatment** with previously chosen non-specific antibiotic such as cotrimoxazole or Amoxicillin.
      b. Discontinue TBIC measures.
      c. **Document** negative TB results in medical record.
      d. **Monitor** response to completed antibiotic regimen.
      e. **Continue** TB screening at each clinical visit.
   3. **Rule out** need for IPT (SOP 308).
   4. **If patient's symptoms do not improve, patient still coughs**, coughs but **cannot produce sputum** for examination, **or has other general complaints, refer to secondary or tertiary facility to rule out smear-negative TB**.
      a. For further information and definitions, refer to Part 4 SOP 403.
      b. Document referral on in medical record and follow up to ensure that referral was completed.

F. Based on clinical exam, if **extrapulmonary and disseminated TB** is suspected, refer to facility for further diagnostic work-up; document referral on in medical record and follow up to ensure that referral was completed.

G. Determine TB type. (MD/CO)
   1. Review all diagnostic data alongside clinical exam and determine TB diagnosis:
      a. **Pulmonary TB (PTB): sputum smear-positive**
      b. Pulmonary TB (PTB): sputum smear–negative; diagnosed at facility level
      c. Extrapulmonary TB (EPTB): diagnosed at facility level
      d. Other (e.g., combination of PTB and EPTB): diagnosed at facility level
   2. Once TB is diagnosed, identify the type of TB by history of previous TB treatment.
      a. First, ask the patient if s/he was ever treated for TB.
      b. Next, using Table 1 as a guide, ask the patient questions related to TB as indicated by symptoms and patient history to help categorize the patient by TB type.
         (1) Answering "yes" may indicate more than one type of TB; further questions are needed to determine TB type.
         (2) TB type definitions are listed after Table 1.

Table 1: Identifying TB Patient Type

Question	New	Relapse	Treatment after failure	Treatment after default	Transfer-in	Other previously treated
Have you ever been treated for TB? • Also ask the following 2 questions: • Have you ever taken injections for more than 1-2 weeks? Why? • Have you ever taken a medicine that turned your urine orange-red?	X	X	X	X	X	X
Have you ever taken anti-TB drugs for < 1 month?	X					
Has a doctor ever said your TB was cured?		X				
Have you ever completed a TB treatment (e.g., taken anti-TB drugs for 6-9 months)?		X				X
Has a doctor in the past ever diagnosed you with "sputum positive" TB; if so, did you complete the treatment?			X			
Has a doctor in the past ever diagnosed you with "sputum negative" TB; if so, did you complete the treatment?						X
Has a doctor in the past ever diagnosed you with TB in another part of your body (e.g., meningitis); if so, did you complete the treatment?						X
Has a doctor ever prescribed for you a new TB treatment regimen a few months after starting a different TB regimen?			X			
Have you ever stopped TB treatment on your own, then returned to your clinic ≥ 2 months later to restart your TB treatment?				X		
Are you a transfer patient from another TB or TB/HIV clinic and need to continue your treatment?					X	X

c. Using data collected so far, match patient to one of the following categories:
   (1) **New:**
      - A TB treatment-naïve patient
      - Taken anti-TB drugs for less than 1 month
   (2) **Relapse:**
      - Previously TB-treated patient
      - Determined cured in past or completed TB treatment
      - Diagnosed with smear or culture positive for TB
   (3) **Re-treatment after failure:**
      - Started on a re-treatment regimen after failing a previous treatment
   (4) **Re-treatment after default:**
      - Returns to treatment
      - Bacterially positive for TB (e.g., could be EPTB or smear-negative TB)
      - Treatment interruption of 2 or more consecutive months
   (5) **Transfer-in:**
      - Transfer patient from another TB Register
      - Needs to continue TB treatment
   (6) **Other previously treated:**
      - Any case not meeting (1. – 5.) above
      - Includes sputum smear microscopy positive cases with unknown history or unknown outcome of previous treatment
      - Previously treated sputum smear microscopy negative
      - Previously treated extra-pulmonary TB
      - Chronic case at the end of re-treatment regimen

3. Ensure TB screening of family contacts
4. **Document** any referrals made (Part 1, SOP 106, 107, 108) and **follow up** to ensure that the **referral was completed and feedback was received**.
    a. If patient requires referral to facility-level for TB treatment (e.g., sputum smear-negative pulmonary TB, EPTB), refer the patient using the Tuberculosis Treatment Referral/Transfer Form (Part 1 Form 104) and follow up on the referral to ensure that it was completed.

H. **As a team,** the site staff (led by the RN) **provides basic information and education about TB, treatment, and monitoring plans to the co-infected patient, family, and treatment supporters** (SOPs 308, 309, 313, Appendix 3 and 4).

SOP 305: TB Treatment

I. Key Concepts:

- Ensure completion of full TB treatment with good adherence.
- Do not start TB treatment for the purpose of confirming TB diagnosis (TB treatment trial).
- Consult or refer to MD/CO if patient is already on ART when a sputum smear for TB is positive or when smear-negative TB is suspected., to rule out: ART treatment failure; TB re-infection or reactivation; active TB resulting from immune reconstitution syndrome; need for change in ART.
- Consider drug-drug interactions between rifampicin, oral contraceptives, and certain antiretroviral drugs (ARVs) such as non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs).

II. Key Personnel: MD, CO, RN

III. Materials: Medical record, prescription(s), TB Register, Tuberculosis Treatment Card, HIV Care/ART Card, Request for Sputum Smear Microscopy Examination Form

IV. Procedures:

A. **If the patient is not severely ill**, and sputum smear is positive, start the recommended TB treatment. (MD/CO)

B. **Choose the TB Treatment.** (MD/CO)

Infants and children

1. Confirm whether the patient is on ART.
   a. **If not on ART**, refer to ART prescriber for consideration of ART based on degree of immune suppression and child's progress during anti-TB treatment.
   b. **If on ART,** begin anti-TB medications that do not interact with the patient's ART regimen, in consultation with TB/HIV specialist as needed.
2. Choose the pediatric TB treatment regimen, using Table 2 as a reference.
   a. **Choose three to four drugs in active TB cases**, according to national guidelines.
      (1) Start Category I (4-drug) anti-TB medications in:
         i. New smear-positive PTB
      (2) Start Category II regimen in previously-treated smear-positive PTB:
         i. Relapse
         ii. Treatment after interruption
         iii. Treatment failure
      (3) **Ethambutol** is safe to use in children when dose is adjusted (see Table 4).
      (4) **Avoid streptomycin when possible.**
         i. **Injections are painful; irreversible auditory nerve damage may occur.**
         ii. Streptomycin use is reserved for the first 2 months of TB meningitis treatment.
      (5) Treat child with rifampicin for the entire treatment duration, if possible.
      (6) Prescribe daily (7 days per week) treatment regimen for both intensive and continuation phase.

Table 2*: Recommended Pediatric TB Treatment Regimens

TB Diagnostic Category	TB Patient Type	TB Treatment Regimens	
		Initial Phase	Continuation Phase
Categories Prescribed at PHC Level			
I	New smear-positive PTB	2 HRZE	4HR or 6HE • This regimen may be associated with a higher treatment failure rate and relapse compared with the 6-month rifampicin continuation regimen.
II	Previously-treated sputum smear-positive PTB • Relapse • Treatment after interruption • Treatment failure	2 HRZES/1HRZE	5HRE
Categories *Not* Prescribed at PHC Level			
I	• Severe EPTB (except TB meningitis – see below) • Severe HIV disease	2 HRZE	4HR or 6HE
I	• - TB meningitis	2RHZS	4RH
III	• - New smear-negative PTB • (other than Category I) • - Less severe forms of EPTB	2 HRZ	4 HR or 6 HE
IV	• - Chronic and MDR-TB cases	Specially designed standardized or individualized regimens are suggested for this category.	

*Resource: WHO, "Guidance for national tuberculosis programmes on the management of tuberculosis in children," 2006.

Adults and adolescents

1. Confirm whether the patient is on ART.
   a. **If not on ART**, and if HIV clinical status allows (e.g., asymptomatic HIV infection or CD4 > 350/mm^3), immediately start and complete TB treatment, then consult with ART prescriber regarding initiation of ART.
   b. **If on ART,** begin anti-TB medications that do not interact with the patient's ART regimen, in consultation with TB/HIV specialist and according to national guidelines. Work with ART prescriber to monitor co-treatment side effects (SOP 310).
2. Choose the TB treatment regimen; refer to Table 3 for the treatment regimen based on the patient's diagnosed TB type.
   a. Whenever possible, drug sensitivity testing is recommended before prescribing Category II treatment in failure cases.
   b. The initial phase requires directly observed therapy (DOT) in smear-positive cases and any treatment including rifampicin.
3. **If the patient is a woman of childbearing age and not on ART, refer to Table 3 and choose a regimen based on the woman's assessed needs.**
   a. **Assess** whether the woman is sexually active and considering pregnancy.
   b. Ask patient if she currently uses a contraceptive method.
   c. Consider with her an appropriate **contraception** choice.
      (1) If not using a safe, effective family planning method, discuss full range of safer sex options.
      (2) Provide patient with condoms.

(3) If rifampicin is in the chosen TB regimen, provide alternative contraceptive to **pills or implants**; rifampicin interacts with and decreases oral contraception protection from pregnancy.

d. If sexually active, **determine pregnancy status**.

e. **If pregnant**:
   (1) Do not use streptomycin.
   (2) Provide or refer for antenatal care and PMTCT interventions.
      i. ART or ARV prophylaxis per clinic standard protocol
      ii. Safer labor and delivery
      iii. Safer infant feeding per clinic standard protocol
      iv. In accordance with PMTCT guidelines regarding safer infant feeding options, encourage the mother to continue breastfeeding the usual way.
      v. Provide infant with IPT (SOP 307).
      vi. Once infant's preventive therapy is complete, check infant immunization record and provide BCG immunization to infant if not already provided.

f. **If ART is indicated**, refer patient to ART prescriber and work together to monitor co-treatment side effects (SOP 310).

Table 3*: Recommended TB Treatment Regimen for Adults and Adolescents

TB Diagnostic Category	TB Patient Type	TB Treatment Regimens	
		Initial Phase	**Continuation Phase**
Categories Prescribed at this Level			
I	New smear-positive PTB with extensive parenchymal involvement	2 HRZE • Daily dose recommended • Can substitute E with S	4 HR or 6 HE daily • This regimen may be associated with a higher treatment failure rate and relapse compared with the 6-month rifampicin continuation regimen.
II	Previously-treated sputum smear-positive PTB • Relapse • Treatment after interruption • Treatment failure	2 HRZES/1 HRZE	5 HRE
Categories *Not* Prescribed at this Level			
I	• New smear-negative • Severe HIV disease or severe EPTB	2 HRZE	4 HR
III	• New smear-negative PTB (other than Category I) • Less severe forms of EPTB	2 HRZE	4 HR or 6 HE daily
IV	Chronic and MDR-TB cases • - Still sputum-positive after supervised re-treatment	Specially designed standardized or individualized regimens are suggested.	

*Source: WHO, "Treatment of Tuberculosis: Guidelines for National Programmes," 2003.

4. **Choose the TB treatment dose.** (MD/CO)

Infants, children, adolescents and adults

5. **Order and review baseline labs.**
   a. Confirm CD4 count/percentage and viral load (if available) when starting TB treatment.
   b. Check hematology, chemistry, and liver function, if available.
6. Consider the patient's current weight; daily dosing is preferred.

Table 4*: Recommended Doses of First-line Anti-TB Drugs for Children and Adults

	Daily		Three times weekly	
Drug (abbreviation)	**Dose and range (mg/kg body weight)**	**Maximum (mg)**	**Dose range (mg/kg body weight)**	**Daily maximum (mg)**
Isoniazid (H)	Children: 10 (10–15) Adults: 5 (4–6)	300	Children: 10-20 Adults: 8–12	Children: 900 Adults: –
Rifampicin (R)	Children: 15 (10–20) Adults 10 (8–12)	600	Children: 10-20 Adults: 8–12	600
Pyrazinamide (Z)	Children: 35 (30–40) Adults: 25 (20–30)	Children: 2000 Adults: –	Children: 30–40 Adults: 30–40	Children: 4000 Adults: –
Ethambutol (E)	Children 20 (15–25) Adults 15 (15–20)	Children: 1200 Adults: –	Children: 25-35 Adults: 25–35	Children: 1200 Adults: –
Streptomycin (S)	Children and Adults: 15 (12–18)	Children: 1000 Adults: –	Children and Adults: 12–18	Children: 1500 Adults: –

Source*: WHO, "Treatment of Tuberculosis: Guidelines for National Programmes," 2003; WHO, "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press).

7. **Prescribe a regimen that contains a fixed-dose combination (FDC), if possible**.
   a. Some regimens are manufactured in FDCs.
   b. FDC regimens help reduce pill burden and improve medication adherence.
   c. Re-treatment regimens require both FDC and an additional pill or injection.
8. If the chosen **regimen contains isoniazid, prescribe pyridoxine 10-50 mg daily** to prevent peripheral neuropathy.
9. If the chosen **regimen contains streptomycin,** make sure the patient can come to the clinic to have the injection given by a trained health worker according to standard precautions (Part 1 SOP 105).

E. **Supporting the chosen treatment regimen.**
1. Once a regimen is chosen, review the length of treatment and the difference between the two treatment phases. (RN)
2. Discuss and arrange **DOT** adherence monitoring with patient. (RN, site staff; SOP 309)
   a. RN identifies and trains a community treatment supporter (SOP 312), if the patient does not already have one.
   b. Discuss importance of adherence.
   c. Confirm the DOT plan.
   d. If the patient has a supporter for ART, include them in the conversation about starting anti-TB medication and consider them for dual treatment support and observation.
3. **Review side effects of the chosen medication regimen**, and which **symptoms require immediate return to the clinic** or **facility**. (RN, MD/CO; SOP 308-310, Appendix 3)
4. Describe and review the **follow-up schedule.** (RN, MD/CO; SOP 308)
5. Determine the need for **cotrimoxazole preventive therapy (CPT).** (MD/CO; SOP 306)
6. **Dispense** all medications or **ensure** access to a pharmacy. (Pharmacist, RN)
7. **Schedule a follow-up** appointment for the following week. (RN, site staff; SOP 108)
8. **Complete documentation** and place in the patient's medical record. (RN, MD/CO)
   a. Indicate assessment, plan, and prescribed medications on all required forms.
      (1) Tuberculosis Treatment Card (Part 1, Form 101)
      (2) HIV/ART Initial Care Form (Part 1, Form 102)
      (3) TB Register (Part 1 Form 103)

SOP 306: Cotrimoxazole Preventive Therapy

I. Key Concepts:

- This medication is given to HIV-infected individuals to stop other infections before they occur in immune-suppressed individuals.
- Offer all symptomatic HIV-positive individuals cotrimoxazole preventive therapy (CPT).
- Ensure all infants and children receive CPT.
- Most TB and HIV co-infected patients benefit from CPT.
- Drugs containing sulfa include: cotrimoxazole/Septrin, Bactrim, Septra, S-P/Fansidar.

II. Key Personnel: MD, CO, RN, pharmacist

III. Materials: HIV Care/ART Card (Part 1 Form 102), Tuberculosis Treatment Card (Part 1 Form 101), prescription, TB Register (Part 1 Form 103)

IV. Procedures:

A. **Assess for sulfa allergy** or previous history taking any sulfa-based drug.

B. **Consider alternatives** if patient allergy is documented. For severe CTX or sulfa allergy, and if prophylaxis is high priority, consider dapsone (100 mg daily), if available.

C. **Prescribe cotrimoxazole (CTX)** if **no allergy is reported or documented**. (MD/CO)

1. **Pediatric** dosing:
   a. **Daily; age- and weight-based; refer to Table 5**
   b. Adjust dose as child grows and gains weight.
   c. If cotrimoxazole syrup is unavailable, give the tablet (age- and weight-based).

Table 5*: Daily Cotrimoxazole Dosing in Infants and Children

Recommended daily dose: Age- or weight-based		Suspension (5ml syrup of 200mg/40mg)	Child tablet (100mg/20mg)	Adult tablet single strength (400mg/80mg)	Adult tablet double strength (800mg/160mg)
< 6 months	< 5 Kg	2.5 ml	one tablet	¼ tablet	–
6 months to 5 years	5-15 Kg	5 ml	two tablets	half tablet	–
6 – 14 years	15-30 Kg	10 ml	four tablets	one tablet	half tablet
> 14 years	>30 Kg	–	–	two tablets	one tablet

Legend	
Daily dosages based on age or weight:	
< 6 months or < 5 kg →	100mg sulfamethoxazole / 20mg trimethoprim
6 months - 5 years or 5- 15 kg →	200mg sulfamethoxazole /40mg trimethoprim
6-14 years or 15-30 kg →	400mg sulfamethoxazole /80mg trimethoprim
< 6 months or > 30 kg →	800mg sulfamethoxazole / 160mg trimethoprim

* Source: WHO, "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press).

2. **Adult** dosing:
   a. Prescribe one double-strength (DS) tablet or two single-strength (SS) tablets daily
      (1) DS tablet = 960 mg of trimethoprim/sulfamethoxazole (TMP-SMX)
      (2) SS tablet = 480 mg of trimethoprim/sulfamethoxazole (TMP-SMX)

3. **Review dose and frequency** with patient. CTX can be given at the same time as TB and ART meds. (RN, MD/CO)
4. **Review possible side effects.** (RN, MD/CO)
    a. Clinical symptoms such as nausea are generally well tolerated in children; side effects are more common in adults.
    b. **Instruct patient to stop CTX** and **go immediately to facility** for:
        (1) Shortness of breath
        (2) Generalized rash
        (3) Pallor changes, bleeding gums
        (4) New jaundice
5. MD/CO **ensures that a one-month supply** is given to the patient, if not in a DOT program.
6. RN or other designated staff member **schedules follow-up appointment in the week before** CTX supply runs out.

D. **Document CTX status in the medical record** and HIV/ART card. (RN, MD/CO)
    1. Document date and dose prescribed in medical record, HIV Care/ART Card and Tuberculosis Treatment Card.
    2. If not prescribed, document rationale (e.g., clinical status, allergy).

E. Review CTX adherence and side effects at every clinical visit.
    1. If patient reports or presents with redness/erythema or a diffuse, dry rash:
        a. Continue CTX with careful, repeated observation and follow-up.
        b. Consider prescribing an antihistamine for symptom relief.
        c. Stop CTX and refer to facility if symptoms do not improve with symptomatic treatment.
    2. **Stop CTX** and **refer immediately to facility** for treatment if any of the following develop:
        d. **A red, itchy, scaly rash**
        e. **New fatigue, fever**
        f. **Blisters** or ulcers in the mouth and mucus membranes
        g. Yellowing of eyes (jaundice)

F. When to stop CPT:
    1. **When any serious adverse event occurs (section "D.2" above).**
    2. **If CD4 rises above 350 cells/mm^3 for more than 6 months;** or
    3. In the absence of CD4 monitoring, **patient has been on ART for > 1 year without being assigned WHO stage 2, 3 or 4**, has a documented adherence record, and a secure drug supply.
    4. **If patient is less than 1 year old, continue CTX regardless of symptoms or CD4 %.**

SOP 307: Isoniazid Preventive Therapy

I. Key Concepts:

- Isoniazid preventive therapy (IPT) has been shown to prevent the development of active TB disease in individuals with latent TB infection.
- In high HIV and TB prevalent areas, the tuberculin skin test (TST) may not provide accurate results in immune compromised individuals; TST interpretation is the responsibility of the treating clinician.
- **Do not** give IPT to anyone with active TB disease.
- Active TB disease **must be** ruled out before prescribing isoniazid.
- BCG immunization of children under two years of age can reduce the risk of developing severe TB (e.g., disseminated, meningitis) by 50–80%.
- If a person is exposed to active multi-drug resistant TB disease, the patient may not be eligible for standard preventive therapy using isoniazid (INH).

II. Key Personnel: MD, CO, RN

III. Materials: Medical record, TB card, HIV/ART card, prescription, treatment register

IV. Procedures:

A. Screening
   1. Assess for active TB disease or IPT eligibility at **every clinic visit** of HIV-infected individuals.
   2. Ask TB-identified patients to bring household contacts to the clinic, specifically:
      a. Any HIV-positive person in the household; HIV-infected individuals with close contact to active TB cases require clinical evaluation to exclude active TB disease.
      b. Children < 5 years old.
      c. People in the household with a cough for more than 2 or 3 weeks.
   3. **Rule out active TB disease** (SOP 302-304).
      a. Initiate IC measures (SOP 301) and begin a thorough, immediate evaluation (e.g., CXR) if HIV-infected child or adult presents with active TB symptoms such as cough, fever, or weight loss, or contact with a TB suspect.
      b. Use TST, where available, to guide IPT screening.

B. **Determining IPT eligibility**
   1. **Prescribe IPT in an HIV-infected individual if** purified protein derivitive (PPD) is positive (induration $\geq$ 5 mm) and active TB disease is ruled out (e.g., asymptomatic, no cough, CXR is clear).
   2. In the absence of TST and PPD results, **consider IPT in HIV-infected individuals when**:
      a. There is no evidence of active TB disease.
      b. Patient lives in a high TB prevalence area.
      c. HIV-infected individual is a healthcare worker.
      d. Patient is a household contact of TB patient(s), especially if a child under five years old.
      e. Patient is a prisoner.
      f. Patient is a minor.

C. **Prescribing IPT**
   1. **Ask if patient drinks alcohol; if yes, advise patient to stop** or reduce to low-risk levels.

2. **Prescribe INH,** the recommended drug for tuberculosis prevention in children, adolescents, and adults.
    a. **Pediatric dose**: 5 mg/kg (maximum dose = 300 mg daily)
    b. **Standard adult dose**: 300mg daily for 6-9 months
    c. **Treatment duration**: at least 6 months (range = 6-9 months), according to national guidelines
    d. **Treatment** can be self-administered; DOT not required.
    e. INH is not contraindicated for **pregnant patients.**
3. The most common side effect of INH is peripheral neuropathy, presenting as a burning sensation in the feet. Treat this in advance by prescribing pyridoxine 50 mg daily.
4. **Review** with patient the need **to stop IPT and come to the facility immediately if major side effects occur**, including:
    a. New itching of skin or skin rash
    b. Dizziness (vertigo or jittery eye movements)
    c. Yellowing of eyes or change in skin color
    d. Vomiting
    e. Confusion
    f. Convulsions
5. **Review minor side effects**; offer suggestions to treat in home setting:
    a. For anorexia, nausea, or abdominal pain, give INH at night instead of in the morning.
    b. For joint pains, advise patient to take aspirin as prescribed.
6. Order **baseline labs.** Include, if available, LFTs **(**e.g., bilirubin, ALT, AST) and FBC. (MD/CO)
7. **Provide IPT** prescription and ensure pharmacy access throughout duration of treatment.

D. Monitoring IPT (RN, MD/CO)
1. Ensure monthly clinical monitoring while the patient is on IPT.
2. At each visit the RN assesses the patient's **medication adherence**.
3. Encourage the patient to immediately report any hepatitis symptoms lasting > 3 days.
    a. **Hepatitis** symptoms include:
        (1) Jaundice
        (2) Dark urine
        (3) Nausea
        (4) Vomiting
        (5) Abdominal pain
        (6) Fever
    b. **Discontinue IPT and refer patient immediately** to the facility care level for signs or symptoms of hepatitis at any point during the therapy; follow up on the referral.
4. Monitor any minor, ongoing side effects of INH.
    a. Patient is at increased risk of neuropathy if on d4T in addition to INH.
    b. If peripheral neuropathy persists, increase pyridoxine to 100 mg daily.
5. **Prescribe a one-month supply of medication** at each visit.
    a. Consider giving patient an additional 2-week emergency supply to encourage adherence in case the patient must miss or defer a monthly appointment.

E. **Documentation**
1. **Document screening, results, and adherence** in patient's medical record. (RN, MD/CO)
2. If given IPT, indicate the **reason and date therapy started in patient's medical record**.
3. **Prepare a Tuberculosis Treatment Card** and **TB Register** (Part 1 Forms 101, 103) to document:
    a. Diagnostic findings
    b. Treatment initiation
    c. Baseline laboratory findings (LFTs, RFTs, FBC) as available

d. Ongoing clinical and laboratory monitoring
e. Treatment discontinuation
   (1) Due to adverse events
   (2) Due to treatment completion

4. Prepare an HIV/ART card (Part 1 Form 102) if household contact is HIV-positive and not enrolled in an HIV care and treatment program. If the HIV-infected household contact is already enrolled in another HIV program:
   a. Notify the program of the IPT and consult with them regarding HIV care and treatment.
   b. Consider transferring care if concerned about treatment adherence.

F. **Completion of IPT**

1. **Once treatment is completed** (usually 6 to 9 months) in adolescents and adults:
   a. **Congratulate the patient on treatment adherence and completion of therapy**.
   b. **Document evaluation of IPT outcome (e.g., withdrawals, completion of therapy) in medical record, Tuberculosis Treatment Card, TB Register, and HIV Care/ART Card**.
   c. Continue bi-annual TST screening per site or national guidelines.
   d. Continue TB screening at every acute and scheduled clinical visit.
2. After IPT course is completed in **children less than 2 years old:**
   a. Check to see if the child has received a **BCG immunization injection**.
   b. Check the immunization record, or
   c. Look for a scar on the upper left arm.
   d. If no record or mark exists, and **once preventive therapy is finished**, give one BCG vaccine dose to the child < 2 years old using sterile technique.
   e. **Only give the immunization once the child completes the IPT.**
   f. **Document** immunization administration in the child's vaccination record and medical chart.

SOP 308: Treatment Monitoring

I. Key Concepts:

- Monitoring is indicated for co-infected patients during the TB treatment period.
- Monitoring allows both assessment of a co-infected individual, and an opportunity to evaluate the performance of the clinical site providing TB and ART treatment.
- Bacteriological monitoring is readily available only for smear-positive PTB patients (usually adults and adolescents); routine CXR is not always indicated.
- Clinical monitoring usually guides sputum smear PTB, EPTB, and pediatric TB cases.
- **PTB patient is no longer infectious after 2 weeks of anti-TB treatment**; reinforce continuation of handwashing and standard precautions (Part 1 SOP 105) during and after completion of anti-TB treatment.
- Patients with DR-TB and extrapulmonary TB must have their TB care treated and monitored at the facility level; DOT can be coordinated with the community site if in accordance with national TB program.
- **If possible,** refer patient to facility-level laboratory for rapid, **baseline drug susceptibility testing (DST)** to avoid mortality from undiagnosed drug-resistant TB.
- **TB transmission precautions can stop after 2 weeks of treatment**; reinforce handwashing and standard precautions (Part 1 SOP 105) at all times.

II. Key Personnel: MD, CO, RN, treatment monitor, HBC volunteer

III. Materials: Clinical diagnostics (e.g., stethoscope, scale, blood pressure cuff, thermometer); visual acuity chart; medical record; TB card (Part 1 Form 101), HIV Care/ART Card (Part 1 Form 102), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106)

IV. Procedures:

A. **Schedule regular clinical and adherence (see SOP 309 for specific adherence strategy) visits** during the TB treatment period.
   1. **As an outpatient, schedule**:
      a. **Weekly clinical exam and adherence review (SOP 109)** for the **first four weeks** of the intensive phase, then
      b. **Every two weeks** until the intensive phase is completed, then
      c. **Monthly appointments** during the continuation phase

B. **Provide a comprehensive clinical assessment** of the co-infected patient at each acute and scheduled appointment.
   1. **RN** ensures measurement and documentation of:
      a. Vital signs, weight, BMI in children
      b. Nutritional status
      c. If trained, visual acuity and color vision (if on ethambutol)
      d. Laboratory results
      e. Schedule patient for laboratory investigations a week in advance of the clinical appointment to allow time for receipt and review.
      f. Track adherence on TB and HIV/ART card (Part 1, Forms 101 and 102).
   2. **MD/CO** assesses and documents complete clinical status, including:
      a. Clinical response to treatment
         (1) Signs/symptoms of immune reconstitution inflammatory syndrome (IRIS)
      b. TB- and ART-related side effects (SOP 310).
         (1) Color vision and visual acuity, if on ethambutol
         (2) Signs/symptoms of hepatitis

c. Laboratory studies
   (1) Expectorated sputum for microscopy (Form 105)
   (2) Chest X-ray
d. Common HIV-related infections such as pneumonia, diarrhea, and fungal infections
   (1) Treat any identified HIV-related infections as indicated in SOPs: Managing Adults and Adolescents Living with HIV/AIDS at the Primary Health Center Level, Including Managing Patients on ART.
e. Baseline laboratory values
f. During the entire treatment period, **if a patient develops new signs or symptoms, the MD/CO assesses, classifies, and treats according to site protocol**.

3. **Reinforce the importance** of the clinic visit, laboratory request, and medication adherence at each interaction.

4. The RN, site staff members, volunteers (as trained), and laboratory technician coordinate referral to the laboratory, and the receipt of results between the site and laboratory.

C. Use laboratory data alongside clinical assessment to determine response to TB treatment.

1. **In sputum smear-positive PTB** HIV-infected patients:
   a. **If on 8-month regimen**, collect sputum samples:
      (1) At the end of the initial phase (month 2)
      (2) In the continuation phase (month 5)
      (3) During the last month of treatment (month 8)
   b. If on a **6-month regimen**, collect sputum samples:
      (1) At the end of the initial phase (month 2)
      (2) In the continuation phase (month 5)
      (3) During the last month of treatment (month 6)
   c. Complete Request for Sputum Smear Microscopy Examination Form (Part 1 Form 105).
      (1) Send samples to the laboratory for smear microscopy.
      (2) The laboratory technician records the exam results on the bottom half of Form 105 and returns it to the requesting site.
   d. **Collect blood specimens**:
      (1) When clinically indicated (e.g., change in pallor, jaundice) during TB treatment
      (2) **Refer patient for drug resistance testing** if patient is sputum smear-positive after intensive phase to rule out MDR-TB.
   e. If indicated, repeat chest X-ray report and review for changes or signs of improvement.
      (1) Follow-up chest radiographs are not routinely recommended in children.
   f. RN records all results on Tuberculosis Treatment Card, and indicates date of each:
      (1) Sputum (record “neg”; if positive, record the highest grading)
      (2) Weight
      (3) Clinical follow-up
2. For **previously treated pulmonary sputum smear-positive patients, collect sputum for smear exam**:
   a. At the end of the initial phase of treatment, e.g., the end of month 3
   b. During the second month after starting the continuation phase
   c. At the end of treatment
3. In HIV-infected patients with **any active TB diagnosis on anti-TB medications and ART**:
   a. The ART prescriber monitors laboratory values.
   b. Monitor clinical symptoms as described in SOP 310, Appendix 3.
4. **Develop a care plan** with the treating facility-based MD in case the patient has community-level care needs.
5. **Reinforce adherence** to all medications and appointments (SOP 309).

D. When to modify or change TB treatment doses or therapy

1. In infants and children, adjust TB and antiretroviral drugs (ARV) dosages according to any weight gained since the last visit.
2. In **smear-positive PTB cases** on Category I treatment:
    a. **If both smear specimens are negative**, the MD/CO discusses sputum smear-negative results with the patient and documents the plan on the TB card (Part 1 Form 101). Patient then begins and completes the continuation phase.
    b. **If sputum smear returns positive at month 2**:
        (1) Extend the initial treatment phase by one extra month.
        (2) Review the patient's medications and treatment schedule.
            (a) If the treatment has not been regular, discuss with the patient the need to take the treatment exactly as prescribed.
            (b) Consider stronger follow-up DOT strategies with the RN, treatment supporter, and patient.
    c. **Check smear at the end of month 3** to evaluate smear conversion in the cohort.
    d. After third month of the initial phase regimen, start the full continuation phase.
    e. **Check sputum again in month 5.** Consider sending specimen for TB culture to confirm treatment failure.
    f. **If month 5 sputum returns positive**, document the patient as a **treatment failure.**
        (1) Close the Tuberculosis Treatment Card (outcome = treatment failure).
        (2) Document and inform the patient of treatment failure.
        (3) Refer/transfer patient to facility-level for consideration of DST (especially in high prevalent TB area) and a new regimen.
3. During the entire treatment period, **if patient develops new signs or symptoms**, the MD/CO assesses, classifies and treats according to site protocol. If no abnormalities, continue regimen and reassess the next month or earlier as needed by acute symptoms.
4. Notify NTP of any treatment changes based on full, comprehensive assessment.
5. Document changes to the treatment dose or regimen on the Tuberculosis Treatment Card and HIV Care/ART Card.
6. If monitoring smear-negative pulmonary cases:
    a. Monitor clinical symptoms and adherence.
    b. Report findings to the prescribing clinician monthly.
    c. The prescribing clinician monitors sputum results and completes Tuberculosis Treatment Card.
7. Refer patients to facility level for clinical and laboratory follow-up evaluation by TB/HIV specialist for:
    a. Severe kidney and liver response to TB medications
    b. **If TB-HIV patient not on ART does not gain weight or develops new HIV-related diseases** (clinical stage 3 or 4), **to start ART**
    c. **All cases indicating ART failure**
8. If **HIV-infected patient in the community-based clinic site is referred to the facility-level, once referred keep in contact with the treating facility**-based MD regarding management of the co-infected patient.

SOP 309: Promoting and Monitoring Treatment Adherence, Directly Observed Therapy

I. Key Concepts:

- Non-adherence causes drug-resistant TB or treatment failure.
- Daily directly observed therapy (DOT) is the preferred method to ensure full adherence to TB treatment.
- Adherence to both anti-TB medicine and antiretroviral drugs (ARVs) is complicated; a patient-centered approach is needed to ensure adherence.
- Make treatment as attractive and organized for the patient as possible.
- All types of treatment supporters, including family members, can be trained to provide DOT for both TB treatment and ART.
- To support adherence in special populations (e.g., homeless population, people with poor understanding of their disease, patients with complex medical problems, substance users) see Part I, SOP 104

II. Key Personnel: MD, RN, treatment supporter, volunteer

III. Materials: Medical record, TB Register (Part 1 Form 103), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106), Adherence Monitoring Record (Part 1 Form 107), IEC, treatment aids (e.g., Appendix 6, calendars, pillboxes), flipcharts of HIV/TB co-infection, photos of HIV-infected patients before and after completing TB treatment (as available).

IV. Procedures:

A. Assess for risks of potential non-adherence, such as alcohol and drug use, pregnancy, mobile population, or mental illness.

B. Once a treatment regimen has been decided upon, the RN meets with the patient to discuss a medication adherence and clinic visit plan.
   1. Decide **where** daily DOT will happen.
      a. Outside the clinic site, such as in the home or workplace
         (1) Explain that a community-based TB treatment supporter can provide DOT.
      b. At the site
         (1) A site staff or volunteer will provide DOT.
         (2) If the patient is prescribed streptomycin, the patient needs to come to the site, as a trained health worker needs to provide the sterile injection.
   2. Decide on and train the treatment supporter (SOP 312).
   3. Obtain patient consent for the home visit.
   4. If off-site DOT is chosen, confirm the DOT location.
   5. Discuss the clinic visit plan, which involves weekly to monthly clinic visits; visits are more frequent if signs, symptoms, or difficulties occur.
   6. If the patient refuses DOT:
      a. Discuss disclosure issues; help patient move toward a disclosure plan that is acceptable.
      b. Discuss options; encourage adherence and emphasize the need to follow up.
      c. Create a patient-centered approach; begin the development of a working relationship with the patient.
      d. Continue close clinical and adherence follow-up, and psycho-social supportive care (Part 1 SOP 104).

