<table>
<thead>
<tr>
<th>Table Title</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>TB Treatment Regimens</td>
<td>This publication is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID) under the terms of Cooperative Agreement AID-OAA-A-14-00046. The contents are the responsibility of AIDSFree and do not necessarily reflect the views of USAID, PEPFAR, or the U.S. Government.</td>
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</table>
The Strengthening High Impact Interventions for an AIDS-free Generation (AIDSFree) Project is a five-year cooperative agreement funded by the U.S. Agency for International Development under Cooperative Agreement AID-OAA-A-14-00046. AIDSFree is implemented by JSI Research & Training Institute, Inc. with partners Abt Associates Inc., Elizabeth Glaser Pediatric AIDS Foundation, EnCompass LLC, IMA World Health, the International HIV/AIDS Alliance, Jhpiego Corporation, and PATH. AIDSFree supports and advances implementation of the U.S. President’s Emergency Plan for AIDS Relief by providing capacity development and technical support to USAID missions, host-country governments, and HIV implementers at the local, regional, and national level.

Recommended Citation

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# ACRONYMS

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<th>Acronym</th>
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<tr>
<td>3TC</td>
<td>lamivudine</td>
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<tr>
<td>ABC</td>
<td>abacavir</td>
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<tr>
<td>AMP</td>
<td>amprenavir</td>
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<tr>
<td>AIDSFree</td>
<td>Strengthening High Impact Interventions for an AIDS-free Generation</td>
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<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>ATV</td>
<td>atazanavir</td>
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<tr>
<td>ATV/r</td>
<td>atazanavir/ritonavir</td>
</tr>
<tr>
<td>AZT</td>
<td>zidovudine</td>
</tr>
<tr>
<td>bDNA</td>
<td>branched deoxyribonucleic acid</td>
</tr>
<tr>
<td>CCR5</td>
<td>cysteine-cysteine chemokine receptor 5</td>
</tr>
<tr>
<td>CD4</td>
<td>cluster of differentiation 4</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>d4T</td>
<td>stavudine</td>
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<tr>
<td>ddI</td>
<td>didanosine</td>
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<tr>
<td>DRV</td>
<td>darunavir</td>
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<tr>
<td>DRV/r</td>
<td>darunavir/ritonavir</td>
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<tr>
<td>EFV</td>
<td>efavirenz</td>
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<tr>
<td>ELISA</td>
<td>enzyme-linked immunosorbent assay</td>
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<tr>
<td>ETV</td>
<td>etravirine</td>
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<tr>
<td>FDC</td>
<td>fixed dose combination</td>
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<tr>
<td>FPV</td>
<td>fosamprenavir</td>
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</tbody>
</table>
FPV/r  fosamprenavir/ritonavir
FTC  emtricitabine
HAART  highly active antiretroviral therapy
HBV  hepatitis B virus
HCV  hepatitis C virus
IDV  indinavir
IDV/r  indinavir/ritonavir
LIP  lymphocytic interstitial pneumonia
LPV/r  lopinavir/ritonavir
MDR TB  multidrug-resistant tuberculosis
MTCT  mother-to-child transmission
MVC  maraviroc
NFV  nelfinavir
NNRTI  nonnucleoside reverse transcriptase inhibitor
NRTI  nucleoside reverse transcriptase inhibitor
NVP  nevirapine
OHL  oral hairy leukoplakia
OI  opportunistic infection
PCR  polymerase chain reaction
PI  protease inhibitor
PI/r  protease inhibitor/ritonavir
PMTCT  prevention of mother-to-child transmission
RAL  raltegravir
RNA  ribonucleic acid
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>RT</td>
<td>reverse transcriptase</td>
</tr>
<tr>
<td>RTV</td>
<td>ritonavir</td>
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<tr>
<td>sdNVP</td>
<td>single-dose nevirapine</td>
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<tr>
<td>SQV</td>
<td>saquinavir</td>
</tr>
<tr>
<td>SQV/r</td>
<td>saquinavir/ritonavir</td>
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<tr>
<td>T20</td>
<td>enfuvirtide</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TDF</td>
<td>tenofovir</td>
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<tr>
<td>TLC</td>
<td>total lymphocyte count</td>
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<tr>
<td>TPV</td>
<td>tipranavir</td>
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<tr>
<td>TPV/r</td>
<td>tipranavir/ritonavir</td>
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<tr>
<td>TWG</td>
<td>technical working group</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>XDR TB</td>
<td>extensively drug-resistant TB</td>
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</table>
INTRODUCTION

AIDSFree has built upon the National Treatment Guidelines Database developed during AIDSTAR-One. The objective of the Database is to provide policymakers, program planners, and clinicians with the most up-to-date treatment guidelines available; create a central location to house updated national guidelines (facilitating cross-country comparisons and serving as a resource to implementers in multiple country settings); and provide a Summary Table that includes an evaluation of concordance with the World Health Organization’s (WHO) 2015 Consolidated Guidelines (enabling countries to determine if their treatment guidelines require updating); and provide multiple treatment guidelines per country (i.e., adult and pediatric HIV, TB, HIV/TB co-infection, and PEP) all in one location, thus increasing ease of access to guidelines for global audiences.

The following tables provide summary tuberculosis (TB) treatment guidelines for adults, pregnant and lactating women, and children that have been collected and summarized by AIDSFree. Guidelines were reviewed for 19 countries in 2017 including Botswana, Burundi, Cameroon, Côte d’Ivoire, Ethiopia, Ghana, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. Efforts were made to identify the most up-to-date treatment guidelines available through internet searches and contacting JSI’s and other AIDSFree partner’s country offices. In some cases there may be updated treatment guidelines that the AIDSFree team did not obtain.

The tables include information on TB screening frequency for people living with HIV (PLHIV), screening recommendations during TB treatment, case definitions, diagnostic methods, TB treatment protocols and alternative regimens, and directly observed therapy (DOTS) recommendations.
<table>
<thead>
<tr>
<th>Population</th>
<th>TB Screening Frequency for PLHIV</th>
<th>Screening Recommendations during TB Treatment</th>
<th>Case definition</th>
<th>Diagnostic methods</th>
<th>Sub-Population</th>
<th>Standard TB Treatment Protocols</th>
<th>Alternatives:</th>
<th>DOTS Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>Abbott</td>
<td></td>
<td>The diagnosis of TB means that a patient has symptomatic disease due to M. tuberculosis. The disease may be either pulmonary, extrapulmonary or both. Pulmonary TB (PTB): Any TB disease that involves the lung parenchyma. Therefore, disease that involves the intrathoracic lymph nodes or pleural effusion is not considered pulmonary TB.</td>
<td>Sputum smear microscopy</td>
<td>Adults</td>
<td>At new adult cases of TB regardless of site, bacteriology or severity of disease, and severe TB in children: Initial phase (daily): 2HRZE / continuation phase (daily): 4HR</td>
<td>The &quot;DOTS&quot; Strategy: Botswana adopted the WHO-recommended &quot;DOTS&quot; strategy in 1993 and reports 100% geographical &quot;DOTS&quot; coverage. The strategy remains at the heart of TB control strategy. Its five components are: Political commitment with increased and sustained financing • Case detection through quality-assured bacteriology • Standardized treatment, with supervision and patient support • Uninterrupted supply of quality-assured drugs • Monitoring and evaluation system and impact measurement</td>
<td></td>
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<tr>
<td>Pregnant and Breastfeeding Women</td>
<td>Abbott</td>
<td></td>
<td>The case definition of TB in children is determined as in adults, i.e., by the site of disease, result of any bacteriological tests, severity of TB disease, and history of previous anti-TB treatment. The presence of three or more of the following should strongly suggest a diagnosis of TB: 1. Chronic symptoms suggestive of TB 2. Physical signs highly suggestive of TB 3. A positive tuberculin skin test 4. Chest X-ray suggestive of TB</td>
<td>Recommended approach to diagnose TB in children: 1. Careful history (including history of TB contact and symptoms consistent with TB) 2. Clinical examination (including growth assessment) 3. Tuberculin skin testing 4. Bacteriological confirmation whenever possible 5. Investigations relevant for suspected pulmonary TB and suspected extrapulmonary TB 6. HIV testing</td>
<td>Children</td>
<td>Severe TB in children: Initial phase (daily): 2HRZE Continuation phase (daily): 4HR</td>
<td>Pregnant Breastfeeding: Ask every woman of childbearing age whether she is pregnant before commencing anti-TB treatment. Most anti-TB drugs are safe in pregnancy but do not give streptomycin because it is ototoxic to the fetus. The successful outcome of pregnancy greatly depends on the successful completion of TB treatment. All first-line anti-TB drugs are safe for use in breastfeeding women as their concentration in breast milk is relative low.</td>
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<tr>
<td>Adults</td>
<td>Not indicated</td>
<td>Category I: New sputum-positive PTB:</td>
<td>If the smear result is positive for M. tuberculosis, the patient is infected by the disease. If the smear result is negative for M. tuberculosis, the patient is not infected by the disease.</td>
<td>Mycobacterial culture TB Drug Susceptibility Testing (DST) Radiography</td>
<td>Adults</td>
<td>At new adult cases of TB regardless of site, bacteriology or severity of disease, and severe TB in children: Initial phase (daily): 2HRZE / continuation phase (daily): 4HR</td>
<td>The &quot;DOTS&quot; Strategy: Botswana adopted the WHO-recommended &quot;DOTS&quot; strategy in 1993 and reports 100% geographical &quot;DOTS&quot; coverage. The strategy remains at the heart of TB control strategy. Its five components are: Political commitment with increased and sustained financing • Case detection through quality-assured bacteriology • Standardized treatment, with supervision and patient support • Uninterrupted supply of quality-assured drugs • Monitoring and evaluation system and impact measurement</td>
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<td>• At the end of 2 months of treatment (2 smears)</td>
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<td></td>
<td>• At 5 – 6 months (2 smears)</td>
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<td>Category II: Previously treated sputum-smear positive PTB:</td>
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<td>• At the end of 3 months of treatment (2 smears)</td>
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<td>• At the end of 6 months (2 smears)</td>
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<td>Once a patient has completed or cured Category I or Category II treatment, there is no need for formalized follow-up unless the attending clinician feels further review(s) are necessary. Category IV (MDR) patients, should receive biannual examinations for at least one year following treatment completion or cure.</td>
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<td>Extrapulmonary TB (EPTB): Any TB disease involving organs other than the lung parenchyma (such as pleura, pericardium, kidneys, lymph nodes, bones or meninges)</td>
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<td>Note: A patient having both pulmonary and extrapulmonary disease is classified as a case of pulmonary TB. Smear-positive cases: Any patient with at least one positive smear result (irrespective of quantity of AFBs seen on microscopy)</td>
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<td>Smear-negative cases: Any pulmonary TB case that does not meet the definition of being smear-positive. This includes: 1. Patients with three negative smear results and radiological findings and doctor's decision 2. Patients with negative smear results and a positive culture result for M. tuberculosis 3. Patients who are unable to produce sputum and with highly suspicious radiological and clinical findings and doctor's decision to treat for TB</td>
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<td>EPTB patients include: 1. Patients with extrapulmonary histological and/or laboratory and clinical evidence and a 2. Patients with one culture positive or positive AFB smear from the extrapulmonary site to treat for TB clinical findings and doctor's decision to treat for TB doctor's decision to treat for TB.</td>
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<td>Previous treated cases of TB: 1. Retreatment after relapse 2. Retreatment after default 3. Retreatment after treatment failure Initial phase (daily): 2 HRZES/1 HRZE Continuation phase (daily): 5 HRE</td>
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<th>Population</th>
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<th>Alternatives:</th>
<th>DOTS Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burundi - National Directives for ART in Burundi (2014)</td>
<td>TB screening recommended every 3-6 months</td>
<td>Sputum microscopy if productive cough. If no cough but at least one other positive screening question: diagnosis made based on clinical signs and symptoms.</td>
<td></td>
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<td></td>
<td>Treatment of new TB cases: 2 months of daily RNZE, followed by 4 months of daily RH</td>
<td></td>
<td>Not specified</td>
</tr>
<tr>
<td>Population</td>
<td>TB Screening Frequency for PLHIV</td>
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<tr>
<td><strong>Adults</strong></td>
<td>Actively screen for TB at every visit using clinical algorithm</td>
<td>For TPM+ patients, sputum sample collected at months 0, 2, 5, 6 of treatment. For patients that still test TB-positive at month 5, microscopy is repeated and pt is treated under retreatment regimen. For TPM- patients and those with extrapulmonary TB, sputum sample is not conducted. For retreatment, sputum samples are tested at months 3 and 8. All cases of retreatment should be cultured for susceptibility.</td>
<td>TB is suspected in patients presenting with the following: Clinical symptoms (cough, weight loss, fever, night sweats) CXR indicative of TB. Diagnosis is confirmed by TB-positive sample detected through direct microscopy, culture, or molecular biology of sputum, bronchial liquid aspiration, serous fluid, or organ biopsy.</td>
<td>Culture Direct Microscopy</td>
<td>Adults</td>
<td>Treatment of new ATB cases is done in 2 phases (an initial intensive phase of 2-3 months, followed by a continuation phase of 4 or 5 months): 2 months of RHEZ 4 months of RH 4 months of RH 4 months of RH 6th months for new cases; at the end of the 2nd, 5th, and 6th months for new cases; at the end of the 3rd, 5th, and 8th month for retreatment.</td>
<td></td>
<td>During the intensive phase of treatment (when each dose is administered via DOTS), should be contacted if he misses more than one dose.</td>
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<tr>
<td><strong>Children</strong></td>
<td>Same as adult</td>
<td>Sputum samples are not considered the gold standard as with adults, due to difficulty collecting them. Gastric aspiration or swabbing of the larynx for culture may be conducted.</td>
<td></td>
<td>Culture Direct Microscopy</td>
<td>Children ≤ 12 months</td>
<td>Surveillance is done throughout treatment (by sputum collection) at the end of the 2nd, 5th, and 6th months for new cases; at the end of the 3rd, 5th, and 8th month for retreatment.</td>
<td></td>
<td>Contact should be made using address and phone number used during registration. Home visits can be conducted by &quot;community relay agents,&quot; a nurse, or health agent.</td>
</tr>
<tr>
<td><strong>Cameroon</strong> - National Directives for the Prevention and Treatment of HIV (2014)</td>
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<tr>
<td><strong>Adults</strong></td>
<td>Actively screen for TB using a clinical algorithm prior to prescription of ARVs and at each visit</td>
<td>Screen for TB in all suspected cases</td>
<td>TB is suspected among children in contact with a person with sputum-positive pulmonary TB who present with insufficient weight gain or are underweight according to growth charts, have cough, fever or weight loss.</td>
<td>Clinical symptoms: cough, weight loss, fever, night sweats; CXR indicative of TB. Diagnosis is confirmed by TB-positive sample detected through direct microscopy, culture, or molecular biology of sputum, bronchial liquid aspiration, serous fluid, or organ biopsy.</td>
<td>Culture Direct Microscopy</td>
<td>Adults</td>
<td>Treatment of new ATB cases is done in 2 phases (an initial intensive phase of 2-3 months, followed by a continuation phase of 4 or 5 months): 2 months of RHEZ 4 months of RH 4 months of RH 4 months of RH 6th months for new cases; at the end of the 2nd, 5th, and 6th months for new cases; at the end of the 3rd, 5th, and 8th month for retreatment.</td>
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<tr>
<td><strong>Children</strong></td>
<td>Same as adult</td>
<td>All HIV-infected children shall receive a chest X-ray as part of the initial assessment at HIV diagnosis</td>
<td></td>
<td>Culture Direct Microscopy</td>
<td>Children &gt; 12 months</td>
<td>Surveillance is done throughout treatment (by sputum collection) at the end of the 2nd and 8th months for new cases; at the end of the 2nd, 5th, and 8th month for retreatment.</td>
<td></td>
<td>Not specified</td>
</tr>
<tr>
<td><strong>Children &lt; 12 months</strong></td>
<td>Same as adult</td>
<td>All HIV-infected children shall receive a chest X-ray as part of the initial assessment at HIV diagnosis</td>
<td></td>
<td>Clinical symptoms</td>
<td>Children &lt; 12 months</td>
<td>Not specified</td>
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</table>

