CMScript

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Issue 11 of 2014

Tuberculosis (TB) is one of the leading causes of deaths in South Africa. According to the World Health Organisation (WHO) statistics in 2011, an estimated 500 000 cases of active tuberculosis were reported. This means that about 1% of the population develop active TB each year. Tuberculosis is a notifiable disease which means that all medical practitioners are legally obliged to notify the National Department of Health of all patients diagnosed with Tuberculosis

What is tuberculosis?

Tuberculosis (TB) is an airborne infectious disease caused by a bacterium named Mycobacterium Tuberculosis. The disease can cause death if it is not treated.

TB most commonly affects the lungs but also can involve almost any organ in the body. In this edition of CMScript we will focus on TB in the lungs (Pulmonary TB).

Types of tuberculosis

Tuberculosis can be classified in the following groups:

- Latent (inactive) TB
- Active TB
- Multi drug resistant TB
- Extensively drug resistant TB

Latent TB

In latent TB, you are infected but the TB bacilli is in an inactive state and you have no symptoms of the disease. In this phase, TB is not contagious or infectious. It is estimated that almost 80% of the South African population is infected with TB, although the vast majority of these people have latent TB.

Latent TB does not require treatment however people who are immunocompromised may need prophylactic treatment to prevent the development of TB disease (symptoms). TB in the latent phase can turn into active TB within the first few weeks or many years later.

Active TB

In this phase the infection becomes active, causes symptoms and is contagious. We then say a person has TB disease. If your immune system is weakened for any reason you have a higher risk of developing active TB. Patients who have had Pulmonary TB (PTB) that was successfully treated may develop PTB again, even after many years.

Multi drug resistant TB (MDR TB)

MDR TB develops when the bacteria are resistant to at least two of the medication used to treat TB called anti-TB drugs. This means that the bacteria resists the effect of the drug, is not killed by the specific drug, and even multiply and spread.

In most cases the bacteria become resistant to isoniazid and rifampicin, two of the most effective anti-TB drugs.

Extensively drug resistant TB (XDR TB)

XDR TB, as with MDR TB, develops when the bacteria is resistant to the effects of drugs that previously killed it. In XDR TB, however, the bacteria is resistant to more than two drugs. In XDR TB the bacteria is resistant to at least rifampicin and isoniazid plus one of the fluoroquinolones. It is also resistant to one of the second line injectable TB drugs amikacin, kanamycin or capreomycin.

Both MDR and XDR TB do not respond to the standard 6 months treatment with the first line anti-TB drugs. Treatment for MDR and XDR TB can take 2 years or longer and require treatment with drugs that are more toxic.

How does TB spread / How can you get it

You can become infected with tuberculosis bacteria when you inhale very small particles of infected sputum from the air. The bacteria gets into the air when someone with tuberculosis lung infection coughs, sneezes, shouts, sings or spits.

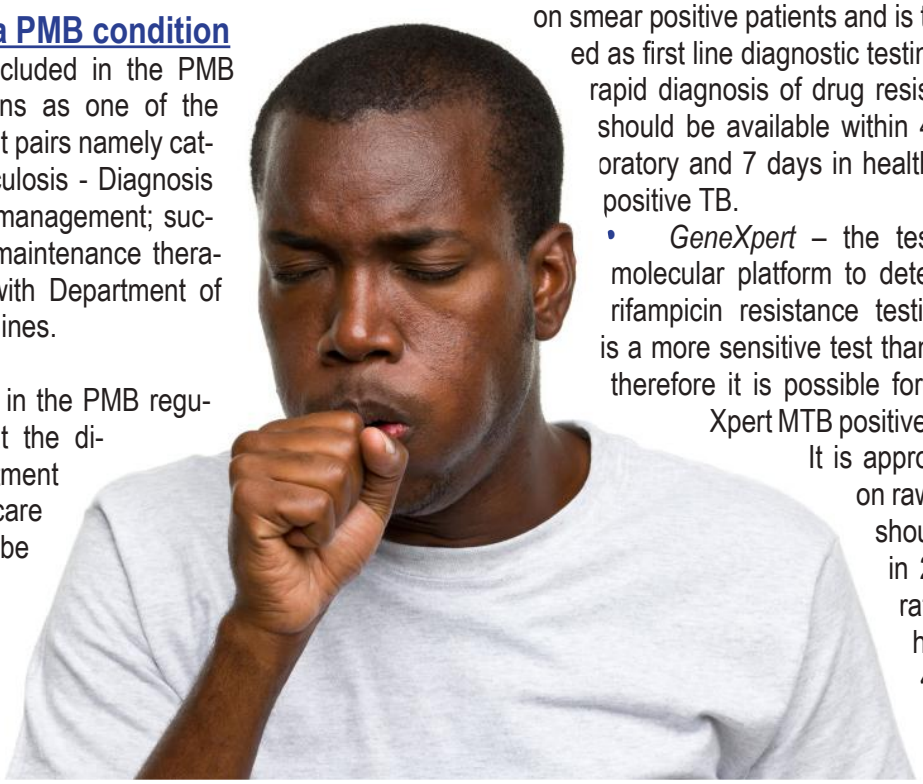
You cannot get TB by just touching the clothes or shaking the hands of someone who is infected.