C. **Review** adherence
   1. **Daily,** by a treatment supporter or RN at the site providing daily treatment
   2. **Monthl**y, by the RN or MD/CO, at every clinic visit

D. **Who** provides TB (and ART) treatment adherence
   1. Treatment Supporter:
      a. Observes the patient taking the prescribed treatment (TB and ART, as needed) on a daily (or 2-3 times per week) basis, and documents adherence on the Tuberculosis Treatment Card
      b. Visits the health site or facility on a monthly basis to collect the next month's drug supply and to review problems with the RN as needed
   2. RN:
      a. **Team leader** for DOT and shares responsibility with other TB educators as well as trained site staff with delegated DOT-related responsibilities
      b. If patient is on **community-based DOT**:
         (1) **Reviews the TB Treatment Card** kept by the treatment supporter, with the patient during the patient's monthly assessment, and before seeing the MD/CO.
            - Copies the days the patient took the treatment onto the original TB Treatment Card kept at the site.
         (2) Occasionally asks the patient to describe the TB treatment supporter's work in helping with adherence and any other issues:
            - How often does the patient receive medicine from the treatment supporter? Does the patient receive medicine at the same time every day?
            - How often does the patient see the treatment supporter fill in the treatment card?
            - What drugs does the patient receive from the treatment supporter?
            - Asks about the relationship between the patient and the treatment supporter.
         (3) Determines whether the relationship between the treatment supporter and patient is positive and working to the patient's benefit.
            - Asks whether the patient is willing to receive medicine from the same treatment supporter until the treatment course is completed, or if the patient wants to change treatment supporters. If a change is requested, probes for reasons why the patient wants or needs to change treatment supporters.
         (4) Continues to reinforce the patient's role in self-management of illness.
         (5) **Reviews the Tuberculosis Treatment Card with the treatment supporter** on a monthly basis when the treatment supporter collects the monthly drug supply and discusses any problems.
            - Records on the front of the Tuberculosis Treatment Card the drugs provided to the supporter for the next month and the date provided.
         (6) Asks about any travel plans and alerts MD/CO to travel needs.
      c. If patient takes site-based DOT:
         (7) RN observes the patient taking the medication.
         (8) Documents adherence on the TB Card, TB/ART Card and the medical record (per site protocol).
   3. **MD/CO:**
      a. Reviews the RN's documentation and discusses the adherence plan with the patient and treatment supporter, if available.
      b. Provides the prescription for the next month's TB (and ART, if prescribed) drug supply.
      c. Asks about any future travel plans. Works with the team to ensure that treatment continues.

E. Providing DOT

1. The treatment supporter or clinic/site staff member providing DOT, once determined, **meets together with the patient** to arrange a specific time and place to give/take medications.
2. The treatment supporter arrives at the designated place on time and **does not make the patient wait.**
3. Ask the patient about possible side effects.
    a. Minor side effects
        (1) If patient reports **nausea, lack of appetite, stomach pain or discomfort**, encourage the patient to eat a small snack with the tablets.
            (a) Refer the patient to the site for an appointment with the RN/MD/CO if nausea continues.
            (b) Document referral on the treatment card.
        (2) If food supplies are low or unavailable:
            (a) Refer patient to community-based programs (as available) offering food supplementation.
            (b) If available, offer patient food by prescription.
        (3) If the patient reports that their **urine is orange/red**, tell them this is a normal side effect.
        (4) If the patient complains about **joint pains or a burning sensation in the hands or feet**, refer the patient to the site for the soonest appointment.
    b. Major side effects
        (1) **Do not give** the TB medication, tell the patient the medication will be stopped for evaluation, and **emergently refer the patient to the health facility** for evaluation by the specialty MD/CO **if a patient reports any of the following**:
            - Itching of the skin
            - Skin rash
            - Hearing loss, deafness
            - New dizziness
            - Jaundice
            - Continued vomiting
            - Vision changes, difficulty seeing
4. Review the patient's medications.
    a. First, check to make sure the drugs are correct.
    b. Next, watch the patient take and swallow all the drugs.
    c. If needed, give the prescribed injection according to protocol.
    d. Finally, document on the treatment card that the patient took the drugs.
5. **Encourage** the patient to continue treatment exactly as prescribed. Praise the patient for completing doses, managing side effects, and keeping scheduled appointments.
6. If the **patient misses one dose**:
    a. Respond immediately
    b. If a patient takes medication at home or work:
        (1) Return the next day and ask the reason for the missed dose; problem solve so doses are not missed again in the future.
        (2) Give the next scheduled dose.
        (3) Extend the treatment by the missed dose day.
        (4) If unable to find the patient or the patient refuses the medication, contact the site the same day for help.
    c. If a patient takes **medication at the site**:
        (1) Visit the patient's home within 24 hours.
        (2) Ask the reason for the missed dose.
        (3) Give the next scheduled dose.
        (4) If unable to find the patient or the patient refuses the medication, make an urgent appointment for the patient in the clinic to see the MD/CO for further support and evaluation.

7. **If providing DOT in the home or workplace**, schedule a time to collect a monthly supply of drugs each month with the site staff/RN.
    a. If possible, ask the patient to come to the clinic or schedule the patient's monthly clinic appointment the same day.
    b. Show the RN the treatment card each month when picking up medications.
    c. Review with the RN the patient's adherence and troubleshoot any problems from the past month.
8. **If providing DOT at the site**, schedule time with the RN and patient at the patient's monthly clinic appointment.
    a. **Review** the treatment card with the RN and patient, if present.
    b. Together, review the adherence pattern; address problems from the past month.
9. If the treatment supporter or patient **travels out of town for a few days**:
    a. Inform each other of travel plans at least 1 week in advance.
    b. The treatment supporter makes arrangements for the patient to have exactly enough drugs to self-administer medication for only one week.
    c. **If travel will be longer than one week**, meet with the clinic team to determine a plan.
        (1) Reinforce with the patient that treatment cannot stop or pause once started but needs to continue until the end.
        (2) Perhaps consider transferring the patient to a site near the patient's destination if travel will be longer than a few weeks.
10. Be aware of the patient's appointments and laboratory schedule.
    a. Patient's clinic appointments should be at least monthly, or more frequent depending on other clinical issues or emergent needs.
    b. **If a pulmonary TB patien**t, the patient will need to go to the site, lab or facility (depending on site resources) for **repeat sputum smear exams.**
        (1) **Usually schedule three times:** at end of initial treatment phase, after 5 months of treatment, and after the last month of treatment.
    c. Make sure the patient goes to the site or laboratory, per site standard, to have labs checked (e.g., hematology, LFTs or sputum collection) at least a week before the clinic appointment, so results will be available for MD/CO evaluation.

F. **Offer TB/ART DOT**
1. DOT is ideal; try to maintain as resources allow.
2. DOT may not be sustainable after the end of TB treatment for lifelong ART.
    a. **Develop a flexible patient-specific approach for maximum adherence**.
    b. **The treatment supporter can observe the patient receiving ART at different intervals, depending on the patient's individual needs**:
        - Once a week
        - Several times a week
        - Daily or twice daily
3. **Combine the daily observation of TB treatment with the one ART dose**, preferably in the morning. The treatment supporter then reminds the patient about the next (unobserved) dose(s) of ART and helps as able to ensure adherence with ART.
    a. Lay out the pills.
    b. Discuss ways that help the specific patient.
    c. The next day, check whether the patient took the other ART doses.

G. **For patients who travel, arrange continued TB/ART treatment**.
1. **Review travel plans at every clinic visit**.
2. If a patient plans to travel out of the area, or will be unable to have treatment directly observed for one or more days:

a. **Give patient the drugs with careful instructions** for how to self-medicate for a short time.
   (1) Instruct the patient to:
      - Swallow the drugs at the same time each day.
      - Swallow pills with water.
      - Swallow all of the TB drugs for the day together.
   (2) Point out the number and color of the drugs in each day's packet.
   (3) Provide both oral and written instructions.
      - If patient does not read, arrange for a traveling companion to come to the clinic visit and help with adherence support, if possible.

b. **Ask checking questions** to make sure that the patient understands when and how to take the drugs.
c. If necessary, provide a drug supply that lasts up to 2 weeks.
d. If the patient's drugs are not pre-packaged, prepare a separate packet of drugs for each day the patient will be gone.
e. **On the patient's Tuberculosis Treatment Card**, mark a tick when you observe treatment; then draw a line through the days on which the patient will self-administer the drugs.

H. If a patient misses doses or appointments, the RN schedules a home visit to find out barriers to proper TB/HIV care and treatment.
   1. The RN attempts to have the treatment supporter present during conversation with the patient in the home setting.
   2. The RN **asks specific questions** about adherence in a non-judgmental way (e.g., avoid "why" questions):
      a. How do you usually take your medications?
      b. When do you usually take your medications?
      c. What happened that you missed your appointment?
      d. What happened that you missed taking your medication?
   3. The RN **listens** to the patient's answers to figure out the barriers to treatment adherence.
      a. Attitudes of the health facility staff who observe treatment
      b. Waiting time at the health facility
      c. Transportation
      d. Work or family commitments
      e. Side-effects of treatment
      f. Other health problems

4. **The RN works with the patient, treatment supporter, and family/friends/household members to solve identified problems:**

Example reasons for missed doses:	Possible solutions:
Coming to the health facility is inconvenient.	• Identify a convenient community TB treatment supporter.
Patient dislikes coming to the health facility because of the long queue.	• Make arrangements so that TB patients do not have to wait in a queue. For example, let them enter through a back or side door.
Supervisor at work kept the patient late.	• Offer to talk with the supervisor and explain the importance of the treatment, or identify a community TB treatment supporter at work.
Patient had troublesome side-effects.	• Give appropriate advice or remedies for side effects, or refer the patient if necessary (see side effects table in SOP 308 and Appendix 5, 6).
Patient had difficulty swallowing because of pain (this could be oral thrush).	• Use IMAI Acute Care or IMAI Palliative Care to classify and provide treatment or to refer patient as necessary.
Patient cannot leave small children at home and is tired of bringing them to the health facility.	• Discuss with the patient other childcare solutions (e.g., support group members, church members). • Remind family members/neighbors that the patient must continue treatment to protect their health, particularly the health of the children. • If possible, identify a community TB treatment supporter closer to the patient's home.

5. The RN works with the patient, treatment supporter and family/friends/household members to **motivate** the patient during conversation.
6. **Use correct statements** to offer hope about taking treatment as prescribed (SOP 313, Text Box 4).
    a. Show photos of patients with TB and HIV co-infection before and after TB treatment.
    b. The photos show that despite HIV infection, TB is curable and these patients, despite difficulties, were cured.
7. The RN gives the patient the missed dose and explains that past missed doses will continue to be given one day at a time until all pills are taken as prescribed.
8. The patient/treatment supporter will be instructed to not give an extra dose on any day.
9. The RN records a zero (0) on the Tuberculosis Treatment Card for each day of missed treatment.
    a. Add a comment on the action taken during the home visit.
    b. For example: "Home visit; treatment resumed."

I. If a patient misses doses or appointments for longer than a month, the RN and/or designated clinic staff member attempts to find the patient.
1. First, **trace the patient** and find their location using family members, friends or other community resources.
2. Once the patient is traced and contacted, **the RN immediately meets with the patient in the clinic**, if possible.
3. The **RN ensures that the patient's health status is stable**, then arranges with the MD/CO to collect 2-3 sputum samples.
4. The RN and MD/CO discuss the reason the patient stopped treatment.
5. As a team, **determine the cause of the treatment interruption and work together with the patient to find ways to prevent future treatment interruption.** If found that the **patient plans to move to another place permanently or for a prolonged period of time**, use SOP 309 to guide the transfer of the patient to another site to continue treatment.
6. If treatment **interruption has been for 1-2 months**, the MD/CO restarts the patient's TB treatment and provides prescriptions for other medications (e.g., prophylaxis medications), as needed, while waiting for sputum results. Prolong the TB treatment to make up for missed doses.

7. If the treatment **interruption has been 2 months or longer**, the patient is considered a treatment defaulter.
   a. Do not restart treatment.
   b. Wait for return of sputum results to restart treatment regimen.
8. Refer to Table 6 to guide TB treatment actions based on sputum results.

Table 6*: Treatment Interruption Guidelines

	All smears return negative, or patient has extrapulmonary TB	**If one or more smears returns positive…**
Treatment interruption length	⇩	⇩
Missed 1 up to 2 months	➢ Continue treatment ➢ Prolong it to make up for missed doses	*…and previously treated for less than 5 months:* ➢ Continue treatment ➢ Prolong it to make up for missed doses
		…and previously treated for 5 months or more: ➢ If was on Cat I, start Cat II (see Table 1) ➢ If was on Cat II, refer to facility or TB specialist o Follow-up on referral recommendation o Document recommended treatment plan on Tuberculosis Treatment Card o Initiate or monitor with referring specialist new regimen
Missed ≥ 2 months	➢ MD/CO decides on individual basis ➢ Options: o Restart or continue treatment o No further treatment	*…and previously treated with Cat I:* ➢ Start Cat II (see Table 1)
		…and previously treated with Cat II: ➢ Refer to facility or TB specialist ➢ Follow-up on referral recommendation ➢ Document recommended treatment plan on Tuberculosis Treatment Card ➢ Initiate or monitor with referring specialist new regimen

*Adapted from WHO "Tuberculosis Care with TB-HIV Co-management" 2007

9. **Discuss** new (or continued) treatment plan with patient and treatment supporter.
10. **Document treatment plan** (TB card, HIV/ART form, TB Register, Adherence Monitoring Record) in medical record based on sputum results and actions taken to support patient and treatment supporter to adhere to the plan.

SOP 310: Monitoring and Managing TB Medication and ART Side Effects

I. Key Concepts:

- Monitoring and managing minor medication side effects early can affect adherence.
- Close monitoring is essential to determine if clinical symptoms or side effects indicate ART failure.
- Especially when a patient is on co-treatment of HIV and TB, monitor for drug-drug interactions.

II. Key Personnel: MD/CO, RN, treatment supporter

III. Materials: Clinical diagnostics (e.g., stethoscope, scale, blood pressure cuff, thermometer); visual acuity chart; medical record; TB card (Part 1 Form 101), HIV/ART card (Part 1 Form 102), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106)

IV. Procedures:

A. Monitor for and address side effects of medications at every clinic appointment.

Infants and children on anti-TB therapy

1. Children have fewer adverse reactions than adults to anti-TB therapy. However, if side effects are present, document their onset, duration, and severity, and manage immediately.

Sign/symptom	Associated TB drug	Management
Mild *Peripheral neuropathy*	Isoniazid	• Offer supplemental pyridoxine 5-10 mg/day
Moderate/Severe *Hepatotoxicity* • - Liver tenderness • - Hepatomegaly • - Jaundice	Isoniazid Pyrazinamide Rifampcin	• Immediately stop all hepatotoxic medications. • Refer to facility level of care for evaluation. • Follow up on care and treatment plan. • Continue to monitor in coordination with facility-level clinician.

2. Document side effect, treatment and response in the medical record.
3. Report adverse events to the NTP.
4. For a child not responding to TB treatment, refer child to facility level for evaluation of:
   a. Drug-resistant TB
   b. An unusual complication of pulmonary TB
   c. Other causes of HIV-related lung disease per facility HIV care and treatment SOPs
   d. Problems with treatment adherence (SOP 309)
   e. Viral failure per facility HIV care and treatment SOPs

Adults and adolescents on anti-TB therapy

1. For **minor side effects**:
   a. Continue anti-TB drugs.
   b. Check drug doses.

c. Encourage patient to report all minor symptoms during monthly visits but to monitor and manage them at home.
d. Review symptomatic management each month:

Symptom	Associated TB drug	Management
Loss of appetite, nausea, stomach pain	Pyrazinamide Rifampicin Isoniazid	• Take medicine with small meal. • Give drug at bedtime.
Joint pains	Pyrazinamide	• Give aspirin.
Burning pain in hand/feet	Isoniazid	• Give pyridoxine 100 mg daily. • Consider prescribing amitriptyline.
Orange/red urine	Rifampicin	• Reassure patient. • Explain that this is a normal finding when taking rifampicin.

e. For minor side effects persisting longer than one month, refer patient to secondary/tertiary level of care.
f. Document response to symptomatic management in the patient's medical record.

2. **For major side effects:**
   a. Evaluate the onset, duration, and severity of each specific symptom.
      (1) Skin rash
      (2) Itching skin
      (3) Hearing loss, deafness (after starting medications)
      (4) Dizziness, balance loss
      (5) Yellowing of skin or eyes (jaundice)
      (6) Vomiting (observe for repeated vomiting)
      (7) Difficulty seeing (visual changes)
   b. Stop use of the offending anti-TB drug.
   c. Refer patient to **go directly to the secondary or tertiary facility** to evaluate:

Symptom	Main anti-TB drug involved	Management
Skin rash	S, H, R, Z	• Stop TB drugs. • Start antihistamines if severe drug reaction occurs. • Refer immediately either to secondary or tertiary facility for evaluation, depending on severity of rash.
Hearing loss, deafness (after TB drug initiation; no wax on auroscopy)	Streptomycin	• Stop streptomycin. • Refer to secondary level of care.
Dizziness, balance loss, vertigo, nystagmus	Streptomycin	• Stop streptomycin. • Refer to secondary level of care.
Jaundice (other causes excluded) hepatitis	Isoniazid, Pyrazinamide Rifampcin	• Stop anti-TB drugs. • Refer immediately to tertiary care level for evaluation and treatment plan. • Follow up with facility for continued care monitoring, as indicated.
Confusion (suspect drug-induced acute liver failure if jaundice present)	Most anti-TB drugs	• Stop anti-TB drugs. • Refer immediately to secondary care level for evaluation and treatment plan. • Follow up with facility for continued care monitoring, as indicated.

Symptom	Main anti-TB drug involved	Management
Visual changes (other causes excluded)	Ethambutol	• Stop ethambutol. • Refer immediately to secondary care level for evaluation and treatment plan and ophthalmic exam. • Follow up with facility for continued care monitoring, as indicated.
Shock, purpura, acute renal failure	Rifampicin	• Stop Rifampicin. • Refer immediately to tertiary care level for evaluation and treatment plan. • Follow up with facility for continued care monitoring, as indicated.

3. Report adverse events to the NTP and document in the patient's medical record.
4. Continue close follow-up.

B. **Clinical monitoring** of HIV-infected patients of all ages taking **both TB treatment and ART**
   1. Evaluate onset, duration, and severity of each specific symptom.
   2. Determine if presentation or treatment requirements indicate referral to facility.

Adverse reaction	Main ARV drug involved	Main anti-TB drug involved	Management
Anemia • Pallor changes • Usually an early side effect	Zidovudine	Rifampicin	• **Refer** to ART provider to consider change from zidovudine to stavudine.
Central nervous system (CNS) dysfunction • Early or late side effect	Efavirenz	Isoniazid (H) Cycloserine	• **Refer** immediately to tertiary facility for **serious** symptoms (e.g., suicidal, gait changes). • Close PHC monitoring and symptomatic treatment in collaboration with the ART initiation site if no emergent or urgent symptoms. o Ensure patient's safety in home setting. o Involve caregivers and family. • Headache pharmacologic intervention: o Acetaminophen if no contraindications, or as prescribed by the ART initiation site • Headache non-pharmacologic interventions: o Decrease activity; rest in a quiet, dark room with eyes closed. o Place cold moist cloth over eyes. o Stay out of the sun; decrease exposure to light. o Stay hydrated: drink boiled water, avoid caffeine (coffee, tea, carbonated soft drinks) and alcohol. o Avoid foods and other stimuli that trigger headaches. • Dizziness interventions: o Collaborate with the ART initiation site re: EFZ dosing.

Adverse reaction	Main ARV drug involved	Main anti-TB drug involved	Management
			○ Avoid driving and accidental falls. ○ Create a safe home environment. ○ Observe PHC-level impaired concentration actions. ○ Avoid situations requiring significant concentration. ○ Use memory/concentration aids. ○ Avoid alcohol/recreational drugs. ○ Consider recommending increased caffeine intake.
GI dysfunction • Diarrhea • Abdominal pain • Early or late side effect	All	All	• Symptomatic treatment if symptoms are present < 2 weeks. • **Refer** to secondary care level if diarrhea is bloody, lasts > 2 weeks, or if condition is unstable.
Hepatitis • Yellowing of eyes (jaundice) • Usually an early side effect	Nevirapine (NVP) PI	Pyrazinamide Rifampicin Isoniazid	• **STOP** all drugs. • **Refer** to the ART initiation site or secondary care level and notify the site and facility that the referral was made.
Loss of appetite, nausea, stomach pain	AZT, DDI, IDV	INH	• Give INH at bedtime. • Take medicine with food (except if taking DDI, IDV). • If on AZT, encourage patient to continue until this common side effect stops.
Peripheral neuropathy • Early or late side effect	Stavudine Didanosine	Isoniazid (H) Cycloserine	• Give pyridoxine as preventive therapy and treatment for H toxicity. • Prescribe analgesics to reduce baseline pain and episodes of worsening pain. ○ Give pyridoxine 100mg daily. ○ Prescribe amitriptyline if no relief. ○ Call for advice if amitriptyline fails. • Educate patient to: ○ Wear loose-fitting shoes or sandals. ○ Keep feet and hands uncovered in bed. ○ Walk around to increase blood circulation to the feet, but not too much. ○ Soak hands/feet in coldest water tolerated. ○ Gently massage hands/feet. • If efforts are unsuccessful, **refer patient** to the secondary care level; notify the facility.

Adverse reaction	Main ARV drug involved	Main anti-TB drug involved	Management
Skin rash – mild to moderate • Red patches that flow into each other, maculo-papular features +/- itching, hives or blistering • Usually an early side effect	Nevirapine Efavirenz	Rifampicin Isoniazid Pyrazinamide Cycloserine	• Check liver function tests (LFTs), if possible: o If the rash develops within the patient's first 18 weeks on NVP o If the rash is associated with systemic symptoms and/or fever o If PHC is unable to check LFTs, refer patient to ART initiation site. • Continue with close PHC monitoring if no signs of mucous membrane involvement or systemic toxicity, and with instructions from the ART initiation site. o Ensure that the patient received a two-week lead in the NVP dose escalation schedule to reduce the effect/intensity of a hypersensitivity reaction as well as hepatotoxicity. o Provide patient education: Bathe with unscented soap. Avoid bathing in extra hot water. Protect skin from sun exposure. Avoid scratching skin. • Medication interventions if prescribed by the ART initiation site: o Consider antihistamines for a mild rash. o Consider H2 blockers or topical/oral steroids for a moderate rash.
Skin rash – moderate to severe • Macules with purple centers merging into blisters • Burning, painful lesions, especially on the face or upper body • Hives (urticaria) • Blistering erosions of the mucous membranes • Raised purple skin discolorations • Swelling of the face or tongue • Erythema	Nevirapine Efavirenz	Rifampicin Isoniazid Pyrazinamide Cycloserine	• Transfer immediately to a tertiary care center, preferably a burn unit; notify the ART initiation site that the transfer has been made. • Discontinue all antiretroviral medications. • Discontinue all other potentially causative medications, including trimethoprim/sulfamethoxazole • Avoid using glucocorticoids.

Source: WHO, "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press); FHI Standard Operating Procedures: Managing Adults AND Adolescents Living with HIV/AIDS at the Primary Health Center Level, Including Managing Patients on ART (2006).

3. If mild to moderate symptoms persist longer than two or three weeks, refer to site prescribing ART for evaluation; consult with medical team and TB/HIV specialist as needed.
4. Refer to Appendix 3 for more symptomatic management guidelines of mild to moderate medication-related symptoms.

5. Meet with clinical team and/or TB/HIV specialist to determine further TB and ART treatment.
6. Review possible IRIS symptoms at each scheduled or acute clinic visit.
    a. Symptoms include:
        (1) High fever
        (2) Worsening cough
        (3) Lymphadenopathy
        (4) Rash
        (5) Repeat or worsening of disease symptoms experienced from the past
        (6) Change in mental status
    b. Symptoms can occur two weeks to several months after anti-TB and HIV therapy.
    c. While usually self-limiting and lasting 10-40 days, some symptoms may be severe.
7. If IRIS symptoms present, **refer** and explain need for patient to **immediately** report to **ART initiation site for diagnosis and management.**
    a. **Continue** antiretroviral and TB medications.
    b. **Notify the site** that the referral has been made.

C. **If TB-HIV patient on ART** does not gain weight or develops new HIV-related diseases (WHO clinical stage 3 or 4), **refer patient** to ART provider and **consider the possibility of either IRIS or ART failure. Counsel** patients and families **to continue prescribed medications until examined by the ART prescriber.**

D. Document actions in patient's medical record; document any medication changes on the Tuberculosis Treatment Card and HIV Care/ART Card.

SOP 311: Determining TB Treatment Outcome

I. Key Concepts:

- Treatment outcomes refer to classifying TB types other than drug-resistant TB.

II. Key personnel: RN, MD/CO

III. Materials: Medical chart, laboratory investigation results, TB/HIV registers, Tuberculosis Treatment Card, HIV Care/ART Card

IV. Procedures:

A. Determine the outcome of the treatment.
   1. Perform a final follow-up medication review.
   2. Review follow-up laboratory investigations.
   3. Decide on the treatment outcome and record on TB treatment register.
   4. Analyze and report patient outcomes:
      a. Use cohort analysis.
      b. Report outcome by HIV co-infection status.

B. **Medication review**
   1. The **RN reviews** the patient's TB treatment monitoring schedule (Part 1 Forms 106, 107, 108) at the visit corresponding with the last scheduled TB treatment dose and asks the patient if all pills were taken.
   2. The RN then reviews the Tuberculosis Treatment Card (Part 1 Form 101) to ensure that documentation shows that all medication doses were taken by the patient.
   3. The RN confirms with the treatment supporter that all doses were completed.
   4. The RN documents findings in the medical chart/TB card.

C. **Laboratory review**
   1. The RN prepares the medical record to include the current laboratory investigations for MD/CO review and documents findings from the medical record:
      a. Sputum results (e.g., microscopy and culture, if available)
      b. Chest X-ray (if pulmonary TB)
      c. Other studies as needed or ordered
   2. The RN provides the medical record and lab results to the MD/CO.
   3. The MD/CO reviews the laboratory results and decides upon a treatment outcome diagnosis.

D. **Treatment outcome**
   1. Using the patient and laboratory register along with adherence data, **the MD/CO examines the patient and performs a confirmatory interview** about medication adherence and symptoms.
   2. The MD/CO determines a treatment outcome and documents it on the back of the Tuberculosis Treatment Card alongside the date the outcome was made (ideally, the last day of treatment), according to the original diagnosis and definitions in SOP 304.
      a. Determine the patient's TB treatment outcome. Definitions follow in Table 7:

Table 7: Identifying TB Treatment Outcomes

	TB treatment outcomes						
Definition (or patient criteria)	***Cure***	***Treatment completed***	***Treatment failure***	***Died***	***Default***	***Transfer out***	***Complete treatment***
A sputum smear-positive patient has 2 negative sputum samples: one in the last month of treatment; another on at least one prior occasion during treatment.	X						
A patient completes treatment but does not meet criteria for either cure or failure.		X					
A **new** patient sputum smear microscopy result is positive at 5 months or later during treatment.			X				
A **new** patient switched to Category IV treatment because sputum was found to be MDR-TB.			X				
A **previously-treated** patient is sputum smea- positive at the end of re-treatment.			X				
A **previously-treated** patient switched to Category IV treatment because sputum was found to be MDR-TB.			X				
A patient dies from any cause during the course of treatment.				X			
A patient's treatment was interrupted for ≥ 2 months in a row because they stopped coming for treatment, cannot be located, or cannot be convinced to resume treatment after 2 months of missed treatment.					X		
A patient was transferred to a health facility in another area and treatment outcome is unknown.						X	
A patient took every prescribed pill; missed doses extend a patient's continuation phase until all doses have been taken.							X

b. **Sputum smear-positive** TB outcomes:
   (1) Cure
   (2) Treatment completed
   (3) Treatment failure
   (4) Died
   (5) Default
   (6) Transfer out
   (7) Treatment success – cure plus treatment completed

c. **Sputum smear-negative and extrapulmonary** TB outcomes are determined by the facility-based clinician.

d. **Transfer patients**
   (1) Transfer out:
      (a) When a patient moves and you transfer TB care out to another site/facility to continue treatment, record the date and mark the outcome "Transfer out" on the back of the Tuberculosis Treatment Card.

(b) If the transfer is confirmed, inquire later about the treatment outcome.
(c) When the patient's outcome is reported from the other site/facility, record the final treatment outcome and the date of that outcome on the card.
(d) Only if you cannot determine another outcome, leave the outcome "Transfer out" with the date of the transfer.
(e) See Part 1, SOP 106 for more information on starting a TB treatment transfer of care.

(2) Transfer in: When a patient transfers care in from another health facility, contact the original facility to report the patient's final treatment outcome.

e. **Incomplete treatment**

(1) People do not complete treatment for many reasons, such as:
(a) Patient dies.
(b) Patient stops coming for treatment.
(c) Patient cannot be located.

(2) When a patient does not complete treatment, return all drugs remaining in the patient's drug box to the drug supply room.

E. **Treatment completion**

1. Document treatment outcome.
   a. Clarify whether treatment stopped due to completion (or death), or restarted, and the date.
   b. If restarted, the RN begins a new treatment card.
2. If treatment is completed, congratulate the patient and the treatment supporter.
3. Educate the patient about the need to continue follow-up for HIV/ART care and treatment, and the need for continued disease prevention precautions.

SOP 312: Treatment Supporter Training and Responsibilities

I. Key Concepts:

- Ideally, the community-based treatment supporter is someone in the patient's home, or near the work place or house.
- Training can be conducted by someone skilled in adherence support, such as an RN, or by a clinic/site staff member or volunteer who has been trained by an expert themselves.

II. Key Personnel: RN, treatment monitor, designated staff member, others trainers as needed or indicated by national guidelines

III. Materials: Reference materials, medical record, IEC, treatment aids such as calendars and pillboxes, treatment cards, training materials

IV. Procedures:

A. **Identify** the treatment supporter.

1. The nurse works with the patient to choose a treatment supporter once TB treatment has been decided upon as discussed in SOP 305, 308, and 309.
2. The treatment supporter **can be chosen from a variety of people**:
   a. Family member (partner, parent, son/daughter)
   b. Community member (teacher, spiritual guide)
   c. Friend (neighbor, support group member)
   d. Site volunteer
   e. Site staff
3. **Essential qualities** of the treatment supporter:
   a. Chosen by or acceptable to the patient
   b. Respected and trusted in the community and by the patient
   c. Accepting of the patient's illness
   d. Committed to supporting the patient throughout the entire treatment period
   e. Able to be educated on the disease and DOT
   f. Flexible in time and schedule
   g. Understanding of confidentiality, since no patient information can be shared beyond the patient, the RN and the MD/CO.

B. **Training**

1. **At baseline**, the RN or other designated, trained staff member arranges a time to train the identified treatment supporter(s).
   a. If possible, the RN schedules a time where a group of treatment supporters can be trained at one time.
   b. Organize a group of supporters from the community/volunteers in case the patient is not able to identify or disclose to someone they know.
2. Baseline training can last as long as a few hours or half a day, depending on the background experience of the identified treatment supporter.
3. **Baseline training topics**:
   a. **Provide an overview** to ensure that the treatment supporter understands and accepts the responsibilities: commitment, confidentiality, basic health knowledge, and knowledge of emergency resources for referral. Only continue with the training once the treatment supporter verbalizes understanding and acceptance of the responsibilities.

b. **Define confidentiality** and provide examples to reinforce the definition.
   (1) Information such as the patient's medical care, treatments, and diagnoses is private.
   (2) Such information can be shared only between the patient, the care provider, and the treatment supporter.
   (3) The only person who can share the patient's medical information with others is the patient.
c. Review **facts about TB** (Text Box 3).
d. Review **facts about HIV and ART,** per site standards.
e. **Address issues of stigma surrounding TB and HIV, both as a care provider and in the community.**
f. Review **how to give medications:**
   (1) Give drugs in a place with good air flow.
   (2) "Daily" treatment usually means giving 6 doses per week, or if using a fixed dose combination (FDC) in a blister pack, 7 days per week.
   (3) **If the patient misses a dose** (e.g, is not at the home or workplace, is too sick to tolerate the pill, or throws up the pill), give the missed dose the next day.
      (a) Do not give a double dose on any one day.
      (b) Continue according to schedule.
      (c) Extend the treatment duration to complete all doses in the regimen.
      (d) Notify the clinic of the need to extend the treatment schedule.
g. Discuss ways the treatment supporter can remind the patient to take the medication while developing a working relationship that encourages the patient to be independent.
h. Discuss the patient's follow-up schedule and the treatment supporter's role:
   (1) Attend all clinic visits.
   (2) Attend support group meetings, if able.
i. Discuss how the treatment supporter can help the patient remember or keep track of test results and clinic visits throughout the course of the treatment.
j. **Review signs/symptoms of provider burn-out.**
   (1) Encourage treatment supporter to identify burn-out early.
   (2) Prevent supporter drop-out.
k. Review how the **clinic will support the treatment supporter**:
   (1) Provide transportation, if able.
   (2) Provide psychosocial support.
   (3) Ensure a quick way to reach a clinic staff member in case of a patient or supporter emergency.

4. Provide the treatment supporter with a small packet of reference information, including:
   a. Important information about TB and HIV
   b. Referral contact information
   c. Tools for DOT visits, such as a Tuberculosis Treatment Card, clipboard, pens, pencils, and a bag or backpack.
5. **Offer regular (e.g., monthly) treatment supporter meetings and scheduled follow-up training** as well as training based on needs, interest, or new developments.
   a. Group support meetings to trouble-shoot medication barriers and burn out
   b. Individual meetings when supporter picks up patient medications
6. **Work with community leaders**, advocates, and other stakeholders, encouraging them to recruit potential treatment supporters for the clinic.

C. **Ongoing treatment supporter responsibilities**
   1. **Treatment**-related responsibilities
      a. Keep the medications.

b. Observe the patient swallow the drugs on a daily basis.
   (1) Tailor to patient's needs.
   (2) Demonstrate respect for patient.
   (3) Trouble-shoot medication adherence barriers.
c. Record the event on a Tuberculosis Treatment Card.
d. Coordinate with site staff to pick up medications, and to discuss treatment card documentation and patient adherence.