**Notes:**
- **Adults:** Since 85% of childhood TB cases are TPM- and are not <12 months.
- **Children:** Children > 12 months.
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</tr>
</thead>
<tbody>
<tr>
<td>Adults, Children, Pregnant Women, Lactating Women</td>
<td>Not specified in this guideline</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Sputum smear microscopy</td>
<td>Adults and children 5 years or older</td>
<td>2RHZ/4RH: • New cases of TB, and • Cases who have received less than one month of treatment, have stopped treatment, and have positive sputum smear 2RHZES/3RH2Z/3RH (re-treatment): • First line treatment failure • Relapse • Resumption of treatment for those who stopped treatment after having received 2 months or more of first line treatment</td>
<td>• Patients with chronic liver failure: 2RHES/6RH Alternatively: 9RE or 2HES/10HE • Patients with acute hepatitis: 3SE/6RH • Patients with renal failure: 2RHZ/4RH</td>
<td>Not specified</td>
</tr>
<tr>
<td>Children under 5 years of age</td>
<td>2RHZ/4RH</td>
<td>2 months of RHZE, followed by 4 months of RH</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2RHZ2/3RH2Z/3RH</td>
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<tr>
<td>Pregnant women</td>
<td>2RHZ/4RH</td>
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<tr>
<td>Lactating women</td>
<td>2RHZ/4RH</td>
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* Côte d'Ivoire - National Directives for the Treatment of Tuberculosis (2011)
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<tr>
<td>Adults</td>
<td>The regular screening for TB among HIV-positive clients, at every stage of the disease, is one key TB/HIV collaborative activity, with the aim to reduce the burden of TB in PLHIV.</td>
<td>• New smear positive cases: As a routine, all sputum-positive patients on TB treatment must have one sputum specimen examined at the end of the 2nd, 5th and 7th 'month'.</td>
<td>Smear-positive pulmonary TB (PTB+): A patient with at least two initial sputum smear examinations positive for AFB by direct microscopy, or A patient with one initial smear examination positive for AFB by direct microscopy and culture positive, or A patient with one initial smear examination positive for AFB by direct microscopy and radiographic abnormalities consistent with active TB as determined by a clinician.</td>
<td>All suspects of any form of TB must be examined according to the standardized diagnostic procedures of which the microscopic examination of sputum is the most important and reliable. Every individual suspected of having tuberculosis must have an examination of 3 sputum smears, to determine whether or not they have infectious tuberculosis. By rank of importance the diagnostic methods to confirm/exclude TB are: • Microscopic examination of sputum smears • Radiological investigation • AFB culture • Histo-pathology</td>
<td>Adults</td>
<td>Category II: New sputum smear-positive</td>
<td>In 1992 a standardized TB prevention and control programme, incorporating Directly Observed Treatment, Short Course (DOTS), was started in a pilot in Amhara and Dire Dawa. The DOTS strategy has been subsequently scaled up in the country and implemented at national level.</td>
<td>PUBLIC-PRIVATE MIX (PPM) DOTS</td>
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<td>Category III: Sputum smear-positive</td>
<td>The term ‘PPM DOTS’ has evolved to represent a comprehensive approach to link all relevant healthcare providers for DOTS implementation. It incorporates all forms of public-private (e.g. government health office with not-for-profit private health facility), public-public (e.g. hospitals, public health centers with army, prison, etc) or private-private (e.g. traditional healers with private-for-profit health facility) collaborations for the common purpose of controlling TB in a community.</td>
<td>Community Based DOTS</td>
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<td>Category IV: New sputum smear-negative, not seriously ill</td>
<td>Community DOTS supporters have the role to sensitize the community about tuberculosis through delivering health education about the disease in public gatherings and through house to house visit. Community DOTS Supporters also trace individuals with symptoms of TB and motivate and convince them to go to health facilities where sputum examination service is given. After the patients are diagnosed to have TB, Community DOTS Supporters will directly observe the patients treatment.</td>
<td>Community Based DOTS</td>
</tr>
<tr>
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<tr>
<td>Children</td>
<td></td>
<td>Primary pulmonary tuberculosis:</td>
<td>Recommended approach to diagnose TB in children</td>
<td>1. Careful history (including history of TB contact and symptoms consistent with TB)</td>
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<td>DOS should be used for all children with tuberculosis. Even when drugs are given under DOT, tolerance of the medications must be monitored closely. Parents should not be relied on to supervise DOT.</td>
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<td>Supportive Evidence:</td>
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<td>2. Clinical examination (including growth assessment)</td>
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<td>- Mediastinal lymphadenopathy with or without infiltration</td>
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<td>3. Tuberculin skin test (if available)</td>
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<td>Diagnostic Confirmation:</td>
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<td>4. Bacteriological confirmation whenever possible</td>
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<td>- Positive spu tum culture (rare, only if there is fistulization of the lymphadenitis into the bronchi)</td>
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<td>5. Investigations relevant for suspected pulmonary TB</td>
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<td>Post-primary pulmonary tuberculosis:</td>
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<td>(Chest X-Ray) and extra-pulmonary TB (lumbar puncture, etc.)</td>
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<td>Supportive Evidence:</td>
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<td>6. HIV testing</td>
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<td>- Pulmonary infiltration affecting upper zones with cavities</td>
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<td>For older children capable of expectorating, sputum samples should be collected as for adults. For all other children, gastric aspiration may be performed to get adequate material for smear examination.</td>
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<td>- AFB on smear and culture of spu tus/gastric</td>
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<td>Pregnant and Breastfeeding Women</td>
<td></td>
<td>Most anti-TB drugs are safe for use in pregnancy with the exception of streptomycin. Therefore ask women patients whether they are or may be pregnant. Do not give streptomycin to a pregnant woman as it can cause permanent deafness in the baby. Pregnant women who have TB must be treated, but their drug regimen does not include streptomycin and ethambutol is used instead of streptomycin.</td>
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### Ghana - Guidelines for Diagnosis and Management of TB in Children (2012)

#### Children

All HIV-infected children need to be screened for TB disease.

**Follow-up by the clinician**
- HIV-uninfected: monthly during intensive phase and 2-monthly on continuation phase
- HIV-infected: review at 2 weeks and 4 weeks following commencement of anti-TB treatment and then monthly thereafter

**CXR is not required in follow up if the child is responding well to anti-TB treatment**

**Scoring system for suspected TB in children:**
- Duration of illness (weeks)
- Weight for age z score (WAZ)
- Family history of TB
- TST test ( Mantoux test)
- Malaria
- Unexplained fever/night sweat
- Clinical findings

**Adapted from Osborne Scoring system. A score of 7 or more indicates a high risk of Tuberculosis.**

**Diagnostic methods**
- Two sputum smears for acid fast bacilli (AFB) microscopy, mycobacterial culture
- Gastric aspirate or induced sputum (usually performed in children unable to provide sputum by cough)
- Chest X-ray
- Tuberculin skin test (TST)
- Interferon Gamma Release Assay (IGRA)
- GeneXpert (recommended for use in tertiary institutions or reference laboratories)

**Recommended treatment for all children with TB regardless of immune status:**
- 2HRZE/4HR***

**Alternatives:** DOTS Recommendations
- **Detreatment:** 2HRZE +2S/10HRE***

**If the physician may extend the duration of treatment in HIV infected children depending on the clinical response.**

- Pyridoxine is recommended for all children on TB treatment, especially in severely malnourished, HIV-infected and children with peripheral neuropathy (Dose: 25 mg daily).
- Breastfeeding infants and children should continue to breastfeed while receiving anti-TB treatment.

