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South Africa

The following provides a summary of specific guidelines from the country's national TB guidance strategy. Use the jump links in yellow to access details on case definitions, diagnostic methods, standard protocols, and DOTS recommendations. This summary can be downloaded or e-mailed to yourself or a colleague. The original country guidance document can also be found below the jump links for download.

Patient Population [Download summary page as PDF](#) [E-mail this page](#)

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Pregnant Women

Year Issued:

2014

TB Screening Frequency for PLHIV:

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.

Screening Recommendations during TB Treatment:

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.

Case definition:

Bacteriologically-confirmed Tuberculosis

A patient with *Mycobacterium 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 Xpert 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 Xpert 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-rays findings or other tests

Diagnostic methods:

Smear microscopy

- LED/ Fluorescent

Culture

- Liquid (MGIT)
- Solid

PCR based assays

1. Xpert® MTB/RIF
2. Line Probe assay

Chest x-rays are necessary in patients who cannot produce sputum or who have negative Xpert results and are HIV positive, and where extrapulmonary TB (such as pleural effusions and pericardial TB) is suspected. While CXR is non-specific for TB, the presence of infiltrates, lymph nodes or cavities is highly suggestive of TB.

Standard TB Treatment Protocols:

Pregnant and Breastfeeding Women:

Untreated tuberculosis represents a far greater hazard to a pregnant woman and the fetus than treating the disease. Therapy must be commenced promptly with the standard daily 6 month treatment regimen. Most TB drugs except for streptomycin are safe for use in pregnant women.

Mothers must be encouraged to breastfeed their babies whilst on TB treatment. All the TB drugs are safe for use during breastfeeding. If the mother is infectious (both smear-positive and smear-negative/ culture positive PTB) surgical masks must be used to protect the child from infection.

Alternatives:

Not Indicated

DOTS Recommendations:

Treatment supporter watches the patient swallowing the tablets, in 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.

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 minimise 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 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 present for DOT on that day and recall them rapidly.

Adults and Children >8yrs or >30 kgs

Year Issued:

2014

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

TB patient (person with tuberculosis)

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- LED/ Fluorescent

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PCR based assays

1. Xpert® MTB/RIF
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Chest x-rays are necessary in patients who cannot produce sputum or who have negative Xpert results and are HIV positive, and where extrapulmonary TB (such as pleural effusions and pericardial TB) is suspected. While CXR is non-specific for TB, the presence of infiltrates, lymph nodes or cavities is highly suggestive of TB.

Standard TB Treatment Protocols:

New and previously treated adults and children >8 years/ >30kg
2(HRZE) / 4(HR)

Alternatives:

- If patient cannot tolerate Isoniazid: Treat with Moxifloxacin/ Rifampicin/ Ethambutol for 12 months (Pyrazinamide may be added during the intensive phase).
- If patient cannot tolerate Rifampicin: Treat with Moxifloxacin/ Isoniazid/ Ethambutol for 18 months (Pyrazinamide or Streptomycin may be added during the intensive phase).
- If patient cannot tolerate Rifampicin and Isoniazid: Treat with Moxifloxacin, Ethambutol and Streptomycin for 18 months.
- If patient cannot tolerate Pyrazinamide: Treat with Rifampicin/ Isoniazid/ Ethambutol for 9 months.
- If the patient is severely ill due to TB, and stopping treatment is not an option, a liver friendly regimen comprising Ethambutol, Moxifloxacin and Streptomycin can be started. This can be stopped if the patient is ready to be re challenged with Rifampicin, Isoniazid (or both).
- Reintroduce Cotrimoxazole after TB treatment once"

DOTS Recommendations:

Treatment supporter watches the patient swallowing the tablets, in 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.

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 minimise the risk of reinfection. The following must be conducted at each encounter with the patient:

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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 present for DOT on that day and recall them rapidly.

Children

Year Issued:

2013

TB Screening Frequency for PLHIV:

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

Screening Recommendations during TB Treatment:

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.

Case definition:

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

Site of TB disease -

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.

Bacteriologically confirmed TB -

Extrapulmonary TB:

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

Xpert positive - Smear positive pulmonary tuberculosis:

A child with a positive Xpert result and at least 1+ AFB in at least 1 sputum smear examination.

Xpert positive - Smear-negative pulmonary tuberculosis:

A child with a positive Xpert result and at least one sputum smear microscopy negative for AFBs or

Xpert positive - Smear not done TB:

A child with a positive Xpert result and a baseline smear was not conducted. This applies to children with

pulmonary TB who are unable to expectorate spontaneously and those who had extrapulmonary TB specimen tested.

Clinically diagnosed TB -

Children who are started on TB treatment without bacteriological confirmation of disease. This includes;

- A child with a negative Xpert result and at least one sputum smear microscopy negative for AFB, with chest x-ray abnormalities that are consistent with active TB or a decision to treat based on the clinical picture or
- A child who had no bacteriological test done, with chest x-ray abnormalities that are consistent with active TB or a decision to treat based on the clinical picture or
- A child who is started on treatment based on clinical picture only (empiric treatment)
- A child who is started on treatment based on histological and biochemical tests suggestive of TB

Diagnostic methods:

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.

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.

Standard TB Treatment Protocols:

For children <8 years and <30 kg with uncomplicated TB disease:

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.

For children <8 years and <30kgs with complicated TB disease:

REGIMEN 3B: 2((RH)ZE/ 4(RH)

This regimen is recommended for the treatment of complicated TB disease. This includes severe forms of TB such as TB pericarditis, abdominal TB, osteo-articular TB and high bacillary load PTB (smear positive disease, extensive parenchymal involvement on chest x-ray, cavities on chest x-ray).