2. **Patient's health status**
   a. Refer patient to clinic and notify clinic of serious side effects or physical symptoms of OIs (see SOP 308).
   b. Monitor the health status of family and other community members who come in contact with the patient on a regular basis. Refer them to clinic as needed.
3. **Advocacy and support**
   a. Discuss how the patient is feeling, regarding symptoms, treatment, and emotions.
   b. Discuss any concerns the patient raises during conversation.
   c. Notify the clinic of key problems, such as:
      (1) Worsening health status
      (2) Continuing problems taking medications
      (3) Food insecurity
      (4) Housing issues
      (5) Interpersonal conflicts with household members, friends
4. **Education** and support
   a. Reinforce the need for adherence to the medication schedule and clinic visits.
   b. Provide information about TB and HIV prevention, as well as other disease prevention such as STIs.
   c. Offer information about TB and HIV treatment.
   d. Discuss and reinforce positive living strategies, such as good nutrition, exercise, support groups, and volunteerism.

SOP 313: TB and HIV Co-infection Continuing Patient Education

I. Key Concepts:

- Patient educational opportunities occur at every patient interaction.
- Ensure effective two-way communication between the provider and the patient.
- Use a non-judgmental tone during patient interactions and give the patient 100% of your attention during appointments.

II. Key Personnel: RN, treatment monitor, volunteer, adherence nurse counseler, MD, CO

III. Materials: Medical record, IEC, treatment aids (e.g., Appendix 3 and 4, calendars, pillboxes)

IV. Procedures:

A. **Who** provides TB and HIV co-infection education:
   1. The **clinical care nurse or adherence nurse counselor** leads patient and family education.
   2. However, any clinician, especially the **MD/MO**, assesses the patient and offers preventive health education during clinical care visits.

B. **When** education is provided:
   1. **Every clinic visit** should include education for patients, family or household members, and treatment supporters.
   2. Education is provided any time a patient, family member, household member, treatment supporter, or other person asks a question about TB and HIV.

C. TB and HIV **co-infection education**
   1. When discussing questions related to TB and HIV, **demonstrate a caring and respectful attitude.**
   2. **Praise and encourage the patient** for asking questions and completing milestones throughout the treatment, such as:
      a. Completing the initial TB medication phase
      b. Adhering to a TB-HIV medication regimen
      c. Managing mild to moderate side effects of medications or of the disease process
   3. First, ask questions to **assess the current level of education about the disease**. Provide messages based on the respondent's answers. Following are suggested questions and answers*:

Q: What do you think TB is?
What do you think may have caused you to get TB?

A: Tuberculosis, or TB, is an illness caused by a germ that is breathed into the lungs. The TB germs can settle anywhere in the body, but they most often land and stay in the lungs. When TB hurts or damages the lungs, a person coughs up sputum from the lungs and cannot breathe well. Without the correct medication, a person can die from TB.

Q: Have you ever known anyone with TB?
What happened to that person?
Do you know that TB can be cured?

A: TB can be cured with the correct medication treatment. A patient must take every

recommended drug for the entire treatment time in order to be cured.
TB drugs are free of charge. Patients do not have to pay for their anti-TB medications.
You can take your TB medications without changing your daily routine or work schedule.

Q: How do you think TB is spread?

A: TB spreads from one person to another when an infected person coughs or sneezes and sprays TB germs into the air. When that happens, other people breathe in the germs and may become infected.
Germs pass easily to family and other household members when many people live together in a close space.
Anyone can get TB, but not everyone infected with TB will become sick.

Q: How can you avoid spreading TB?

A: Take prescribed anti-TB medications on a regular basis (daily, every other day) to become cured of TB.
Cover the mouth and nose when coughing or sneezing.
Open windows and doors to allow fresh air through the home; use a fan if available.
Make use of sunlight, for example, by drying clothes outside during the morning hours.
There is no need to eat special foods if infected with TB and taking anti-TB medications; eat a balanced meal.
There is no need to use separate plates, dishes, or household items when you have a family member on TB treatment.
Do not spit on the ground in the home, outside the home, in the workplace, or in the general community.
Spit sputum into a disposable paper, tissue, or old cloth and discard (burn, bury, or dispose of in a toilet or covered garbage receptacle).

Q: How many people live with you, and what ages are they?
Does anyone else in your household have a cough? If so, who?

A: All children under 5 years of age living in the household should be evaluated for TB symptoms; children this age are at risk of severe forms of TB. Young children may need preventive medications or referral to a specialist for evaluation.
Other household members need to be tested for TB, especially if they are HIV-infected or have a cough.

Q: Can you explain why it is important that somebody else observes and supports you to swallow your TB and/or HIV medications?

A: A good health service should ensure that a patient takes every medicine dose without any problem. If problems come up, the health service is there to help.
A health worker must watch you swallow all your prescribed TB and HIV drugs according to the prescribed schedule. This will ensure that you take the correct drugs for the correct period of time. If you need to take injections to cure TB, they will be given safely. When a health worker sees you on a regular basis, the health worker will see if you have side effects or other problems from the drugs or the disease.
If you do not take all of your prescribed drugs, you will continue to spread TB to others in your family and community, and your TB will not be cured. It is dangerous to stop or take a break from treatment. If you do this, the disease may never be cured. With direct observed therapy (DOT), the health worker will know if you miss a dose and will quickly find out the problem.
If you must travel or move away, tell the health worker so that plans can be made to continue your treatment without taking any breaks.

Q: How long should you take your anti-TB drugs? How frequent and where are your clinic visits?

*A: The medication and clinic visit schedule (**treatment length, visit frequency, and where to go for treatment) is individualized** for each patient.*
If preassembled drug boxes are used, all the drugs needed to treat TB (and HIV, if applicable) are kept in a box with the patient's name on it so that the clinic will never run out of medications.

Q: What should you expect when taking the drugs? What should you do next?

*A: If **taking rifampicin**, your urine may turn orange/red. This **is expected and is not harmful**. If you feel nauseous from the drugs, bring a bit of food to eat at the time you take your next dose.*
***TB and HIV treatment does not have to interrupt normal life and work**.*
Be sure that you know exactly where and when to go for the next treatment visit. (Ask questions to be sure the patient can make the next scheduled visit and that the patient is committed to returning to the clinic.)
Remember to bring family, friends, and other close contacts to the clinic for TB testing.

*Adapted from WHO, "Tuberculosis Care with TB-HIV Co-managemen,t" 2007.

4. Offer motivational statements throughout treatment duration (see Text Box 4).
5. Review issues related to HIV and TB, including:
   a. Transmission
   b. How TB and HIV care are interrelated
6. **Support the disclosure** of the patient's TB and HIV status.
   a. Discuss the advantages.
   b. Discuss the patient's concerns about disclosing status to partner, family members, children, and friends.
      (1) If patient has not disclosed yet, assess their readiness to disclose their disease status.
      (2) Assess the patient's social network; encourage disclosure to the most trustworthy person first.
      (3) Assess the patient's social support and needs.
      (4) Reassure the patient that you will keep all results confidential.
      (5) Offer another appointment if needed; offer more help as needed, such as peer counseling.
7. After finishing the question and answer session, **ask review questions** to make sure the patient fully understood the information discussed.
   a. Make sure the patient knows what to do before leaving the clinic.
   b. Reinforce earlier messages and give more information as needed.
8. Always ask the patient if s/he has any further questions before completing the appointment.

Text Box 4: Motivational Statements

TB can be cured if you keep coming for the medicine, and then you will not have to worry about it any more.

You only have __ more doses to take every day. After that, you will come less often.

These are the safest, most effective drugs available to treat TB anywhere in the world.

Almost all patients who take their medicines as recommended are cured.

If you keep taking your medicine, you will not spread TB to your family.

Taking only some of the drugs, or taking them irregularly, is dangerous and can make the disease difficult or impossible to cure.

* Adapted from WHO, "Tuberculosis Care with TB-HIV Co-management," 2007.

D. Document the educational session in the patient's medical record.

Appendices

Appendix 1: TB Drug Information and Monitoring Guide

TB Drug Information and Monitoring Guide

Drug	Dose	Use	Side Effects for Patient Monitoring	Side Effects for Referral to Secondary or Tertiary Facility
Pyrazinamide (PZA)	• Active TB (induction): 20-25mg/kg (max 2gm) daily • DOT dose changes for 2x/week and 3x/week dosing • If CD4 < 100, dose DOT 3x/week	• New TB: smear (+), smear (-), EP, smear (-) relapse • TB smear (+) re-treatment: treatment failure, treatment after default, smear (+) relapse • MDR-TB	• Joint pain • Nausea, vomiting • Stomach discomfort	• Severe stomach pain • Severe joint pain • Persistent vomiting • Yellowing of eyes
Rifampicin (RIF)	• Active and latent: 10 mg/kg (max 600mg) daily • DOT: 600mg 2-3x/week • If CD4 < 100, dose DOT 3x/week • With LPV/r: LPV/r 400/100mg (3 caps) + RIF 300mg bid • With EFV: EFV 800mg + RIF 600mg daily	• TB treatment • Latent TB • Contraindicated with all PIs except LPV/r	• Orange discoloration of urine, tears, sweat • Nausea, vomiting • Stomach discomfort • Signs/symptoms of hepatitis in first month • Flu-like symptoms (fever, chills, dizziness, bone pain, generalized itching)	• Hypersensitivity • Thrombocytopenia • Hemolytic anemia • Headache • Dizziness • Jaundice
Isoniazid (INH) *Co-administer with pyridoxine 50mg/day or 100mg 2x/week to prevent neuropathy*	• Active and latent: 5 mg/kg (max 300mg) daily • DOT: 15mg/kg (max 900mg) 2-3x/week • If CD4 < 100, dose DOT 3x/week • Give drug 1 hour before or 2 hours after meals	• Active TB treatment • Latent TB	• Nausea, vomiting, diarrhea • Stomach discomfort • Peripheral neuropathy (consider increased dose of pyridoxine) • Joint pain •	• Hypersensitivity • Signs/symptoms of hepatitis • Bone marrow suppression • Fever • Vision changes (optic neuropathy) • Rash, exfoliative dermatitis, itching, swelling • Psychosis (CNS toxicity) • Jaundice
Ethambutol (EMB)	• 15-20 mg/kg (max 2 grams) daily • DOT: 50 mg/kg 2x/week (max 4 grams) or 25-30 mg/kg 3x/week (max 2.4 grams) • If CD4 < 100, dose DOT 3x/week	• New TB: smear (+), smear (-), EP, smear (-) relapse • TB smear (+) re-treatment: treatment failure, treatment after default, smear (+) relapse • MDR-TB	• Anorexia • Nausea, vomiting • Stomach discomfort • Vision changes: decreased acuity, decreased color vision, constricted visual fields, blind spots	• Thrombocytopenia • Leukopenia • Neutropenia • Lymphadenopathy • Peripheral neuropathy • Confusion • Dizziness • Rash, itching, dermatitis, exfoliative dermatitis • Acute gout • Interstitial nephritis
Streptomycin *Avoid co-administration with loop diuretics and nephrotoxic drugs (e.g., cidofovir, foscarnet, ampho B)*	• 15 mg/kg (usually 1 gram) intramuscular (IM) injection daily • If > 50 years old, 10 mg/kg (usually 750mg) daily • DOT: 25-30 mg/kg IM 2-3x/week • If CD4 < 100, dose DOT 3x/week	• Second-line treatment • Added during TB smear (+) re-treatment: treatment failure, treatment after default, smear (+) relapse • MDR-TB *Avoid use when pregnant, elderly, or with poor renal function*	• Rare	• Renal failure • Vision changes: decreased acuity, decreased color vision, constricted visual fields, blind spots • Hearing changes • Neuromuscular blockade • Encephalopathy

Source: WHO, ""Treatment of Tuberculosis: Guidelines for National Programmes, Third Edition," 2003; Johns Hopkins University Antibiotic Guide accessed online http://prod.hopkins-abxguide.org/antibiotics 2009; WHO: Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008.

Appendix 2: Common Antiretroviral Drug Guide

Drug	Dose	Formulation	Comments
Zidovudine (AZT)	• 300 mg bid	• Syrup: 10 mg/ml • Capsules: 100 mg; 250 mg • Tablet: 300 mg	• Large volume of syrup not well-tolerated in older children • Needs storage in glass jars; is light sensitive • Can give with food • Do not give with d4T • Dose = 600 mg/m^2 bid in HIV encephalopathy
Stavudine (d4T)	• > 60 kg: 40 mg bid • < 60 kg: 30 mg bid	• Oral solution: 1 mg/ml • Capsules: 15 mg, 20 mg, 30 mg, 40 mg	• Large volume solution • Keep solution refrigerated; stable for 30 days • Must shake well before administration • Store in glass bottles • Can open capsules and mix with food – well-tolerated (stable in solution for 24 hours if kept refrigerated) • Do not use with AZT
Lamivudine (3TC)	• 150 mg bid	• Oral solution: 10 mg/ml • Tablet: 150 mg	• Well-tolerated • Can give with food • Store solution at room temperature (use within one month of opening) • Tablet can be washed, mixed with small amount of water or food and taken immediately
Abacavir (ABC)	• 300 mg bid	• Oral solution: 20 mg/ml • Tablet: 300 mg	• Syrup well-tolerated or can crush tablet • Can give with food • WARN patient about hypersensitivity reaction • Stop and never restart if patient experienced hypersensitivity reaction to ABC
Tenofovir (TDF)	• 300 mg daily	• Tablet: 300 mg	• Well-tolerated • Can take with or without food
Efavirenz (EFV)	• Capsule (liquid) dose for > 3 years: 10-15 kg: 200 mg (270 mg = 9 ml) once daily • 15-20 kg: 250 mg • (300 mg = 10 ml) once daily • 20-25 kg: 300 mg (360 mg = 12 ml) once daily • 25-33 kg: 350 mg (450 mg = 15 ml) once daily • 33-40 kg: 400 mg (510 mg = 17 ml) once daily • Maximum dose: >40 kg: 600 mg daily	• Syrup: 30 mg/ml (note: syrup requires higher doses than capsules) • Capsules: 50 mg, 100 mg, 200 mg	• Capsules may be opened and added to food but have very peppery taste; can mix with sweet foods or jam to disguise taste • Can give with food but avoid high-fat meals which increase absorption by 50% • Best if given at bedtime, especially for the first 2 weeks of administration • Watch for drug interactions • Only for children > 3 years

Drug	Dose	Formulation	Comments
Nevirapine (NVP)	• 15-30 days: 5 mg/kg once daily for 2 weeks, then 120 mg/m^2 bid for 2 weeks, then 200 mg/m^2 bid • > 30 days to 13 years: 120 mg/m^2 once daily for 2 weeks, then 120-200 mg/m^2 bid • Maximum dose: >13 years: 200 mg daily for 14 days, then 200 mg bid	• Oral suspension: 10 mg/ml • Tablet: 200 mg	• Avoid co-administration with rifampicin. • Store suspension at room temperature; shake well. • Can give with food • MUST warn about rash; do not escalate dose if rash occurs. • Drug interactions exist.
Nelfinavir (NFV)	• <1 year: 40-50 mg/kg tid or 75 mg/kg bid • >1 year to < 13 years: 55 to 65 mg/kg bid • Maximum dose: 1250 mg bid	• Powder for oral suspension (mix with liquid): 200 mg per level 5 ml teaspoon (50 mg per 1.25 ml scoop) • Tablet: 250 mg (tablets can be halved; can be crushed and added to food or dissolved in water)	• Powder is hard to dissolve; must be reconstituted immediately prior to administration in water, milk, formula, pudding, etc. Do not use acidic food or juice —increases bitter taste. • Because of difficulties using powder, crushed tablets are preferred (even for infants) if appropriate dose can be given. • Powder and tablets can be stored at room temperature. • Take with food. • Drug interactions exist (less than with the RTV-containing PIs).
Lopinavir / ritonavir	• >6 months to 13 years: 225mg/m^2 LPV/57.5 mg/m^2 RTV bid or weight-based dosing: • 7-15 kg: 12 mg/kg LPV 3 mg/kg RTV bid • 15-40 kg: 10 mg/kg LPV 2-5 mg/kg RTV bid Capsules • Maximum dose >40 kg: 400 mg LPV/100 mg RTV (3 capsules or 5 ml) bid Tablets • Treatment-naïve 2 tablets bid (400/100 mg bid) regardless of co-administration with EFV or NVP • Treatment-experienced: 3 tablets bid (600/150 mg bid) when combined with EFV or NVP	• Oral solution: 80 mg/ml LPV plus 20 mg/ml RTV • Capsules: 133.3 mg LPV plus 33.3 mg RTV • Tablet: 200 mg LPV plus 50 mg RTV	• Ideally, oral solution should be refrigerated; however, can store at room temperature up to 25 C (77 F) for 2 months. • Heat stable tablets can be stored at room temperature. • Liquid formulation has low volume but bitter taste. • Capsules are large. • Take with food. • Drug interactions exist.

Drug	Dose	Formulation	Comments
Indinavir / ritonavir (IDV/r)	• 800 mg/100 mg bid • Other doses include: 800/200 mg bid, or 400/100 mg bid	• Capsule: 200 mg IDV, 400 mg IDV (RTV separate)	• Take with water. • Drink plenty of fluid throughout the day while on this medication — preferably 6 8-ounce glasses a day — to prevent kidney stones. • Can take with or without food (light meal preferred). • Avoid taking medicine while eating any foods high in fat, calories, or protein.

Source: WHO, "TB/HIV: A Clinical Manual, Second Edition," 2004.

Appendix 3: Symptom-based Treatments for Minor–Moderate Medication Side Effects

Minor side effects: monitor and manage at each clinical visit; encourage home-based management

Symptom	Treatment
Loss of appetite, nausea, stomach pain →	• Give INH at bedtime. • Take medicine with food, except if taking didanosine (DDI) or IDV. • If on AZT, encourage patient to continue until this common side effect stops.
Joint pain →	• Give aspirin, paracetamol, or non-steroidal anti-inflammatory drugs (NSAIDS).
Burning pain in hands/feet →	• Give pyridoxine 100mg daily. • Prescribe amitriptyline if no relief. • Call for advice if amitriptyline fails.
Orange/red urine →	Explain that this is a normal finding when taking rifampicin. •
Headache →	• Give aspirin, paracetamol, or NSAIDS. • Assess for signs/symptoms of meningitis (e.g., neck stiffness, sensitivity to light); if suspected, refer to facility for evaluation and treatment. • If meningitis is ruled out and patient is on AZT or EFV, encourage patient to continue treatment until the common side effect stops. • Provide supportive care and follow up in 2 weeks.
Blue/black nails →	• This symptom is unrelated to TB medications. • Explain that this is a normal finding for people taking AZT.
Changes in body fat →	• This symptom is unrelated to TB medications. • Explain that this is a normal finding. • Discuss whether patient can accept this body image change.

Moderate side effects: monitor and manage closely (e.g., daily, or weekly)

Symptom	Treatment
Diarrhea →	• Rehydrate following site protocols. • Make sure patient is able to tolerate fluids. • Instruct patient to try a bland diet. • If just started ART, encourage patient that diarrhea may stop in a few more days. • Make follow-up appointment for 2 weeks. • Instruct patient to go to facility if condition worsens before 2-week follow-up appointment.
Fatigue →	• Check hemoglobin (if available) for anemia, especially if patient has started on AZT. • If hemoglobin is low, manage according to site protocols and notify MD/CO prescribing ART. • If hemoglobin is normal, encourage patient that symptom can last 4-6 weeks then go away. • Call for advice or refer to facility if fatigue is severe and lasts longer than 4-6 weeks. • If unable to check hemoglobin, refer to secondary facility for evaluation.

Anxiety, nightmares →
- This symptom is usually unrelated to TB medications.
- If on EFV, ensure it is given at night.
- Explain that these symptoms usually end 3 weeks after starting EFV.
- Consider prescribing amitriptyline during initial EFV administration.
- If severe depression, suicidal thoughts or psychosis occur, ensure patient's safety and refer immediately to facility for hospitalization.

Skin rash, itching
All over body
Peeling →
- Stop TB/ART medications and refer immediately to tertiary facility for evaluation.

Yellow eyes or skin (jaundice) →
- If on TB medications only, stop TB drugs and immediately refer to tertiary facility for evaluation.
- If on TB/ART, refer immediately to ART provider.

Vomiting →
- If severe, stop TB/ART and refer to secondary or tertiary facility immediately.
- If mild or moderate:
  - Rehydrate with oral rehydration salts if not contraindicated.
  - Observe patient in the PHC for at least four hours.
  - Reassess the patient during and after observation.
  - Drape a comfortably warm, moist towel around patient's neck until symptoms decrease.
  - If the patient's clinical status is improving, then:
    - Attempt feeding in clinic.
    - Provide ORS education and take-home supply for patient.
  - Provide patient education:
    - Stay hydrated: drink boiled water; peppermint or ginger tea.
    - Eat small, bland snacks throughout the day (bananas, white rice, applesauce, porridge, potatoes).
    - Avoid foods and smells that trigger nausea/vomiting or decrease appetite (spicy, greasy, acidic foods such as oranges or tomatoes).
  - Teach signs and symptoms that require a return visit to PHC or secondary care.
  - Refer to local nutritional support programs.
  - Send patient home; arrange to reassess patient within 5 days.
  - If patient has not improved significantly, refer to the secondary care level and notify facility that the referral has been made.

Fever →
- **Determine the onset, duration, and pattern of the patient's fever/chills** and whether it is associated with other signs or symptoms.
- Rule out common causes.
- Send labs as available, needed, or indicated according to site protocols (e.g., hemoglobin, urinalysis, WBC, malaria smear, or dipstick).
- Refer patient to the ART initiation site or secondary care level, and notify the site or facility that the referral was made.

Jaundice with abdominal or flank pain →
- Stop TB/ART, especially if the patient is taking DDI or D4T.
- Refer patient immediately to tertiary facility for evaluation and care.

Cough, difficulty breathing →

- If unstable, refer patient immediately to secondary level of care.
- If stable, manage as outpatient at the PHC.
  - For a patient with suspected pneumonia symptoms, including:

    No- bloody cough
    Mild shortness of breath
    Active with activities of daily living (ADLs)
    CD4 count > 300/mm^3
    - Interventions:

      Give antibiotic treatment for suspected pneumonia.
      Re-evaluate patient within 48 hours.
      If the patient is not improving, refer to the secondary care level, and notify the facility that the referral has been made.
  - For patient with cough as only primary symptom:
    - Interventions:

      Follow the patient closely and manage his/her symptoms.
      Encourage the patient to stop smoking.
      Counsel patient to return to the PHC or nearest open hospital if s/he develops fever, shortness of breath or bloody cough symptoms.
- If unexplained cough continues, refer to the secondary care level and notify the facility that the referral has been made.

Lymphadenopathy →

- Could indicate immune reconstitution syndrome
- Refer to ART provider to rule out IRIS.

Appendix 4: Symptom Management Educational Aid*

Symptom	Strategies to Manage
Headache	• Decrease activity; rest in a quiet, dark room with eyes closed. • Place cold moist cloth over eyes. • Stay out of the sun: decrease exposure to light. • Stay hydrated: drink boiled water; avoid caffeine (coffee, tea, carbonated soft drinks) and alcohol. • Avoid foods and other stimuli that trigger headaches.
Nausea/Vomiting/Anorexia	• Stay hydrated: drink boiled water, or peppermint or ginger tea. • Eat small, bland snacks throughout the day (bananas, white rice, toast, applesauce, porridge, potatoes). • Avoid foods and smells that trigger nausea/vomiting or decrease appetite: spicy, greasy, acidic foods (e.g., oranges, tomatoes). • For nausea/vomiting: drape a comfortably warm moist towel around the neck until the nausea/vomiting subsides.
Diarrhea	• Stay hydrated: drink boiled water or weak tea. • Don't stop eating, but avoid foods and fluids that can increase diarrhea (fruits, vegetables, milk products, high fat foods, very sweet foods). • Eat bland foods, such as white rice and porridge. • Maintain good hygiene: wash hands after going to the bathroom, before and after eating, before and after handling any food. • *Gently* clean skin around rectal area after each episode of loose stool.
Mild tingling, burning, or pain in hands or feet	• Wear loose-fitting shoes or sandals. • Walk around to help blood circulation to the feet, but not too much. • Soak hands/feet in the coldest water that can be tolerated. • Gently massage hands/feet. • Keep hands and feet uncovered in bed.
Insomnia	• Reduce noise and light; sleep in a quiet, dark room. • Avoid exercise and other energetic activity several hours before bedtime. • Avoid eating a large meal 3-4 hours before bedtime. • Avoid drinking fluids with caffeine at least four hours before going to bed (coffee, tea, carbonated soft drinks). • Avoid drinking alcohol. • Consciously relax muscles, especially in shoulders, arms and legs. • Perform quiet activities that usually make you sleepy, such as listening to soft music.
Dizziness	• Change positions very slowly (for example, from lying down to sitting). • Use nearby furniture and walls for support if dizziness occurs when walking. • Ask family members and friends for support if intense dizziness occurs when walking. • Stay hydrated: drink boiled water and fluids without caffeine. • Avoid alcohol.
Bad dreams	• Talk about your dreams with a family member or friend. • Recognize that dreams are imaginary and are not real.
Confusion/difficulty concentrating	• Talk about your feelings of confusion or difficulty concentrating with a family member or friend. • Ask a family member or friend to clarify what confuses you. • Focus on one activity or thought at a time.
Mild rash	• Bathe with unscented mild soap (for example, oatmeal) • Avoid bathing in extra hot water. • Protect your skin from sun exposure. • Don't scratch your skin.

* Adapted from Family Health International: "SOPs for ART Adherence Counseling," 2005.

Part 4: Standard Operating Procedures for Collaborative TB/HIV Care Delivery *Facility-based Guidelines*

Appendices

SOP 401: TB Infection Control

I. Key Concepts:

- **The goal of TB infection control (IC)** is to **minimize the risk of TB transmission by** detecting patients with TB disease early, isolating them promptly, and treating them quickly.
- Every health facility should **have an IC implementation plan** that describes appropriate activities and measures for the health center, including four control levels: managerial, administrative, environmental, and respiratory.
- Implement IC along with universal or standard precautions (Part I SOP 105).
- HIV-infected healthcare workers (HCWs) and support staff are at increased risk of TB infection and active disease because of frequent exposure to TB suspects and undiagnosed individuals with TB disease in the workplace.
- Any pulmonary TB (PTB) patient during the first two weeks of treatment is considered infectious**; PTB patients may spread TB to others via airborne transmission.**
- The reference to "TB" in this and other SOPs refers to the transmission or spread of *Mycobacterium tuberculosis*, or TB bacilli, that the recommended TBIC measures mean to prevent.
- A TB patient is considered non-infectious after:
  - having 2-3 consecutive negative sputum smears on two different days while on TB treatment
  - completing at least two weeks of correct anti-TB therapy
  - completing a diagnostic evaluation or full TB treatment course

II. Key Personnel: MD, CO, RN, patient, family members, health workers

III. Materials:

- Face/surgical masks: Help prevent TB transmission from the patient wearing the mask to others by capturing the large wet particles near the mouth and nose
- Paper tissues: Less costly; lower stigma as tissue use does not readily mark one as a TB suspect; less likely to be used correctly
- Personal respiratory protection: US-certified N95 (or greater) respirator; EU-certified FFP2 (or greater) respirator; powered air purifying respirators that have a half or full facepiece, breathing tube, battery-operated blower, and particulate filters (HEPA only)
  - Used by staff to wear in high risk areas and during high risk procedures as described in the infection control implementation plan

IV. Procedures:

A. **Managerial** control measures

1. **Develop a TBIC Steering Committee**
   a. Identify a person with expertise in IC, planning, architecture, and engineering to lead the team.
   b. Carry out a risk assessment to identify risk of TB transmission to PLHA in the clinic.
2. Develop policies and procedures to ensure proper implementation of controls.
   a. Rethink the use of available spaces and consider renovation of the health facility, as able, to optimize the implementation of IC measures.
   b. Design the entire health facility, particularly the waiting areas and examination rooms, with the most natural ventilation possible.
   c. Develop a TBIC Implementation Plan based on findings from the risk assessment.
   d. Include clinic management and staff in creating a feasible IC plan. A sample plan is presented as an Annex in the Addendum to *WHO Guidelines for the Prevention of Tuberculosis in Health Care Facilities in Resource-Limited Settings, 1999.*

e. Work with local coordinating bodies, including human resources, in the development and implementation of TBIC.
f. Participate in research efforts to improve the TBIC plan.

3. Monitor the TBIC implementation plan.
   a. The lead IC team member regularly supervises and monitors the IC plan; the TBIC steering committee meets annually to assess the plan.
   b. Include civil society involvement, behavioral change campaigns, and reinforcement of positive messages for health workers, patients, and visitors.
4. Schedule annual all-staff training about TB, TB infection control, and the clinic's TBIC implementation plan.

B. **Administrative** control measures
   1. **Promptly identify potential and known infectious cases of TB; separate and treat them with minimal delay.**
   2. **Triage and screening**
      a. Promote safety without stigma:
         (1) Educate patients and health workers on proper cough etiquette and cough hygiene.
         (2) Place educational posters about infection control measures in outpatient waiting areas as well as in procedure rooms and other areas where they can be seen and easily read by patients and staff.
      b. The triage RN screens all patients in a well-ventilated area and **identifies people with a cough lasting > two weeks** as soon as possible upon arrival to the clinic.
      c. Explain to patients that **safety without stigma** is the goal of IC, and that screening for and prevention of TB transmission is part of providing quality care.
      d. **If symptomatic, initiate IC measures**.
   3. **Encourage proper cough hygiene**.
      a. Work together to help patients adhere to proper cough hygiene and etiquette.
      b. Ask the coughing person to **cover their mouth when they cough or sneeze** and to practice **handwashing.**
      c. **For outpatients: Provide face masks, tissues, or disposable cloth scraps** to TB suspects for immediate use.
         (1) If a face mask is available, give to TB suspect to wear over their mouth and nose until they leave the clinic.
         (2) If tissues or cloth scraps are available, instruct TB suspects to cover their mouth and nose when coughing or sneezing.
      d. **For inpatients: Provide face masks, tissues, or disposable cloth scraps** to TB suspects or those with active disease to use when leaving isolation areas to complete procedures in other areas of the hospital, or when healthcare workers are taking care of them.
   4. **Place TB suspects in a separate or designated area**.
      a. Follow diagnostic protocols (SOPs 402 and 403) in an outpatient setting whenever possible.
      b. **If the TB suspect is an inpatient,** place the person in a separate, well-ventilated room. If this is not possible, place the TB suspect in a separate ward far away from other HIV-infected inpatients.
      c. **Expedite** the patient's receipt of **outpatient clinic services**; if possible, the RN should fast-track TB suspects to receive care and attention from the MD/CO as soon as possible**.**
         (a) **Move suspects to the front of the queue** for whatever services they require (e.g. medication refills, medical evaluation).
         (b) When the RN or lab staff collects sputum samples for TB, **collect the specimen outside in a designated procedure room or an open environment**, away from other people. Do not collect sputum samples in enclosed spaces such as small rooms, bathrooms, or toilets.

d. **Wash hands** between each patient interaction (Part 1 SOP 105).

5. Ensure a **rapid diagnosis process and initiation of treatment**.
   a. Follow up daily on sputum smear and culture results from the laboratory. (Ideal turnaround time for sputum acid-fast bacilli (AFB) is less than 24 hours.)
   b. Evaluate chest X-ray (CXR) results as soon as they are available.
   c. Monitor TB suspect frequently for symptomatic improvement.
   d. Provide diagnosis and treatment plan to patient and family.
   e. Implement daily directly observed therapy (DOT).
   f. **Initiate isoniazid preventive therapy** (IPT) in HIV-infected individuals who definitively **do not have active TB disease** (SOP 407).
6. Offer a rapid screening mechanism for potential contacts of TB suspects, such as symptomatic patients, or visitors accompanying a TB suspect.
7. **Provide all staff with intensified screening for active TB disease**.
   a. Periodically screen staff for symptoms of active TB disease.
   b. Schedule all-staff TB testing twice a year in high TB and HIV-prevalence areas.
   c. Document results in the staff member's occupational file.
8. **In high-burden TB and HIV settings, test all HCWs for HIV in addition to TB**.
   a. Offer staff voluntary, confidential HIV counseling/testing, and annual repeat testing if HIV-negative on previous occasions.
   b. Refer staff members for assessment of and preferential access to ART.
   c. Provide cotrimoxazole preventive therapy (CPT) for co-infected HCWs.
   d. Provide IPT as indicated (SOP 407).
9. **Do not assign HIV-infected HCWs** to work in high-prevalent TB settings, if possible.
10. **Prevent HIV-infected HCWs from coming in contact with**:
    a. Patients assessed for but not yet diagnosed with TB, such as in outpatient department (OPD) waiting rooms and emergency departments.
    b. Sputum collection procedures
    c. Bronchoscopy
    d. Routine laboratory test site for diagnosing TB
    e. Autopsy area
    f. Inpatient medical, pediatric, and TB wards

C. **Environmental control measures**

1. **Use environmental control measures together with the recommended clinic practices to reduce the transmission of TB bacilli**.
2. Dilute the concentration of TB bacilli in the room air, or move the air in a building and replace it with fresh air from outside.
   a. **Tailor** environmental controls to local climatic and socioeconomic conditions.
      (1) **Natural ventilation**
         (a) Use in inpatient wards, outpatient clinic waiting rooms, and rooms used for sputum collection and cough-inducing procedures.
         (b) Weather permitting, arrange for sputum collection to be done outdoors.
         (c) In warm climates, use an open-air shelter with a roof to protect patients from sun and rain.
         (d) If indoors, keep clinic doors and windows on opposite sides of the area open to bring in air from the outside.
      (2) **Mechanical ventilation**
         (a) Use propeller fans mounted in ceilings or in a window opening to distribute and direct airflow.
         (b) Ensure that the air flows across the room if used in a high-risk area; place the fan behind the HCW and direct air past the HCW, past the TB suspect, and out the opposite window.
   b. **Sputum collection rooms**
      (1) Post written instructions on how to correctly collect sputum (SOP 403).
      (2) Instruct patient to stay in the room post-procedure until coughing stops.

(3) After the TB suspect leaves the room, allow enough time for at least 99% of the airborne contaminants to be removed before the next sputum collection.
(4) Refer to Table 1 for help in estimating the time needed to clean airborne *M. tuberculosis* after the source patient leaves the area, or when aerosol-producing procedures are complete.

Table 1: Estimated Time Needed to Clear Air of Airborne M. tuberculosis After the Source Patient Leaves the Area or When Aerosol-producing Procedures are Complete

	Minutes required to reduce airborne concentration by:	
Air change per hour (ACH)	**99%**	**99.9%**
2	138	207
4	69	104
6	46	69
12	23	35
15	18	28
20	7	14
50	3	6
400	<1	1

Source: WHO, "Guidance for National Tuberculosis and HIV Programmes on the management of Tuberculosis in HIV-infected Children," 2009 (in press).