#### Pregnant Women

All pregnant women with HIV should be screened for symptoms of TB and in the same way pregnant women with suspected TB should be tested for HIV.

**Treatment of TB in pregnant women is similar to that for non-pregnant women.**

#### Newborn of a mother with TB

At the end of 6 months, if the infant remains asymptomatic, treatment with INH is stopped and a TST is performed. BCG is given after 2 weeks if the TST remains negative and the baby is HIV-uninfected.

If the mother is non-infectious, the infant should be screened for TB. If there is no evidence of TB infection, then the infant should be regularly followed-up to ensure that TB disease does not develop.

**Symptoms of TB in the neonate are usually nonspecific and include lethargy, poor feeding, low birth weight and poor weight gain.**

**CXR and specimens from the appropriate sites should be collected to confirm the diagnosis of TB in the neonate.**

**At the end of 6 months, if the infant remains asymptomatic, treatment with INH is stopped and a TST is performed. BCG is given after 2 weeks if the TST remains negative and the baby is HIV-uninfected.**

If the mother is non-infectious, the infant should be screened for TB. If there is no evidence of TB infection, then the infant should be regularly followed-up to ensure that TB disease does not develop.

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<td>Adults, Adolescents, Children</td>
<td>For TPM+ patients: Sputum culture conducted at months 0, 2, 5, 6 of treatment (collected first thing in the AM) for patients that still test TB positive at month 5, a sensitivity test to INH and rifampicin should be conducted. For TPM- patients: Sputum culture is done at end of month 2 only for symptomatic patients. If it comes back TPM+, they are followed up according to TPM+ guidelines. For patients being retreated: Sputum collection is done at months 3, 5, and 8. For patients that still test TB positive at month 5, a sensitivity test to INH and rifampicin should be conducted. HIV/TB coinfected patients: All pulmonary TB patients are to receive sensitivity testing for INH and rifampicin.</td>
<td>Positive culture is considered the only definitive diagnosis. Sputum smear positive PTB: 2 positive sputum samples, or 1 positive sputum sample and X-ray changes typical of PTB, or 1 positive sputum sample and culture positive for M. tuberculosis. Sputum smear negative PTB: At least 3 negative sputum samples, and X-ray changes compatible with active PTB, and no response to antibiotic treatment, and a doctor's decision to provide complete TB treatment.</td>
<td>Direct microscopy (bacilloscopy) Sputum culture CXR</td>
<td>HIV/TB coinfected patients: All pulmonary TB patients are to receive sensitivity testing for INH and rifampicin.</td>
<td>For new cases of TB (TPM+, TPM-, TEP): 2 months of RHEZ, followed by 4 months of RHE. For cases of retreatment or treatment failure: 2 months of SRHEZ/ 1 RHEZ, followed by 5 months of RHE.</td>
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<td>Haiti - Guide of Standards for the National Program to Fight Against TB (2010)</td>
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<td>Haiti - Clinical Care and Therapeutic Standards Guide for Adults and Adolescents living with HIV/AIDS (2013)</td>
<td>All HIV positive patients should have a PPD test at first clinical exam and yearly. TB/HIV coinfected patients should have a complete examination every visit to look for OI's, associated pathologies, or reactions to medications. Sputum culture should be conducted at months 0, 2, 5, and 6 of treatment.</td>
<td>Active TB is diagnosed through bacilloscopy (3 smears, although in HIV positive patients, one positive smear is sufficient for diagnosis in the presence of clinical symptoms).</td>
<td>Direct microscopy (bacilloscopy) Sputum culture CXR</td>
<td>HIV/TB coinfected patients: All pulmonary TB patients are to receive sensitivity testing for INH and rifampicin.</td>
<td>Note: a rapid sensitivity test for INH and rifampicin is done for all TB/HIV coinfected patients.</td>
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<td>Haiti - National Directives for the Care and Treatment of Newborns, Children, and Adolescents exposed to HIV or carriers of the virus (2013)</td>
<td>Children are screened for TB in the initial clinical visit. Definitive diagnostic criteria for PTB in HIV infected children &lt;15 years old: One or more positive sputum sample and/or CXR changes typical for TB and/or culture positive.</td>
<td>Sputum culture Positive sputum culture Direct microscopy</td>
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<td>For pregnant women dx with active TB: HIV infected pregnant women with TB receive the standard TB treatment intensive phase (2RHZ2E) followed by ART 2-8 weeks later.</td>
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<td>Children are screened for TB in the initial clinical visit. Definitive diagnostic criteria for PTB in HIV infected children &lt;15 years old: One or more positive sputum sample and/or CXR changes typical for TB and/or culture positive.</td>
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<td>Adults</td>
<td>All persons found to be HIV positive at HIV testing sites including VCT centers, STI clinics, PMTCT sites etc should be screened for TB and referred to the nearest TB diagnostic centres. This is more critical in clients who have a cough, fever, weight loss, or have lymph node enlargement. All HIV infected individuals should be screened for TB at initial enrolment into HIV care and at each clinical/ follow-up appointment.</td>
<td>Patients on TB treatment should be monitored for bacteriologic response - follow up sputum smears for all smear positive patients:</td>
<td>Pulmonary tuberculosis, sputum smear positive (PTB+). Two or more initial sputum smear examinations positive for acid fast bacilli (AFB), or One sputum smear positive examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician, or One sputum smear positive for AFB plus sputum culture positive for mycobacteria tuberculosis.</td>
<td>Spumum culture examination Chest X-ray</td>
<td>Adults</td>
<td>The treatment regimen for new adult category 1 and 3 TB patients is: 2RHZ/4RH or 2RH/6RH which is offered through WEEKLY drug collection during the intensive phase and TWO monthly (E1H) or monthly (E1H) during the continuation phase. Since most defaults happen in the first two months of treatment, weekly drug collection during the intensive phase is particularly important to identify potential defaulters.</td>
<td></td>
<td>The Division of Leprosy, Tuberculosis and Lung Disease (DLTLD), in line with international trends, has launched several new approaches to increase access to DOTS and truly expand population DOTS coverage. These approaches include community based DOTS (CBS-DOTS), Public-Private Mix for DOTS (PPMxDOTS), collaboration between TB and HIV control programs and the development of an elaborate advocacy, communication and social mobilization strategy aimed at influencing communities to seek care early when TB symptoms occur and to remain on treatment until this is completed when treatment is initiated.</td>
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<td>Children</td>
<td>Ideally, each child should be clinically assessed at 2 weeks after treatment initiation, at the end of intensive phase, and every month until treatment completion. The assessment should include, at a minimum, a symptom assessment, an assessment of adherence, inquiry about any adverse events, and weight measurement. Medication dosages should be adjusted to account for any weight gain. Adherence should be assessed by reviewing the treatment card. A follow up sputum smear for microscopy in 2 months should be obtained for any child who was smear-positive at diagnosis. Follow up chest radiographs are not routinely required in children, particularly as many children will have a low radiological response to treatment. A child who is not responding to TB treatment should be referred for further assessment and management.</td>
<td>TB should be suspected in any child who presents with the following: Chronic unrelenting cough for more than two weeks. Physical signs suggestive of TB (e.g. fever of greater than 38°C for two or more weeks, failure to gain weight or weight loss (growth faltering). A positive tuberculin skin test (e.g. Mantoux test) or suggestive chest X-ray Presence of 3 or more of the above strongly suggests TB.</td>
<td>The key elements to a successful diagnosis of PTB in children include: Careful history taking (including history of TB contact and symptoms consistent with TB) Clinical examination (especially growth monitoring) Smear microscopy Tuberculin skin test (TST) Chest radiography HIV testing</td>
<td></td>
<td>Children</td>
<td>The recommended regimen for all forms of TB in children in Kenya is 2RHZ/4RH. In childhood TB cases where anti-tuberculosis treatment fails or a relapse occurs, every effort should be made to find the most likely cause for the failure of treatment or relapse. Failure of treatment in confirmed TB is more likely to be due to drug resistant TB. Therefore all children who fail first line anti-TB treatment should as far as feasible have specimens submitted to a laboratory for mycobacterial culture and Drug Susceptibility Testing (DST). While results are awaited the child should be placed on the 2SRH2 (E)/2RHZE (E) regimen.</td>
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<td>The management of all children with TB should be in line with the DOTS strategy, including daily directly observed treatment.</td>
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### Pregnant and Breastfeeding Women

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In general, pregnancy should be avoided during anti-TB treatment. However when it occurs, termination of pregnancy should not be recommended. Like most drugs, anti-TB drugs have not been specifically studied in pregnancy. There is always some risk of teratogenicity with any drugs especially when the drug is given in the first trimester. There have been no significant reports that anti-TB drugs pose a greater than usual risk of teratogenicity and therefore all pregnant women with active TB should be treated with a full complement of anti-TB drugs. It is useful to give Pyridoxine with Isoniazid to avoid the small risk of damaging the infant’s nervous system. Streptomycin should not be used in pregnancy because it may cause deafness in the infant. When treating drug resistant TB the aminoglycosides (Kanamycin, Amikacin and Capreomycin) and the thioamides (Ethionamide and Prothionamide) should not be used in pregnancy because of associated ototoxicity.
Adults

HIV infected people (including children) should be screened for TB serial sputum smear examinations should be performed at recommended intervals to verify the effectiveness of the treatment in killing the bacilli. Two sputum samples should be examined at the end of the second and fifth month and at the end of treatment for all sputum smear positive TB patients.

The two samples should be collected as ‘early morning samples’. Category 1 treatment

- 6-month treatment regimen: At time of diagnosis: sputum smear (end month 2). In continuation phase: sputum smear (end month 3). During last month of treatment: sputum smear( and month 6).

Category 2 regimen:

- 8-month treatment regimen: At time of diagnosis: sputum smear. At end of initial phase: sputum smear (end month 2). In continuation phase: sputum smear (end month 3). In conclusion phase: sputum smear (end month 5). During last month of treatment: sputum smear (end month 6).

Smear-positive pulmonary tuberculosis:

A TB suspect is diagnosed as smear positive TB case if:

- Two sputum smears positive for AFB, or
- One sputum smear examination positive for acid-fast bacilli (AFB) with Chest X-ray abnormalities consistent with active TB and
- Laboratory confirmation of HIV infection or
- Strong clinical evidence of HIV infection.

Smear-negative pulmonary tuberculosis:

A TB suspect is diagnosed smear negative pulmonary TB if:

- At least two sputum specimens negative for AFB and
- Radiographic abnormalities consistent with active tuberculosis and
- Laboratory confirmation of HIV infection or
- Strong clinical evidence of HIV infection. and
- Decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy OR
- A patient with AFB smear-negative sputum which is culture-positive for Mycobacterium tuberculosis.

Quanti-smear microscopy

Chest X-ray (CR)

Diagnostic methods

Adults

Treatment of New tuberculosis cases: 2

HRZ24HR

Recommended treatment regimen and dosages for new treatment (category 1)

Adults cases: 2HRZ2/4HRZ2/8HRZ2/5HRZ2

Alternatives:DOTS Recommendations

Children

HIV infected people (including children) should be screened for TB

Weekly, each child should be assessed by the NTP (or those designated by the NTP to provide treatment) at least at the following intervals: 2 weeks after treatment initiation, at the end of the intensive phase and every 2 months until treatment completion.