3. **Filtration and ultraviolet germicidal irradiation**
   a. This method is complex and expensive.
   b. More often found in referral hospitals to go with ventilation
   c. Requires regular maintenance service
   d. **Must ensure** proper functioning by periodical servicing and cleaning

D. **Respiratory** control measures for all HCWs and administrative staff
1. **Do not use a face mask** as a TB prevention method when working with TB suspects.
   a. Face masks only reduce transmission from symptomatic person(s) to others.
   b. The best prevention of TB transmission occurs when TB suspects are diagnosed promptly with TB, started immediately on the correct TB drugs, and the drugs are taken by patients exactly as prescribed. In this way patients usually become non-infectious in a week or two.
2. **Respirators**
   a. **Restrict use to specific high-risk areas,** such as rooms where diagnostic incentive spirometry or bronchoscopy are performed, or specialized MDR-TB treatment centers.
   b. Require specialized equipment to determine the correct fit (e.g., N95 facemask)
   c. Work best with other environmental controls alongside proper work practices to protect HCWs from inhaling TB bacilli
   d. Expensive

SOP 402: Screening for TB in HIV-infected Individuals

I. Key Concepts:

- TB is the most frequent opportunistic infection (OI) of HIV-infected persons, demanding routine and symptom-based TB screening and testing in HIV-infected individuals.
- Regular TB screening can lead to early detection of TB; screening facilitates provision of TB preventive therapy.
- Always consider TB in a patient with a cough, or even in the absence of cough but with other symptoms.
- When screening for TB, use purified protein derivative (PPD) if available, and if staff is trained to administer and evaluate the results of a tuberculin skin test (TST) (refer to Appendix 1).

II. Key Personnel: MD, CO, RN, health worker

III. Materials: Stethoscope, thermometer, scale, medical record, HIV Care/ART Card (Part 1 Form 102), BMI chart, area to isolate TB suspects, face mask for TB suspects (if available), specimen cups, SOP 401: TB Infection Control

IV. Procedures:

A. The RN and MD/CO screen HIV-infected infants, children, adolescents, and adults for TB at each visit, whether an acute or scheduled chronic HIV care visit, or acute hospitalization.

Infants and children

1. Check **vital signs**. (RN or designated, trained staff member) Note and record all findings in medical record.
   a. Weight
   b. Length/height
   c. Respiration rate
      (1) Recount if fast (for children 5-12 years old: fast = 30/minute, very fast ≥ 40/minute)
   d. Temperature
   e. Heart rate
   f. Blood pressure
   g. Nutritional status; look for failure to thrive on the Road-to-Health Chart (weight-for-age chart)
2. **Assess history.** (RN, MD/CO)
   a. **Contacts**
      (1) Determine whether the child has had close contact with active or suspected TB patients; ask:
         i. "Is anyone at home ill and if so, what are the symptoms?"
         ii. "Does anyone in the household or someone in regular contact with the child have a chronic cough or other symptoms suggestive of TB?"
         iii. "Does anyone in the home have TB?"
      (2) Ask about the general health of friends, family, caretakers, and specifically the mother if the TB suspect is an infant.
   b. **Current/past medical history**
      (1) Prior TB exposures, especially to persons with sputum-positive pulmonary TB
      (2) Prior TB treatments
      (3) History of pulmonary disease or infection (e.g., asthma, pneumonia); heart failure
      (4) History of previous clinical presentations of recurrent lung disease(s)

3. **Evaluate** for **TB symptoms**. (RN, MD/CO)
    a. Chronic, progressive cough > three weeks; does not improve on broad-spectrum antibiotics
    b. Fever
    c. Night sweats
    d. Weight loss
    e. Failure to thrive
4. Perform a thorough "head-to-toe" **physical exam. (**MD/CO)
    a. Always examine the respiratory and cardiac systems.
    b. Presentation of auxiliary lymphadenopathy on the same side as the BCG should alert clinician to rule out BCG disease.
5. **Evaluate** for **physical signs of TB**. (MD/CO)
    a. Signs/symptom commonly suggestive of pulmonary TB (PTB) in HIV-infected children:
        (1) Chronic, progressive cough unrelieved by a course of broad-spectrum antibiotics; this is more common in children over 3 years old.
        (2) Can present as acute pneumonia in HIV-infected children.
        (3) Respiratory exam findings are focal, marked, and persistent in an ambulatory child not in respiratory distress.
    b. Signs **highly** suggestive of **extrapulmonary TB** (EPTB):
        (1) Non-painful, asymmetrical lymphadenopathy (TB adenitis)
        (2) Spinal mass (gibbus), especially of recent onset (spinal TB)
        (3) Distended abdomen with painless ascites (peritoneal TB)
    c. Other **physical signs suggestive** of EPTB:
        (1) Meningitis (e.g., light sensitivity, neck stiffness, bulging fontanelle) unresponsive to antibiotic treatment; can have subacute onset or raised intracranial pressure
        (2) Pleural effusion (e.g., diminished lung sounds)
        (3) Pericardial effusion
        (4) Non-painful enlarged lymph nodes without fistula formation
        (5) Non-painful enlarged joint
        (6) Signs of tuberculin hypersensitivity (e.g., phlyctenular conjunctivitis, erythema nodosum)
    d. **Documented weight loss or failure to gain weight**, especially following nutritional rehabilitation treatment

Adults and adolescents

1. **Check vital signs.** (RN or designated, trained staff member)
    a. Temperature
    b. Weight, BMI
    c. Respiration rate
    d. Recount if fast (> 20/minute = fast, > 30/minute = very fast)
    e. Heart rate
    f. Blood pressure
2. **Evaluate** for **TB symptoms**. (RN, MD/CO)
    a. **Cough**
        (1) Assess if **≥ 2 weeks**
        (2) Ask if cough is **productive.** If so, ask **if sputum is blood-tinged.**
        (3) Ask if cough wakes patient up at night, occurs more in the morning, or occurs with exercise.
    b. Difficulty breathing, chest pain
    c. Persistent fever
    d. Unexplained weight loss

e. Severe malnutrition
f. Suspicious lymph nodes (> 2 cm)
g. Night sweats

3. **Assess history**. (RN, MD/CO)
   a. Social history
      (1) Any TB contact(s)
      (2) General health of friends, family
      (3) Current living situation (e.g., group home, homeless, prison)
   b. Current/past medical history
      (1) History of TB
      (2) Family history of TB
      (3) History of asthma, bronchitis or COPD, heart failure
      (4) Ask if patient is a smoker.
4. **Perform** thorough "head-to-toe" **physical exam. (**MD/CO) Carefully examine the lung and cardiac systems.

B. If patient is **symptomatic** and history is suspicious of TB:
   1. **Initiate** and explain to patient and family TBIC measures (SOP 401).
   2. Determine the severity of disease. (MD/CO)
      a. Severe (e.g., very fast breathing, pulse > 120, fever $\geq$ 39 C)
         (1) Begin treatment with supplemental oxygen as needed, and antibiotics (SOP 403).
         (2) Start diagnosis protocol for TB (SOP 403).
      b. Symptomatic but stable
         (1) Start diagnosis protocol for TB.
   3. **For infants and children only**, perform a TST (Appendix 1).
   4. **Document screening procedures and results** in patient's medical record.

C. If HIV-infected patient is **asymptomatic**:
   1. Document negative TB screening results in medical record.
   2. If **baseline** visit for adult or adolescent, perform a TST (Appendix 1).
      a. Repeat TST **every six months** if in high-burden TB area.
      b. Document results in medical record.
   3. In children < 5 years old, offer isoniazid preventive therapy (IPT) if child was exposed to a TB-infected individual (SOP 407).
   4. In adults and adolescents in high-prevalence HIV areas, offer IPT (SOP 407).

SOP 403: Diagnosing TB in HIV-infected Individuals

I. Key Concepts:

- Evaluate TB suspects in an outpatient setting whenever possible (SOP 401).
- In patients with advanced HIV infection, atypical TB presentation is more common (e.g., non-cavitary, lower- and mid-lobe involvement, extrapulmonary disease) alongside other clinical symptoms such as prolonged fevers and low BMI.
- The highest risk of extrapulmonary disease is in advanced HIV disease (e.g., when CD4 < 50 cells/mm^3); TB meningitis is fatal if untreated; if suspected, diagnose and treat immediately.
- Diagnosing TB in HIV-infected children is difficult; recognizing signs and symptoms and determining the exposure source often prove more definitive than sputum sample, TST, and CXR results.
- Bacteriological confirmation is especially important for HIV-infected children; pulmonary TB (PTB) in HIV-infected children is often smear-negative.
- Base TB diagnosis on clinical assessment and diagnostic results (sputum smear microscopy, CXR, TB culture).
- When diagnosing TB in HIV-infected individuals, always define the disease classification (site), the type of patient, and their HIV clinical status as recommended in national guidelines.

II. **Key Personnel:** MD, CO, RN, radiologist, laboratory staff, nasal cannula, oxygen face mask, non-rebreather mask, mechanical intubation depending on level of hypoxia and facility protocol

III. Materials: Clinical diagnostics (e.g., stethoscope, thermometer), sputum collection container, medical record, laboratory form (site standard form), Request for Sputum Smear Microscopy Examination Form (Part 1 Form 105), HIV Care/ART Card (Part 1 SOP 102), TB Register (Part 1 SOP 103)

IV. Procedures:

Infants and children

A. If the infant or child is severely ill when assessed **(e.g., very fast breathing, change in mental status):**
   1. **Continue TB Infection Control measures** (SOP 401).
   2. **If clinical findings require hospitalization**, place the child with suspected TB disease in a separate, well-ventilated room or separate ward, ideally away from other HIV-infected children, and notify designated IC staff of admission.
   3. **Treat acute symptoms.**
      a. **Support child with oxygen. Consider** nasal cannula, oxygen face mask, non-rebreather mask, or mechanical intubation, depending on level of hypoxia and facility protocol.
      b. **Begin broad-spectrum antibiotics. Avoid the use of fluoroquinolones.**
      c. **Treat for pneumocystis pneumonia (PCP),** especially in acute, severely symptomatic infants < 6 months old.
         (1) If no sulfa allergy is documented, start cotrimoxazole (15 mg/kg of TMP component, tablets, liquid or intravenous equivalent) for 21 days.
         (2) Consider administration of intravenous steroids in cases of severe hypoxia.
         (3) Provide intravenous fluids, if indicated.

4. **Order CXR**.
    a. While preparing for CXR, review the history carefully: positive TB contact; symptoms; clinical examination information, including growth assessment.
    b. MD/CO or radiologist evaluates radiographic exam and confirms results (Text Box 1).
    c. Using CXR to diagnose TB in HIV-infected children is complicated by other HIV-related lung diseases, such as LIP, bacterial/PCP/viral pneumonia, and concurrent respiratory infections.
5. **Order and begin collection of sputum specimens** (Section "C" below).
6. **Monitor TST site** (Appendix 1).
7. **Assess the patient daily**. Document in the medical chart:
    a. Is the breathing slower?
    b. Has the fever gone down?
    c. Is pleuritic chest pain less?
    d. How long has the patient been coughing?
8. **If breathing is slower or fever has gone down**:
    a. Discontinue TBIC measures.
    b. Start or continue first-line oral antibiotics for bacterial pneumonia; finish prescribed course.
    c. If PCP treatment has started, continue cotrimoxazole for three weeks.
    d. Document therapeutic response and sputum results sent to laboratory, in medical chart.
    e. Continue TB screening at every acute and chronic appointment.
    f. Persistent opacification which does not improve after a course of antibiotics, requires further investigation for TB and a repeat CXR.

Text Box 1:
CXR findings in Pediatric TB-HIV

PTB
- Cavitation (unusual in young children; more common in older children and adolescents)
- Persistent opacification
- Enlarged perihilar lymph nodes
- Focal abnormalities

Miliary TB
- Diffuse, bilateral, micronodular, evenly distributed small miliary shadows (differentiate from LIP)

Source: WHO, "TB/HIV: A Clinical Manual, Second Edition" 2004; WHO "Guidance for National Tuberculosis and HIV Programmes on the management of Tuberculosis in HIV-infected

B. If the infant or child is not severely ill **(e.g., is ambulatory), but is clinically symptomatic or** highly suspicious of TB**:**
    1. **Order CXR**.
        a. While preparing for CXR, review the history carefully: positive TB contact; symptoms; clinical examination information, including growth assessment.
        b. MD/CO or radiologist evaluates radiographic exam and confirms results (Text Box 1).
    2. Order and begin collection of sputum specimens (Section C below).
    3. Monitor TST site (Appendix 1).

C. **To rule out pulmonary TB, send specimen(s) for AFB smear microscopy and mycobacterial culture (if available) evaluation** using one of the following methods:
    1. **Expectorated sputum**
        a. **Obtain any expectorated sputum sample in a well-ventilated room**, outside, or in a room designated and designed for sputum collection.
        b. **Instruct child (and parent/family member** monitoring child) on how to vigorously cough up a specimen into the specimen cup; refer to Text Box 2.
            (1) Encourage the child during this procedure. Many children cannot produce sputum from deep in the lungs after only a few minutes; it may take a few tries.
            (2) Give the child enough time to produce an expectorated sample everyone feels is produced by the deep cough.

c. **Obtain three sputum specimens** in children able to produce a specimen:
   (1) An "on-the-spot" specimen (at first evaluation)
   (2) An early morning specimen (the next day)
   (3) A second "on-the-spot" specimen (at third follow-up visit, or 8 hours after the second specimen)

d. Once obtained, the **RN** (or other designated, trained staff member) **labels and sends specimen to lab with** Form 105 "Request for Sputum Smear Microscopy Examination."

2. **Gastric aspiration**
   a. Collect a gastric aspirate sample from a young child **unable or unwilling to expectorate sputum**.
   b. Perform this procedure first thing in the morning at the child's bedside, in a routine procedure room, or as an outpatient if supplies are available, using a nasogastric tube (NGT) per facility protocol. (Gastric aspiration in children is generally considered a low risk procedure for TB transmission as young children are at low risk of transmitting disease.)
   c. **Do not perform gastric aspiration procedure if** child has a low platelet count or a bleeding disorder.
   d. Obtain **one gastric aspirate** on **three consecutive mornings**.
   e. Once obtained, the RN (or other designated, trained staff member) labels and sends specimen to the lab, preferably for *M. tuberculosis* culture.
3. **Sputum induction**
   a. Procedure is safe and effective in children of all ages; bacterial yields are as good as or better than for gastric aspirates.
      (1) Training and specialized equipment are required to properly perform this procedure.
      (2) Do not perform in children with severe respiratory distress, intubation, bleeding disorders, decreased level of consciousness, or a history of significant asthma.
   b. **Pre-procedure**:
      (1) Examine child before the procedure; make sure child is well enough to complete the test.
      (2) Make sure the child has fasted for at least 3 hours prior to procedure; reschedule procedure if child has eaten.
   c. **Perform** the sputum induction.
      (1) First, administer a brochodilator to reduce the risk of wheezing.
      (2) Administer nebulized hypertonic saline (3% NaCl) for 15 minutes or until 5cm^3 of solution is fully administered to the child.
      (3) Give chest physiotherapy to help move secretions.
      (4) In older children now able to expectorate, collect sputum (Text Box 2).
      (5) If child is unable to expectorate, either suction the nasal passages to remove nasal secretions, or perform nasopharyngeal aspiration to collect the specimen.
      (6) Disinfect and sterilize any reusable equipment before next use (Part 1 SOP 105).

Text Box 2
Procedure:
Expectorated Sputum

1. Explain the reason for collecting sputum.
2. Instruct the patient to rinse her mouth with water before producing the specimen.
3. Instruct the patient to take a deep breath, hold the breath for a few seconds and then exhale slowly. Repeat two times.
4. After the third inhale, instruct the patient to forcefully blow the air out.
5. Ask the patient to breathe in a fourth time and then cough; this should produce sputum from deep in the lungs.
6. Ask the patient to hold the sputum container close to the lips and spit into it gently after a productive cough.
7. If the sputum coughed up is not enough to send for the test, ask the patient to cough again until a good specimen is in the container.
8. If the patient cannot bring up sputum from a cough, consider the container used and safely dispose of it.

Source: WHO: Guidance for national tuberculosis programmes on the management of tuberculosis in children,

d. Once obtained, the RN (or other designated, trained staff member) labels and sends the specimen to the lab for AFB sputum smear and TB culture.

4. Specialized tests such as computerized chest tomography and bronchoscopy are not recommended for the routine diagnosis of pulmonary TB in children. Interferon-gamma Release Assays (IGRAs) are currently being tested and could be useful in the future.

Adults and adolescents

D. If the patient is severely ill when assessed **(e.g., breathing very fast or unable to walk without assistance)**:

1. **Continue TBIC** measures (SOP 401).
2. **If clinical findings require hospitalization**, place TB suspect in a separate, well-ventilated room or separate ward, ideally away from other HIV-infected individuals, and notify designated IC staff of admission.
3. **Address acute clinical needs immediately**:
   a. **Administer oxygen** (e.g., nasal cannula, oxygen face mask, non-rebreather mask, mechanical intubation) depending on hypoxia and facility protocol.
   b. Begin broad-spectrum antibiotics; avoid use of fluoroquinolones.
   c. Treat for pneumocystis pneumonia (PCP).
      (1) If no sulfa allergy is documented, start cotrimoxazole (15 mg/kg of TMP component) in 2 double-strength or 4 single-strength tablets, or intravenous equivalent, three times a day for 21 days.
      (2) Consider steroids in cases of severe hypoxia.
      (3) Support with intravenous fluids, if indicated.
4. Order **CXR.**
   a. While preparing for CXR, review the history carefully: positive TB contact; symptoms; and clinical examination information, including weight.
   b. MD/CO or radiologist evaluates radiographic exam and confirms results (Text Box 3).
   c. CXR changes reflect the degree of HIV disease severity.
5. Order and begin collection of sputum specimens (Section "F" below).
6. **Visit the patient daily in the hospital ward to assess and document** in the medical chart:
   a. Is the breathing slower?
   b. Has the fever gone down?
   c. Is pleuritic chest pain less?
   d. How long has the patient been coughing?
7. **If breathing is slower or fever has gone down**:
   a. Discontinue TBIC measures.
   b. Start first-line oral antibiotics for bacterial pneumonia; finish 7-day course.
   c. If PCP treatment has started, continue cotrimoxazole for three weeks.
   d. Document therapeutic response and sputum results sent to laboratory, in medical chart.
   e. Continue TB screening at every acute and chronic appointment.

Text Box 3:
CXR findings in HIV-infected adult with PTB

Mild HIV-disease:
- Cavitation
- Upper lobe infiltrates

Advanced HIV-disease: "Atypical"
- Interstitial infiltrates especially in lower zones
- Intrathoracic lymphadenopathy
- Lack of cavitation
- No abnormalities
- Pleural + pericardial involvement

Source: WHO, "TB/HIV: A Clinical Manual, Second Edition," 2004.

E. **If patient is not severely ill, but is clinically symptomatic and highly suspicious of TB**:

1. Begin broad-spectrum antibiotics; avoid use of fluoroquinolones.
2. Order CXR.
   a. While preparing for CXR, review the history carefully: positive TB contact; symptoms; and clinical examination information, including weight.
   b. MD/CO or radiologist (e.g., someone trained to read CXR reports) evaluates radiographic exam and confirms TB results (Text Box 4).

F. **To rule out pulmonary TB, collect, send, and interpret sputum results for AFB smear and culture (if available).**
   1. **Collect two or three consecutive (8 hours apart) expectorated sputum specimens, according to national guidelines, site protocols, and HIV prevalence of the particular setting.**
      a. First "spot" specimen: can be produced in a well-ventilated area or in patient's hospital room.
      b. Second specimen: one early morning specimen; can be brought to clinic
      c. Third specimen: a "spot" specimen, produced at least 8 hours after second sputum specimen.
   2. The nurse obtains the specimen and works with trained facility staff to transport specimens to the laboratory with **Form 105** "Request for Sputum Smear Microscopy Examination."
   3. Send one sputum specimen for TB culture, if laboratory resources are available.
   4. Follow up on and document sputum results in the patient's medical record using Form 105 "Request for Sputum Smear Microscopy Examination."
   5. If patient **coughs but does not produce sputum** for evaluation, or **if nodes are present**, continue to section "H – I" below.
   6. Specialized tests such as computerized chest tomography and bronchoscopy are not recommended for the routine diagnosis of pulmonary TB.

Infants, children, adolescents and adults

G. **Interpreting POSITIVE sputum sample** results
   1. Diagnose HIV-infected **infants and children** with smear-positive, infectious pulmonary TB if:
      a. Two or more initial sputum smear exams are AFB positive**, or**
      b. One sputum smear exam is AFB positive, plus clinician decides that CXR abnormalities are consistent with active PTB, **or**
      c. One sputum smear exam is AFB positive, plus sputum culture is positive for *M. tuberculosis.*
   2. Diagnose HIV-infected **adults and adolescents** with smear-positive (infectious pulmonary) TB if one AFB smear sample is positive.
   3. Always attempt to confirm PTB diagnosis based on sputum smear-positive results with culture positive results for *Mycobacterium tuberculosis*
   4. Stage HIV-positive patients diagnosed with smear-positive pulmonary TB as WHO HIV clinical stage 3

H. Interpreting **NEGATIVE sputum results (MD/CO)**
   1. If all sputum samples are negative, the HIV-infected person may or may not have TB; sputum smear microscopy is generally negative in a person with severe immune suppression.
   2. **If patient's symptoms improve on broad-spectrum antibiotics**, sputum results are negative, and CXR does not indicate TB disease, do not diagnose patient with TB.
      a. **Continue treatment** with previously chosen non-specific antibiotic such as cotrimoxazole or Amoxicillin.
      b. Discontinue TBIC measures.
      c. **Document** negative TB results in patient's medical record.
      d. **Monitor** response to completed antibiotic regimen.
      e. **Continue** TB screening at each clinical visit.
   3. **Consider the** need for IPT (SOP 407).
   4. **If patient's symptoms do not improve, patient still coughs**, coughs but **cannot produce sputum** for examination, **or has other general complaints, rule out smear-negative TB and extrapulmonary TB** (Section "I" below).

I. Diagnosing **smear-negative pulmonary TB**
   1. Confirm that three (in infants and children) or two (in adolescents and adults) sputum specimens return smear-negative for AFB.
   2. Review CXR for radiographic abnormalities consistent with active tuberculosis.
   3. Confirm that patient is not responsive to a course of broad-spectrum antibiotics.
   4. If a decision is made that the patient has smear-negative pulmonary TB, stage the co-infected individual as WHO HIV clinical stage 3, **or**
   5. Confirm diagnosis with culture-positive results for *Mycobacterium tuberculosis*, if available.

J. Based on clinical exam, if **extrapulmonary and disseminated TB** is suspected, coordinate a full exam (radiology and biopsy of extrapulmonary site) for interpretation.

Infants and children

1. Diagnostics of common pediatric EPTB include:
   a. Peripheral lymph nodes (especially cervical) → Lymph node biopsy or fine needle aspiration (FNA)
   b. FNA (staining of AFB and histology) can be useful with high bacteriological yields
   c. Miliary TB (e.g. disseminated) → CXR; lumbar puncture (to test for meningitis)
   d. TB meningitis → Lumbar puncture (computerized tomography, where available)
   e. Pleural effusion (older children and adolescents) → CXR; pleural tap for analysis (protein and glucose), cell count and culture
   f. Abdominal TB (e.g. peritoneal) → Abdominal ultrasound; tap ascitic fluid
   g. Ostoarticular → X- ray; joint tap or synovial biopsy
   h. Pericardial TB → Cardiac ultrasound and pericardial tap

Adults and adolescents

2. Diagnostics of common adult and adolescent EPTB include:
   a. Enlarged lymph node(s); suspicious joints → fine needle aspiration cytology
   b. Histological exam of biopsied samples
   c. Pleural and pericardial TB → CXR (Text Box 2)
   d. Pericardial fluid → Pericardial tap
   e. CSF exam for TB meningitis → Lumbar puncture
   f. Genitourinary, bone or joint TB → Radiology
   g. Genitourinary TB → Urine culture

Infants, children, adolescents, and adults

3. Review diagnostic results of suspected extrapulmonary TB site.
4. If results are positive, stage HIV-positive patients diagnosed with EPTB (other than lymphadenopathy) as WHO HIV clinical stage 4.

K. **Once active TB has been diagnosed, discuss the TBIC** plan depending on diagnosis, location and site of TB; educate patient and family about individualized IC measures as diagnosis indicates.

L. If possible, **perform rapid, baseline drug susceptibility testing** (DST) for **initial MDR-TB screen** using the Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test (Part 1 Form 109) to avoid mortality from undiagnosed drug-resistant TB (SOP 412). If at increased risk of XDR-TB, send DST for isoniazid, rifampicin, second-line injectable agents and a fluoroquinolone (SOP 412).

M. **Determine TB type. (MD/CO)**

1. Review all diagnostic data alongside clinical exam and determine TB diagnosis:
   a. PTB: sputum-smear positive or sputum-smear negative
   b. EPTB
   c. Other (e.g., combination of PTB and EPTB)
2. Once TB is diagnosed, identify the type of TB by history of previous TB treatment.
   a. First, ask the patient if s/he was ever treated for TB.
   b. Next, using Table 2 as a guide, ask the patient questions related to TB as indicated by symptoms and patient history to help categorize the patient by TB type.
      (1) Answering "yes" may indicate more than one type of TB; further questions are needed to determine TB type.
      (2) TB type definitions are listed after Table 2.

Table 2: Identifying TB Patient Type

Question	New	Relapse	Treatment after failure	Treatment after default	Transfer-in	Other previously treated
Have you ever been treated for TB? Also ask the following 2 questions: • Have you ever taken injections for more than 1-2 weeks? Why? • Have you ever taken a medicine that turned your urine orange-red?	X	X	X	X	X	X
Have you ever taken anti-TB drugs for < 1 month?	X					
Has a doctor ever said your TB was cured?		X				
Have you ever completed a TB treatment (e.g., taken anti-TB drugs for 6-9 months)?		X				X
Has a doctor in the past ever diagnosed you with "sputum-positive" TB; if so, did you complete the treatment?			X			
Has a doctor in the past ever diagnosed you with "sputum-negative" TB; if so, did you complete the treatment?						X
Has a doctor in the past ever diagnosed you with TB in another part of your body (e.g., meningitis)? If so, did you complete the treatment?						X
Has a doctor ever prescribed for you a new TB treatment regimen a few months after starting a different TB regimen?			X			
Have you ever stopped TB treatment on your own, then returned to your clinic $\geq$ 2 months later to restart your TB treatment?				X		
Are you a transfer patient from another TB or TB/HIV clinic and do you need to continue your treatment?					X	X

   c. Using data collected so far, match the patient to one of the following categories:
      (1) **New:**
         - A TB treatment-naïve patient
         - Taken anti-TB drugs for less than 1 month
      (2) **Relapse:**
         - Previously TB-treated patient
         - Determined cured in past or completed TB treatment
         - Diagnosed with smear or culture-positive for TB
      (3) **Treatment after failure:**
         - Started on a re-treatment regimen after failing a previous treatment

(4) **Treatment after default:**
- Returned to treatment
- Bacterially positive for TB (e.g., could be EPTB or smear-negative TB)
- Treatment interruption of 2 or more consecutive months

(5) **Transfer-in:**
- Transfer patient from another TB register
- Needs to continue TB treatment

(6) **Other previously treated:**
- Any case not meeting (1) – (5) above
- Includes sputum smear microscopy-positive cases with unknown history or unknown outcome of previous treatment
- Previously-treated sputum smear microscopy-negative
- Previously-treated EPTB
- Chronic case at the end of re-treatment regimen

N. **Ask patient about the health of family and household members** to identify other possible TB suspects; **screen contacts** of confirmed, co-infected individual for TB.

Example: If an infant is determined to have TB disease, screen household and family members, especially the mother if she has not yet already been recently screened.

O. **Document any referrals made** (Part 1 SOP 107, 108) and follow up to ensure the referral was completed and feedback was received.

Example referrals: Internal referrals to laboratory or radiology department; external referrals to outside laboratories (e.g., DST)

P. As a team, **the facility staff (led by RN)** educates and provides information about TB diagnosis to the co-infected patient and family (SOPs 413 and 414).

SOP 404: TB Treatment

I. Key Concepts:

- Children and adults with clinical stage 4 disease or severe immune suppression and TB disease need immediate attention and treatment of both infections.
- Ensure completion of full TB treatment with good adherence.
- Do not begin TB treatment trial.
- Consult with prescribing MD/MO if patient is already on ART when a sputum smear for TB is positive, or when smear-negative TB is suspected, for MD/MO to rule out: ART treatment failure; TB re-infection or reactivation; active TB resulting from immune reconstitution syndrome; need for change in ART.
- Most pulmonary TB patients can be treated in the outpatient setting, whether the clinic is facility- or community-based.

II. Key Personnel: MD, CO, RN, pharmacist, treatment supporter

III. Materials: Medical record, prescription(s), TB Register (Part 1 Form 103), Tuberculosis Treatment Card (Part 1 Form 101), HIV Care/ART Card (Part 1 Form 102)

IV. Procedures:

A. Choose the TB treatment. (MD/CO)

Infants and children

1. Confirm whether the patient is on ART.
   a. **If not on ART**, consider prescribing ART (SOP 405) based on the degree of immune suppression and the child's progress during anti-TB treatment.
   b. **If on ART,** begin anti-TB medications that do not interact with the patient's ART regimen (SOP 405); consult with TB/HIV specialists as needed.
2. Choose the pediatric TB treatment regimen; refer to Table 3.
   a. **Choose three to four drugs in active TB cases,** according to national guidelines.
      (1) Start Category I (4-drug) anti-TB medications in:
         i. New smear-positive PTB
         ii. New smear-negative PTB with extensive parenchymal involvement
         iii. Severe forms of EPTB
      (2) Start Category III (3-drug) anti-TB medications in:
         i. New smear-negative PTB (other than Category I)
         ii. Less severe forms of EPTB
      (3) Start Category II regimen in previously-treated smear-positive PTB:
         i. Relapse
         ii. Treatment after interruption
         iii. Treatment failure
      (4) Use Category IV individualized regimens for chronic and MDR-TB (SOP 412)
      (5) **Ethambutol** is safe to use in children when dose is adjusted (Table 5).
      (6) Avoid streptomycin when possible.
         i. **Injections are painful; irreversible auditory nerve damage may occur**.
         ii. Reserve streptomycin use for the first 2 months of TB meningitis treatment.
      (7) Treat child with rifampicin for the entire treatment duration, if possible.
      (8) Prescribe daily (7 days per week) treatment regimen for both intensive and continuation phases.

Table 3*: Recommended Pediatric TB Treatment Regimens

TB Diagnostic Category	TB Patient Type	TB Treatment Regimens	
		Initial Phase	Continuation Phase
III	New smear-negative PTB (other than Category I) Less severe forms of EPTB	2 HRZ • In comparison with Cat I, E may be omitted during initial phase for: o HIV-negative, non-cavitary, smear-negative PTB o Patients known to be infected with fully drug-susceptible bacilli o Young children with primary TB	4 HR or 6 HE
I	New smear-positive PTB New smear-negative PTB with extensive parenchymal involvement Severe EPTB (except TB meningitis – see below) Severe HIV disease	2 HRZE	4HR or 6HE • This regimen may be associated with a higher treatment failure rate and relapse compared with the 6-month rifampicin continuation regimen.
I	TB meningitis • Corticosteroids (usually prednisone) recommended for all children with TB meningitis (2 mg/kg daily x 4 weeks); taper (reduce) dose over 1-2 weeks before stopping. • In seriously ill children, can increase prednisone to 4 mg/kg (max dose 60 mg/day), though high dose can also cause greater immune suppression.	2RHZS • Streptomycin replaces Ethambutol to penetrate blood-brain barrier.	4RH
II	Previously-treated sputum smear-positive PTB • relapse • treatment after interruption • treatment failure	2 HRZES/1HRZE	5HRE
IV	Chronic and MDR-TB cases	Specially designed standardized or individualized regimens are suggested for this category.	

*Resource: WHO "Guidance for national tuberculosis programmes on the management of tuberculosis in children," 2006.

Adults and adolescents

1. Confirm whether the patient is on ART.
   a. **If not on ART**, and if HIV clinical status allows (e.g., asymptomatic HIV infection or CD4 > 350/mm^3), immediately start and complete TB treatment, then consider prescribing ART (SOP 405).
   b. **If on ART,** begin anti-TB medications that do not interact with the patient's ART regimen (SOP 405); consult with TB/HIV specialist as needed.
2. Choose the TB treatment regimen; refer to Table 4 for the treatment regimen based on the patient's diagnosed TB type.
   a. Whenever possible, drug sensitivity testing is recommended before prescribing Category II treatment in failure cases.

b. In a patient with proven MDR-TB, use Category IV regimens (SOP 412). Consider early culture and sensitivity testing for contacts of patients with culture-proven MDR-TB.
c. Initial phase requires directly observed therapy (DOT) in smear-positive cases and any treatment including rifampicin.

3. **If the patient is a woman of childbearing age, and not on ART, refer to Table 4 and choose a regimen based on the woman's assessed needs**.
   a. **Assess** whether the woman is sexually active and considering pregnancy.
   b. Ask patient if she currently uses a contraceptive method.
   c. Discuss with her an appropriate **contraception** choice.
      (1) If patient is not using a safe, effective family planning method, discuss a full range of safer sex options.
      (2) Provide patient with condoms.
      (3) If rifampicin is in the chosen TB regimen, provide an alternative contraceptive to **pills or implants**; rifampicin interacts with and decreases oral contraception protection from pregnancy.
   d. If patient is sexually active, determine her pregnancy status.
   e. **If pregnant**:
      (1) Do not use streptomycin
      (2) Provide or refer for antenatal care and PMTCT interventions:
         - ART or ARV prophylaxis per clinic standard protocol
         - Safer labor and delivery
         - Safer infant feeding per clinic standard protocol
   f. **If breastfeeding**:
      (1) In accordance with PMTCT guidelines regarding safer infant feeding options, encourage the mother to continue exclusive breastfeeding the usual way.
      (2) Provide infant with IPT (SOP 407).
      (3) Once the infant's preventive therapy is complete, check infant's immunization record and provide BCG immunization to infant if not already provided.
   g. **If ART is indicated**, refer to SOP 405.

Table 4*: Recommended TB Treatment Regimen for Adults and Adolescents

TB Diagnostic Category	TB Patient Type	TB Treatment Regimens	
		Initial Phase	Continuation Phase
I	New smear-positive New smear-negative PTB with extensive parenchymal involvement Severe HIV disease or severe EPTB	2 HRZE • Can substitute E with S • In meningeal TB, E should replace S • Daily dose recommended	4 HR or 6 HE daily • This regimen may be associated with a higher treatment failure rate and relapse compared with the 6-month rifampicin continuation regimen.
II	Previously-treated sputum smear-positive PTB • relapse; • treatment after interruption • treatment failure	2 HRZES/1 HRZE	5 HRE
III	New smear-negative PTB (other than Category I) Less severe forms of EPTB	2 HRZE • E may be omitted during initial treatment phase for patients known to be infected with fully drug-susceptible bacilli and young children with primary TB.	4 HR or 6 HE daily • This regimen may be associated with a higher treatment failure rate and relapse compared with the 6-month rifampicin continuation regimen.
IV	Chronic and MDR-TB cases • - still sputum-positive after supervised re-treatment	Specially designed standardized or individualized regimens are suggested for this category.	

*Source: WHO "Treatment of Tuberculosis: Guidelines for National Programmes," 2003.

B. **Choose the TB treatment dose**. (MD/CO)

Infants, children, adolescents and adults

1. **Order and review baseline labs**
   a. Confirm CD4 count/percentage and viral load (if available) when starting TB treatment.
   b. Check hematology, chemistry, and liver and function if not already available.
2. Consider the **patient's current weight**; daily dosing is preferred (Table 5).

Table 5*: Recommended Doses of First-line Anti-TB Drugs for Children and Adults

	Daily		Three times weekly	
Drug (abbreviation)	**Dose and range (mg/kg body weight)**	**Maximum (mg)**	**Dose range (mg/kg body weight)**	**Daily maximum (mg)**
Isoniazid (H)	Children: 10 (10–15) Adults: 5 (4–6)	300	Children: 10-20 Adults: 8–12	Children: 900 Adults: –
Rifampicin (R)	Children: 15 (10–20) Adults 10 (8–12)	600	Children: 10-20 Adults: 8–12	600
Pyrazinamide (Z)	Children: 35 (30–40) Adults: 25 (20–30)	Children: 2000 Adults: –	Children: 30–40 Adults: 30–40	Children: 4000 Adults: –
Ethambutol (E)	Children 20 (15–25) Adults 15 (15–20)	Children: 1200 Adults: –	Children: 25-35 Adults: 25–35	Children: 1200 Adults: –
Streptomycin (S)	Children and Adults: 15 (12–18)	Children: 1000 Adults: –	Children and Adults: 12–18	Children: 1500 Adults: –

Source*: WHO "Treatment of Tuberculosis: Guidelines for National Programmes" 2003; WHO "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press).

3. **Try to prescribe a regimen that contains a fixed-dose combination (FDC), if possible**.
   a. Some regimens are manufactured in fixed-dose combinations.
   b. FDC regimens help reduce pill burden and improve medication adherence.
   c. Some regimens require both FDC and an additional pill, or injection.
4. If the chosen **regimen contains isoniazid, prescribe pyridoxine 10-50 mg daily** to prevent peripheral neuropathy.
5. If the chosen **regimen contains streptomycin,** make sure the patient can come to clinic to have the injection given by a trained health worker according to standard precautions (Part 1 SOP 105).
6. For **EPTB**, choose age- and weight-based treatment/duration on TB location.
   a. Common **EPTB locations**:
      (1) Lymph nodes (disseminated, pleural, genitourinary, peritoneal pleural) – treat for 6 months
      (2) Bone or joint – treat for 6 to 9 months
      (3) Pericarditis – treat for 6 months
      (4) CNS – treat for 9 to 12 months; replace ethambutol with streptomycin
   b. Consider **steroids in the treatment** regimen, especially if **pericarditis or CNS TB**.
      (1) TB meningitis: Dose prednisolone 60 mg (adult) or 1-2 mg/kg (children) daily for weeks 1-4, then decrease over several weeks.
      (2) TB pericarditis: Dose prednisolone 60 mg (adult) or 1-2 mg/kg (children) daily for weeks 1-4; 30 mg (adult) or 0.5-1 mg/kg (child) daily for weeks 5-8, then decrease over several weeks.
      (3) TB pleural effusion: 30 mg (adult) or 0.5-1 mg/kg (child) daily for 1-2 weeks
      (4) If steroids are prescribed: monitor FBC for glucose and WBC during treatment.
7. If **drug resistant TB** (MDR, XDR TB) is suspected or known, refer to SOP 412.
   a. If suspected, and awaiting laboratory results of DST, continue chosen regimen until results are received.

8. If patient has **kidney problems**
    a. Isoniazid, rifampicin and pyrazinamide are safe to use in standard doses.
    b. Avoid streptomycin and ethambutol, if alternatives exist. If there are no alternatives, give in reduced dose at less frequent intervals and monitor renal function closely.
    c. **Safe regimen in renal failure**: 2HRZ/4HR
    d. In cases of severe renal failure, prescribe pyridoxine with isoniazid to prevent peripheral neuropathy.
    e. Do not give thioacetazone.
9. If the patient has documented **chronic liver disease**:
    a. Consider isoniazid and rifampicin plus one or two non-hepatotoxic drugs, such as streptomycin and ethambutol, for a total treatment duration of eight months.
    b. In cases of severe liver damage, consider streptomycin + isoniazid + ethambutol in the initial phase, then isoniazid + ethambutol in the continuation phase, for a total treatment duration of 12 months.
    c. **Recommended regimens**:
        (1) 2 SRHE/6 HR
        (2) 2 SHE/10 HE
        (3) 9 RE
    d. Do not give pyrazinamide.
10. If the patient has acute hepatitis (e.g., viral hepatitis):
    a. Since TB treatment is critical, treat TB during acute hepatitis in consult with a hepatitis specialist.
    b. The safest combination is SE for 3 months.
    c. If the hepatitis resolves, patient can then receive continuation phase of 6 HR.
    d. If hepatitis does not resolve, continue SE for a total of 12 months.
    e. Do not give pyrazinamide.
11. Determine the need for **cotrimoxazole preventive therapy (CPT)** (SOP 406); **provide** patient with a **prescription** for CPT. (MD/CO)

C. Determine where to treat the co-infected patient, according to NTP and HIV/AIDS national guidelines. (MD/CO)
1. **Treat a TB-infected patient in the hospital**:
    a. **If an infant or child has severe disease throughout the intensive phase of TB treatment**, including:
        (1) TB meningitis
        (2) Miliary TB
        (3) Any child with respiratory distress
        (4) Spinal TB
        (5) Children with severe adverse reactions (e.g., hepatotoxicity)
        (6) An ill child in whom it is difficult to ensure proper treatment adherence because of social or logistical reasons
    b. **If an adult or adolescent patient is extremely ill** as evidenced by vital signs and clinical status, including:
        (1) **Hemoptysis**
        (2) **Pneumothorax** or
        (3) **Large accumulation of pleural fluid leading to severe shortness of breath**
    c. Admit to a separate ward, if possible, following TBIC procedures (SOP 401) and standard precautions (Part 1 SOP 105).
    d. **Discharge patient as soon as possible, once stable**, to reduce the risk of disease transmission.
2. **Treat patient at the facility level as an outpatient** if their clinical status is stable**:**
    a. Sputum smear-positive TB and **treatment after default,** or
    b. **Chronic, MDR- or XDR-TB**, or
    c. EPTB
3. Consider transferring a **sputum smear-positive PTB patient**, **not on ART**, to the primary

healthcare level for treatment monitoring if the TB type is:
   a. New
   b. Relapse
   c. Treatment after failure
4. If transportation to the facility for treatment and care may negatively impact adherence, consider transferring TB/HIV treatment adherence monitoring of patients with sputum smear-negative TB to a TB/HIV trained primary care site.
5. For **HIV-positive patients with TB who are already on ART:**
   a. Coordinate with the MD/MO monitoring their ART before starting TB treatment if you are not the ART provider.
   b. See SOP 405.IV.B.5 (infants and children) or SOP 405.IV.E.4 (adults and adolescents).

D. **Support the chosen treatment regimen**. (RN, MD/CO, pharmacist, other facility staff)
1. Once a regimen is chosen, review the length of treatment and the difference between the two treatment phases. (RN)
2. **Discuss and arrange DOT** (SOPs 408 and 409). (RN, facility care coordinator)
   a. **Identify a community treatment supporter** (SOPs 409 and 413). (RN)
   b. If the patient has a supporter for ART, include the supporter in conversation about starting anti-TB medication for dual treatment support and observation, and consider the person as a TB treatment supporter, if patient and supporter are in agreement.
3. Review side effects of chosen medication regimen and discuss which symptoms require immediate return to the clinic (SOP 410, Appendix 4 and 5). (RN, MD/CO)
4. Describe and review the **follow-up schedule** (SOP 408). (RN, MD/CO)
5. **Dispense medications** or ensure access to a pharmacy. (pharmacist, RN)
6. **Schedule a follow-up appointment** one month away to monitor for improvement and adherence (SOPs 408 and 409; Part 1 Forms 101/110, 106, 107). (RN, facility coordinator)
7. Report the patient's diagnosis and initiation of treatment plan to the NTP.
8. **Complete documentation** and place in the patient's medical record. (RN, MD/CO) Indicate assessment, plan, and prescribed medications on all required forms.
   a. Tuberculosis Treatment Card
   b. HIV Care/ART Card
   c. TB Register
9. **If TB-HIV patient not on ART** does not gain weight or develops new HIV-related diseases (WHO clinical stage 3 or 4), consult with a TB/HIV specialist, or if trained, prescribe ART.

SOP 405: TB-ART Co-treatment Regimens

I. Key Concepts:

- Always treat TB first, especially PTB (with positive sputum smear microscopy), to stop TB transmission.
  In general, introduce ART as soon as possible after starting anti-TB medications; emerging studies show that delaying ART in TB patients might increase the risk of poor treatment outcomes including death.
- If on ART when found to have TB, continue ART.
  - Development of PTB after six months of ART (without other clinical and immunological evidence of disease progression) should not represent ART failure.
  - If EPTB develops $\geq$ 6 months after ART initiation, consider or investigate the possibility of ART failure; simple lymph node TB or uncomplicated pleural disease may be less significant than disseminated TB.
- If possible, do not treat TB and HIV at the same time due to adverse drug interactions, drug toxicities, medication adherence burden, and risk of immune reconstitution (IRIS). IRIS is reported in 11-45% of ART patients within 6 weeks of beginning TB treatment.
- Consider co-treatment of ART and TB in advanced HIV infection.
- Overall, if prescribing ART during TB treatment period, consider: patient's age; pill burden; potential drug interactions; overlapping toxicities; possibility of immune reconstitution syndrome; and social support.
- Always follow national ART policy and guidelines when counseling the patient and his/her treatment supporter in preparation of ART initiation, a life-long treatment.

II. Key Personnel: MD, CO, TB/HIV specialist, RN

III. Materials: Medical record, TB Register (Part 1 Form 103), HIV Register (site standard form), Tuberculosis Treatment Card (Part 1 Form 101), HIV Care/ART Card (Part 1 Form 102), prescription(s)

IV. Procedures:

Infants and Children

A. **Evaluate the need to start ART** in pediatric patients diagnosed with TB, who are starting anti-TB medications and are not yet on ART.
   1. **Start ART two to eight weeks after the start of anti-TB treatment if**:
      a. The HIV-infected infant (< 12 months old) has any TB diagnosis.
      b. An HIV-infected child (> 12 months) is diagnosed with EPTB (except TB lymphadenopathy), regardless of CD4 count.
      c. A child is co-infected, with WHO-defined severe or advanced immunodeficiency.
      d. CD4 measurements are unavailable, and the child has documented HIV and TB infection.
   2. **Consider starting ART** alongside TB treatment in children diagnosed with **PTB or TBLN**.
      a. Use CD4 measurements to guide ART initiation according to WHO and national guidelines. Consider ART if:
         (1) CD4 count < 24% in child 12-34 months old
         (2) CD4 count < 19% in child 36-59 months old
         (3) Child < 5 years old with CD4 < 15% or < 200 cells/mm^3
   3. **Consider delaying ART until TB treatment is completed**.
      a. Base ART deferment on CD4 percentage or cell count.
         (1) Child aged 12-35 months: consider delay if CD4 is above 25%
         (2) Child aged 36-59 months: consider delay if CD4 is above 20%
         (3) Child above 5 years old: consider delay if CD4 is >15% or > 200 cells/mm^3

b. In the absence of a CD4 count, if a co-infected child's response to anti-TB treatment is excellent during the first two to eight weeks of the intensive phase, and there is no evidence of immune suppression other than TB, monitor the child closely and continue delaying ART until the end of TB treatment.

4. Choose an ART regimen from Table 5 for a co-infected child taking, or recently started on, anti-TB medications. The **preferred ART regimen is a triple NRTI** if the child has rifampicin in the TB regimen.

Table 6: ART Regimens for HIV-infected Infants and Children Taking a Rifampicin-based Anti-TB Regimen

Age	WHO Recommendation
< 3 years old	Triple NRTI first-line regimen: d4T or AZT + 3TC + ABC *or* Standard first-line regimen: 2 NRTIs + NVP
> 3 years old	Triple NRTI first-line regimen: d4T or AZT + 3TC + ABC *or* Standard first-line regimen: 2 NRTIs + EFV

5. If well tolerated, continue ART after completing TB treatment.

B. If a pediatric patient diagnosed with TB is starting anti-TB medications and **already on ART, continue ART.**
   1. **Consult immediately with the ART provider** for a co-treatment plan if this facility MD is not the ART provider.
   2. Review the ARV regimen. Evaluate the need for adjustment, checking drug-drug interactions with anti-TB medications. Adapt the TB regimen to the ART regimen, as needed, in consultation with the ART provider.
   3. If the child is on a **first-line ARV** regimen, consider the following:
      a. If on two NRTIs + one NNRTI, and TB occurred because of primary infection or as part of IRIS, change ART to a triple NRTI first-line regimen.
      b. If on an EFV-based regimen, keep child on the standard regimen (2 NRTIs + 1 NNRTI).
      c. If on an NVP-based regimen, and EVF is not recommended, administer the standard dose. If giving rifampicin and NVP concurrently, follow up on clinical and laboratory (if available) parameters more frequently.
   4. If the TB diagnosis indicates first-line regimen treatment failure, switch to a second-line regimen if the child received more than 24 weeks of ART, initially responded to it, and has not responded to anti-TB treatment. Consult with a TB/HIV specialist to construct a second-line ART regimen.
   5. If the child is on a **second-line ARV** regimen:
      a. The choice of ARVs is complicated because of likely resistance to first-line NRTIs and varying interactions between rifampicin and the PIs.
      b. Confer with a TB/HIV specialist to consider second-line and other salvage regimens.
         (1) Single PIs and PIs given with low dose RTV/r boosting are not recommended with rifampicin administration because of decreased PI drug levels.
         (2) Hepatocellular toxicity in adults found when administrating rifampicin with SQV and full-dose RTV boosting suggests avoidance of this combination in children.
         (3) Although there is no supporting data, using LPV/r could be administered with additional RTV dosing. However, cold chain needs to be ensured.
         (4) Do not administer NFV with rifampicin.
   6. **Document** revised regimen on Tuberculosis Treatment Card and HIV Care/ART Card (Part 1 Forms 101 and 102).

Adults and adolescents

C. If the TB-infected person is not on ART, decide whether to start ART.
   1. **Start ART two to eight weeks after the start of anti-TB treatment, if**:
      a. CD4 < 200/mm^3
      b. ETB is present.
      c. CD4 count is unknown and patient has documented HIV and TB disease.
   2. **Consider starting ART** eight weeks after TB treatment is initiated (after intensive phase) when **CD4 is between 200-350/$mm.^3$**
   3. Consider delaying ART until TB treatment is completed when:
      a. **CD4 > 350/$mm.^3$** Consider early ART initiation if non-TB, HIV clinical stage 3 or 4 conditions present, despite CD4 count.
      b. Some TB diagnoses that generally respond well to anti-TB therapy (e.g., lymph node TB, uncomplicated pleural effusion) are present.

D. **If the decision is made to start a co-treatment regimen**, determine a safe plan.
   1. Address and treat the following, using facility protocols, before starting ART:
      a. Opportunistic infections (OIs)
      b. Mental health issues
      c. Alcohol and substance use
   2. Once ongoing issues in D.1 above are addressed, choose an ART regimen that fits with the chosen TB regimen containing rifampicin.
      a. **Two NRTIs + boosted EFV**
         (1) Ideal regimen
         (2) Increase EFV dose from 600 mg to 800 mg daily if > 60kg
         (3) **Do not use** in women of childbearing potential without adequate contraception, or in women in the first trimester of pregnancy.
      b. Two NRTIs + NVP
         (1) Perform close clinical monitoring; evaluate liver enzymes at weeks 4, 8 and 12.
         (2) **In women, do not prescribe unless**: it is a life-threatening situation; no alternative regimen to a rifampicin-based one exists; CD4 200-350 cells/mm^3; the woman needs to start ART.
      c. Triple NRTI regimen
         (1) Substitute EFV with ABC or TDF.
         (2) **If a co-infected pregnant woman is in her first trimester**, use the ABC option.
      d. If a pregnant woman changed her original ART during a co-treatment TB treatment, returning to NVP from EFV post-partum is acceptable.
   3. Decide when to introduce the ART regimen to the patient's TB regimen.
      a. Option 1: Begin ART as soon as the patient tolerates the TB medication regimen (e.g., 2 weeks into treatment).
      b. Option 2: Begin ART at the same time as the TB medication regimen.
      c. Option 3: Begin ART at the start of the continuation phase of TB treatment.

E. If **a** patient is diagnosed with TB, starting anti-TB medications, and already **on ART, continue ART.**
   1. **Consult immediately with the ART provider** for a co-treatment plan if this facility MD is not the ART provider.
   2. Review the ARV regimen; evaluate the need for adjustment, checking drug-drug interactions with anti-TB medications. Adapt the TB regimen to the ART regimen, as needed, in consultation with the ART provider, if the patient developed TB within six months of starting a first- or second-line ART regimen.
   3. Consider options for current **first-line ART**.
      a. If **2 NRTIs + EFV,** continue current ART.
      b. If 2 NRTIs + NVP:
         (1) Substitute NVP with EFV.

i. Consider substituting back to the original regimen once the rifampicin-containing regimen is complete.

ii. Do not use EFV in women of childbearing potential if adequate contraception cannot be ensured, or in women in the first trimester of pregnancy.

(2) Substitute to triple NRTI regimen. Consider substituting back to the original regimen once the rifampicin-containing regimen is complete.

(3) Continue with 2 NRTIs + NVP. Monitor clinical symptoms and ALT.

c. If **triple NRTI regimen**, continue current ART.

4. Consider options for current **second-line ART**.
   a. If **2 NRTIs + PI** (with rifampicin)**:**
      (1) Substitute to or continue (if already taking) LPV/r- or SQV/r-containing regimen.
      (2) Adjust RTV dose to 400 mg twice daily.
      (3) Consider substituting back to the original regimen once the rifampicin-containing regimen is complete.
   b. Recommendations for women of childbearing age and pregnant women are the same as for other TB patients.
   c. Ensure close clinical and laboratory monitoring for liver toxicity.
   d. If rifabutin is available and used instead of rifampicin**:**
      (1) Other boosted PI regimens can be administered.
      (2) Monitor for vision changes due to uveitis risk.
      (3) Do not use rifabutin if WBC < 1000/mm^3 and platelets < 50,000 $mm.^3$
5. **Document** revised regimen on Tuberculosis Treatment Card and HIV Care/ART Card (Part 1 Forms 101 and 102)

Adults, adolescents, children, infants

F. **Review** what **immune reconstitution syndrome (IRIS)** is and signs and symptoms suggestive of IRIS before starting the patient on both ART and anti-TB medications.
   1. IRIS is more common in co-infected patients with advanced immune suppression and disseminated TB.
   2. IRIS can occur 2 weeks to several months after anti-TB and HIV therapy.
      a. Review possible symptoms, including:
         (1) High fever
         (2) Worsening cough
         (3) Lymphadenopathy
         (4) Rash
         (5) Repeat or worsening of disease symptoms experienced in the past
         (6) Change in mental status (e.g., signs of expanding CNS lesions)
      b. Symptoms usually are self-limiting and last 10-40 days, though some symptoms may be severe.
   3. Explain the need for the patient to **immediately** report to facility if any IRIS symptoms occur.
   4. **Counsel** patients and families **to continue prescribed medications even if they feel the treatment is failing**.
      a. **Communicate** with the patient and family that:
         (1) Signs or symptoms of IRIS indicate that the immune system is recovering or awakening.
         (2) Previously dormant infections are now recognized by the body's recovering immune system.
         (3) IRIS does not indicate a failing of ART, but rather shows that ART is working and the body is now awake and fighting.
   5. **Monitor and manage signs and symptoms of IRIS** at each scheduled or acute clinic visit.

a. **Document the onset, duration, and severity** of symptoms upon presentation.
b. **Monitor the patient closely (e.g., daily if hospitalization is required),** and document their response to management and treatments in the medical record.

Infants and children

Mild signs/symptoms	→	Management
• Low grade fever • Worsening cough	→	• Continue TB and ART medications. • Administer anti-inflammatory drugs (aspirin, ibuprofen).
Moderate/severe	→	**Management**
• High fever • New/enlarging lymph nodes • Worsening respiratory symptoms • Radiological manifestations • New/worsening CNS tuberculosis • Enlarging pleural, pericardial and peritoneal effusions	→	• Continue TB and ART medications. • Add prednisone: 2-4 mg/kg/day (max: 60 mg/day). • Taper steroids in gradually decreasing doses.

Adults and adolescents

Mild signs/symptoms	→	Management
• Low grade fever • Worsening cough	→	• Continue TB and ART medications. • Administer anti-inflammatory drugs (aspirin, ibuprofen).
Moderate/severe	→	**Management**
• High fever • Tuberculosis • Cryptococcal meningitis • Large effusions, pneumonitis, ARDS • Parotitis • Epididymitis • Ascites • Adenopathy	→	• Continue TB and ART medications. • Add prednisone: 1-2 mg/kg/day for 1-2 weeks. • Taper steroids in gradually decreasing doses. • Encourage patient to continue all treatment.

G. **Ensure that** the patient has been **prescribed and** is **taking CTX** (SOP 406).

H. Discuss the chosen co-treatment plan with the patient and treatment supporter/family member/caretaker.
   1. **Counsel on TB-ART adherence**; begin (or continue) the Adherence Monitoring Records (Part 1, Forms 106 and 107), discussing:
      a. Higher pill burden
      b. When to take medications (e.g. morning and evening dose times)
      c. When the TB initial phase will end and the continuation phase will begin
      d. The possibility of more medication side effects (Appendix 3, 4, 5)
      e. That ART will continue once the TB regimen is complete
   2. **Review how to manage mild/moderate side effects** using Appendix 4 and 5, and SOP 410; including IRIS (Section "F" above).
   3. **Review the DOT plan**, including support and monitoring (SOPs 408, 409, 414).

a. Continue partnership with the patient.
b. Encourage patient to develop self-management skills.
c. Reinforce the need for frequent clinical, adherence, and laboratory follow-up.

I. Provide the patient with an education card specific to the patient's TB/ART regimen.

J. **Dispense medications** or ensure access to a pharmacy. (pharmacist, RN)

K. **Schedule a follow-up appointment** for 1 month away to monitor for improvement and adherence (SOPs 408 and 411; Part 1 Forms 106, 107). (RN, facility coordinator)

L. **Offer needed referrals** as indicated during the visit, whether internal (Part 1 SOP 107) or outside the facility network (Part 1 SOP 108). (RN, MD/CO)
1. Examples: gynecology specialist; peer group support; home-based care
2. Link patient to community care and support groups based on their needs (Part 1 SOP 108).

M. **Assure continuity of HIV care** and treatment throughout TB treatment.

N. **Complete documentation** and place in the patient's medical record. (RN, MD/CO)
1. Indicate assessment, plan, and prescribed medications on all required forms.
   a. Tuberculosis Treatment Card (Part 1 Form 101); Highlight the start or modification of ART on the TB treatment card so an opportunity to begin ART (if not already initiated) is not missed.
   b. HIV Care/ART Card (Part 1 Form 102)
   c. TB Register (Part 1 Form 103 – Standard; or 111 – Expanded)

SOP 406: Cotrimoxazole Preventive Therapy

I. Key Concepts:

- As all persons with symptomatic HIV infection are eligible for cotrimoxazole (CTX) preventive therapy (CPT), a patient co-infected with HIV and TB is by definition eligible for CPT.
- HIV-infected individuals with PTB = WHO clinical stage 3; with EPTB = clinical stage 4.
- **Most TB and HIV co-infected individuals benefit from CPT; it may prevent secondary bacterial, parasitic, and fungal infections.**
- Offer all symptomatic HIV-positive individuals CPT.
- Ensure that all infants and children receive CPT.
- Drugs containing sulfa include: cotrimoxazole/Septrin, Bactrim, Septra, and S-P/Fansidar.

II. Key Personnel: MD, CO, RN

III. Materials: Medical record, HIV Care/ART Card (Part 1 Form 102), TB Treatment Card (Part 1 Form 101), prescription, TB Register (Part 1 Form 103)

IV. Procedures:

A. **Assess patient for sulfa allergy** or previous history taking any sulfa-based drug.

B. **Consider alternatives** if a patient allergy is documented. For severe CTX or sulfa allergy, and if prophylaxis is a high priority, consider dapsone (100 mg daily) if available.

C. **Prescribe CTX if no allergy is reported or documented**. (MD/CO)

1. **Pediatric** dosing:
   a. **Daily, age and weight-based; refer to Table 7**
   b. Adjust dose as child grows and gains weight.
   c. If cotrimoxazole syrup is unavailable, give the tablet (age and weight-based).

Table 7*: Daily Cotrimoxazole Dosing in Infants and Children

Recommended daily dose: age or weight-based		Suspension (5ml syrup of 200mg/40mg)	Child tablet (100mg/20mg)	Adult tablet single strength (400mg/80mg)	Adult tablet double strength (800mg/160mg)
< 6 months	< 5 Kg	2.5 ml	one tablet	¼ tablet	–
6 months to 5 years	5-15 Kg	5 ml	two tablets	half tablet	–
6 – 14 years	15-30 Kg	10 ml	four tablets	one tablet	half tablet
> 14 years	>30 Kg	–	–	two tablets	one tablet

Legend	
Daily dosages based on age or weight:	
< 6 months or < 5 kg →	100mg sulfamethoxazole / 20mg trimethoprim
6 months – 5 years or 5- 15 kg →	200mg sulfamethoxazole /40mg trimethoprim
6-14 years or 15-30 kg →	400mg sulfamethoxazole /80mg trimethoprim
< 6 months or > 30 kg →	800mg sulfamethoxazole / 160mg trimethoprim

* Source: WHO "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press).

2. **Adult** dosing:

a. Prescribe one double-strength (DS) tablet or two single strength (SS) tablets daily.
   (1) DS tablet = 960 mg of trimethoprim/sulfamethoxazole (TMP-SMX)
   (2) SS tablet = 480 mg of trimethoprim/sulfamethoxazole (TMP-SMX)

D. **Review dose and possible side effects** with the patient. (RN, MD/CO)
1. With treatment supporter and patient, discuss giving CPT at the same time as the TB meds.
2. Review the overall tolerability. CPT is generally well-tolerated in children; side effects are more common in adults.
3. Clinical symptoms of CPT include:
   a. Shortness of breath, nausea
   b. Rash, pallor, jaundice
4. **Instruct patient to stop CTX and go immediately to the facility for evaluation for the following side effects**:
   a. Generalized rash
   b. Pallor changes, bleeding gums
   c. New jaundice
5. **Ensure that a one-month supply is** given to the patient, if not in a DOT program; **Schedule a follow-up appointment** for the week before the CTX supply runs out.
6. **Document** CPT status in the medical record and on the HIV/ART Card. (RN, MD/CO)
   a. If prescribed, document the date and dose.
   b. If not prescribed, document the rationale (e.g., clinical status, allergy).

E. **Monitor and document CPT adherence** at every monthly visit. (RN)

F. **Monitor side effects at every clinical visit.** (RN, MD/CO)
1. If the patient reports or presents side effects: assess, determine the severity and needed intervention(s); and continue CPT with symptomatic treatment, if possible.
2. For **redness/erythema or a diffuse, dry rash**:
   a. Continue CPT with careful and repeated observation and follow-up.
   b. Consider prescribing an antihistamine for symptom relief.
3. For **vesiculation or ulcers on the mucus membranes**:
   a. Stop CPT until symptoms completely resolve (about 2 weeks).
   b. Reintroduce CPT or consider desensitization.
4. For exfoliative dermatitis, Stevens-Johnson syndrome, or erythema multifore with moist desquamination:
   a. Stop CTX.
   b. Do not rechallenge with CTX.
   c. Document CTX/sulfa allergy in patient's medical record.

G. **Discontinue CPT** when:
1. Side effect/drug reaction/toxicity shows:
   a. Liver damage (jaundice)
   b. Bone marrow suppression (severe anemia)
   c. Other serious condition (e.g., Stevens-Johnson syndrome)
2. **CD4 rises above 350** for more than 6 months, or
3. In the absence of CD4 monitoring, **patient has been on ART for > 1 year without WHO clinical stage 2, 3 or 4** designation, has documented adherence, and a secure drug supply.

H. **If patient is < 1 year old, continue CTX regardless of improved symptoms** or CD4 %.

SOP 407: Isoniazid Preventive Therapy (IPT)

I. Key Concepts:

- Isoniazid preventive therapy (IPT) has been shown to prevent the development of active TB disease in individuals with latent TB infection.
- In high HIV and TB prevalent areas, a tuberculin skin test (TST) may not provide accurate results in immune compromised individuals; TST interpretation is the responsibility of the treating clinician.
- **Do not** give IPT to anyone with active TB disease.
- Active TB disease **must be** ruled out before prescribing isoniazid.
- If a person is exposed to active multi-drug TB disease, the patient may not be eligible for standard preventive therapy using INH.
- BCG immunization of children under two years of age can reduce the risk of developing severe TB (e.g., disseminated, meningitis) by 50–80%.

II. Key Personnel: MD, CO, RN

III. Materials: Medical record, TB Care Card (Part 1 Form 101), HIV Care/ART Card (Part 1 Form 102), TB Register (Part 1 Form 103)

IV. Procedures:

A. **Screening**

1. Assess for active TB disease or IPT eligibility at **every clinic visit** of HIV-infected individuals.
2. Ask TB-identified patients to bring household contacts to the clinic, specifically:
   a. Any HIV-positive person in the household. HIV-infected individuals with close contact to active TB cases require clinical evaluation to exclude active TB disease. Encourage HIV positive TB patients to bring their partner or spouse to the clinic for TB screening.
   b. Children < 5 years old.
   c. People in the household with a cough lasting more than 2 or 3 weeks.
3. **Rule out active TB disease** (SOPs 402 and 403).
   a. Initiate infection control (IC) measures (SOP 401) and begin a thorough, immediate evaluation (e.g., CXR) if an HIV-infected child or adult presents with active TB symptoms such as cough, fever, weight loss, or contact with a TB suspect.
   b. Use TST, where available, to guide IPT screening.

B. **Determine IPT eligibility**.

1. **Prescribe IPT in an HIV-infected individual if** PPD is positive (induration $\geq$ 5 mm) and active TB disease is ruled out (e.g., asymptomatic, no cough, CXR is clear).
2. In the absence of TST and PPD results, consider IPT in HIV-infected individuals when:
   a. There is no evidence of active TB disease.
   b. The patient lives in a high TB prevalence area.
   c. The HIV-infected individual is a healthcare worker.
   d. The patient is a household contact of TB patient(s), especially if a child under 5 years old.
   e. The patient is a prisoner.
   f. The patient is a miner.

C. **Prescribe IPT**.
   1. **Ask if the patient drinks alcohol; if yes, advise the patient to stop** or reduce to low-risk levels.
   2. **Prescribe isoniazid,** the recommended drug for tuberculosis prevention, in children, adolescents, and adults, according to national guidelines.
      a. **Pediatric dose**: 5 mg/kg (maximum dose = 300 mg daily)
      b. **Standard adult dose**: 300mg daily for 6-9 months
      c. **Treatment duration**: at least 6 months (range = 6-9 months)
      d. **Treatment** can be self-administered; DOT not required.
      e. INH is not contraindicated for **pregnant patients.**
   3. The most common side effect of isoniazid is peripheral neuropathy, presenting as a burning sensation in the feet. Treat this in advance by prescribing pyridoxine 50 mg daily.
   4. **Review** with the patient the need **to stop isoniazid and come to the facility immediately** if major side effects occur, such as;
      a. New itching of skin or skin rash
      b. Dizziness (vertigo and jittery eye movements)
      c. Yellowing of eyes or change in skin color
      d. Vomiting
      e. Confusion
      f. Convulsion
   5. **Review minor** side effects; offer suggestions for treating in the home setting.
      a. Anorexia, nausea, abdominal pain: Give INH at night instead of in the morning.
      b. Joint pain: Tell patient to take aspirin as prescribed.
   6. Order **baseline labs.** (MD/CO) Include: LFTs (e.g., bilirubin, ALT, AST); FBC
   7. **Provide IPT** prescription and ensure pharmacy access throughout the duration of treatment.

D. **Monitor IPT.** (RN, MD/CO)
   1. Ensure monthly monitoring while the patient is on IPT.
   2. At each visit the RN assesses **medication adherence.**
   3. Encourage the patient to immediately report any hepatitis symptoms lasting more than three days. **Hepatitis** symptoms include:
      a. Jaundice
      b. Dark urine
      c. Nausea
      d. Vomiting
      e. Abdominal pain
      f. Fever
   4. Monitor any ongoing side effects of INH.
      a. Patient is at increased risk of neuropathy if on d4T, too.
      b. If peripheral neuropathy persists, increase pyridoxine to 100 mg daily.
   5. **Prescribe a one-month supply of medication** at each visit. Consider giving the patient an additional two-week emergency supply to encourage adherence in case the patient must miss or defer a monthly appointment.
   6. Order and review **laboratory investigations as indicated by clinical signs and symptoms. Discontinue** isoniazid if major drug side effects persist in the absence of other causes.

E. **Documentation**
   1. **Document screening, results, and adherence** in the patient's medical record. (RN, MD/CO)
   2. Indicate **in the patient's medical record** the **reason and date therapy started**, if given IPT.
   3. **Prepare a Tuberculosis Treatment Card** and **TB Register** (Part 1 Forms 101, 103); document:

a. Diagnostic findings
b. Treatment initiation
c. Baseline laboratory findings (LFTs, RFTs, FBC)
d. Ongoing clinical and laboratory monitoring
e. Treatment discontinuation
   (1) Due to adverse events
   (2) Due to treatment completion

4. **Prepare an HIV Care/ART Card** (Part 1 Form 102) if a household contact is HIV-positive and not enrolled in an HIV care and treatment program. If the HIV-infected household contact is already enrolled in another HIV program:
   a. Notify the program of the IPT; consult with them regarding HIV care and treatment.
   b. Consider transferring care if concerned about treatment adherence.

F. **Complete IPT**.
1. **Once treatment is completed** (e.g, 6 to 9 months) in adolescents and adults:
   a. **Congratulate the patient on treatment adherence and completion of therapy**.
   b. **Document evaluation of IPT outcome (e.g., withdrawals, completion of therapy) in patient's medical record, TB treatment card, TB register and HIV care card**.
   c. Continue bi-annual TST screening per site or national guidelines.
   d. Continue TB screening at every acute and scheduled clinical visit.
2. After IPT course is completed in **children less than 2 years old:**
   a. Check to see if the child has received a **BCG immunization injection.**
   b. Check the immunization record, or
   c. Look for a scar on the upper left arm.
   d. If no record or mark exists, and **once preventive therapy is finished,** give one BCG vaccine dose to the child < 2 years old using sterile technique.
   e. **Only give the immunization once the child completes the IPT.**
   f. **Document** immunization administration in the child's vaccination record and medical chart.