The assessment should include, as a minimum; symptom assessment, assessment of treatment adherence, enquiry about any adverse events and weight measurement. Medication dosages should be adjusted to account for any weight gain.

Treatment adherence should be assessed by reviewing the treatment card. A follow-up sputum sample for smear microscopy at 2 months after treatment initiation should be obtained for any child who was smear-positive at diagnosis.

Follow-up Chest X-rays are not routinely required in children, particularly as many children will have a slow radiological response to treatment. A child who is not responding to anti-TB treatment should be referred for further assessment and management. These children may have drug-resistant TB, an unusual complication of pulmonary TB, other causes of lung adherence.

A TB suspect is diagnosed as smear positive TB case if:

- Two initial sputum smear examinations positive for acid-fast bacilli; or
- One sputum smear examination positive for acid-fast bacilli plus CRX abnormalities consistent with active pulmonary TB as determined by a clinician; or
- One sputum smear examination positive for acid-fast bacilli plus sputum culture positive for M. tuberculosis.

A child with a diagnosis of smear-positive pulmonary TB should be treated with at least two of the following: isoniazid (INH), rifampicin, ethambutol or pyrazinamide.

A case of pulmonary TB in children is smear-positive pulmonary TB. The criteria are:

- Clinical examination (including growth assessment)
- Tuberculin skin testing
- Bacteriological confirmation whenever possible
- Investigations relevant for suspected pulmonary TB and suspected extrapulmonary TB
- HIV testing (in high HIV prevalence areas)

Pregnant and Breastfeeding Women

Pregnant and breastfeeding women

The benefit of treating an active TB disease in a pregnant woman far outweighs the risks that the drugs may pose to both the mother and the foetus. Most TB drugs are safe for use in pregnant women with the exception of thiacetazone which is toxic to the foetus and should therefore not be used in pregnancy.

A woman who is breastfeeding and has TB should receive a full course of TB treatment. Timely and properly applied chemotherapy is the best way to prevent transmission of the bacilli to the baby. All the TB drugs are compatible with breastfeeding and a woman taking them can safely continue to breastfeed her baby.
Active TB case finding in adults


Adults

Active TB case finding in HIV testing and counselling clinics

Up to 20% of HIV infected individuals have active tuberculosis when first seeking knowledge of their HIV status. Symptomatic screening detects most, but not all, active TB cases. TB culture and not chest X-rays seems to add substantially to sensitivity and specificity. Every opportunity should be taken to screen HIV-infected individuals for active TB, just as every patient with tuberculosis should be screened for HIV.

In settings where both infections (TB and HIV) are common and occur in the same individuals, the number of cases of TB increases due to the increased risk of development of active TB. In 2003, it was reported that tuberculosis incidence was 3 times higher in HIV-positive than HIV-negative African population. In Africa, HIV prevalence in tuberculosis is 38% while in Malawi, about 70% of TB patients are HIV-seropositive. The increased numbers of TB cases will lead to an increase in the transmission of TB microorganisms in the community. To reduce this excess transmission, it is imperative to rapidly identify and treat all infectious cases of TB.

Eligible smear-positive patients must have follow-up sputum smear examination at 2 and 5 months.

6. Tuberculosis ‘case’ is a patient who has been reliably diagnosed with TB.

Cases are classified into those with Pulmonary TB (either smear-positive or smear-negative) and those with Extrapulmonary TB. The patient with smear positive TB is very important in tuberculosis control because he/she is the main source of infection. Such persons need to be diagnosed as early as possible and treated effectively to cure them and prevent a further spread of the disease to other members of the community.

STANDARDISED TUBERCULOSIS CASE DEFINITIONS

A Tuberculosis ‘case’ is a patient who has been reliably diagnosed with TB.

Diagnosis of pulmonary tuberculosis depends on the identification of the tubercle bacilli either by sputum smear microscopy or by culture.

Direct sputum smear examination should be done on all tuberculosis suspects, especially in patients having a cough lasting for more than three weeks. In high-risk institutions where people are crowded together, for example prisons, patients coughing for more than one week should submit sputum specimens for smear microscopy.

Health institutions without microscopy facilities should, if possible, send sputum specimens or fixed slides rather than tuberculosis suspects to microscopy centres. A maximum of three sputum smears needed to be done on each tuberculosis suspect.

Chest X-ray findings suggestive of pulmonary tuberculosis in patients with smear-negative microscopy should always be supported by clinical findings and an experienced medical/clinical officer should decide on the actual diagnosis. Chest X-ray appearances alone do not always indicate pulmonary tuberculosis.

Collection of sputum specimens from TB suspects

Whenever tuberculosis is suspected, three sputum specimens should be collected and sent for direct microscopy whenever, possible within a period of 7 days. These should be collected within 24 hours;

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Adults and Children

Treatment Regimens for Patients Previously Treated for TB

Failure and Recurrent Tuberculosis.

Treated for TB

Treatment Regimens in New Adults and Children with TB

2HRZE/4RH

Initial intensive phase: In district and CHAM hospitals newly diagnosed TB patients are admitted for two weeks in hospital where they receive daily treatment. The remaining six weeks of the intensive phase is taken daily either in hospital or in the community according to the patient’s DOT option. The DOT options are either hospital, Health centre, guardian or community member supervision.

In central hospitals, patients are started on ambulatory treatment depending on the condition of the patient from the first day, but treatment is on daily basis just like the district hospitals.

Continuation phase: Patients take supervised drugs which they collect from the nearest health facilities every fortnight.

Treatment Regimens for Patients Previously Treated for TB

For Relapse, Return after default, Treatment Failure and Recurrent Tuberculosis.

2HRZE/1HRZE/5RHE

This regimen consists of two months of daily streptomycin, rifampicin, isoniazid, pyrazinamide and ethambutol given under supervision, one month of daily rifampicin, isoniazid, pyrazinamide and ethambutol given under supervision followed by five months of daily rifampicin, isoniazid and ethambutol given under supervision.

NB: Tuberculosis positive cases that have previously taken anti-tuberculosis drugs for one month or more must be suspected of discharging tubercle bacilli resistant to one or more anti-TB drugs. These patients must submit sputum specimens for drug sensitivity testing before starting the re-treatment regimen.

Directly observed treatment is one element of the DOTS strategy, i.e. the WHO-recommended policy package for TB control. Direct observation of treatment means that a supervisor watches the patient swallowing the tablets. This ensures that the TB patient takes the right drugs, in the right doses, at the right intervals.

Supervisors are usually health workers, but in the context of decentralisation of care in Malawi, supervisors may also be guardians or community members.
### Population TB Screening Recommendations during TB Treatment

<table>
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<tr>
<th>Case definition</th>
<th>Diagnostic methods</th>
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**TWO MONTH SPITUM SMEAR EXAMINATION.**

When 8 weeks of initial phase of treatment are completed, two activities take place.

1. **First,** all patients are changed to the continuation phase of treatment, i.e. daily RH.
2. **Second,** patients with smear-positive PTB submit two sputum specimens for microscopy. Guardian-based patients will be given a sputum container when given their last 2 weeks supply of drugs. The patient must return to the health centre at the end of the initial phase with a filled sputum container and must give a second on the spot sputum at this visit.
   - If the 2-months sputum results are negative the patient stays on continuation phase (Daily RH).
   - If the 2-months sputum results are positive, the patient is contacted and re-admitted to hospital. The patient stays on continuation phase and if a week has passed the patient submits another sputum sample.
   - If the second 2-months sputum is negative, the patient stays on continuation phase and gets discharged home.
   - If the result is positive, the patient is changed to daily RHZE. This is continued with the patient admitted in hospital.
   - Repeat sputum smears are checked at weekly intervals.
   - If the sputum result becomes negative the patient is discharged to continuation phase.
   - If the sputum result is still positive, the patient continues on daily RHZE for a total of 4 weeks at which point the patient is changed to daily RH. At this point, take sputum for culture and sensitivity in two universal containers and discharge the patient.
   - Remember to check sputum at 5 months: if still positive collect another sputum sample for culture and sensitivity and the patient started on re-treatment as a treatment failure.
**Adults**

Provide HIV counseling and testing to all TB patients.

- **Smear-positive pulmonary TB:**
  - New cases; repeat sputum smear after 2 and 5 months of treatment.
  - Retreatment cases: repeat sputum smear after 5, 6, and 7 months of treatment.
  - If sputum smear after 2 (or 3) months of treatment is positive, request culture and sensitivity testing and continue intensive phase for one additional month. Then repeat sputum smear exam after 5 and after 6 months of treatment.

- **Smear-negative pulmonary TB:**
  - Use clinical criteria to assess treatment efficacy, especially weight gain.
  - In case of smear-negative PTB, repeat chest X-ray after 3-4 months of treatment.
  - Sputum smear exam and culture are indicated in PTB cases with suspected treatment failure.

- **Smear-negative PTB and extrapulmonary TB:**
  - Use clinical criteria to assess treatment efficacy, especially weight gain.
  - In case of smear-negative PTB, repeat chest X-ray after 3-4 months of treatment.
  - Sputum smear exam and culture are indicated in PTB cases with suspected treatment failure.

- **Smear-negative pulmonary TB:**
  - A sample from an extrapulmonary location that is culture-positive for M. tuberculosis, or
  - Radiographic changes consistent with active PTB; and
  - The decision by a clinician to treat with a full course of anti-TB therapy.

- **Extrapulmonary TB:**
  - Sputum smear exam: Two sputum samples should be examined: the first provided immediately during the consultation, the second to be produced the next morning. The sputum sample is tested for AFB immediately after waking up and delivered to the lab the same morning.

**Screening Recommendations during TB Treatment**

- **Clinical suspicion is raised by symptoms including cough during more than two weeks, productive cough, hemoptysis, chest pain, and dyspnea. Systemic symptoms include fever, weight loss, anorexia, and night sweats. Patients with a suspicious clinical picture should receive sputum smear exams.**

- **Special cases:**
  - In case of pregnancy, do not give Streptomycin or Isoniazid.

**Diagnosis of TB in children**

- **Diagnosis of TB in children is made using a scoring system that includes the following characteristics:**
  - Duration of illness
  - Nutritional status
  - Past or present TB contact
  - Fever and night sweats
  - Tuberculosis test result
  - Local changes including lymph nodes, bone and joint swelling, effusions, central nervous system changes, or deformations of the vertebral column

- The total score is then used in a flowchart that guides further diagnostic and treatment interventions.

**TB therapy.**

- The decision by a clinician to treat with a full course of anti-TB therapy.

- **Confirmed (or strong clinical evidence of)**
  - HIV infection; and
  - Extrapulmonary TB; and
  - Histology or strong clinical evidence consistent with active TB; and
  - A sample from an extrapulmonary location that is culture-positive for M. tuberculosis, or
  - Smear-negative pulmonary TB case should either:
    - Have sputum that is smear-negative but culture-positive for M. tuberculosis, or
    - Be at least two sputum specimens that are smear-negative for M. tuberculosis, or
    - A) More sputum smear specimens are positive for AFB
    - B) At least two sputum specimens that are smear-negative for M. tuberculosis, or
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- Special cases:
  - In case of pregnancy, do not give Streptomycin or Isoniazid.