SOP 408: Treatment Monitoring

I. Key Concepts:

- Monitoring is indicated for co-infected patients during the TB treatment period.
- Monitoring allows for the assessment of a co-infected individual, as well as a performance evaluation of the clinical site providing TB (and ART) treatment.
- Bacteriological monitoring is readily available only for smear-positive PTB patients (usually adults and adolescents); routine CXR is not always indicated.
- Clinical monitoring usually guides sputum smear PTB, EPTB, and pediatric TB cases.
- **A PTB patient may not be infectious after two weeks of anti-TB treatment**; only a negative sputum smear microscopy or culture result **confirms that** a patient is not infectious.
- Reinforce the continuation of handwashing and standard precautions (Part 1 SOP 105) during and after completion of anti-TB treatment.

II. Key Personnel: RN, MD/CO, laboratory technician, treatment monitor, others as needed

III. Materials: Clinical diagnostics (e.g., stethoscope, scale, blood pressure cuff, thermometer); visual acuity chart; medical record; Tuberculosis Treatment Card (Part 1 Form 101), HIV Care/ ART Card (Part 1 Form 102), laboratory form (site standard form), Request for Sputum Smear Microscopy Examination Form (Part 1 Form 105), Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test (Part 1 Form 109), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106)

IV. Procedures:

A. **Schedule regular clinical and adherence visits (see SOP 409 for specific adherence strategy)** during the TB treatment period.
   1. **If patient is hospitalized**:
      a. Assess and monitor the patient daily.
      b. Provide DOT.
      c. Order labs as indicated by acute clinical status and per facility protocol.
      d. Discharge the co-infected patient as soon as clinically stable, and move to the outpatient monitoring schedule.
   2. **If an outpatient, schedule clinical exams**:
      a. **Weekly, including treatment follow-up and intensive adherence review as outlined in SOP 409**, for the **first four weeks** of the intensive phase, then
      b. **Every two weeks** until the intensive phase is completed, then
      c. **Monthly** during the continuation phase.
   3. If a co-infected patient from another site (e.g., community-based clinic) with EP or DR TB disease is referred/transferred to your facility:
      a. Register the patient in your clinic with all the needed forms.
      b. Schedule regular visits as outlined in "A.1-2" according to the patient's diagnosis, clinical status, and where the patient is in the TB treatment plan.
      c. **Maintain contact with the referring clinician** regarding patient management.
      d. Develop a care plan with the referring clinician.
      e. **Facilitate communication and referrals between** the two sites. Over time, the patient may develop needs that can be met at the community-level site, such as DOT and primary care management.

B. **Provide a comprehensive clinical assessment** of the co-infected patient at each acute and scheduled appointment.
   1. **RN** ensures measurement and documentation of:
      a. Vital signs, weight, BMI in children
      b. Nutritional status
      c. Visual acuity and color vision, if on ethambutol
      d. Laboratory results: Schedule the patient for laboratory investigations a week in advance from the clinical appointment to allow time for receipt and review.
      e. Adherence tracking on Tuberculosis Care Card and HIV Care/ART Card
   2. **MD/CO** assesses and documents complete clinical status, including:
      a. Clinical response to treatment; signs/symptoms of IRIS
      b. TB- and ART-related side effects (SOP 410); signs/symptoms of hepatitis
      c. Common HIV-related infections such as pneumonia, diarrhea, fungal infections; treat as indicated in SOPs for HIV clinical care and treatment
   3. **MD/CO** orders the tests and studies required/indicated in Section "C" below.
      a. Baseline laboratory values
      b. During the entire treatment period, **if the patient develops new signs or symptoms,** the **MD/CO assesses, classifies, and treats according to site protocol.**
   4. **Reinforce the importance** of clinic visits, laboratory requests, and medication adherence at each interaction.
   5. The RN, site staff members, and laboratory technician coordinate referral to (if laboratory is offsite), and receipt of, results between the facility and laboratory.

C. Use laboratory data alongside clinical assessment to determine patient's response to TB treatment.
   1. **In sputum smear-positive PTB** HIV-infected patients:
      a. **If on an eight-month regimen**, collect sputum samples:
         (1) At the end of the initial phase (month two)
         (2) In the continuation phase (month five)
         (3) During the last month of treatment (month eight)
      b. If on a **six-month regimen**, collect sputum samples:
         (1) At the end of the initial phase (month two)
         (2) In the continuation phase (month five)
         (3) During the last month of treatment (month six)
      c. Complete Request for Sputum Smear Microscopy Examination Form.
         (1) Send samples to the laboratory for smear microscopy.
         (2) The laboratory technician records the exam results on the bottom half of the **Sputum Examination Request Form** and returns it to the requesting site.
      d. **Send sputum for drug resistance testing** if patient is sputum smear-positive after the intensive phase, to rule out MDR-TB (SOP 412; Part 1 Form 109).
      e. **Collect blood specimens** when clinically indicated (e.g., change in pallor, jaundice) during TB treatment.
      f. If indicated, repeat CXR report and review for changes or signs of improvement. Follow-up chest radiographs are not routinely recommended in children.
      g. RN records all results on the patient's TB Treatment Card, and indicates date of each:
         (1) Sputum (record "neg"; if positive, record the highest grading)
         (2) Weight
         (3) Clinical follow-up
   2. For **previously-treated pulmonary sputum smear-positive patients**, collect sputum for smear exam:
      a. At the end of the initial phase of treatment (the end of month 3)
      b. During the second month after starting the continuation phase
      c. At the end of treatment
   3. In HIV-infected sputum **smear-negative PTB patients**:

a. **Collect sputum at the end of month two** (two specimens), in order to:
   (1) Monitor disease progress due to non-adherence, and
   (2) Check for an error at the time of the initial diagnosis (e.g., true sputum smear-positive misdiagnosed as smear-negative), and
   (3) Check for drug resistance.
b. Otherwise, **clinical monitoring is the primary measure of a patient's progress**. Use body **weight** as a progress indicator.
c. **Collect blood specimens** when clinically indicated (e.g., change in pallor, jaundice) during TB treatment.

4. In HIV-infected sputum **EPTB patients:**
   a. **Clinical monitoring is the primary measure** of a patient's progress. Use body **weight** as a progress indicator.
   b. **Collect blood specimens** when clinically indicated (e.g., change in pallor, jaundice) during TB treatment.
5. In HIV-infected patients with **any active TB diagnosis on anti-TB medications and ART, collect blood specimens**:
   a. Acutely, when clinically indicated (e.g., change in pallor, jaundice)
   b. Every six months
      (1) CD4 count (and %, if child)
      (2) Viral load
      (3) Fasting glucose, cholesterol, and triglycerides
   c. Monthly, until normal on two consecutive occasions
      (1) FBC
      (2) LFTs

D. Modifying or changing TB treatment doses or therapy
1. In infants and children, adjust TB (and ARV) dosages according to any weight gained since the last visit.
2. In **smear-positive PTB cases** on Category I treatment:
   a. **If both smear specimens are negative**, discuss sputum smear-negative results with the patient and documents plan on the Tuberculosis Treatment Card; begin and then complete the continuation phase.
   b. **If sputum smear returns positive at month two**:
      (1) Extend the initial treatment phase by one extra month.
      (2) Review the patient's medications and treatment schedule.
         (a) If the treatment has not been regular, discuss with the patient the need to take the treatment exactly as prescribed.
         (b) Consider stronger follow-up DOT strategies with the RN, treatment supporter, and patient.
      (3) **Check smear at the end of month three** to evaluate smear conversion in the cohort.
      (4) After the third month of the initial phase regimen, start the full continuation phase.
      (5) **Check sputum again in month five.** Consider sending specimen for TB culture to confirm treatment failure.
      (6) **If month five sputum returns positive**, document the patient as a **treatment failure**.
         (a) Close the TB Treatment Card (outcome = treatment failure).
         (b) Open a new TB Treatment Card (patient type = treatment after failure).
         (c) Begin Category II re-treatment; if considering Category IV regimen, refer to SOP 412 for MDR-TB diagnosis protocol and prescribe the regimen according to national guidelines and NTP.
         (d) **Send sputum** to laboratory for **culture and drug sensitivity**; use Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test (Part 1 Form 109).

3. In **previously-treated pulmonary sputum smear-positive** patients:
    a. If sputum smear-positive at the end of month three, extend the initial phase with four drugs by one month.
    b. Check sputum smear at the end of month four.
    c. If sputum-positive at month four, send sputum to the lab for culture and sensitivity testing.
    d. Start patient on the continuation phase.
    e. If culture and sensitivity show resistance to two of the three drugs in the continuation phase, consult a TB/HIV specialist and consider using reserve anti-TB drugs.
    f. If culture and sensitivity testing is unavailable, continue patient treatment until the end of the re-treatment regimen.
    g. If sputum-positive at the end of month five, document and inform the patient of re-treatment failure.
    h. Consider a drug resistant regimen (SOP 412).
4. For new **smear-negative pulmonary cases** (Category III):
    a. If patient has two positive smears at the end of month two, start a full course of Category II treatment.
        (1) Record the outcome as “failure.”
        (2) Re-register the patient.
    b. If sputum smears remain negative at the end of the initial treatment phase, open a new TB Treatment Card (patient type = other).
    c. Begin Category II treatment.
5. Adjust the dose or change drug based on clinical assessment of severe kidney and liver response to TB medications, confirmed by laboratory investigations.
    a. **Review the case** in a multidisciplinary team meeting (Part 1 SOP 110).
    b. Consult with a TB/HIV specialist, nephrologist, or gastrointestinal specialist as needed.
6. **All cases indicating TB treatment or ART failure** require evaluation by a TB/HIV specialist.
7. Notify NTP of any treatment changes based on a full, comprehensive assessment.
8. Document changes to the treatment dose or regimen on the Tuberculosis Treatment Card and HIV Care/ART Card.

SOP 409: Promoting and Monitoring Treatment Adherence, Directly Observed Therapy

I. Key Concepts:

- Non-adherence causes drug-resistant TB and treatment failure.
- Daily directly observed therapy (DOT) is the preferred method to ensure full adherence to TB treatment.
- Adherence to both anti-TB medicine and ARVs is complicated; a patient-centered approach is needed to ensure adherence.
- Make treatment as attractive and organized for the patient as possible.
- All types of treatment supporters, including family members, can be trained to provide DOT for both TB treatment and ART, given proper training.
- For adherence support with special populations such as the homeless, people with a poor understanding of their disease, patients with complex medical problems, or substance users, see Part I SOP 104.

II. Key Personnel: RN, MD, CO, treatment supporter

III. Materials: Medical record, TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106), Adherence Monitoring Record (Part 1 Form 107), IEC, treatment aids (e.g., Appendix 5, calendars, pillboxes); flipcharts of TB/HIV co-infection; photos of patients with TB and HIV co-infection taken before and after completing TB treatment

IV. Procedures:

A. Assess patients for risks of potential non-adherence: alcohol and drug use, pregnancy, mobile population, or mental illness.

B. If a patient is hospitalized, DOT may be administered and monitored by the inpatient RN as directed by the facility TBIC plan until the patient transfers to outpatient care.

C. If the patient is treated as an outpatient, the RN **meets with the patient to discuss a medication adherence and clinic visit plan**.

1. **Decide where daily DOT will happen**.
    a. If outside the clinic site, such as in the home or workplace, explain that a community-based TB treatment supporter can provide DOT.
    b. If at the site:
        (1) A site staff or volunteer will provide DOT
        (2) If the patient is prescribed streptomycin, the patient needs to come to the site as a trained health worker needs to provide the sterile injection.
2. **Decide on and train the treatment supporter** (SOP 413).
3. Obtain patient consent for the home visit.
4. If off-site DOT is chosen, confirm the DOT location (e.g, workplace).
5. **Discuss clinic visit plan:** Weekly to monthly clinic visits; more frequent if signs/symptoms or difficulties occur
6. If the patient refuses DOT:
    a. Discuss disclosure issues; help the patient move toward a disclosure plan that is acceptable.
    b. Discuss options; encourage adherence and the need to follow up.

c. Create a patient-centered approach; begin developing a working relationships with the patient.
d. Continue close clinical and adherence follow-up, and psycho-social supportive care (Part 1 SOP 104).

D. **When adherence is reviewed**
1. **Daily**: by treatment supporter or RN at the site providing daily treatment
2. **Monthly:** by RN or MD/CO at every clinic visit

E. **Who** provides TB (and ART) treatment adherence
1. **Treatment supporter**:
a. **Observe the patient taking the prescribed treatment** (TB and ART, as needed) on a daily (or 2-3 times per week) basis. Document adherence on the TB Treatment Card.
b. **Visit the health site/facility on a monthly basis** to collect the next month's drug supply and to review problems with the RN as needed.
2. **RN**:
a. **Serve as the team leader for DOT,** sharing responsibility with other TB educators and trained site staff for delegated DOT-related issues.
b. If the patient is on **community-based DOT**:
(1) **Review the TB Treatment Card, which is** kept by the treatment supporter, with the patient during the patient's monthly assessment, and before seeing the MD/CO.
- Copy the days the patient took the treatment onto the original TB Treatment Card kept at the site.
(2) Occasionally ask the patient to describe the TB treatment supporter's work in helping with adherence and any other issues:
- How often does the patient receive medicine from the treatment supporter? Does the patient receive medicine at the same time every day?
- How often does the patient see the treatment supporter fill in the treatment card?
- What drugs does the patient receive from the treatment supporter?
- How is the relationship between the patient and the treatment supporter?
(3) Determine whether the relationship between the treatment supporter and patient is positive and is working to the patient's benefit.
- Ask whether the patient is willing to receive medicine from the same treatment supporter until the treatment course is completed, or if the patient wants to change treatment supporters.
- If a change is requested, probe for reasons why the patient wants or needs to change treatment supporters.
(4) Continue to reinforce the patient's role in self-management of the illness.
(5) **Review the TB Treatment Card with the treatment supporter** on a monthly basis when the treatment supporter collects the monthly drug supply, and discuss any problems.
- Record on the front of the TB Treatment Card the drugs provided to the supporter for the next month, and the date provided.
(6) **Ask about any travel plans** and alert the MD/CO to the patient's travel needs.
c. If the patient takes **site-based DOT**:
(1) Observe the patient taking the medication.
(2) Document adherence on the TB Card, TB/ART Card and the medical record (per site protocol).
3. **MD/CO**:
a. Review the RN documentation and discuss the adherence plan with the patient and the treatment supporter, if available.

b. Provide the prescription for the next month's TB (and ART, if prescribed) drug supply.
c. Ask about any future travel plans. Work with team to ensure that treatment continues.

F. **Providing DOT**

1. The treatment supporter or site staff member providing DOT, once determined, meets together with the patient to arrange a specific time and place to give/take medication(s).
2. The treatment supporter arrives at the designated place on time and **does not make the patient wait.**
3. Ask the patient about possible side effects.
   a. **Minor** side effects
      (1) If patient reports **nausea, lack of appetite, stomach pain or discomfort**, encourage the patient to eat a small snack with the tablets; for patients who do not have food to eat, refer to an NGO or welfare service for food support.
         (a) Refer the patient for an appointment with the RN/MD/CO if nausea continues.
         (b) Document referral on the treatment card.
         (c) If available, offer the patient food by prescription.
      (2) If the patient reports that their **urine is orange/red**, tell them this is a normal side effect.
      (3) If the patient complains about **joint pain or a burning sensation in the hands or feet**, refer the patient to the site for the soonest appointment.
   b. **Major** side effects
      (1) **Do not give** the TB medication, tell the patient the medication will be stopped for evaluation, and **immediately refer the patient to the health facility** for evaluation by the specialty MD/CO **if a patient reports any of the following**:
         - Itching of the skin
         - Skin rash
         - Hearing loss, deafness
         - New dizziness
         - Jaundice
         - Continued vomiting
         - Vision changes, difficulty seeing
4. Review the patient's medications.
   a. First, check to make sure the drugs are correct.
   b. Next, watch the patient take and swallow all the drugs.
   c. If needed, give the prescribed injection according to protocol.
   d. Finally, document on the treatment card that the patient took the drugs.
5. **Encourage** the patient to continue the treatment exactly as prescribed. Praise the patient for completing doses, managing side effects, and keeping scheduled appointments.
6. If the **patient misses one dose**:
   a. **Respond immediately**.
   b. If a patient **takes medication at home or work**:
      (1) Return the next day and ask the reason for the missed dose; problem solve so doses are not missed again in the future.
      (2) Give the next scheduled dose.
      (3) Extend the treatment by the missed dose day.
      (4) If unable to find the patient or the patient refuses the medication, contact the site the same day for help.
   c. If a patient **takes medication at the site**:
      (1) Visit the patient's home within 24 hours.
      (2) Ask the reason for the missed dose.

(3) Give the next scheduled dose.
(4) If unable to find the patient or the patient refuses the medication, make an urgent appointment for the patient in the clinic to see the MD/CO for further support and evaluation.

7. **If providing DOT at home or workplace**, schedule a time to collect a monthly supply of drugs each month with the site staff/RN.
   a. If possible, ask the patient to come to the clinic or schedule the patient's monthly clinic appointment the same day.
   b. Show the RN the treatment card each month when picking up medications.
   c. Review with the RN the patient's adherence and troubleshoot any problems from the past month.
8. **If providing DOT at the site**, schedule time with the RN and the patient at the patient's monthly clinic appointment.
   a. Review the treatment card with the RN and patient, if present.
   b. Altogether, review the adherence pattern and troubleshoot any problems from the past month.
9. If the treatment supporter or patient **travels out of town for a few days**:
   a. Inform each other of travel plans at least one week in advance.
   b. The treatment supporter makes arrangements for the patient to have exactly enough drugs to self-administer medication for only one week.
   c. **If travel will be longer than one week**, meet with the clinic team to determine a plan.
      (1) Reinforce with the patient that treatment cannot stop or pause once started but needs to continue until the end.
      (2) Perhaps consider transferring the patient to a site near the patient's destination if travel will be longer than a few weeks.
10. **Be aware of the patient's appointments and laboratory schedule**.
    a. The patient's clinic appointments should be at least monthly, and more frequent depending on other clinical issues or emergent needs.
    b. **If a pulmonary TB patien**t, the patient will need to go to the site, lab, or facility (depending on site resources) for **repeat sputum smear exams. These are usually schedule three times:** at end of the initial treatment phase, after five months of treatment, and during the last month of treatment.
    c. Make sure the patient goes to the site or laboratory, per site standard, to have labs checked (e.g., hematology, LFTs or sputum collection) at least a week before the clinic appointment, so that results will be available for MD/CO evaluation.

G. **Offer TB/ART DOT**.
   1. DOT is ideal; maintain as resources allow.
   2. DOT may not be sustainable after the end of TB treatment for lifelong ART.
      a. **Develop a flexible patient-specific approach** for maximum adherence.
      b. The treatment supporter can observe the patient receiving ART at different intervals, depending on the patient's individual needs:
         - Once a week
         - Several times a week
         - Daily or twice daily
   3. **Combine the daily observation of TB treatment with the one ART dose**.
      a. Preferably this is offered in the morning.
      b. The treatment supporter then reminds the patient about the next (unobserved) doses of ART and helps as able to ensure adherence with ART.
         (1) Lay out the pills.
         (2) Discuss ways that help the specific patient.
         (3) The next day, check whether the patient took the other ART doses.

H. **For patients who travel, arrange continued TB/ART treatment**.
   1. Review travel plans at every clinic visit.
   2. If a **patient plans to travel out of the area**, or will be unable to have treatment directly observed for one or more days:
      a. **Give patient careful instructions and drugs** for self-medication for a short time.
         (1) Instruct the patient to:
            - Swallow the drugs at the same time each day.
            - Swallow pills with water.
            - Swallow all of the TB drugs for the day together.
         (2) Point out the number and color of the drugs in each day's packet.
         (3) **Provide both oral and written instructions**.
            - If patient does not read, arrange for a traveling companion to come to the clinic visit and help with adherence support, if possible.
      b. **Ask checking questions** to make sure that the patient understands when and how to take the drugs.
      c. If necessary, provide a drug supply that lasts up to two weeks.
      d. **If the patient's drugs are not pre-packaged,** prepare a separate packet of drugs for each day the patient will be gone.
      e. **On the patient's TB Treatment Card,** mark a tick when you observe treatment; draw a line through the days on which the patient will self-administer the drugs.

I. **If a patient misses doses or appointments, the RN schedules a home visit** to find out barriers to proper TB/HIV care and treatment.
   1. The **RN attempts to have the treatment supporter present during conversation** with the patient in the home setting.
   2. The **RN asks specific questions** about adherence in a non-judgmental way (e.g., avoid "why" questions):
      a. How do you usually take your medications?
      b. When do you usually take your medications?
      c. What happened that you missed your appointment?
      d. What happened that you missed taking your medication?
   3. The RN **listens to the patient's answers** to figure out the barriers to treatment adherence:
      a. Attitudes of the health facility staff who observe treatment
      b. Waiting time at the health facility
      c. Transportation
      d. Work or family commitments
      e. Side effects of treatment
      f. Other health problems

4. The RN works with the patient, treatment supporter, and family/friends/household members to solve identified problems:

Example reasons for missed doses:	Possible solutions:
Coming to the health facility is inconvenient.	• Identify a convenient community TB treatment supporter.
The patient dislikes coming to the health facility because of the long queue.	• Make arrangements so that TB patients do not have to wait in a queue. For example, let them enter through a back or side door.
A supervisor at work kept the patient late.	• Offer to talk with the supervisor and explain the importance of the treatment, or identify a community TB treatment supporter at work.
The patient had troublesome side effects.	• Give appropriate advice or remedies for side effects (Appendix 4, 5); refer the patient if necessary.
The patient had difficulty swallowing because of pain (this could be oral thrush).	• Use IMAI Acute Care or IMAI Palliative Care to classify and provide treatment or to refer patient as necessary.
The patient cannot leave small children at home and is tired of bringing them to the health facility.	• Discuss with the patient other childcare solutions (e.g., support group members, church members). • Remind family members/neighbors that the patient must continue treatment to protect their health, particularly the health of the children. • If possible, identify a community TB treatment supporter closer to the patient's home.

5. The **RN works with the patient, treatment supporter, and family/friends/household members to motivate** the patient during the conversation.
6. **Use correct statements** to provide hope about taking prescribed treatment (SOP 414, Text Box 5).
    a. Show photos of patients with TB and HIV co-infection, before and after TB treatment.
    b. The photos show that despite HIV infection, TB is curable and these patients, despite difficulties, were cured.
7. The RN gives the patient the missed dose and explains that past missed doses will continue to be given one day at a time until all pills are taken as prescribed.
8. Instruct the patient and treatment supporter to **not** give an extra dose on any day.
9. The RN records a zero (0) on the TB Treatment Card for each day of missed treatment.
    a. Add a comment on the action taken during the home visit.
    b. For example: "Home visit; treatment resumed."

J. If a patient **misses doses or appointments for longer than a month**, the RN or designated clinic staff member **attempts to find the patient**.
1. **First**, trace the patient and find their location using family members, friends, or other community resources.
2. **Once the patient is traced** and contacted, the RN **immediately meets with the patient** in the clinic, if possible.
3. The RN ensures that the patient's health status is stable, then arranges with the MD/CO to collect two or three sputum samples.
4. The RN and MD/CO discuss the reason the patient stopped treatment.
5. As a team, **determine the cause of the treatment interruption**.
    a. Work together with the patient to find ways to prevent future treatment interruptions.
    b. If found that the **patient plans to move to another place permanently or for a prolonged period of time**, use SOP 409 to guide the transfer of the patient to another site or facility to continue treatment.

6. If **treatment interruption has been for one to two months**:
   a. The MD/CO restarts the patient's TB treatment and provides prescriptions for other medications (e.g., prophylaxis medications), as needed, while waiting for sputum results.
   b. Prolong the TB treatment to make up for missed doses.
7. **If the treatment interruption has been two months or longer**, the patient is considered a treatment defaulter.
   a. Do not restart treatment.
   b. Wait for return of sputum results to restart treatment regimen.

8. Refer to Table 8 to guide TB treatment actions based on sputum results.

Table 8*: Treatment interruption guidelines

	All smears return negative, or patient has extrapulmonary TB	**If one or more smears returns positive…**
Treatment interruption length	⇩	⇩
Missed 1 up to 2 months	➢ Continue treatment. ➢ Prolong it to make up for missed doses.	*…and previously treated for less than 5 months:* ➢ Continue treatment. ➢ Prolong it to make up for missed doses.
		…and previously treated for 5 months or more: ➢ If was on Cat I, start Cat II (see Table 1) ➢ If was on Cat II, refer to facility or TB specialist o Follow up on referral recommendation. o Document recommended treatment plan on TB Treatment Card. o Initiate or monitor new regimen with referring specialist.
Missed ≥ 2 months	➢ MD/CO decides on individual basis ➢ Options: o Restart or continue treatment o No further treatment	*…and previously treated with Cat I:* ➢ Start Cat II (see Table 1)
		…and previously treated with Cat II: ➢ Refer to facility or TB specialist. ➢ Follow up on referral recommendation. ➢ Document recommended treatment plan on TB Treatment Card. ➢ Initiate or monitor new regiment with referring specialist.

*Adapted from WHO "Tuberculosis Care with TB-HIV Co-management," 2007.

9. Discuss the new (or continued) treatment plan with the patient and treatment supporter.
10. Document the treatment plan (Tuberculosis Treatment Card, HIV Care/ART Card, TB Register, Adherence Monitoring Record) in patient's medical record based on sputum results, and actions taken to support the patient and treatment supporter in adhering to the plan.

SOP 410: Monitoring and Managing TB and ART Medication Side Effects

I. Key Concepts:

- Monitoring and managing minor medication side effects early can affect adherence.
- Close monitoring is essential to determine if clinical symptoms or side effects indicate ART failure.

II. Key Personnel: RN, MD/CO, laboratory technician, treatment monitor, others as needed

III. Materials: Clinical diagnostics (e.g., stethoscope, scale, blood pressure cuff, thermometer); visual acuity chart; medical record; Tuberculosis Treatment Card (Part 1 Form 101), HIV Care/ART Card (Part 1 Form 102), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106)

IV. Procedures:

A. Monitor for and address side effects of medications at every clinic appointment.

Infants and children on anti-TB therapy

1. If present, document the onset, duration, and severity, and manage immediately. Children have fewer adverse reactions than adults to anti-TB therapy.

Sign/symptom	Associated TB drug	Management
Hepatotoxicity • Liver tenderness • Hepatomegaly • Jaundice • Serum liver enzymes > 5 times the normal value	Isoniazid Pyrazinamide Rifampcin	• Immediately stop all hepatotoxic medications. • Screen for other causes of hepatitis. • Do not reintroduce hepatotoxic drugs until liver function normalizes. • Consult an expert in managing drug-induced hepatotoxicity in further patient management. • If severe TB form requires continued TB treatment, introduce non-hepatotoxic anti-TB drug (e.g., ethambutol, an aminoglycoside and a fluoroquinolones).
Peripheral neuropathy	Isoniazid	• Offer supplemental pyridoxine 5-10 mg/day.

2. Document the side effect, treatment, and response in the medical record.
3. Report adverse events to the NTP.
4. For a child not responding to TB treatment, evaluate thechild for:
   a. Drug-resistant TB (SOP 412)
   b. An unusual complication of pulmonary TB
   c. Other causes of HIV-related lung disease per facility HIV care and treatment SOPs
   d. Problems with treatment adherence (SOP 409; Part 1 SOP 104)
   e. Viral failure per facility HIV care and treatment SOPs

Adults and adolescents on anti-TB therapy

5. For minor side effects
   a. Continue anti-TB drugs.
   b. Check drug doses.
   c. Encourage the patient to report all minor symptoms during monthly visits, but to monitor and manage them at home.

d. Review symptomatic management each month:

Symptom	Associated TB drug	Management
Loss of appetite, nausea, stomach pain	Pyrazinamide Rifampicin isoniazid	• Take medicine with a small meal. • Give drug at bedtime.
Joint pain	Pyrazinamide	• Give aspirin.
Burning pain in hands/feet	Isoniazid	• Give pyridoxine 100 mg daily. • Consider prescribing amitryptiline.
Orange/red urine	Rifampicin	• Reassure patient. • Explain that this is a normal finding when taking rifampicin.

e. Document response to symptomatic management in the patient's medical record.

6. **For major side effects**:
   a. Stop the offending anti-TB drug.
   b. Evaluate the onset, duration and severity of each specific symptom.
   c. Determine if presentation or treatment requirements indicate hospitalization.
   d. Consult with the medical team and TB/HIV specialist as needed.

Symptom	Main anti-TB drug involved	Management
Skin rash	S, H, R, Z	• Stop TB drugs. • Start antihistamines; observe closely. • Reintroduce anti-TB medications after the rash resolves, starting with the least offending agent (Isoniazid) at a small dose, gradually increasing the dose over 3 days. • Repeat the procedure adding one drug at a time. • If the drug responsible is Z, E or S, resume treatment without the offending drug; if possible, replace the offending drug and consider extending the treatment regimen.
Hearing loss, deafness (after TB drug initiation; no wax on auroscopy)	Streptomycin	• Stop streptomycin; use ethambutol.
Dizziness, balance loss, vertigo, nystagmus	Streptomycin	• Stop streptomycin; use ethambutol.
Jaundice (other causes excluded) hepatitis	Isoniazid, Pyrazinamide Rifampcin	• Stop anti-TB drugs. • Wait until LFTs return to normal. • If LFTs are unavailable, wait 2 weeks after jaundice disappears, then restart TB treatment. • Reintroduce anti-TB drugs one at a time. • Avoid Z if hepatitis caused jaundice. • Suggested regimen: 2 SHE/10 HE • Option: Treat with S and E and then the usual TB treatment after hepatitis resolves.
Confusion (suspect drug-induced acute liver failure if jaundice present)	Most anti-TB drugs	• Stop anti-TB drugs. • Order urgent liver function tests and prothrombin time.
Visual changes (other causes excluded)	Ethambutol	• Stop ethambutol.
Shock, purpura, acute renal failure	Rifampicin	• Stop rifampicin.

7. Report adverse events to the NTP and document in the patient's medical record.
8. Continue close follow-up.

B. **Clinical monitoring** of any-aged HIV-infected patients taking **both TB treatment and ART**
   1. Evaluate the onset, duration, and severity of each specific symptom.
   2. Determine if presentation or treatment requirements indicate hospitalization.
   3. Try to determine the offending agent: anti-TB medication or ART component.

Adverse reaction	Main ARV drug involved	Main anti-TB drug involved	Management
Peripheral neuropathy • Early or late side effect	Stavudine Didanosine	Isoniazid (H) Cycloserine	• Give pyridoxine as preventive therapy and treatment for H toxicity.
Hepatitis • sually early side effect	Nevirapine PI	Pyrazinamide Rifampicin Isoniazid	• STOP all drugs. • Once resolved, restart with TB therapy.
GI dysfunction • Diarrhea • Abdominal pain • Early or late side effect	All	All	• Symptomatic treatment
Skin rash • Usually early side effect	Nevirapine Efavirenz	Rifampicin Isoniazid Pyrazinamide Cycloserine	• Anti-histamine if mild • If severe, STOP all drugs; once resolved, restart with TB therapy.
CNS dysfunction • Early or late side effect	Efavirenz	Isoniazid (H) Cycloserine	• Give pyridoxine as preventive therapy and treatment for H toxicity.
Anemia • Usually early side effect	Zidovudine	Rifampicin	• Change zidovudine to stavudine.

Source: WHO "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press).

4. Consult with the medical team and TB/HIV specialist as needed.
5. Refer to Appendix 4 for comprehensive symptomatic management of minor and moderate medication-related symptoms.
6. Meet with the clinical team or TB/HIV specialist to determine further TB and ART treatment.

C. **If a TB-HIV patient on ART** does not gain weight or develops new HIV-related diseases (WHO clinical stage 3 or 4), **consider the possibility of IRIS or ART failure.**
   1. Treat acute symptoms.
   2. Order TB and HIV resistance testing, as indicated.
   3. Reassure the patient.
   4. If **IRIS** is identified in the first six months of starting ART, do not presume treatment failure. Follow procedures described in SOP 405.
   5. If **ART failure** is suspected, **discuss case with the multidisciplinary team and TB/HIV specialist** to reconstruct an ART regimen or start a salvage regimen.
   6. Document actions in patient's medical record; document any medication changes on the Tuberculosis Treatment Card and HIV Care/ART Card.

SOP 411: Determining TB Treatment Outcome

I. Key Concepts:

- Treatment outcomes refer to classifying TB types once the anti-TB treatment regimen is completed.

II. Key personnel: RN, MD/CO

III. Materials: Medical chart, laboratory investigation results, TB Register (Part 1 Form 103), HIV Register (site standard form), Tuberculosis Treatment Card (Part 1 Form 101 or 110), HIV Care/ART Card (Part 1 Form 102), TB/HIV Medication Adherence Monitoring Record (Part 1 Form 106), Adherence Monitoring Record (Part 1 Form 107)

IV. Procedures:

A. Determine the outcome of the treatment.
   1. Perform a final follow-up medication review.
   2. Review follow-up laboratory investigations.
   3. Decide on the treatment outcome and record on TB register.
   4. Analyze and report patient outcomes:
      a. Use cohort analysis.
      b. Report outcome by HIV co-infection status.

B. **Medication review**
   1. The **RN reviews** the patient's TB treatment monitoring schedule (Part 1 Forms 106, 107) at the visit corresponding with the last scheduled TB treatment dose and asks the patient if all pills were taken.
   2. The RN then reviews the Tuberculosis Treatment Card (Part 1 Form 101 or 110) to ensure that documentation shows all medications doses were taken by the patient.
   3. The RN confirms with the treatment supporter that all doses were completed.
   4. The RN documents findings in the medical chart and on the Tuberculosis Treatment Card.

C. **Laboratory review**
   1. The RN prepares the medical record to include the current laboratory investigations for MD/CO review, and documents findings from the medical record:
      a. Sputum results (e.g., microscopy and culture, if available)
      b. CXR (if pulmonary TB)
      c. Other studies as needed or ordered
   2. The RN provides the medical record and lab results to the MD/CO.
   3. The MD/CO reviews the laboratory results and decides upon a treatment outcome diagnosis.

D. **Treatment outcome**
   1. Using the patient and laboratory register, along with adherence data, **the MD/CO examines the patient and performs a confirmatory interview** about medication adherence and symptoms.
   2. The MD/CO determines a treatment outcome and documents it on the back of the TB treatment card alongside the date the outcome determination was made (ideally, the last day of treatment), according to the original diagnosis and definitions in Section I.
      a. Determine the patient's TB treatment outcome; definitions follow in Table 9.

Table 9: Identifying TB Treatment Outcomes

	TB treatment outcomes						
Definition (or patient criteria)	***Cure***	***Treatment completed***	***Treatment failure***	***Died***	***Default***	***Transfer out***	***Complete treatment***
A sputum smear microscopy-positive patient has 2 negative sputum samples: one in the last month of treatment; another on at least one prior occasion during treatment.	X						
A patient completes treatment but does not meet criteria for either cure or failure.		X					
A **new** patient is sputum smear microscopy-positive at 5 months or later during treatment.			X				
A **new** patient switched to Category IV treatment because sputum was found to be MDR-TB.			X				
A **previously-treated** patient is sputum smear microscopy-positive at the end of re-treatment.			X				
A **previously-treated** patient switched to Category IV treatment because sputum was found to be MDR-TB.			X				
A patient dies from any cause during the course of treatment.				X			
A patient's treatment was interrupted for $\geq$ 2 months in a row (e.g., stopped coming for treatment, cannot be located, cannot be convinced to resume treatment after 2 months of missed treatment).					X		
A patient transferred to a health facility in another area and their treatment outcome is unknown.						X	
The patient took every prescribed pill; missed doses extend a patient's continuation phase until all doses have been taken.							X

b. **Sputum smear-positive** TB outcomes:
   (1) Cure
   (2) Treatment completed
   (3) Treatment failure
   (4) Died
   (5) Default
   (6) Transfer out
   (7) Treatment success – cure plus treatment completed

c. **Sputum smear-negative and EPTB** outcomes
   (1) "Cure" and "Treatment failure" are not possible outcomes as they depend upon sputum conversion in follow-up sputum smear examinations.
   (2) Possible outcomes include:
      (a) Treatment completed
      (b) Died

(c) Default
(d) Transfer out

(3) An exception is a smear-negative PTB patient who becomes sputum smear-positive at 2 months.
(a) Record the outcome for this patient as "Treatment failure."
(b) Reregister the patient as "Other" and start Category II treatment.

d. **Transfer patients**

(1) Transfer out
(a) When a patient moves and you transfer TB care out to another site/facility to continue treatment, record the date and mark the outcome "Transfer out" on the back of the TB Treatment Card.
(b) If the transfer is confirmed, inquire later about the treatment outcome.
(c) When the patient's outcome is reported from the other site/facility, record the final treatment outcome and the date of that outcome on the card.
(d) Only if you cannot determine another outcome, leave the outcome "Transfer out" with the date of the transfer.
(e) See Part 1, SOP 106 for more information on starting a TB treatment transfer of care.

(2) Transfer in
(a) When a patient transfers care in from another health facility, contact the original facility to report the patient's final treatment outcome.

e. **Incomplete treatment**

(1) People do not complete treatment for many reasons:
(a) Death
(b) Stopped coming for treatment
(c) Cannot be located

(2) When a patient does not complete treatment, return all drugs remaining in the patient's drug box to the drug supply room.

E. **Treatment completion**

1. Document the treatment outcome.
a. Clarify whether treatment stopped due to completion (or death), or restarted, and the date.
b. If restarted, the RN begins a new treatment card.
2. If treatment is completed, congratulate the patient and the treatment supporter.
3. Educate the patient about continuing follow-up for HIV/ART care and treatment, and the need for continued disease prevention precautions.

F. Determining the **treatment outcome in MDR-TB (as diagnosed in SOP 412).**

1. **Use** the **laboratory smear and culture** as a monitoring tool.
2. **Assign a Category IV patient the first outcome** experienced for the treatment prescribed.

a. **Cured**

(1) Completed treatment according to program protocol.
(2) Had at least five consecutive negative cultures, from samples collected at least 30 days apart, in the final 12 treatment months.
(3) If only one positive culture is reported during that time, with no concomitant clinical evidence of deterioration, patient may still be considered cured, **but** requires the positive culture to be followed by a minimum of three consecutive negative cultures taken at least 30 days apart.

b. **Treatment completed**

(1) Completed treatment according to program protocol but does not meet the definition for cure.
(2) Lacks bacteriological results; for example, fewer than five cultures were performed in the final 12 months of treatment.

c. **Died** of any cause during the course of DR-TB treatment.
d. **Failed**
   (1) If two or more of the five cultures recorded in the final 12 months of therapy are positive, or
   (2) If any one of the final three cultures is positive
   (3) If a clinical decision terminated treatment early because of poor clinical or radiological response, or adverse events
e. **Defaulted:** Treatment was interrupted for two or more consecutive months for any reason without medical approval.
f. **Transferred out** to another reporting and recording unit; treatment outcome unknown

3. **Notify patient; document treatment outcome** in medical record and Tuberculosis Treatment Card (Part 1 Form 110).
4. Notify national TB program per protocol.
5. **Continue intensified support** and determine next steps with the patient and TB/HIV specialist if patient fails treatment.
6. **Ensure** the continuation of HIV/AIDS treatment and care, regardless of outcome.

SOP 412: Diagnosis and Treatment of Resistant TB

I. Key Concepts

- Mono-resistance is TB bacilli resistant to only one TB drug, such as INH.
- Multi-drug resistant TB (MDR-TB) is TB bacilli resistant to both INH and RIF.
- Extremely drug resistant TB (XDR-TB) is MDR-TB bacilli also resistant to fluoroquinolones + a second-line injectable (e.g., capreomycin); **an emergency situation.**
- Reports show high mortality rates among HIV-infected patients with drug resistant (DR) TB and in those coinfected with XDR-TB and HIV.
- Essential program components include early diagnosis of DR-TB and HIV, prompt treatment with adequate regimens, sound patient support, and strong infection control (IC) measures.
- Design a program strategy that takes into consideration access to high-quality DST, rates of DR-TB, HIV prevalence, technical capacity, and financial resources.
  - **Involve key stakeholders** in DR-TB/HIV activities.
  - **Educate all health workers** providing care to drug-resistant TB patients co-infected with HIV about the DR-TB treatments and common adverse effects of medication regimens.
- Generally, recommended treatment regimens for drug-resistant forms of TB are similar regardless of the TB site; defining the site is primarily for recording and reporting purposes.
- Refer to international and national guidelines as well as specialized facilities for the treatment of MDR-TB.

II. Key Personnel: MD, CO, TB/HIV specialist, RN

III. Materials: Resistance testing laboratory, medical record. Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test (Part 1 Form 109), Tuberculosis Treatment Card – Expanded (Part 1 Form 110), TB Register in Basic Management Unit Using Routine Culture and DST (Part 1 Form 111)

IV. Procedures:

A. **Screen HIV-infected patients failing to respond to therapy or those who experience recurrent TB episodes for DRTB**.

Infants and children

1. **Suspect DRTB in the following pediatric cases:**
   a. A child has a close contact, such as a household member, caregiver or grandparent, with an infectious drug-resistant/MDR TB case.
   b. A child was in contact with a TB patient who died while on treatment, and there are reasons to suspect that the patient had drug-resistant/MDR TB.
   c. A child with bacteriologically-proven TB or probable TB is not responding to first-line anti-TB treatment where adherence to therapy is ensured.

Adults, adolescents, children and infants

2. **Differential diagnosis** includes: non-adherence to TB and HIV medications; incorrectly prescribed treatment regimen; irregular treatment due to poor drug supply; re-infection with TB; severe immunosuppression; failure of ART; poor absorption of anti-TB drugs; and incorrect diagnosis of the HIV-related lung disease.
3. If resistant TB is suspected, review:
   a. Medication adherence with the patient and caregiver
   b. TBIC measures (SOP 401), especially in symptomatic patients

B. **Testing** (MD/CO, RN)
   1. Collect and send specimens from **all available sources,** sputum or other fluids and tissues, as described in SOP 403.
   2. Send specimens for mycobacterial culture and drug sensitivity testing (DST).
      a. a. Send specimen with the Request for Sputum Smear Microscopy, Culture, Drug Susceptibility Test (Part 1 Form 109).
      b. Smear microscopy cannot reliably diagnose many HIV-coinfected patients, especially in advanced HIV disease.
      c. Mycobacterial load may be high in children with advanced HIV disease allowing for higher culture yield.
   3. If available, use rapid test methods such as gene sequencing, line-probe tests, fast-plaque tests on *M. tuberculosis* isolates or, in some cases, on smear-positive specimens. Develop a referral network or communication with specialty national and international laboratories as needed, especially if XDR-TB is suspected.
   4. Ensure that patient continues the current regimen until results are received.
   5. **Follow up on laboratory results**.

C. **Diagnosis** (MD/CO)
   1. Base pulmonary and EPTB diagnosis on laboratory testing. Since sputum is sometimes difficult to collect in children, smear- and culture-negative children with active TB who are close contacts of patients with DR-TB can be started on Category IV regimens.
   2. Notify the patient and the national TB program immediately if sputum grows bacilli positive for resistant TB.
      Definition: At least one of the pre-treatment cultures or smears was positive; the collection date of the sample on which the culture or smear was performed was less than 30 days before, or 7 days after, the start of Category IV treatment.

D. **Infection control (IC)**
   1. **MDR-TB**
      a. Avoid admission to a general hospital ward; if isolated in a separate unit, ensure that the room is well ventilated; refer to SOP 401.
      b. If treating as an outpatient or at home, advise patient to sleep in a separate room or space of the house that is well-ventilated.
      c. Provide routine care outside of the HIV care center until the patient is no longer infectious.
   2. **XDR-TB**
      a. Place XDR-TB patients on hospital ward isolation until they are no longer infectious.
      b. Explain the rationale to patient, family members and staff; avoid stigmatizing the patient.
      c. Follow a patient-centered approach.
      d. Ensure that WHO ethical and legal guidelines are met.

E. **Classify** Category IV patient **in two different ways**:
   1. According to **history of previous anti-TB drug use**
      a. **New**:
         (1) Patient received no, or less than one month of, anti-TB treatment.
         (2) Sputum was collected for DST at the start of a Category I regimen and then patient switched to a Category IV regimen because MDR-TB was later confirmed.
         (3) DST was performed within one month of the start of treatment.
      b. **Previously treated with first-line drugs only**, for one month or more
      c. **Previously treated with second-line drugs,** for more than one month, with or without first-line drugs
   2. **According to the history of their previous treatment**; depends on the country's DST target groups policy

a. **New:** Same definition as in classification according to previous drug use
b. **Relapse:** A patient whose most recent treatment outcome was "cured" or "treatment completed", then was diagnosed with TB by sputum smear microscopy or culture
c. **Treatment after default:** A patient who returns to treatment, TB positive by sputum smear microscopy or culture, following interruption of treatment for two or more consecutive months
d. **Treatment after failure of Category I**
   (1) Patient received Category I treatment for TB, and treatment failed.
   (2) Failure: sputum smear-positive at five months or later during treatment
e. **Treatment after failure of Category II**
   (1) Patient received Category II treatment for TB, and treatment failed.
   (2) Failure: sputum smear-positive at five months or later during treatment
f. **Transfer in:** Patient transferred in from another register for treatment of DR-TB to continue Category IV treatment.
g. **Other**
   (1) Patient may not fit into any of the above categories.
   (2) Classify into meaningful groups according to the local epidemiology of disease.
   (3) Examples include the following:
      i. Sputum smear-positive patients with unknown previous treatment outcome
      ii. Sputum smear-positive patients who received treatment other than Category I or II (possibly in the private sector)
      iii. Previously-treated patients with EPTB
      iv. Patients who received several unsuccessful treatments, were considered incurable by health staff, and lived with active TB disease with no or inadequate treatment (duration depends on country situation) until Category IV treatment became available (so-called "back-log" patients)

3. **Document type and classification** in medical record, TB Register and Tuberculosis Treatment Card – *Expanded.* **Adapt** forms to fit DR-TB as needed or required by the national TB program.

F. **Treatment (MD/CO)**

Overall

1. **Follow the national TB program and HIV/AIDS national guidelines, consult with TB/HIV specialists**, and discuss patient treatment with the medical team (Part 1 SOP 110).
2. Design treatment regimens with a consistent approach based on the hierarchy of the five groups of antituberculosis drugs.
   a. Use at least four drugs with either certain, or almost certain, effectiveness.
   b. Do not prescribe thiacetazone in HIV-infected individuals to treat DRTB.
3. Use DST to guide therapy; however do not depend on DST in individual regimen design for ethambutol, pyrazinamide, and Group 4 and 5 drugs.
4. Use adjunctive measures appropriately, including surgery, nutritional support, and social support.
5. Aggressively treat XDR-TB whenever possible.

Infants and children

1. Discuss frankly the risks and benefits of drug-resistant anti-TB therapy with family members, especially at the outset of therapy.
2. Do not withhold second-line drugs from a child unless hypersensitivity or an intractable adverse reaction has been documented.
3. **INH-resistant TB**
   a. If diagnosis is made before treatment is initiated (e.g., laboratory DST confirmation on the child's isolate or adult source case's isolate DST):
      (1) **Use a four-drug first line regimen for 9-12 months**.

(2) **Recommended regimen**: 2 HRZE/7-10 HRE, using high-dose INH (15-20 mg/kg)
(a) New (primary) isoniazid resistance often is low-level resistant.
(b) High dose INH adds value in the treatment of children with DR TB but should never replace another drug in the regimen.
(3) In **TB meningitis or miliary TB**, consider drugs with better CSF penetration such as ethionamide or a fluoroquinolones in place of or in addition to ethambutol.
(4) If treatment response is inadequate, extend treatment duration.

b. If **INH monoresistance** is diagnosed **after standard TB regimen is started**:
(1) Add at least two new drugs to the standard treatment.
(2) Treat for nine months.

4. **MDR-TB**
a. **Principles are the same in children as in adults with MDR-TB**.
(1) Use any oral first-line agent to which the isolate (child or source case) is susceptible for the duration of therapy.
(2) Use an injectable agent (aminoglycoside or capreomycin) for six months.
(a) Second-line aminoglycoside (kanamycin or amikacin)
(b) Do not use streptomycin unless no other aminoglycoside or capreomycin is available.
(3) Use a fluoroquinolone for the duration of therapy.
(4) Choose two to three second-line agents (ethionmide/prothionamide, para-aminosalicylic acid or cycloserine/terizidone) for the duration of therapy.
(5) Manage rifampicin-mono-resistant TB as a MDR TB case.
b. **Treat early paucibacillary disease** (e.g. mediastinal or hilar lymphadenopathy with or without limited lung infiltrates) **with three to five drugs to which** the child's or source case's **strain in susceptible.**
c. Treat extensive PTB with or without cavitation, and disseminated disease with five or more drugs.
d. Prescribe ethambutol and pyrazinamide if the isolate is susceptible or of unknown susceptibility; add a fluoroquinolone and up to three additional second-line drugs for the duration of therapy.

5. Refer to Appendix 6 for commonly used drugs and doses. Prescribe the total duration of therapy for 18 to 24 months (or at least 18 months after the first negative culture).
6. Prescribe pyridoxine, especially if on high-dose INH, HAART and if malnourished, dose: 1-2 mg/kg/day.
7. Ensure that child is on CPT. Give an alternative prophylaxis for PCP if hypersensitivity to CTX occurs (SOP 406).

Adults and adolescents

1. **Design the anti-TB regimen** based on the patient's previous history of anti-TB treatment and individual DST results.
2. Construct a regimen consisting of at least four drugs with either certain, or almost certain, effectiveness.
a. If the evidence about the effectiveness of a certain drug is unclear, use the drug in the regimen but do not depend upon it for success.
b. Start more than four drugs if the susceptibility pattern is unknown, effectiveness is questionable for an agent, or if extensive bilateral pulmonary disease is present.
3. **Refer to the anti-TB** drug classification groups (Appendix 7), based on efficacy, experience of use, and drug class system, when choosing the four (or more) drugs.
a. **Step 1:** Choose a drug from Group 1 if good laboratory evidence exists and clinical history suggests a drug from this group is effective.
(1) If a Group 1 drug was used in a previous regimen that failed, question its efficacy even if DST results suggests susceptibility.
(2) For example, most Category IV regimens used in treatment failures of Category II do not include ethambutol because of likely resistance based on treatment history.

b. **Step 2:** Choose a drug from Group 2 if susceptibility is documented or suspected; use kanamycin or amikacin as the first choice of an injectable agent. Avoid streptomycin, even if DST suggests susceptibility, because of high rates of resistance with DRTB strains, and higher ototoxicity incidence.
c. **Step 3:** Prescribe a Group 3 drug the strain is susceptible to, or if the agent is thought to have efficacy.
   (1) Use in the order listed in Appendix 7.
   (2) In cases where resistance to ofloxacin or XDR-TB is suspected, use a higher-generation fluoroquinolone but do not rely upon it as one of the four core drugs.
   (3) Do not use ciprofloxacin as an anti-TB agent.
d. **Step 4:** Add a Group 4 drug based on estimated susceptibility, drug history, efficacy, side-effect profile, and cost, and until you have at least four drugs likely to be effective.
   (1) Consider ethionamide or protiomamide.
   (2) If cost is not a constraint, add PAS first.
   (3) When two agents are needed, use cycloserine in conjunction with ethionamide or protionamide or PAS.
e. Step 5: Consider adding a drug from Group 5 in consultation with an MDR-TB expert if there are not four drugs likely to be effective from Groups 1-4. If a situation requires Group 5 drugs, use at least two drugs from the group.

4. Choose a therapy strategy according to patient group (refer to Appendix 8).
5. Base dose on patient's weight.
   a. Refer to Appendix 3 for list of anti-TB drugs, doses and use.
   b. Consider baseline liver and kidney function when choosing the dose (Appendix 2).
6. Start most anti-TB drugs at full dose.
   a. For cycloserine, ethionamide and PAS, the drug dose can be increased over a two-week period.
   b. The injectable agent treatment duration in the intensive phase is guided by culture conversion.
      (1) Continue for at least six months, and at least four months after the patient first becomes and remains smear- or culture-negative
      (2) X-rays and the patient's clinical status guide whether to continue an injectable agent longer than the above recommendation.
7. **Consider potential drug-drug interactions** when choosing a co-treatment regimen.
   a. The benefit of using drugs with overlying toxicities may outweigh the risk.
   b. If two drugs with overlapping toxicities are essential in a patient's regimen, increase monitoring of adverse effects rather than avoiding a certain combination.
      (1) Avoid using D4T, ddI and ddC in combination with Cycloserine or Linezolid due to increased risk of peripheral neuropathy.
      (2) Rifampin interacts with many HIV drugs (e.g., RTV, Kaletra, EFV, NVP) requiring dose adjustments; it also interacts with many other drugs, such as fluconazole, clarithromycin, warfarin, and dapsone.
      (3) Cycloserine and INH together may increase the risk of peripheral neuropathy; monitor closely.
      (4) Avoid cycloserine and ethionamide; co-administration may cause neurotoxicity.
      (5) Monitor PAS with ethionamide closely; may increase the risk of hepatotoxicity; given together with isoniazid, may cause INH toxicity.
8. **Treatment duration**
   a. Guided by culture conversion
   b. MDR-TB: 18 months from culture conversion date; the date of the first set of negative cultures and smears is used as the date of conversion as well as the date to determine the length of the initial phase and treatment
   c. Extension to 24 months of therapy may be indicated in chronic cases with extensive pulmonary damage.

9. Extrapulmonary DRTB is treated with the same strategy and duration as pulmonary DRTB. In CNS involvement, use drugs with adequate CNS penetration, such as pyrazinamide, protionamide/ethionamide and cycloserine.
10. In patients with pulmonary DRTB, the most common operative procedure is resection surgery.
    a. Effective and safe under appropriate surgical conditions
    b. An adjunct to chemotherapy
    c. Most beneficial when skilled thoracic surgeons and excellent post-operative care are available
    d. If considered:
        (1) Give at least two months of Category IV therapy prior to resection surgery.
        (2) Pre-operative work-up includes: CT, PFTs and quantitative lung perfusion/ventilation.
        (3) Even if successful, provide 12-24 months of post-operative chemotherapy.
        (4) Specialized surgical facilities should include stringent IC measures during surgery, mechanical ventilation, and post-operative pulmonary hygiene maneuvers.
    e. Not indicated in patients with extensive bilateral disease.
11. **Introduce ART as soon as possible**, if not already prescribed, for both MDR- and XDR-TB patients (SOP 405). Mortality in MDR-TB/HIV patients not taking ART is extremely high.
12. Ensure that patient is prescribed **CPT** (SOP 406).
13. **Review medication side effects** with the patient and treatment supporter (Appendix 3, 4).
14. The treatment team explains the need for special treatment to the patient, treatment supporter, and family/household members.
15. **Provide prescriptions and document** the chosen treatment regimen on the TB card and any facility-specific DRTB forms (Part 1, Forms 108 – 111).

Adults, adolescents, children, infants

1. If patient is not on HAART, initiate as early as possible (SOP 405). Drug doses of antiretroviral agents do not need adjustment if rifampicin is excluded.
2. Prescribe corticosteroids as needed for drug susceptible TB and in IRIS (SOP 405).

G. **Monitoring** (TB/HIV specialist, MD/CO, RN)
    1. Give treatment **daily** and under **direct observation.**
    2. **Schedule** intensive clinical, laboratory and adherence follow-up.
        a. **Clinical care**
            (1) **Monitor clinical symptoms at baseline, and then monthly.**
            (2) **After conversion**, collect and monitor sputum smear monthly and culture quarterly.
            (3) **Repeat DST** for patients who remain smear- and culture-positive during treatment or when you suspect treatment failure. Usually it is not necessary to repeat DST within three months of treatment completion.
            (4) **Evaluate** chest radiographs at least every six months, when a surgical intervention is being considered, or whenever the patient's clinical situation worsens.
            (5) **Laboratory investigations**:
                (a) Baseline, then every one to three weeks: serum creatinine, potassium
                (b) Monthly: serum LFTs, hemoglobin, WBC
                (c) TSH: every six months if receiving ethionamide/protionamide and/or PAS
        b. **Adherence strategy**
            (1) Intensify DOT (SOP 409) and enforce the plan with a specialized team.
            (2) RN ensures the special adherence plan (Part 1 SOP 104) and gives emotional support.

3. **Monitor overlying medication side effects and toxicity** closely; refer to Appendix 9.
    a. Expect a high incidence of adverse effects, especially when multiple DR-TB medicines are given along with ART. (Children typically experience fewer treatment-related side effects.)
    b. Symptomatically manage side effects whenever possible (Table 8).
    c. Document side effect, toxicity, and action taken in the patient's medical record.
    d. Report adverse events to NTP.
4. **Document weight** (and height, for children) at each clinical visit.
    a. Evaluate the need for **additional nutritional support**; refer to a nutritionist as available.
    b. Prescribe pyridoxine to all patients receiving cycloserine or terizidone to prevent neurological adverse effects.
    c. Give vitamin (especially vitamin A) and mineral supplements where these deficiencies are prevalent.
    d. If minerals (e.g., zinc, iron, calcium) are prescribed, dose apart from the fluoroquinolones.
    e. Monitor, if present, severe wasting, diarrhoeal disease, and malabsorption syndromes.
5. The team addresses any socioeconomic and cost issues (Part 1 SOP 111) that may affect adherence.

H. **Determining treatment progress**
1. **Review lab results**
    a. Persistent, positive smears at month five defines treatment failure.
    b. Consider performing culture and DST earlier based on the overall clinical picture.
    c. **Switch patients found to have MDR-TB to Category IV regimens before** they meet the traditional diagnosis of failure. When possible, classify these patients separately.
2. Determine **sputum conversion**: two sets of consecutive negative smears and cultures, from samples collected at least 30 days apart.

I. **Documentation**
1. **Document clinical and laboratory** monitoring results in the patient's medical record and on the Tuberculosis Treatment Card; note trends. (MD/CO, RN)
2. **Ensure** that the recording and reporting system assesses the smear- and culture-status six months after the start of treatment as an interim outcome. Consider using the smear and culture conversion rate at six months to assess the clinical effectiveness of the treatment plan.

J. Determine and document the **treatment outcome; refer to SOP 411**.

SOP 413: Treatment Supporter Training and Responsibilities

I. Key Concepts:

- Ideally the community-based treatment supporter is someone in the patient's home, or near the work place or house.
- Training can be conducted by someone skilled in adherence support, such as an RN, or by a clinic staff member or volunteer who has been trained by an expert.

II. Key Personnel: RN, treatment monitor, designated staff member, others trainers as needed or indicated by national guidelines

III. Materials: References, medical record, IEC, treatment aids (e.g., calendars, pillboxes), treatment cards, training materials

IV. Procedures:

A. **Identify the treatment supporter**.

1. The **nurse works with the patient to choose a treatment supporter** once TB treatment has been decided on, as discussed in SOP 409.
2. The treatment supporter **can be chosen from a variety of people**:
   a. Family member (partner, parent, son/daughter)
   b. Community member (teacher, spiritual guide)
   c. Friend (neighbor, support group member)
   d. Site volunteer
   e. Site staff
3. **Essential qualities** of the treatment supporter:
   a. Chosen by or acceptable to the patient
   b. Respected and trusted in the community and by the patient
   c. Accepting of the patient's illness
   d. Committed to supporting the patient throughout the entire treatment period
   e. Able to be educated on the disease and DOT
   f. Flexible in time and schedule
   g. Understanding of confidentiality (no patient information can be shared outside of the patient, the RN, and the MD/CO)

B. **Training**

1. At baseline, the RN or other designated, trained staff member arranges a time to train the identified treatment supporter(s).
   a. If possible, the RN schedules a time where a group of treatment supporters can be trained at one time
   b. Organize a group of supporters from the community in case the patient is not able to identify or disclose to someone they know.
2. **Baseline training can last as long as a few hours or a day**, depending on the background experience of the identified treatment supporter.
3. Baseline training topics:

a. **Provide an overview** to ensure that the treatment supporter understands and accepts the responsibilities: commitment, confidentiality, basic health knowledge, and emergency resources for referral. Only continue with the training once the treatment supporter verbalizes understanding and acceptance of the responsibilities.
b. **Define confidentiality** and provide examples to reinforce the definition.
   (1) Private information includes medical care, treatments, and diagnoses.
   (2) This information can be shared only with the patient, care provider, and the treatment supporter.
   (3) The only person who can share the patient's medical information is the patient.
c. Review **facts about TB** (Text Box 4).
d. Review **facts about HIV and ART**, per site standard.
e. **Address issues of stigma surrounding TB and HIV, both as a care provider and a community member**.
f. Review **how to give medications**.
   (1) Give drugs in a place with good air flow.
   (2) "Daily" treatment in the beginning usually means giving six doses per week, or if using a fixed dose combination (FDC) in a blister pack, seven days per week.
   (3) **If the patient misses a dose** (e.g, not at the home or workplace, too sick to tolerate the pill, throws up the pill), give missed dose upon returning the next day.
      (a) **Do not give a double dose** on any one day.
      (b) Continue according to schedule.
      (c) Extend treatment duration to complete all doses in the regimen.
      (d) Notify the clinic of the need to extended the treatment schedule.
g. Discuss **ways the treatment supporter can remind the patient to take the medication and develop a working relationship that encourages the patient to be independent**.
h. Discuss the **patient's follow-up schedule and the treatment supporter's role**:
   (1) Attend all clinic visits.
   (2) Attend support group meetings, if able.
i. Discuss **how the treatment supporter can help the patient remember or keep track of test results and clinic visits** throughout the course of the treatment.
j. Review **signs/symptoms of provider burn-out**.
   (1) Encourage the treatment supporter to identify burn-out early.
   (2) Prevent supporter drop-out.
k. Review **how the clinic will support the treatment supporter**.
   (1) Provide transportation, if able.
   (2) Provide psychosocial support.

Text Box 4:
Basic TB Information

- **TB…**
  - is caused by a germ that cannot be seen
  - is found most often in infected people's lungs
  - is spread through the air when someone coughs or sneezes
  - can be stopped from spreading by covering one's mouth when coughing or sneezing
  - most often shows up as a cough that lasts more than 2 to 3 weeks; other symptoms (fever, night sweats) may occur, too
  - can be cured by taking medications exactly as prescribed for the full treatment schedule until all doses are taken
  - is no longer infectious once a patient takes anti-TB drugs exactly as prescribed for 2 weeks
- **TB may become incurable if…**
  - the patient does not take all TB medications exactly as prescribed
- **To prevent the spread of TB…**
  - take all prescribed medicines
  - cover the mouth and nose when sneezing and coughing
  - keep windows and doors open in the household to allow fresh air flow

** Adapted from WHO "Tuberculosis Care with TB-HIV Co-management," 2007.*

(3) Ensure a quick way to reach a clinic staff member in case of a patient or supporter emergency.

4. Provide the treatment supporter with a small packet of reference information which includes:
   a. Important information about TB, HIV (SOP 114, facility-based IEC)
   b. Referral contact information
   c. Tools for DOT visits (e.g., TB Treatment Card, clipboard, pens, pencils, bag/backpack)
5. Offer regular (e.g., monthly) **treatment supporter meetings and scheduled follow-up training** as well as training based on needs, interest, or new developments.
   a. Group support meetings, to trouble shoot medication barriers and burn out
   b. Individual meetings, when supporter picks up patient medications)
6. **Work with community leaders**, religious leaders, and other identified advocates, and encourage them to recruit potential treatment supporters for the clinic.

C. **Ongoing treatment supporter responsibilities**

1. Treatment-related
   a. Keep the medications.
   b. Observe the patient swallowing the drugs on a daily basis.
      (1) Tailor method to patient's needs.
      (2) Demonstrate respect for the patient.
      (3) Trouble shoot medication adherence barriers.
   c. Record the event on a TB Treatment Card.
   d. Coordinate with site staff to pick up medications and discuss Treatment Card documentation and patient adherence.
2. **Health status**
   a. Refer patient to clinic and notify clinic of serious side effects, physical symptoms of side effects, or other infections (SOP 410).
   b. Monitor the health status of family members and other community members who come in contact with the patient on a regular basis; refer them to the clinic as needed.
3. **Advocacy and support**
   a. Discuss how the patient is feeling, regarding symptoms, treatment, and emotions.
   b. Discuss any concerns the patient raises during conversation.
   c. Notify the clinic of key problems, including:
      (1) Worsening health status
      (2) Problems taking medications that are not fixed
      (3) Food insecurity
      (4) Housing issues
      (5) Interpersonal conflicts with household members, friends
4. **Education and support**
   a. Reinforce the need for adherence to the medication schedule and clinic visits.
   b. Provide information about TB and HIV prevention and other disease prevention,such as STIs.
   c. Offer information about TB and HIV treatment.
   d. Discuss and reinforce positive living strategies, including nutrition, exercise, support groups, and volunteerism.

SOP 414: TB and HIV Co-infection Patient Education

I. Key Concepts:

- Patient educational opportunities occur at every patient interaction.
- Ensure effective two-way communication between the provider and the patient.
- Use a non-judgmental tone during patient interactions and give the patient 100% of your attention during appointments.

II. Key Personnel: RN, clinical care nurse/adherence nurse counselor, MD, CO

III. Materials: Medical record, IEC, treatment aids (e.g., Appendix 4 and 5, calendars, pillboxes)

IV. Procedures:

A. **Who** provides TB and HIV co-infection education
   1. The **clinical care nurse/adherence nurse counselor** is the lead for patient and family education.
   2. Any clinician, especially the **MD/CO**, assesses and offers preventive health education during clinical care visits.

B. **When** education is provided
   1. At **every clinic visit** include education for patients, family and household members, and treatment supporters.
   2. Any time a patient, family member, household member, treatment supporter, or other person asks a question about TB and HIV, provide education.

C. TB and HIV **co-infection education components**
   1. When discussing questions related to TB and HIV, demonstrate a caring and respectful attitude.
   2. **Praise and encourage** the patient for asking questions and completing milestones throughout the treatment, such as:
      a. Completing the initial TB medication phase
      b. Adhering to a TB-HIV medication regimen
      c. Managing mild to moderate side effects of medications and the disease process
   3. First, ask questions to **assess the current level of education** about the disease. Provide messages based on the respondent's answers. Following are suggested questions and answers.*

Q: What do you think tuberculosis is?
What do you think may have caused you to get TB?

A: Tuberculosis, or TB, is an illness caused by a germ that is breathed into the lungs. The TB germs can settle anywhere in the body, but they most often land and stay in the lungs. When TB hurts or damages the lungs, a person coughs up sputum from the lungs and cannot breathe well. Without the correct medication, a person can die from TB.

Q: Have you ever known anyone with TB?
What happened to that person?
Do you know that TB can be cured?

A: TB can be cured with the correct medication treatment. A patient must take every recommended drug for the entire treatment time to be cured.
TB drugs are free of charge. Patients do not have to pay for their anti-TB medications.

You can take your TB medications without changing your daily routine or work schedule.

Q: How do you think TB is spread?

A: TB spreads from one person to another when an infected person coughs or sneezes and sprays TB germs into the air. When that happens, other people breathe in the germs and may become infected.
Germs pass easily to family and other household members when many people live together in a close space.
Anyone can get TB, but not everyone infected with TB will become sick.

Q: How can you avoid spreading TB?

A: Take prescribed anti-TB medications on a regular basis (daily, every other day) to become cured of TB.
Cover the mouth and nose when coughing or sneezing.
Open windows and doors to allow fresh air through the home; use a fan if available.
Use sunlight to dry clothes outside during the morning hours.
Use UV lights, if available.
There is no need to eat special foods if infected with TB and taking anti-TB medications; eat a balanced meal.
There is no need to use separate plates, dishes, or household items when you have a family member on TB treatment.
Do not spit on the ground in the home, outside the home, in the general workplace, or in the community.
Spit sputum into a disposable paper, tissue, or old cloth and discard by burning, burying, or placing in toilet or covered garbage receptacle if available.

Q: How many people live with you, and what ages are they?
Does anyone else in your household have a cough? If so, who?

A: All children under 5 years of age living in the household should be evaluated for TB symptoms; children this age are at risk of severe forms of TB. Young children may need preventive medications or referral to a specialist for evaluation.
Other household members, especially if HIV-infected, need to be tested for TB, especially if they have cough.

Q: Can you explain why it is important that somebody else observes and supports you while you swallow your TB and/or HIV medications?

A: A good health service should ensure that a patient takes every medicine dose without any problem. If problems come up, the health service is there to help.
A health worker must watch you swallow all your prescribed TB and HIV drugs according to the prescribed schedule. This will ensure that you take the correct drugs for the correct period of time. If you need to take injections to cure TB, they will be given safely. When a health worker sees you on a regular basis, the health worker will see if you have side effects or other problems from the drugs and/or disease.
If you do not take all of your prescribed drugs, you will continue to spread TB to others in your family and community and your TB will not be cured. It is dangerous to stop or take a break from treatment. If you do this, the disease may never be cured. With direct observed therapy, the health worker will know if you miss a dose and will quickly find out the problem.
If you must travel, or move away, tell the health worker so plans can be made to continue your treatment without taking any breaks.

Q: How long should you take your anti-TB drugs? How frequent and where are your clinic visits?

*A: The medication and clinic visit schedule is individualized for each patient: **treatment length, visit frequency, and where to go for treatment**.*

If preassembled drug boxes are used, all the drugs needed to treat TB (and HIV, if applicable) are kept in a box with the patient's name on it so the clinic will never run out of medications.

Q: What should you expect when taking the drugs? What should you do next?