**TB treatment follow-up is done by those community workers.**

- In communities with trained community DOTS workers, treatment follow-up is done by those community workers.
For follow-up of all new patients, one sputum smear examination should be performed:
- 6 weeks of treatment and
- after 5 months of treatment if smear was positive at the beginning
If follow-up spu tum is positive at 6 weeks or if patient is not improving clinically, then
- the patient needs to be reassessed by the doctor
- In patients who are smear positive at 6 weeks, extend the initial phase by 1 month and repeat
- sputum smear examination at 10 weeks (2 1/2 months) of treatment
If sputum is still smear positive at 3 months (10 week results) then:
- send one sputum sample for rapid DST
- review the results of rapid DST
- change to continuation phase of treatment if appropriate
If sputum is smear negative at 3 months (10 week results):
- change to the continuation phase of treatment
If sputum is smear positive after 5 months of treatment:
- send one sputum for rapid DST +/- follow-up C/T
- register patient as “treatment failure” establish if this is true medicine failure (i.e. patient was on strict DOT and still failed) in which case inform the CCRC with a view to starting 2nd line treatment or
- if failure is due to patient not taking medicines, the CCRC may be consulted and the retreatment regimen with first line medicines considered.
For retreatment: Before TB treatment is started, collect one additional sputum sample and send it for DST
Perform one sputum smear examination at:
- 12 weeks of treatment
- 5 months of treatment, and
- 7 months of treatment
If sputum-smear is positive at the 3 month visit (10 week results):
- follow up, and review baseline DST results (if not already done so)
- if results show pan-susceptible TB, are indeterminate or are unavailable, then collect sample for a rapid DST (and C/T if indicated)
- review the results of rapid DST
- Change to continuation phase, if appropriate
If sputum-smear is positive at the 6 month visit (5 months results):
- Send sputum for testing/DST
- Register patient as “treatment failure” refer to CCRC with a view to start the standard regimen for DR TB patients
If sputum-smear positive at the 8 month visit (7 month results):
- Send sputum for testing/DST
- Register patient as “treatment failure” refer to CCRC with a view to start the standard regimen for DR TB patients

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<tr>
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- All new patients with any form of TB in TB meningitis add streptomycin for at least 1 months to ensure maximum bactericidal efficacy; total duration of treatment in these cases is 9-12 months
- Isoniazid should not be used in pregnancy
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## Case definition

All new cases in children:

**2(HRZE)/4(HRE)**

Add Streptomycin during intensive phase in case of severe form of TB (e.g. miliary TB or TB meningitis)

### Diagnostic methods

Many children may be treated as outpatients; however children with severe disease should be hospitalised. Children with any of the following conditions must be admitted:
- Respiratory distress
- Severe forms of EPTB such as TB meningitis, miliary TB, spinal TB and pericardial TB
- Severe adverse reactions such as hepatotoxicity

It is also reasonable to admit any child in whom it is not possible to ensure good adherence to treatment due to social or logistical reasons.

As with adults, the choice of TB treatment regimen in a child is determined by whether the child has new TB, previously treated TB, or DR TB, irrespective of HIV status. TB treatment in children should be given daily (7 days per week) during the intensive and continuation phases of therapy. Response to TB treatment in even young and immunocompromised children is generally good and swift.

### Sub-Population

### Standard TB Treatment Protocols

#### Alternatives: DOTS Recommendations

It is recommended that all children with TB receive directly observed therapy (DOT) for the complete duration of therapy. Parents and caregivers need to be counselled about the importance of adherence for the full treatment period and the potential adverse effects of the medicines. This counselling should be repeated at each follow-up visit.


#### Children

A strategy to delay routine BCG for HIV-exposed infants with unknown status, the majority of whom will be HIV-negative until confirmed HIV-negative, could result in many such infants becoming infected with and dying from TB. Hence even HIV-exposed newborns in Namibia, a high TB prevalence setting, should be given BCG vaccination unless they already show signs of HIV infection.

Children should be assessed by a healthcare worker at 2 and 4 weeks after treatment initiation, at the end of the intensive phase, and every month thereafter until treatment is completed. At each visit there should be:
- A symptom assessment including, for example, presence of cough, fever, poor appetite, and fatigue
- A weight measurement
- A directed physical examination depending on symptoms
- An assessment of adherence to treatment
- An inquiry about any adverse events
- Review of any relevant specimen collections done or due
- Assignment of date for next visit

Adherence is assessed by reviewing the treatment card. If medicines have been dispensed to the caregiver (DOT supporter) to take at home, they should be asked to show any remaining tablets that they have, and should demonstrate to the HCW the number of each type of tablet that the child is taking. TB treatment dosages must be adjusted according to increase in weight. The new treatment dosages should be carefully explained and demonstrated to the caregiver.

Bacteriologic response to TB therapy in children should be monitored in the same way as in adults (Chapter 5). A follow-up sputum specimen for microscopy should be obtained at 6 weeks and after the 5th month of treatment for any child who was sputum smear positive at diagnosis, unless this would mean an invasive procedure such as gastric aspiration. Regimen adjustments and the need for specimens for culture and DST should follow the schedule delineated for adults (Chapter 5).

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<th>Population</th>
<th>TB Screening Frequency for (PYR) &gt;8 yrs/ &gt;30 kg</th>
<th>Screening Recommendations during TB Treatment</th>
<th>Case definition</th>
<th>Diagnostic methods</th>
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<tr>
<td>Adults and Children &gt;8 yrs/ &gt;30 kg born</td>
<td>[0x-6] 20 yrs/ &gt;30 kg</td>
<td></td>
<td>Children aged 8 yrs/ &gt;30 kg with symptoms of TB disease, either by smear microscopy, culture or molecular assays.</td>
<td>One week before the end of the 2 months intensive phase of treatment (at 7 weeks).  For those remaining positive at 2 months: Repeat smear one week before the end of the 3rd month (11 weeks).  End of continuation phase: One week before the end of the 4 months continuation phase (at 23 weeks).  Aim: To determine the final outcome of treatment for the patient.</td>
<td>Smear microscopy - LED/ Fluorescent - Culture - Liquid (MGIT) - Solid - PCR based assays 1. Xpert® (MTB/RIF 2. Line Probe assay 3. Xpert® MTB/RIF) 4. AFB smear microscopy 5. Culture positive TB: A positive Xpert result and at least 1+ acid-fast bacillus (10-99 AFB per 100 oil immersion fields) in at least one sputum smear microscopy 6. Smear negative/ culture positive TB: A positive culture result with or without a Xpert result.</td>
<td>Breastfeeding women and children 18 years/ &gt;30 kg</td>
<td>Treatment supporter watches the patient swallowing the tablets, in a way that is sensitive and supportive to the patient’s needs. Treatment supporter may be a healthcare worker or a trained workplace or community health worker, family member or whichever the patient chooses. The role of the treatment supporter is to motivate patients to continue treatment and to counter any factors that might result in treatment interruption.</td>
<td>2(HRZE) / 4(HR)</td>
</tr>
<tr>
<td>Pregnant and Breastfeeding women</td>
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<td>Not Indicated</td>
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</table>

- **TB diagnosis depends on symptom screening of all patients (including HIV positive patients) presenting to the health facility and contacts of people with laboratory confirmed pulmonary TB disease. All those who have symptoms of TB disease must be investigated for TB.**

- **Bacteriologically confirmed Tuberculosis**
  - A patient with M. tuberculosis complex identified from a clinical specimen, either by smear microscopy, culture or molecular assays.

- **Xpert positive TB:** A positive Xpert result or MTB detected in at least one specimen tested.

- **Xpert negative TB:** A negative Xpert result or MTB not detected in at least one specimen tested.

- **Smear positive PTB:** A positive smear result and at least 1+ acid-fast bacilli (10-99 AFB per 100 oil immersion fields) in at least one sputum smear microscopy.

- **Smear negative PTB:** A positive smear result and at least one sputum smear microscopy negative for AFBs.

- **Culture positive TB:** A positive culture result with or without a Xpert result.

- **TB patient (person with tuberculosis):**
  - A person who has been diagnosed with bacteriologically confirmed TB or started on TB treatment by a healthcare worker based on clinical presentation, X-ray findings or other tests.

- **High Risk of reinfection.**
  - The DOT services must be organised to suit the patient’s circumstances and where possible treatment should be provided as close to home as possible.
  - Patients who live close to a clinic may take their treatment at the clinic if convenient for them. There must be a fast tracking system for these patients and good infection control to minimize the risk of reinfection.
  - The following must be conducted at each encounter with the patient:
    1. Ask about side effects the patient may be experiencing and record in the patient card.
    2. Provide treatment for minor side effects.
    3. Refer patient to a professional nurse or doctor if serious side effects.
    4. Give the patient their daily dose and observe intake.
    5. Record doses taken in patient-held green card and patient treatment record.
    6. Update the TB patient diary to identify patients who did not recall them rapidly.

- **Treatment supporter:**
  - The DOT worker, family member or workplace or community health worker may take their treatment at the clinic if convenient for them. There must be a fast tracking system for these patients and good infection control to minimize the risk of reinfection. There must be a way that is sensitive and supportive to the patient’s needs. The treatment supporter may be a healthcare worker or a trained workplace or community health worker, family member or whoever the patient chooses. The role of the treatment supporter is to motivate patients to continue treatment and to counter any factors that might result in treatment interruption.

- **TB treatment once:**
  - Cotrimoxazole after 6 weeks.

- **TB treatment for HIV positive patients:**
  - Rifampicin, Isoniazid, Ethambutol, Streptomycin are safe for use in pregnant women.

- **Orientation:**
  - Most TB drugs except for streptomycin are safe for use in pregnant women.

- **TB treatment for severely ill due to TB:**
  - Streptomycin may be added during the intensive phase.
  - If patient cannot tolerate Rifampicin (or both):
    - Treat with Moxifloxacin/ Ethambutol for 12 months.
  - If patient cannot tolerate Rifampicin and Isoniazid:
    - Treat with Moxifloxacin/ Ethambutol for 18 months.

- **TB treatment for pregnant women:**
  - If patient cannot tolerate isoniazid:
    - Treat with Moxifloxacin/ Ethambutol for 12 months.
  - If patient cannot tolerate isoniazid and ethambutol:
    - Treat with Moxifloxacin/ Ethambutol and streptomycin for 18 months.
  - If patient cannot tolerate rifampicin and isoniazid:
    - Treat with Moxifloxacin/ Ethambutol and streptomycin for 18 months.

- **TB treatment for children:**
  -rifampicin/isoniazid/ethambutol/ streptomycin for 18 months.

- **TB treatment for elderly patients:**
  - rifampicin/isoniazid/ethambutol/ streptomycin for 18 months.
### Population: Children <8 years

**HIV positive children on treatment and care must be screened for TB exposure and symptoms at each clinical visit.**

- Screening should be offered routinely to all children presenting to the health facility.
- High risk groups who should be routinely screened include:
  - Children who live in the same household with a person diagnosed with smear and/or culture positive PTB (infectious TB),
  - HIV positive children
  - Children less than five years
  - Children with severe malnutrition

The systematic screening should include a symptom screen followed by thorough history taking, clinical examination, chest x-ray and bacteriological testing for all those with a positive symptom screen. A chest x-ray, where available may be used to screen for PTB in children.