*A: If you are **taking rifampicin**, your urine may turn orange/red. This **color is expected and not harmful**. If you feel nauseous from the drugs, bring a bit of food to eat at the time you take your next dose.*

TB and HIV treatment does not have to interrupt normal life and work.

Be sure that the patient knows exactly where and when to go for the next treatment visit. Ask questions to be sure the patient can make the next scheduled visit and that the patient is committed to return to the clinic.

Remind the patient to bring family, friends, and other close contacts for TB testing.

*Adapted from WHO "Tuberculosis Care with TB-HIV Co-management," 2007.

4. Offer motivational statements throughout treatment duration (see Text Box 5).
5. Review issues related to HIV and TB.
   a. Transmission
   b. How TB and HIV care are interrelated
6. **Support disclosure** of TB and HIV status.
   a. Discuss advantages.
   b. Discuss concerns of disclosure to partner, family members, children, and friends.
      (1) If patient has not disclosed yet, assess readiness to disclose disease status.
      (2) Assess social network; encourage disclosure to the most trustworthy person first.
      (3) Assess social support and needs.
      (4) Reassure the patient that you will keep results confidential.
      (5) Offer another appointment if needed; offer more help as needed, such as peer counselors.
7. After finishing the question and answer session, **ask review questions** to make sure the patient fully understood the information discussed.
   a. Make sure the patient knows what to do before leaving the clinic.
   b. Reinforce earlier messages and give more information as needed.
8. Always ask the patient if she/he has any further questions before completing the appointment.

Text Box 5: Motivational Statements

TB can be cured if you keep coming for the medicine, and then you will not have to worry about it any more.

You only have __ more doses to take every day. After that, you will come less often.

These are the safest, most effective drugs available to treat TB anywhere in the world.

Almost all patients who take their medicines as recommended are cured.

If you keep taking your medicine, you will not spread TB to your family.

Taking only some of the drugs, or taking them irregularly, is dangerous and can make the disease difficult or impossible to cure.

* Adapted from WHO "Tuberculosis Care with TB-HIV Co-management," 2007.

D. **Document educational session completed** in the patient's medical record.

Appendices

Appendix 1: Administering, Reading and Interpreting a Tuberculin Skin Test*

I. Notes:

- The tuberculin skin test (TST) is an intradermal injection of a combination of mycobacterial antigens.
- Once injected under the skin, it is used to elicit an immune response (delayed-type hypersensitivity), represented by induration and measured in millimeters.
- The Mantoux method is the standard way to evaluate a TST to identify people infected with *M. tuberculosis.*
- HIV-infection can cause false-negative TST results; BCG vaccination can cause false-positive TST results.

II. Key Personnel: RN, MD, trained health worker

III. Materials: sterile, short bevel (¼- to ½-inch) 27-gauge needle; single dose tuberculin syringe; 5 tuberculin units (TU) of tuberculin PPD-S per patient; alternative to 5 TU of tuberculin PPD-S is 2 TU of tuberculin PPD RT2 3; single use exam gloves; clear, flexible ruler

IV. Procedures:

A. **Explain the reason for the TST** and the steps involved to the patient.

B. Gather the needed materials.
   1. Check the expiration date on the vial.
   2. Ensure that the vial contains tuberculin PPD-S (5 TU per 0.1 ml).

C. **Wash hands** thoroughly and dry; **put on a clean set of exam gloves**.

D. **Examine** the patient's forearm.
   1. Choose an injection site on the inner aspect of the forearm, 5–10 cm (2–4 inches) below the elbow joint.
   2. Avoid areas with a rash, scar or broken skin.

E. **Prepare** the injection site.
   1. Place forearm palm-side up on a firm, well-lit surface.
   2. Clean the area with an alcohol swab.

F. Prepare and **perform TST.**
   1. Fill (or draw up) the syringe with 0.1 ml tuberculin PPD.
   2. Insert the needle slowly, bevel up, at an angle of 5–15 ° from the patient's forearm.
   3. Ensure that the needle bevel is visible just below the skin surface.
   4. Inject the PPD, forming a flat intradermal wheal of 8-10 mm diameter.
   5. Withdraw the needle and dispose of it, according to standard precautions (Part 1 SOP 105).
   6. Inspect the injection site; if wheal is not visible, repeat the injection (using a new needle and syringe) at a site at least 5 cm (2 inches) away from the original site.
   7. Remove gloves and wash hands thoroughly after disposing of needle.
   8. If possible, mark the area around the wheal with a pen to indicate the location of PPD.

G. **Document TST**.
   1. Record in medical chart the date and time of test administration, injection site location, and the lot number of tuberculin.

H. **Evaluate** TST results.
   1. Schedule with the patient a time to examine the TST site between 48 and 72 hours after placing the PPD. Reschedule and repeat TST if patient does not return within 72 hours following PPD placement for evaluation.
   2. Inspect the injection site visually under good light.
   3. Measure the extent of induration (thickening of the skin) rather than erythema (reddening of the skin).
   4. Use fingertips to find induration margins and for marking the widest edges of induration across the forearm.
      a. Measure the diameter of induration using a clear, flexible ruler.
      b. Place "0" of ruler line on the inside-left edge of the induration.
      c. Read the ruler line on the inside-right edge of the induration (use lower measurement if between two gradations on mm scale).
   5. Record the diameter of induration.
      a. Do not record as "positive" or "negative"; only record measurement in millimeters.
      b. If no induration, record as 0 mm.

I. **Interpret TST results**.
   1. Base interpretation on the diameter of induration, the person's risk of being infected with TB, and the risk of progression to disease if infected.
   2. The diameter of induration indicates TB infection.
      a. Infants and children
         (1) $\geq$5 mm is considered significant or positive if the child is HIV-infected or severely malnourished
         (2) $\geq$10 mm diameter of induration when read 48-72 hours after administration irrespective of BCG immunization
      b. HIV-infected adults
         (1) $\geq$5 mm diameter of induration when read 48-72 hours after administration

Appendix 2: Renal Insufficiency Anti-TB Dose Adjustments*

Drug	Frequency change	Recommended dose and frequency for patients with creatinine clearance < 30 ml/min or for patients receiving hemodialysis
Isoniazid	No change	300 mg once daily, or 900 mg three times per week
Rifampicin	No change	600 mg once daily, or 600 mg three times per week
Pyrazinamide	Yes	25–35 mg/kg per dose three times per week (not daily)
Ethambutol	Yes	15–25 mg/kg per dose three times per week (not daily)
Ofloxacin	Yes	600–800 mg per dose three times per week (not daily)
Levofloxacin	Yes	750–1000 mg per dose three times per week (not daily)
Moxifloxacin	No change	400 mg once daily
Cycloserine	Yes	250 mg once daily, or 500 mg/dose three times per week
Terizidone	–	Recommendations not available
Protionamide	No change	250–500 mg per dose daily
Ethionamide	No change	250–500 mg per dose daily
p-aminosalicylic acid	No change	4 g/dose, twice daily
Streptomycin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)
Capreomycin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)
Kanamycin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)

*Source: WHO: Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008.

Appendix 3: TB Drug, Dose, Use, Monitoring, and Side Effects Guide*

Drug	Dose	Use	Monitoring for MD/CO	Side Effects for Patient Monitoring	Side Effects for Clinician Monitoring
Pyrazinamide (PZA)	• Active TB (induction): 20-25mg/kg (max 2gm) daily • DOT dose changes for 2x/week and 3x/week dosing • If CD4 < 100, dose DOT 3x/week	• New TB: smear (+), smear (-), EP, smear (-) relapse • TB smear (+) retreatment: treatment failure, treatment after default, smear (+) relapse • MDR-TB	• Bilirubin, AST, ALT – at baseline, 2, 4 and 6 weeks • Uric acid – in patients with gout and if symptomatic	• Joint pain • Nausea, vomiting • Stomach discomfort	• Severe stomach pain • Severe joint pain • Persistent vomiting • Yellowing of eyes
Rifampicin (RIF)	• Active and latent: 10 mg/kg (max 600mg) daily • DOT: 600mg 2-3x/week • If CD4 < 100, dose DOT 3x/week • With LPV/r: LPV/r 400/100mg (3 caps) + RIF 300mg bid • With EFV: EFV 800mg + RIF 600mg daily	• TB treatment • Latent TB • Contraindicated with all PIs except LPV/r	• LFTs as indicated by symptoms of hepatitis or in patients with known liver problems • FBC as indicated by symptoms of anemia	• Orange discoloration of urine, tears, sweat • Nausea, vomiting • Stomach discomfort • Signs/symptoms of hepatitis in first month • Flu-like symptoms (fever, chills dizziness, bone pain, generalized itching)	**Infrequent:** • Hypersensitivity • Thrombocytopenia • Hemolytic anemia • Headache • Dizziness • Jaundice
Isoniazid (INH) *Co-administer with pyridoxine 50mg/day or 100mg 2x/week to prevent neuropathy*	• Active and latent: 5 mg/kg (max 300mg) daily • DOT: 15mg/kg (max 900mg) 2-3x/week • If CD4 < 100, dose DOT 3x/week • Give drug 1 hour before or 2 hours after meals	• Active TB treatment • Latent TB	• Monitor monthly for clinical hepatitis symptoms • LFTs at baseline and occasionally during both phases • Consider monthly LFTs in those with prior liver problems • FBC at baseline and occasionally during both phases	• Nausea, vomiting, diarrhea • Stomach discomfort • Peripheral neuropathy (consider increase dose of pyridoxine) • Joint pains	**Common:** • Increased ALT (d/c if LFTs > 5x upper limit of normal range) **Infrequent:** • Signs/symptoms of hepatitis • Bone marrow suppression • Fever • Vision changes (optic neuropathy) • Hypersensitivity reaction (rash, exfoliative dermatitis, itching, swelling) • CNS toxicity (psychosis) • Jaundice

Drug	Dose	Use	Monitoring for MD/CO	Side Effects for Patient Monitoring	Side Effects for Clinician Monitoring
Ethambutol (EMB)	• 15-20 mg/kg (max 2 grams) daily • DOT: 50 mg/kg 2x/week (max 4 grams) or 25-30 mg/kg 3x/week (max 2.4 grams) • If CD4 < 100, dose DOT 3x/week	• New TB: smear (+), smear (-), EP, smear (-) relapse • TB smear (+) retreatment: treatment failure, treatment after default, smear (+) relapse • MDR-TB	• Baseline (then monthly, especially if dose 25 mg/kg/day) vision check: visual acuity, color vision • FBC as indicated by symptoms of anemia (e.g., pallor changes, bruises easily)	• Anorexia • Nausea, vomiting • Stomach discomfort • Vision changes: decreased acuity, decreased color vision, constricted visual fields, blind spots	**Infrequent:** • Hypersensitivity • Thrombocytopenia • Leukopenia • Neutropenia • Lymphadenopathy • Peripheral neuropathy • Confusion • Dizziness • Rash, itching, dermatitis, exfoliative dermatitis • Acute gout • Interstitial nephritis
Streptomycin *Avoid co-administration with loop diuretics and nephrotoxic drugs (e.g., cidofovir, foscarnet, ampho B)*	• 15 mg/kg (usually 1 gram) intramuscular (IM) injection daily • If > 50 years old, 10 mg/kg (usually 750mg) daily • DOT: 25-30 mg/kg IM 2-3x/week • If CD4 < 100, dose DOT 3x/week	• Second-line treatment • Added during TB smear (+) retreatment: treatment failure, treatment after default, smear (+) relapse • MDR-TB *Avoid use in pregnancy, renal function problems, elderly*	• Baseline (then monthly, especially if dose 25 mg/kg/day) vision check: visual acuity, color vision • RFT as indicated by symptoms or baseline poor renal function	• Rare	**Infrequent:** • Renal failure • Vision changes: decreased acuity, decreased color vision, constricted visual fields, blind spots • Hearing changes • Neuromuscular blockade • Encephalopathy
Cycloserine	• 10-15 mg/kg/day, usually 500-750 mg bid *Titrate based on serum concentration levels; (1-2 hr goal peak): 20-35 mg/ml* *Not recommended if renal function is poor*	• DRTB	• Frequent		• Monitor CNS: anxiety, confusion, somnolence, disorientation, headache, hallucinations, tremor, hyperreflexia, depression (with suicidal ideation), psychotic disturbances • CNS toxicity associated with peak serum concentration greater than 30 mcg/mL • Seizures may be prevented with large doses of pyridoxine 100mg PO q8h
Ethionamide	• 15-20 mg/kg/day, usually 500-750 mg bid	• DRTB	• Frequent		• Primary: severe GI intolerance – nausea, vomiting, metallic taste, anorexia, and abdominal pain • Occasional side effects: allergic reactions; reversible hepatitis (2%), jaundice (1-3%); endocrine – gynecomastia,

Drug	Dose	Use	Monitoring for MD/CO	Side Effects for Patient Monitoring	Side Effects for Clinician Monitoring
					menstrual irregularities; neurotoxicity – prevent w/pyridoxine; diarrhea; = – depression, anxiety, psychosis, dizziness, visual disturbances; orthostatic hypotension • Rare: optic neuritis
Amikacin / kanamycin / capreomycin		• DRTB	• Frequent	• Same as streptomycin	• Same as streptomycin
p-aminosalicylic acid (PAS)	• 8 to 12 grams/day, divided in 2-3 doses per day	• DRTB	• Frequent		• Common: GI intolerance: anorexia and diarrhea (severe in some cases); hypersensitivity reaction (in 5-10% of patients, generally in the first 5 weeks with fever, rash, conjunctivitis, and pruritis) • Occasional: hypothyroidism; thyroid enlargement; malabsorption syndrome (steatorrhea, and secondary folic acid, B12, iron deficiencies and hypokalemia); fever; neutropenia; hemolytic anemia (in G6PD deficiency); crystalluria (especially with dehydration, renal insufficiency)
Levofloxacin	• 500-1000 mg/day	• DRTB	• Frequent	• Generally well tolerated	• Occasional: diarrhea; CNS effects; allergic reactions; photosensitivity
Moxifloxacin	• 400 mg/day	• DRTB	• Frequent	• Generally well tolerated	• Occasional: diarrhea; CNS effects; increased transaminases; photosensitivity
Rifabutin	• 300 mg daily (half the standard rifampicin dose)	• DRTB	• Frequent	• Common: orange discoloration of urine, sweat and tears	• Occasional: uveitis • Rare: neutropenia, hepatotoxicity

* Sources: WHO ""Treatment of Tuberculosis: Guidelines for National Programmes Third Edition," 2003; Johns Hopkins University Antibiotic Guide, accessed online at http://prod.hopkins-abxguide.org/antibiotics 2009; WHO: Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008.

Appendix 4: Symptom-based Treatments for Minor–Moderate Medication Side Effects

Minor side effects: monitor and manage at each clinical visit; encourage home-based management

Symptom	Treatment
Loss of appetite, nausea, stomach pain →	• Give INH at bedtime. • Take medicine with food (except if taking DDI, IDV). • If on AZT, encourage patient to continue until this common side effect stops.
Joint pains →	• Give aspirin, paracetamol, NSAIDS.
Burning pain in hand/feet →	• Give pyridoxine 100mg daily. • Prescribe amitryptiline if no relief. • Call for advise if amitryptiline fails.
Orange/red urine →	• Explain that this is a normal finding when taking rifampicin.
Headache →	• Give aspirin, paracetamol, NSAIDS. • Assess for signs/symptoms of meningitis (e.g., neck stiffness, sensitivity to light); if suspected, refer to facility for evaluation and treatment. • If meningitis is ruled out, and patient is on AZT or EFV, encourage patient to continue treatment until the common side effect stops. • Provide supportive care and follow-up in 2 weeks.
Blue/black nails →	• Symptom is unrelated to TB medications. • Explain that this is a normal finding for people taking AZT.
Changes in body fat →	• Symptom is unrelated to TB medications. • Explain that this is a normal finding. • Discuss whether patient can accept this body image change.

Moderate side effects: monitor and manage closely (e.g., daily, or weekly)

Symptom	Treatment
Diarrhea →	• Rehydrate following site protocols. • Make sure patient is able to tolerate fluids. • Instruct patient to take try bland diet. • If just started ART, encourage patient that diarrhea may stop in a few more days. • Make follow-up appointment for 2 weeks. • Instruct patient to go to facility if condition worsens before 2-week follow-up appointment.
Fatigue →	• Check hemoglobin for anemia, especially if patient started on AZT. • If hemoglobin is low, manage according to site protocols and notify MD/CO prescribing ART. • If hemoglobin is normal, encourage patient that symptom can last 4-6 weeks then go away. • Call for advice or refer to facility if fatigue is severe and if it lasts longer than 4-6 weeks.
Anxiety, nightmares →	• Symptom is usually unrelated to TB medications. • If on EFV, ensure that EFV is given at night. • Explain that these symptoms usually end 3 weeks after starting EFV. • Consider prescribing amitryptiline during initial EFV administration. • If severe depression, suicidal thoughts or psychosis occur, ensure patient's safety and refer immediately to facility.

Symptom	Treatment
Skin rash, itching • All over body • Peeling	• If patient is on NVP or ABC, evaluate rash type (wet vs. dry). • If not on NVP, stop TB/ART medications and consider admission to hospital ward.
Yellow eyes or skin (jaundice)	• Send blood for ALT. • Stop TB/ART drugs. • Treat according to hospital protocols. • Consider hospital ward admission. • Consider alternative TB and HIV treatments with TB/HIV specialist, as needed.
Vomiting	• If unable to keep down medication or food, rule out other non-medication related causes. • If not due to other cause, stop TB/ART. • Treat dehydration, offer anti-emetics. • Reevaluate TB/HIV regimen and determine need for new medications.
Fever	• Rule out common causes. • Send blood cultures as needed or indicated according to site protocols. • Determine if due to medication, OI, new infection or IRIS. • If unable to determine treatable reason for fever, consider admission to hospital ward.
Jaundice with abdominal or flank pain	• Stop TB/ART, especially if patient is taking DDI or D4T. • Check ALT. • Treat symptoms per unit protocol. • Work with team to determine need for new medication regimen(s).
Pallor changes	• Check hemoglobin. • Rule out anemia versus OI. • If on AZT, substitute with D4T per national guidelines. • Consider blood transfusion and/or admission to hospital ward for severe pallor or very low hemoglobin (<8 g/dL; <7 g/dL in pregnant women) per facility standards.
Cough, difficulty breathing	• Treat acute symptoms with oxygen and nebulizers as needed or indicated by facility standards. • Send sputum for bacterial culture. • Could indicate IRIS or OI.
Lymphadenopathy	• Could indicate IRIS. • Monitor for other symptoms to support or rule out IRIS.

Appendix 5: Symptom Management Educational Aid – Symptom-based Management Strategies in the Home*

Symptom	Strategies to Manage
Headache	• Decrease activity; rest in a quiet, dark room with eyes closed. • Place cold moist cloth over eyes. • Stay out of the sun: decrease exposure to light. • Stay hydrated: drink boiled water; avoid caffeine (coffee, tea, carbonated soft drinks) and alcohol. • Avoid foods and other stimuli that trigger headaches.
Nausea/Vomiting/Anorexia	• Stay hydrated: drink boiled water; peppermint or ginger tea. • Eat small, bland snacks throughout the day (bananas, white rice, toast, applesauce, porridge, potatoes). • Avoid foods and smells that trigger nausea/vomiting or decrease appetite: spicy, greasy, acidic foods (e.g., oranges, tomatoes). • For nausea/vomiting: drape a comfortably warm moist towel around the neck until the nausea/vomiting subsides.
Diarrhea	• Stay hydrated: drink boiled water, weak tea. • Don't stop eating, but avoid foods and fluids that can increase diarrhea (fruits, vegetables, milk products, high fat foods, very sweet foods). • Eat bland foods: white rice, porridge. • Maintain good hygiene: wash hands after going to the bathroom, before and after eating, before and after handling any food. • *Gently* clean skin around rectal area after each episode of loose stool.
Mild tingling, burning, or pain in hands or feet	• Wear loose-fitting shoes or sandals. • Walk around to help blood circulation to the feet, but not too much. • Soak hands/feet in coldest water tolerated. • Gently massage hands/feet. • Keep hands and feet uncovered in bed.
Insomnia	• Reduce noise and light: sleep in a quiet, dark room. • Avoid exercise and other energetic activity several hours before bedtime. • Avoid eating a large meal 3-4 hours before bedtime. • Avoid drinking fluids with caffeine at least four hours before going to bed (coffee, tea, carbonated soft drinks). • Avoid drinking alcohol. • Consciously relax muscles, especially in shoulders, arms and legs. • Perform quiet activities that usually make you sleepy (for example, listening to soft music).
Dizziness	• Change positions very slowly (for example, from lying down to sitting). • Use nearby furniture and walls for support if dizziness occurs when walking. • Ask family members and friends for support if intense dizziness occurs when walking. • Stay hydrated: drink boiled water and fluids without caffeine. • Avoid alcohol.
Bad dreams	• Talk about your dreams with a family member or friend. • Recognize that dreams are imaginary and not real.
Confusion/difficulty concentrating	• Talk about your feelings of confusion or difficulty concentrating with a family member or friend. • Ask a family member or friend to clarify what confuses you. • Focus on one activity or thought at a time.
Mild rash	• Bathe with unscented mild soap (for example, oatmeal). • Avoid bathing in extra hot water. • Protect the skin from sun exposure. • Don't scratch your skin.

* Adapted from Family Health International: "SOPs for ART Adherence Counseling," 2005.

Appendix 6: Pediatric Drug-resistant TB Treatments, Doses, Common Adverse Events*

Anti-TB drug	Daily dose (mg/kg)	Maximum dose (mg)	Adverse event(s)
First-line anti-TB drugs			
Isoniazid (INH)	15-20	400	Hepatotoxicity, skin rash, peripheral neuropathy
Rifampicin (only if not resistant)	10-20	600	Hepatotoxicity, thrombocytopenia
Pyrazinamide (often not tested and given as additional drug)	25-35	2000	Hepatotoxicity, arthralgia
Ethambutol	25 (20-25)	1200	Optic neuritis
Streptomycin (high rate of resistance in MDR TB cases – use only if no other injectable available)	15-30	1000	Ototoxicity, nephrotoxicity
Second-line anti-TB drugs			
Fluoroquinolones • Ofloxacin • Ciprofloxacin • Levofloxacin • Moxifloxacin	 15-20 20-40 7.5-10 7.5-10	 800 1500 750 400	Arthralgia, insomnia
Ethionamide/Prothionamide	15-20	750	Gastrointestinal upset, hypothyroidism, gynaecomastia in boys
Aminoglycoside • Kanamycin • Amikacin	 15-30 15-22.5	 1000 1000	Ototoxicity, nephrotoxicity
Capreomycin (injectable)	15-30	1000	Ototoxicity, nephrotoxicity
Para-aminosalicylic acid (PAS)	150	12 000	Gastrointestinal upset, hypothyroidism

*Source: WHO "Guidance for National Tuberculosis and HIV Programmes on the Management of Tuberculosis in HIV-infected Children," 2009 (in press).

Appendix 7: Anti-TB Drug Groups*

Group	Anti-TB agent
Group 1 – First-line oral agents	isoniazid (H); rifampicin (R); ethambutol (E); pyrazinamide (Z); rifabutin (Rfb)
Group 2 – Injectable agents	kanamycin (km); amikacin (Am); capreomycin (Cm); streptomycin (S)
Group 3 – Fluoroquinolones	moxifloxacin (Mfx); levofloxacin (Lfx); ofloxacin (Ofx)
Group 4 – Oral bacteriostatic second-line agents	ethionamide (Eto); protionamide (Pto); cycloserine (Cs); terizidone (Trd); p-aminosalicylic acid (PAS)
Group 5 – Agents with unclear efficacy (not recommended by WHO for routine use in MDR-TB patients)	clofazimine (Cfz); linezolid (Lzd); amoxicillin/ clavulanate (Amx/Clv); imipenem/cilastatin (Ipm/Cln); high-dose isoniazid (high-dose H); clarithromycin (Clr)

*Source: WHO: Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008.

Appendix 8: Recommended MDR-TB Therapy Strategies by Patient Groups*

Patient Group	Background Susceptibility Data	Recommended Strategy
Patient in whom Category I failed	High percentage Category I failures have MDR-TB Second-line drug resistance is rare	• Perform DST of isoniazid and rifampicin at a minimum in all patients before treatment starts. • Start Category Iv treatment: IA-FQ- two Group 4 agents- +/– Z.
	High percentage Category I failures have MDR-TB Second-line drug resistance is common	• Perform DST of H, R, IA, FQ before treatment starts. • Start Category Iv treatment: IA-FQ- three Group 4 agents- +/– Z while awaiting DST results. • Adjust regimen according to DST if using an individualized approach.
Patient in whom Category II failed	High percentage of failures of Category II have MDR-TB Second-line drug resistance is rare	• Perform DST of H and R at a minimum before treatment starts. • Start Category IV treatment: IA-FQ-two Group 4 agents - +/- Z while awaiting DST results. • Adjust regimen according to DST if using an individualized approach.
	High percentage of failures of Category II have MDR-TB Second-line drug resistance is common	• Perform DST of H, R, IA, FQ before treatment starts. • Start Category IV treatment: IA-FQ-three Group 4 agents - +/z Z while awaiting DST. • Adjust regimen according to DST results if using an individualized approach.
Patient with history of relapse or patient returning after default	Low to moderate rate of MDR-TB common	• Perform DST of H and R at a minimum in all patients before treatment starts. • Start Category II treatment while awaiting DST. • Adjust regiment to a Category IV regimen if DST returns DR-TB.
Patient with documented MDR-TB	Documented, or almost certain, susceptibility to a FQ and IA	• Start Category IV treatment: IA-FQ—two Group 4 agents - +/z Z.
	Documented, or almost certain, susceptibility to FQ Documented, or almost certain, resistance to an IA	• Start Category IV treatment: IA-FQ-three Group 4 agents - +/z Z. • Use an IA with documented susceptibility. • If the strain is resistant to all IAs, use one where resistance is relatively rare.
	Documented, or almost certain, resistance to a FQ Documented, or almost certain, susceptibility to IA	• Start Category IV treatment: IA-FQ-three Group 4 agents - +/z Z. • Use a later generation FQ.
	Documented, or almost certain, resistance to a FQ and IA	• Start Category IV treatment for XDR-TB.
Category IV failed or Documented MDR-TB & history of extensive second-line drug use	Moderate to high rate of XDR-TB in this group	• Perform DST of IA and FQ (and H and R if not already done) before treatment starts. • Start Category IV treatment for XDR—TB while awaiting DST. • Adjust regimen according to DST results.

Patient Group	Background Susceptibility Data	Recommended Strategy
Patient with documented XDR-TB	Documented resistance to H, R, IA and FQ	• Start Category IV treatment for XDR-TB. • Use any Group 1 agents that may be effective. • Use an injectable agent to which the strain is susceptible. • Consider extended duration of use (12 months or possibly the whole treatment). • If resistant to all injectables, use one the patient has never used before. • Use a later-generation fluoroquinolone such as moxifloxacin. • Use all Group 4 agents that have not been used extensively in a previous regimen or any that are likely to be effective. • Use ≥ 2 Group 5 agents. • Consider high-dose INH treatment if low-level resistance is documented. • Consider adjuvant surgery if localized disease present. • Ensure strong infection control measures.

*Source: WHO: Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008.

Appendix 9: Recommendations for ART and/or Anti-TB Drug Symptom and Toxicity Management When Managing MDR-TB*

Symptom, toxicity	Antiretroviral agent	Anti-TB agent	Recommendation
Peripheral neuropathy	D4T, ddI, ddC	LZD, Cs, H, aminoglycosides, Eto/Pto, E	• Avoid D4T, ddI and ddC in combination with Cs or Lzd. • If occurs, increase pyridoxine to maximum daily dose (200mg). • Change injectable to capreomycin if patient has documented susceptibility to capreomycin. • Initiate therapy with tricyclic antidepressants (e.g., amitriptylene); nonsteroidal anti-inflammatory drugs or acetaminophen may help. • If agent(s) used and toxicity develops, replace ARV agent with less neurotoxic agent. • Restart suspected agent or reinitiate suspected agent at lower dose, if essential to the regimen. • Discontinue suspected agent if possible without compromising regimen.
Seizures	–	Cs, H, fluoroquinolones	• Suspend suspected agent pending resolution of symptom. • Initiate anticonvulsant therapy (e.g., phenytoin, valproic acid). • Increase pyridoxine to maximum daily dose (200mg). • Restart suspected agent or reinitiate suspected agent at lower dose, if essential to the regimen. • Discontinue suspected agent if possible without compromising regimen.
CNS toxicity Psychotic symptoms	EFV • Confusion • Impaired concentration • Depersonalization • Abnormal dreams • Insomnia • Dizziness	**Cs**, H, Eto/Pto, fluoroquinolones	• EFV-related symptoms usually resolve within 3 weeks; if symptoms do not resolve on their own, consider substituting EFV. • EFV can be used with Cs with frequent CNS toxicity monitoring. • For psychotic symptoms, stop suspected agent for a short period of time (1-4 weeks) until symptoms under control. • Initiate anti-psychotic therapy. • Lower dose of suspected agent if possible without compromising regimen. • Discontinue suspected agent if possible without compromising regimen.
Depression	EFV	**Cs**, fluoroquinolones, H, Eto/Pto,	• Severe depression more associated with EFV. • Consider substituting EFV if it develops. • Severe socioeconomic circumstances may contribute to depression in many patients; if possible, improve socioeconomic conditions. • Offer group or individual counseling. • Initiate anti-depressant therapy. • Lower dose of suspected agent if possible without compromising regimen. • Discontinue suspected agent if possible without compromising regimen.

Symptom, toxicity	Antiretroviral agent	Anti-TB agent	Recommendation
Hearing loss	–	S, Km, Am, Cm, Clr	• Document hearing loss and compare with baseline audiometry if available. • Change parenteral treatment to capreomycin if patient has documented susceptibility to capreomycin. • Decrease frequency and/or lower dose of suspected agent if this can be done without compromising the regimen (e.g., dose three times per week). • Discontinue suspected agent if possible without compromising regimen.
Headache	AZT, EFV	Cs	• Rule out more serious causes of toxicity (e.g., bacterial and fungal meningitis, CNS toxoplasmosis). • Use ibuprofen or paracetamol. • Encourage proper hydration. • If on AZT, EFV or Cs it is usually self-limiting.
Nausea and vomiting	**RTV, D4T,** NVP, most others	**Eto/Pto, PAS, H, E, Z** and others	• Assess for dehydration; treat if present. • Monitor electrolytes if vomiting severe. • Initiate antiemetic agent if symptoms are mild to moderate. • If persistent, check laboratory values for developing lactic acidosis and/or hepatitis. • Lower dose of suspected agent if possible without compromising regimen. • Discontinue suspected agent if possible without compromising regimen (rarely necessary).
Abdominal pain	**All ART**	**Cfz, Eto/Pto, PAS**	• Common and often benign • If persists, check laboratory values for pancreatitis, hepatitis or lactic acidosis.
Gastritis		**PAS, Eto/PTO**	• Prescribe H2-blockers, proton-pump inhibitors or antacids; instruct patient to take antacid 2 hours before or 3 hours after medications. • Stop suspected agent(s) for short periods of time (e.g., 1-7 days). • Lower dose of suspected agent if possible without compromising regimen. • Discontinue suspected agent if possible without compromising regimen.
Pancreatitis	**D4T, ddI, ddC**	**Lzd**	• Avoid using these agents together. • If pancreatitis presents, stop suspected agent permanently. • Do not use any pancreatitis-producing ART (D4T, ddI, ddC) in the future. • Rule out gallstones and alcohol use.
Diarrhea	**All PIs, ddI (buffered formula)**	**Eto/Pto, PAS,** fluoroquinolones	• Common. • Consider OIs or clostridium difficile.
Hepatotoxicity	**NVP, EFV, all PIs** (RTV > other PIs), **all NRTIs**	**H, R, E, Z,** PAS, Eto/Pto, fluoroquinolones	• Consider CTX as potential cause. • Rule out viral etiologies (hepatitis A, B, C and CMV). • Stop all therapy pending resolution of hepatitis. • Consider suspending most likely agent permanently. Reintroduce remaining drugs, one at a time, with the most hepatotoxic agents first, while monitoring liver function.
Skin rash	**ABC, NVP, EFV, D4T,** others	**H, R, Z, PAS**, fluoroquinolones, others	• Do not rechallenge with ABC. • Do not rechallenge with any agent causing SJS. • Consider CTX as potential cause.
Lactic acidosis	**D4T, ddI, AZT, 3TC**	**Lzd**	• If occurs, replace with agent less likely to cause lactic acidosis.

Symptom, toxicity	Antiretroviral agent	Anti-TB agent	Recommendation
Renal toxicity	TDF (rare)	**Aminoglycosides, Cm**	• Use TDF with caution if co-administered with aminoglycosides or Cm. • Monitor creatinine and electrolytes every 1-3 weeks if possible. • If presents, discontinue suspected agent. • Consider using capreomycin if an aminoglycoside had been the prior injectable in regimen. • Consider dosing 2-3 times a week if drug is essential to the regimen and patient can tolerate; monitor creatinine closely. • Adjust all anti-TB medications according to creatinine clearance.
Neprholithiasis	**IDV**	None	• No overlapping toxicities documented • Provide adequate hydration if taking IDV. • If toxicity develops while on IDV, substitute with another PI if possible.
Electrolyte disturbances	TDF (rare)	**Aminoglycosides, Cm**	• Check potassium; if low, check magnesium (and calcium if deficit suspected). • Replete electrolytes as needed. • If hypokalemia is severe, consider hospitalization. • Amiloride 5-10mg daily or spironolactone 25mg daily may decrease potassium and magnesium wasting. • Diarrhea and/or vomiting contributes to disturbances. • Even without concurrent use of TDF, increased risk of both renal toxicity and electrolyte imbalance secondary to aminoglycosides, Cm is present.
Bone marrow suppression	AZT	**Lzd**, R, Rfb, H	• Monitor blood counts regularly. • Replace AZT if toxicity develops. • Consider suspension of Lzd. • Consider CTX as potential cause. • Consider adding folinic acid supplements, especially if taking CTX.
Optic neuritis	ddI	**E**, Eto/Pto (rare)	• Suspend responsible agent permanently. • Refer to ophthalmologist. • Replace with agent that does not cause this toxicity. • Rare cases reported with S.
Hyperlipidemia	P**Is**, **EFV**	None	• No overlapping toxicities documented. • Manage according to SOPs on HIV care and treatment.
Lipodystrophy	**NRTIs**	None	• No overlapping toxicities documented. • Manage according to SOPs on HIV care and treatment.
Disturbed blood sugar regulation	**PIs**	**Gfx**, Eto/Pto	• PIs can cause insulin resistance and hyperglycemia. • Eto/Pto can make insulin control in diabetics more difficult, resulting in hypoglycemia and poor glucose regulation. • Gtx is no longer recommended for TB.
Hypothyroidism	D4T	Eto/Pto, PAS	• Initiate thyroxine therapy. • Completely reversible with discontinuation of anti-TB agent.

*Source: WHO: Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008.