### Screening Recommendations during TB Treatment

<table>
<thead>
<tr>
<th>Case definition</th>
<th>Diagnostic methods</th>
<th>Sub-Population</th>
<th>Standard TB Treatment Protocols</th>
<th>Alternatives: DOTs Recommendations</th>
</tr>
</thead>
</table>
| The case definitions for children are determined by:
  - Site of disease
  - Results of any bacteriological test
  - Severity of TB disease
  - History of previous TB disease | The diagnosis of TB is based on a combination of history of exposure, clinical presentation, Mantoux test and chest x-ray. The approach to the diagnosis of TB in children depends on the resources that are available. In areas where Mantoux skin test and chest x-ray are limited, the diagnosis can still be made through taking a good history and doing a thorough clinical examination. | South Africa - National Tuberculosis Management Guidelines (2014) | Children who have a positive Xpert, LPA, culture and smear microscopy result are considered to have bacteriologically confirmed TB disease. All children diagnosed with pulmonary TB using Xpert should have a sputum smear microscopy done. This baseline smear microscopy is used to identify those with infectious TB disease for contact investigation and for bacteriological monitoring of response to treatment. Patients are classified as “Xpert positive smear positive” or “Xpert positive-smear negative” pulmonary TB. | REGIMEN 3A: 2(RH)Z / 4 (RH) TB treatment is the same in both HIV-infected and HIV-uninfected children. The treatment principles are the same as for adults. Treatment is comprised of 2 phases: an intensive phase of 2 months with 3/4 drugs and a continuation phase of 4 months with 2 drugs. In severe/complicated TB disease the treatment may be given for a longer time by prolonging the continuation phase to 7 months (instead of 4 months). The drug dosages depend on the body weight of the child and should be adjusted as weight changes during the course of treatment. Parents and caregivers should be counselled about TB and the importance of adherence to treatment. |

### Case definition: PTB

- Pulmonary TB: Disease involving the lung parenchyma. A patient with both a parenchymal lesion in the lungs (pulmonary TB) and extrapulmonary TB is classified as pulmonary TB.
- Extrapulmonary TB: Disease involving organs other than the lungs: e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones and meninges. Intra-thoracic TB such as mediastinal or hilar lymphadenopathy or pleural effusion without a parenchymal lesion in the lungs, is classified as extrapulmonary TB. Where several sites are affected, the site representing the most severe form of disease determines the case definition of extrapulmonary TB.

### Treatment

- **Regimen 3A:** 2(RH)Z / 4 (RH)
  - TB treatment is the same in both HIV-infected and HIV-uninfected children. The treatment principles are the same as for adults.
  - Treatment is comprised of 2 phases: an intensive phase of 2 months with 3/4 drugs and a continuation phase of 4 months with 2 drugs.
  - In severe/complicated TB disease the treatment may be given for a longer time by prolonging the continuation phase to 7 months (instead of 4 months). The drug dosages depend on the body weight of the child and should be adjusted as weight changes during the course of treatment.
  - Parents and caregivers should be counselled about TB and the importance of adherence to treatment.

### Dosage:

- Drug dosages depend on the body weight of the child and should be adjusted as weight changes during the course of treatment.

### Monitoring:

- The diagnosis of TB is monitored through regular drug sensitivity testing and programme evaluation.

### Results:

- Patients are classified as “Xpert positive smear positive” or “Xpert positive-smear negative” pulmonary TB.

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### Breastfeeding Women

Persons who are breastfeeding and have TB should be asked of

- **Breastfeeding Women**
  - The benefit of treating an active TB disease in a pregnant woman for outweighs the risks that the drugs may pose to both the mother and the foetus. Most TB drugs are safe for use in pregnant women with the exception of streptomycin which is ototoxic to the foetus and should therefore not be used in pregnancy. Every woman of child-bearing age diagnosed with TB should be asked of pregnancy status before starting TB treatment.
  - Breastfeeding Women: A woman who is breastfeeding and has TB should receive a full course of TB treatment. Timely and properly applied chemotherapy is the best way to prevent transmission of tubercle bacilli to the baby. All the TB drugs are compatible with breastfeeding and a woman taking them can safely continue to breastfeed her baby. The mother and baby should stay together and the baby should continue to be breastfed in the normal way, but be given prophylactic isoniazid for at least six months (isoniazid 10mg/kg). BCG vaccination of the newborn should be postponed until the end of isoniazid prophylaxis. Pyridoxine supplementation is recommended for all pregnant or breastfeeding women taking isoniazid.

### Pregnant Women

Persons who are breastfeeding and have TB should be asked of

- **Pregnant Women**
  - The benefit of treating an active TB disease in a pregnant woman for outweighs the risks that the drugs may pose to both the mother and the foetus. Most TB drugs are safe for use in pregnant women with the exception of streptomycin which is ototoxic to the foetus and should therefore not be used in pregnancy. Every woman of child-bearing age diagnosed with TB should be asked of pregnancy status before starting TB treatment.

### Adult Adolescents

Persons who are breastfeeding and have TB should be asked of

- **Adult Adolescents**
  - The benefit of treating an active TB disease in a pregnant woman for outweighs the risks that the drugs may pose to both the mother and the foetus. Most TB drugs are safe for use in pregnant women with the exception of streptomycin which is ototoxic to the foetus and should therefore not be used in pregnancy. Every woman of child-bearing age diagnosed with TB should be asked of pregnancy status before starting TB treatment.

### New Sputum Smear-Positive Pulmonary TB Patients

Persons who are breastfeeding and have TB should be asked of

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### Swaziland - National Tuberculosis Programme Manual (2012)

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| Children   | For children starting TB treatment, the first follow-up is recommended at 2 weeks, 4 weeks and monthly thereafter. To assure a good outcome, on each visit the following should be monitored:  
- Weight: It has to be checked each visit and documented in the TB card. An increase in the weight is one of the best indicators we have of successful treatment.  
- Doses: They need to be adjusted every visit, according to the weight.  
- Adherence: Good adherence is essential to assure good treatment outcomes. The HWC need to assess in each visit:  
  - Who is the main caregiver?  
  - Who is in charge of giving the tablets (DOT is highly encouraged)?  
  - What happens when the main caregiver is not at home?  
  - If there is any other problem compromising the adherence.  
  Orphans are especially vulnerable, and they need special attention to assure good adherence. If adherence is compromised due to the social situation, we can consider long-term hospital admissions while the social situation is solved together with the child welfare services. | The following actions are key to trace TB contacts in children:  
- All children aged 0-4 years and children aged 5 years and above who are symptomatic, who have been in close contact with a smear-positive TB case, must be screened for TB.  
- Effort should be made to detect the source case (usually an adult with sputum smear-positive pulmonary TB) and any other undiagnosed cases in the household when any child aged less than 15 years is diagnosed with TB.  
- If a child presents with infectious TB, child contacts must be sought and screened, as for any smear-positive source case. Children should be regarded as infectious if they have sputum smear-positive pulmonary TB or cavitary TB on CXR.  
- Chest X-ray in children is a useful tool to assist in the diagnosis. Lateral X-rays should be routinely done in children.  
- The tuberculin skin test (TST) is a tool for detection of latent TB infection (LTBI). The test involves intradermal injection of purified protein derivative (PPD), a crude mixture of mycobacterial antigens, which stimulates a delayed type hypersensitivity response and causes induration at the injection. However, the TST detects only infection with MTB, not necessarily active disease.  
- Bacteriological confirmation of childhood TB: Diagnosis of TB in a child should be confirmed using whatever specimens and laboratory facilities are available. Bacteriological confirmation is especially important for children who have:  
  - presumptive drug-resistant TB  
  - HIV infection  
  - complicated or severe cases of disease  
  - an uncertain diagnosis.  
- DR-TB can also affect children, but due to the difficulty in obtaining samples, they are rarely diagnosed. It is crucial that we make all possible efforts to collect a specimen for GeneXpert/Xpert and DST and refer the children for further assessment. | Children  
- A child should start TB treatment when there are TB symptoms not responding to adequate antibiotic therapy, even in the absence of a CXR. This is especially important in infants and young children, as symptoms are less specific and the mortality is higher.  
- Due to the high HIV prevalence and INH resistance, all children starting TB treatment need to receive a four-drug regimen (HRZE) during the initial phase, followed by a continuation phase of 2 drugs (RH) for a minimum period of 4 months.  
- All children starting TB treatment should be initiated on 2RHZE/4RH  
- Children with severe immune-suppression and severe forms of TB disease need to complete 9 months of treatment on 2RHZE/7RH  
- Children with TBIM and owtarticular TB should complete 1 year of treatment on 2RHZE/10RH | |  | |
Adults

NTLP will promote screening for TB among PLHIV in collaboration with NACP as part of intensified case finding. The screening will be done using as a minimum, a set of questions based on symptoms and ages to identify TB suspects. The questions will be asked by trained counselors at services provision sites. Screening will be followed by early diagnosis and prompt treatment. This aims at improving chances of survival, quality of life and reducing transmission of TB in the community.

Routine sputum smear examination of an early-morning sputum at the end of the intensive phase is required. The majority of patients will have converted to negative sputum. If the sputum is still positive at the end of the intensive phase, the intensive phase treatment (RHZL) should be continued for another month. The sputum is checked again at the end of the third month but regardless of the result, the patient should continue with the continuation regimen (RH). If the result is positive after three months, a sputum sample should be sent to TB Reference laboratory for culture and susceptibility testing.

Patients on Category II retreatment, failing to convert after three months intensive phase should continue one more month with RHZL and have their sputum checked at the end of the fourth month. If the sputum smear is still positive after 4 months, at least one sputum sample should be sent for culture and susceptibility testing. The patient should continue on the Category II continuation phase treatment RHE.

All smear positive patients should have another early morning sputum sample checked at 5 and 7/8 (retreatment) months. A negative smear at 5 and 7/8 months means that the patient is bacteriologically cured. A positive result means treatment failure.

All-smear results (0, 2, 3, 5 and 7/8 months) should be registered in the District Tuberculosis Register.

Smear positive pulmonary tuberculosis (PTB+)

Tuberculosis in a patient with at least two initial smear examinations positive by direct microscopy for Acid Fast Bacilli (AFB+)

OR

Tuberculosis in a patient with one initial smear examination positive by direct microscopy AND positive by culture for mycobacteria.

Smear negative pulmonary tuberculosis (PTB−)

Tuberculosis in a patient with three initial smear examinations by direct microscopy for Acid Fast Bacilli (AFB−) AND non-response to a course of broad-spectrum antibiotics, AND x-ray abnormalities suggestive of active tuberculosis as determined by the treating Medical Doctor.

Screening Recommendations during TB Treatment

Case definition

The diagnosis of tuberculosis rests mainly on the identification of the tubercle bacilli by sputum smear microscopy. Every tuberculosis suspect should submit three sputum specimens for smear microscopy.

In Tanzania sputum culture for isolation of mycobacterium is performed on Lowenstein Jensen medium (a solid egg enriched) and formally for:

• Surveillance of tuberculosis drug resistance as an integral part of evaluation of NTLP performance.

• Follow-up of tuberculosis patients who fail to cure, relapse or become chronic excreters after a standardized course of treatment and who may be at risk of harbouring drug resistant organisms. Other microbiological techniques that could be used include:

• cultivation in liquid media,

• serological techniques

• molecular techniques – PCR, DNA probes

Diagnostic methods

Sub-Population

Standard TB Treatment Protocols

Alternatives: DOTS Recommendations

- Adult Category I: New smear positive PTB

- New seriously ill patients with severe forms of tuberculosis: 2 RHZE/4 RH

- Category II: Relapse, Treatment failure and sputum smear positive return: 1 RHZE/2 RHZE/3 RHZE3

- Category III: New smear positive and extrapulmonary TB (less severe forms): 1 RHZE/4 RH

- Adult Category IV: Chronic patients

- These are patients who remain or become smear positive after completing a fully supervised re-treatment regimen. It is important to identify patients with Multidrug Resistant (MDR) TB among chronic patients. Not every chronic patient is an MDR-TB case. Many of these, although persistently smear positive, may still be partially or fully sensitive to the first line anti-TB drugs. This situation may occur due to poor adherence to therapy (patients who collect their drugs but don't take them “hidden defaulter”) or chronic diseases such as chronic malabsorption which is quite common in HIV positive patients.

- Direct observation of treatment means that a supervisor watches the patient swallow the tablets. This ensures that a TB patient takes the right drugs, in the right doses, at the right intervals. In principle, DOT is always required when rifampicin is given, since rifampicin is the strongest and most valuable of currently used anti-TB drugs and one cannot afford to risk the development of rifampicin resistance because of poor compliance to medication.

- This implies that DOT is provided throughout 6 months treatment for new cases and 8 months for re-treatment regimen. To ensure adherence to treatment, DOT should be provided as convenient as possible to the patient (close to the patients' home or workplace). The type of DOT is recorded in the TB register and patients identify card.

- DOTS services are provided through:

- 1. Health facility

- 2. Community/home based DOT

- The arrangements for DOT must be fully integrated in the management of health services at each health facility. Health facilities providing DOT should be supervised at least once per month by the DTLC.

- NTLP is recommending Patient Centred TB Treatment (PCT) approach as part of community based DOT activities. Patient Centred TB Treatment (PCT) means that TB patients are given an opportunity to choose where their daily treatment is supervised and by whom. This means that, patients can choose to come to the health facility for their daily DOT or they can take their treatment at home with a treatment supporter of their own choice (home-based DOT). at home with a treatment supporter of their own choice (home-based DOT).
Children

NTLP will promote screening for TB among PLHIV in collaboration with NACP as part of intensified case finding. The screening will be done using a minimum, a set of questions based on symptoms and signs to identify TB suspects. The questions will be asked by trained counselors at services provision sites. Screening will be followed by early diagnosis and prompt treatment. This aims at improving chances of survival, quality of life and reducing transmission of TB in the community.

Smear positive pulmonary tuberculosis (PTB+)
Tuberculosis in a patient with at least two initial smear examinations positive by direct microscopy for Acid Fast Bacilli (AFB+) OR Tuberculosis in a patient with one initial smear examination positive by direct microscopy AND positive by culture for mycobacteria OR Tuberculosis in a patient with one initial smear examination positive by direct microscopy for Acid Fast Bacilli (AFB+) AND X-ray abnormalities suggestive of active tuberculosis as determined by the treating Medical Doctor.

Smear negative pulmonary tuberculosis (PTB-)
Tuberculosis in a patient with three initial negative smear examinations by direct microscopy for Acid Fast Bacilli (AFB-) AND non-response to a course of broad-spectrum antibiotics, AND again three negative smear examinations by direct microscopy, AND X-ray abnormalities suggestive of active tuberculosis as determined by the treating Medical Doctor. OR Tuberculosis in a patient with three initial smear examination negative by direct microscopy but positive by culture for mycobacteria.

The tuberculin skin test is valuable as a diagnostic tool in young children. In a child who did not receive a BCG, an induration of 10 mm or more is interpreted as positive. If the child did receive a BCG, the induration should be at least 15 mm to be positive. A positive tuberculin skin test should only be one clue to be interpreted in combination with other findings to favor the diagnosis of TB (see diagnosis of TB in children). A score chart below can help to reach the diagnosis of tuberculosis. Older children who are able to cough up sputum should go through the same assessment as adults using smear microscopy as the “gold standard”.

Children

In principle TB treatment in children does not differ from that in adults. Nearly all pulmonary TB in children is smear negative (actually smear “not done”) or extra-pulmonary tuberculosis and thus fall into category II. However, severe forms of TB such as meningitis, miliary TB or TB of the spine should be defined as category I. Treatment can be provided with adult formulation following the dose-body weight relationship.

Children who develop tuberculosis following BCG vaccination, which is sometimes seen in HIV positive children (see BCG), should be treated with 2(RH)E/4RH, as M.bovis is usually resistant to Pyrazinamide.

During continuation phase parents/guardians can supervise DOT to their children and keep record of the medication. Parents/guardians should collect the drugs once per week from a health facility.

<table>
<thead>
<tr>
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<tr>
<td>Adult</td>
<td>Intensified TB case-finding comprises: Screening for symptoms and signs of TB suspects in settings where HIV-infected people are concentrated or in congregate settings (e.g., prisons, police, military barracks, internally displaced persons camps, outpatient departments, HIV clinics, inpatient wards, schools).</td>
<td>- Sputum smears are performed at the end of the initial phase (2 months), at 5 months and in the 8th month of treatment. This should be done for both smear-positive and smear-negative pulmonary TB patients.</td>
<td>[i] TB suspect is any patient who presents with symptoms and signs suggestive of TB, in particular a cough that has lasted 2 or more weeks.</td>
<td>[ii] Case of TB is a patient in whom TB has been bacteriologically confirmed (1 sputum smear positive or culture) or diagnosed by a clinician.</td>
<td>[iii] Definite case of TB is a patient with a positive culture for Mycobacterium tuberculosis complex. In the absence of a culture result, a patient with 2 sputum smears positive for acid-fast bacilli (AFB) can be considered a &quot;definite&quot; case. Sputum smear examination is positive for acid-fast bacilli (AFB).</td>
<td>By rank of importance the diagnostic methods to confirm/exclude TB are:</td>
<td>Adults (12 years and older)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- At least 2 sputum specimens negative for AFB and: Radiological abnormalities consistent with active TB disease and: Non-response to a course of broad spectrum antibiotics (excluding fluoroquinolones) for 7 days and: Decision by a clinician to treat as pulmonary TB with a full course of anti-TB drugs.</td>
<td></td>
<td></td>
<td></td>
<td>Microscopic examination of sputum smears</td>
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**Sputum smears** are performed at the end of the initial phase (2 months), at 5 months and in the 8th month of treatment. This should be done for both smear-positive and smear-negative pulmonary TB patients.

- TB suspect is any patient who presents with symptoms and signs suggestive of TB, in particular a cough that has lasted 2 or more weeks.
- Case of TB is a patient in whom TB has been bacteriologically confirmed (1 sputum smear positive or culture) or diagnosed by a clinician.
- Definite case of TB is a patient with a positive culture for Mycobacterium tuberculosis complex. In the absence of a culture result, a patient with 2 sputum smears positive for acid-fast bacilli (AFB) can be considered a "definite" case. Sputum smear examination is positive for acid-fast bacilli (AFB).

**By rank of importance the diagnostic methods to confirm/exclude TB are:**

- Microscopic examination of sputum smears
- AFB culture
- Histopathology

**Smear-positive pulmonary TB:**

- One or more sputum smear examination positive for acid-fast bacilli (AFB)

**Smear-negative pulmonary TB:**

- At least 2 sputum specimens negative for AFB and:
- Radiological abnormalities consistent with active TB disease and:
- Non-response to a course of broad spectrum antibiotics (excluding fluoroquinolones) for 7 days and:
- Decision by a clinician to treat as pulmonary TB with a full course of anti-TB drugs.

**Treatment in Patients with Liver Disease:**

<table>
<thead>
<tr>
<th>Drug Regimen</th>
<th>Clinical Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2SHz/5H</td>
<td>Treatment of Patients with Liver Disease: 2SHz/5H or 2SHz/3H2.</td>
</tr>
<tr>
<td>2SHz/4R4H</td>
<td>Retreatment cases (Relapses, Treatment Failure, Default): 2SHz/1zH2/5RHE.</td>
</tr>
</tbody>
</table>

**Treatment of Patients with Renal Failure:**

<table>
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<th>Drug Regimen</th>
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<tr>
<td>2SRHZE/1RHZE/5RHE</td>
<td>Treatment of Patients with Renal Failure: 2SRHZE/1RHZE/5RHE.</td>
</tr>
</tbody>
</table>

**Patients with severe renal failure who are receiving isoniazid should also receive pyridoxine to prevent peripheral neuropathy. Ethambutol can accumulate as a result of reduced excretion and cause optic neuropathy. The use of aminoglycosides and capreomycin should be avoided in patients with renal failure.**

**Individuals on haemodialysis should receive anti-TB drug treatment by direct observation after dialysis because several of the drugs are eliminated during dialysis. The safe regimen for patients with renal failure is 2HRZ/4HR.**

**Community-based DOT:**

- TB patients who are diagnosed in the health facilities and do not require hospitalization, should be enrolled in community-based DOT.
- The Sub-county Health Worker (SCHW) will brief, orient and supervise the treatment supporters. After training is completed, the SCHW provides the treatment supporter with a 2-week supply of the anti-TB drugs and a patient treatment card for each patient with TB in the community.

**Facility-based DOT:**

- Patients who for some reason cannot follow the CB-DOTS options described above should have their anti-TB treatment observed daily by the health worker at the health facility at least during the intensive phase of treatment.
<table>
<thead>
<tr>
<th>Population</th>
<th>TB Screening Frequency for PLHIV</th>
<th>Screening Recommendations during TB Treatment</th>
<th>Case definition</th>
<th>Diagnostic methods</th>
<th>Sub-Population</th>
<th>Standard TB Treatment Protocols</th>
<th>Alternatives</th>
<th>DOTS Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>Intensified TB case-finding comprises: Screening for symptoms and signs of TB suspects in settings where HIV-infected people are concentrated or in congregate settings (e.g., prisons, police, military barracks, internally displaced persons camps, outpatient departments, HIV clinics, inpatient wards, schools).</td>
<td>Health workers providing TB treatment to children should assess progress: at 2 weeks after start of treatment at the end of the initial phase of treatment and monthly thereafter until treatment completion. The child should be assessed for symptoms, treatment adherence, adverse events and weight change. Medication dosage should be adjusted for any weight gain. For sputum smear-positive children, sputum should be examined at these points: end of 2 months, 5 months, during the last month of treatment. Chest X-rays are not routinely required for treatment follow-up in children as many children have slow radiological response to treatment, especially those with hilar and mediastinal adenopathy. A child not responding to anti-TB treatment in the first 2 months should be referred for further assessment and management. These children may have drug-resistant TB, unusual complications of pulmonary TB, other causes of lung disease or problems of treatment adherence. A good history, a thorough physical examination and a high index of suspicion are vital aids to diagnosis. TB diagnosis in children is based on a combination of clinical features, history of exposure to adult patients with TB, the result of a tuberculin (Mantoux) test and radiological findings. Procedure for diagnosis of TB in children: Pulmonary secretions (sputum, gastric washout or induced sputum). The recommended test is the Mantoux test. Consider TST positive as shown below: 5 mm or more is positive if the person is: • HIV-positive • A recent contact of TB case • Severe malnutrition • Children in other immunosuppressive states • Recent measles or whooping cough 10 mm or more is positive in all children except the above listed category.</td>
<td>Children</td>
<td>TB treatment category 1: • New smear-positive pulmonary TB • Severe forms of extrapolumonary TB • Severe concomitant HIV disease • New smear-negative pulmonary TB with extensive parenchymal disease Initial: 2HRZE Continuation: 4HR</td>
<td>TB treatment category 2: • Previously treated smear-positive pulmonary TB Initial: 2HRZE/1HRZE Continuation phase: 4HR</td>
<td>TB treatment category 3: • New smear-negative pulmonary TB (other than in category 1) • Less severe forms of extrapolumonary TB Initial: 2HRZ Continuation: 4HR</td>
<td>TB treatment category 4: • Chronic and MD- TB Specially designed standardized regimens or individualized regimens</td>
<td>Pregnant and breastfeeding women</td>
</tr>
</tbody>
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**Population TB Screening Frequency for PLHIV**

**Screening Recommendations during TB Treatment**

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<td>Smear positive pulmonary tuberculosis (PTB+)</td>
<td>Sputum-smear microscopy</td>
<td>Category I Patients: All new patients (Smear positive, negative and extrapulmonary).</td>
<td></td>
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</tr>
<tr>
<td>Tuberculosis in a patient with at least one initial smear examinations positive by direct microscopy for Acid Fast Bacilli (AFB+).</td>
<td>Sputum culture</td>
<td>Intensive Phase: 2(RHZE)</td>
<td>Continuation Phase: 6(RH) or 4(RH).</td>
<td></td>
</tr>
<tr>
<td>Retreatment patients</td>
<td>Tuberculin skin test</td>
<td>Category II Patients: All previously treated patients including smear positive retreatment, smear negative retreatment and treatment failures, treatment after default and relapse cases.</td>
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<td>Before the start of the re-treatment regimen, two sputum specimens must be collected and sent as soon as possible to the nearest Reference Laboratory for sputum-smear and culture and drug susceptibility tests.</td>
<td></td>
<td>Intensive Phase: 2(SRHE)/1(RHZE)</td>
<td>Continuation Phase: 5(RHE)</td>
<td></td>
</tr>
<tr>
<td>Should the sputum smear be positive at 3 months, the 4 oral drugs are continued for another 4 weeks. If the patient is still smear positive at the end of the fourth month, all drugs are stopped for 3-4 days, when sputum specimens are taken for culture and sensitivity testing. The patient is then started on the continuation phase.</td>
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<td>Sputum specimens should be examined for AFB two months after start of the continuation phase and at the end for confirmation of the treatment result. Patients who are smear positive after the completion of the continuation phase are no longer eligible for the re-treatment therapy.</td>
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**Zambia - THE NATIONAL TUBERCULOSIS AND LEPROSY PROGRAMME TB MANUAL (no date)**

- Adults: All patients suspected or known to be HIV-positive should be examined for tuberculosis, in particular when there is a cough.
- Sputum smear is still the first line of diagnosis.
- New Patients: All patients should have 2 sputum specimens taken for AFB smear at 2, 5 and 6 months in case of an eight month treatment and at 2 and 6 months in case of 6 months treatment. Results should be available at these visits and must be recorded on the patient treatment cards and in the registers.
- The continuation phase can only start after 2 months supervised intensive treatment, if the sputum specimens are negative for AFB.
- Retreatment patients: Before the start of the re-treatment regimen, two sputum specimens must be collected and sent as soon as possible to the nearest Reference Laboratory for sputum-smear and culture and drug susceptibility tests.
- Should the sputum smear be positive at 3 months, the 4 oral drugs are continued for another 4 weeks. If the patient is still smear positive at the end of the fourth month, all drugs are stopped for 3-4 days, when sputum specimens are taken for culture and sensitivity testing. The patient is then started on the continuation phase.
- Sputum specimens should be examined for AFB two months after start of the continuation phase and at the end for confirmation of the treatment result. Patients who are smear positive after the completion of the continuation phase are no longer eligible for the re-treatment therapy.

**Diagnosis of tuberculosis (TB)**

- **Smear positive pulmonary tuberculosis (PTB+)**: Tuberculosis in a patient with at least one initial smear examinations positive by direct microscopy for Acid Fast Bacilli (AFB+).
- **Smear negative pulmonary tuberculosis (PTB-)**: Tuberculosis in a patient with three initial negative smear examinations by direct microscopy for Acid Fast Bacilli (AFB-), and again three negative smear examinations by direct microscopy, and X-ray abnormalities suggestive of active tuberculosis as determined by the treating Medical Doctor. OR Tuberculosis in a patient with three initial smear examinations negative by direct microscopy but positive by culture for mycobacterium.

**Category I Patients**: All new patients (Smear positive, negative and extrapulmonary).

<table>
<thead>
<tr>
<th>Intensive Phase</th>
<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>2(RHZE)</td>
<td>6(RH) or 4(RH).</td>
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**Category II Patients**: All previously treated patients including smear positive retreatment, smear negative retreatment and treatment failures, treatment after default and relapse cases.

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<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>2(SRHE)/1(RHZE)</td>
<td>5(RHE).</td>
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</tbody>
</table>

**Renal Failure**: 2(RH)/4(RH)

**Liver Disease**: 2(2RH)/14(RH) or 15(EM)/20 (EM)

**Drugs are administered under direct observation of designated trained observer:** this may include healthcare worker, community volunteer or trained relative.
- Drug intake is recorded daily immediately after each intake.
- The identity and address of the patient is properly recorded.
- The patient and his relatives are well aware of the importance of daily observed treatment for the sake of the patient's own health.
- Health staff are available for tracing irregular and defaulting patients in collaboration with local community based organisations.
- The treatment centre is supervised by the District TB/Leprosy Officer, at least once monthly.
### Zambia - National Tuberculosis and Leprosy Programme TB Manual (no date)

**Population: TB Screening Frequency for PLHIV**

**Screening Recommendations during TB Treatment**

<table>
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<th>Case definition</th>
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<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| All patients suspected or known to be HIV-positive should be examined for tuberculosis, in particular when there is a cough. Sputum smear is still the first line of diagnosis. | Always look for these important clues to TB in children:  
- Contact with an adult or older child with smear-positive PTB.  
- Failure to thrive or weight loss (growth faltering). This is a good indicator of chronic disease in children, but is not specific.  
- Respiratory symptoms such as cough lasting for more than two to three weeks in a child who has received a course of broad-spectrum antibiotics.  
- It is important to confirm diagnosis of TB in a child using whatever specimens and laboratory facilities are available.  
Specimens can be obtained in the following ways:  
1. Expectoration: Sputum should always be obtained in older children (10 years of age or older) who are pulmonary TB suspects. Among younger children, especially children under 5 years of age, sputum is difficult to obtain and most children are sputum smear-negative. However, in children who are able to produce a specimen, it is worth sending it for smear microscopy (and mycobacterial culture if available). Bacterial yields are higher in older children (more than 5 years of age) and adolescents, and in children of all ages with severe disease. As with adult TB suspects, three sputum specimens should be obtained: an on-the-spot specimen (at first evaluation), an early morning specimen and a second on-the-spot specimen (at a follow-up visit).  
2. Gastric aspiration: Gastric aspiration using a naso-gastric feeding tube can be performed in young children who are unable or unwilling to expectorate sputum. Gastric aspirates should be sent for smear microscopy and mycobacterial culture. A gastric aspirate should be obtained on each of three consecutive mornings.  
3. Sputum induction: Several recent studies have found that sputum induction is safe and effective in children of all ages and the bacterial yields are as good as or better than for gastric aspirates. However, training and specialized equipment are required to perform this procedure properly.  
4. Lymph node aspirates: Lymph nodes should be aspirated with a medium to large bone needle attached to a small syringe. Any material obtained should be sprayed onto a slide, air-dried and stained for acid fast bacilli. The tuberculin skin test is valuable as a diagnostic tool in young children. In a child who did not receive a BCG, an induration of 10 mm or more is interpreted as positive. If the child did receive a BCG, the induration should be at least 15 mm to be positive. A positive tuberculin skin test should only be one clue to be interpreted in combination with other findings to favour the diagnosis of TB.  
Laboratory confirmation:  
- Expectoration: Sputum should always be obtained in older children (10 years of age or older) who are pulmonary TB suspects.  
- Gastric aspiration  
- Sputum induction  
- Lymph node aspirates  
Suspected pulmonary TB: Chest X-rays are useful in the diagnosis of TB in children. | | | |

| **Children Category I Patients:** All new patients (smear positive, negative and extra-pulmonary) | | | |
| **Intensive Phase:**  | 2(RHZ) | | | |
| **Continuation Phase:**  | 4(RH) | | | |

| **Children Category II Patients:** All previous treated patients including smear positive re-treatment, smear negative re-treatment and treatment failures, treatment after default and relapse cases. | | | |
| **Intensive Phase:**  | 2(HRS) | | | |
| **Continuation Phase:**  | 10(H) | | | |
Children Children known or suspected of having HIV infection should be screened for TB at every contact with health services.

| New sputum smear positive PTB: Examine sputum at month 3 only, thereafter by clinical monitoring. | New sputum smear negative TB: Examine sputum at end of months 2, 5, 6. |
| Previously treated sputum smear positive PTB: Examine sputum at the end of Months 3, 5, 6. |

The following are bacteriological definitions of pulmonary TB:
- Pulmonary tuberculosis, sputum smear-positive (PTB+) - One or more sputum smear examinations positive for AFB (irrespective of quantity of AFBs seen on microscopy).
- Pulmonary tuberculosis, sputum smear-negative (PTB-) - Two or more negative smears, and
- Radiographic abnormalities consistent with active PTB as determined by a clinician, and
- Decision by a medical officer to treat with a full course of anti-TB medicines and
- Following failure to respond to an adequate course of broad-spectrum antibiotics (not including fluoroquinolones, streptomycin and other anti-TB medicines). All HIV positive patients should receive a course of broad-spectrum antibiotics. The response to treatment should no longer be used to diagnose PTB in PLHIV as they may have two or more chest infections including PTB.

Children with suspected TB:
- Very young and acutely ill children in the absence of robust evidence of disease if the child is older and not acutely ill, there is no urgency for starting the treatment. Wait and assess. Any child with a persistently negative Mantoux reaction and whose condition remains good or improves over months does not have TB.

Recommended approach to diagnose TB in Children:
1. Careful history (including history of TB contact and symptoms consistent with TB disease), and
2. Clinical examination (including growth assessment)
3. Tuberculin skin testing
4. Bacteriological confirmation whenever possible
5. Investigations relevant for suspected pulmonary TB and suspected extrapulmonary TB
6. HIV testing

Children with CONFIRMED TB:
- AFB are seen on microscopy
- Culture of M. tuberculosis has been obtained from any body fluids, tissues, fluids or secretion.

Children with PROBABLE TB:
- Positive ( Mantoux test) tuberculosis skin test
- CXR showing unilateral hilar or paratracheal adenopathy, or a pulmonary picture
- Histology suggestive of TB

Children with SUSPECTED TB:
- AFB are seen on microscopy
- Culture of M. tuberculosis has been obtained from any body fluids, tissues, fluids or secretion.

Children with UNCONFIRMED TB: Children with evidence of disease possibly extrapulmonary, e.g. miliary picture, or clinical assessment suggests disease outside the lungs.

Sputum smear examination
Sputum Culture
Chest x-ray
Other tools for diagnosing TB:
- Tuberculin skin test (TST)/ Mantoux test
- Light-emitting diode (LED) fluorescence microscopy has been recently introduced and will be widely available in due course
- The investigations below will be available in major centres in the country:
  - Molecular line-probe assay.
  - Automated liquid culture and DST.

| Recommended approach to diagnose TB in Children |
| Children with CONFIRMED TB: |
| 1. Careful history (including history of TB contact and symptoms consistent with TB disease), and |
| 2. Clinical examination (including growth assessment) |
| 3. Tuberculin skin testing |
| 4. Bacteriological confirmation whenever possible |
| 5. Investigations relevant for suspected pulmonary TB and suspected extrapulmonary TB |
| 6. HIV testing |

| New Cases: |
| All forms of intra-thoracic disease without cavitation or extensive exudate consolidation |
| - Uncomplicated extrapulmonary disease e.g. - TB lymphadenitis and Tuberculosis pleural effusion |
| - Spinal smear-positive disease |
| - Extensive parenchymal involvement on CXR |
| - Cavitation pulmonary TB |
| - TB pericarditis |
| - Abdominal TB |
| - All children with HIV co-infection: 2HRZ/4HR – TB meningitis, miliary TB and extra-arterial TB: 2HRZ/2HR |

Retreatment: Previously treated smear-positive pulmonary TB
- Relapse
- Treatment after interruption
- Treatment failure: 2HRZ/1HRZE/5HRE

Adults

New TB Patient: 2HRZE/4HR

Previously treated TB Patient: 2HRZE/1HRZE/5HRE

Patients with renal failure: INH, ethambutol and pyrazinamide are contraindicated almost entirely by the hepatobiliary system or metabolized into non-toxic compounds in severe renal failure. Give pyridoxine to prevent INH-induced peripheral neuropathy. Streptomycin and ethambutol are excreted by the kidneys, and should be avoided unless there is a specialist care.

The safest regimen to give in renal failure is 2HRZ/4HR.