Signs and symptoms

The main symptoms of pulmonary tuberculosis are generalized tiredness or weakness, weight loss of more than 1.5 kg per month, fever and/or night sweats for more than 2 weeks , coughing, chest pain, coughing up of sputum and/or blood (hemoptysis), and shortness of breath. Some patients may present wheezing symptoms.

TB as a PMB condition

TB is included in the PMB regulations as one of the diagnostic, treatment pairs namely category 11S – Tuberculosis - Diagnosis and acute medical management; successful transfer to maintenance therapy in accordance with Department of Health (DOH) guidelines.



The inclusion of TB in the PMB regulations ensures that the diagnostic tests, treatment and the follow-up care of the disease must be funded.

As you will notice the regulations state successful transfer to maintenance therapy in accordance with the DOH guidelines. This sentence should not be interpreted that maintenance therapy must be provided in the state sector. If the treatment that is prescribed is available from your private doctor or pharmacy, it is still included as PMB level of care.

Diagnosis

TB diagnostic tests are included in the PMB regulations. These tests include the following:

- *Sputum microscopy (Acid Fast Bacilli)* – the test is used to identify bacteria in the sputum. The test is highly specific and the results are available quickly. The test may however be negative in HIV positive people even when the people have disease. This test should be done as first line investigation. Other tests may be requested when this test is negative despite signs and symptoms suggestive of TB. Sometimes it is difficult to obtain sputum especially in children. If that it is the case, saline nebulisation, gastric washing or bronchoscopy is necessary to obtain fluid that may contain bacteria.
- *Sputum cultures and drug sensitivity*– the test is more sensitive than sputum microscopy, however it is expensive and the results are only available after 6 weeks. The test is indicated in patients who have negative smears on microscopy despite symptoms highly suggestive of TB (e.g. HIV negative patients and other immunocompromised patients), for drug susceptibility in people who previously had TB and have a recurrence or who still have positive smears after treatment, for drug susceptibility in people at risk of MDR or XDR TB.
- *PCR based assays (Genotype® MTBDRplus assay)*– the test has reduced sensitivity although it is useful in diagnosing INH resistance. It can only be performed on smear positive patients and is therefore not indicated as first line diagnostic testing. The test provides rapid diagnosis of drug resistant TB and results should be available within 48 hours in the laboratory and 7 days in health facilities for smear positive TB.
- *GeneXpert* – the test is an automated molecular platform to detect tuberculosis and rifampicin resistance testing. Xpert MTB/RIF is a more sensitive test than smear microscopy, therefore it is possible for a TB patient to be Xpert MTB positive but smear negative. It is approved for use directly on raw sputum and results should be available within 2 hours in the laboratory but available in health facilities within 48 hours. This test has the following advantages:
  - It detects MTB and Rifampicin resistance from one specimen at the same time.
  - Processing time for the test itself is approximately 2 hours.
  - It is specific for MTB complex; (it can differentiate MTB from other mycobacteria).
  - It can also be used on the following processed samples - CSF, aspirates (gastric, lymph node) and tissue (i.e. pleural biospy).
- *Drug susceptibility testing*- Pleural tap may be done when a patient has an effusion and fluid send to laboratory for analysis. It should be noted that pleural effusions may not necessarily contain bacteria but the protein content of the effusion is used as a proxy to TB as a cause.
- *Interferon gamma Release Assays (IGRA)*- IGRAs are blood tests that detect MTB infection but cannot distinguish latent TB from active TB. WHO does not recommend these tests for program purposes in low and middle income settings which includes South Africa. This test will not be funded at PMB level of care for screening or diagnosis of TB.
- *Tuberculin skin test*-The tuberculin test has limited value in clinical work, especially where TB is common. The test shows hypersensitivity to proteins of the TB

https://stories.wsrcdn.net/wp-content/uploads/2012/11/iStock_000017647954Small.jpg

bacillus, as a result either of infection with M. tuberculosis or induced by Bacille Calmette-Guérin (BCG) vaccination. A positive TST does not indicate TB disease, only infection. Infection is one of the criteria used in the diagnosis of TB in children. The WHO has recently reviewed data on the performance of serological tests for TB and has strongly recommended that these tests should not be used in the diagnosis of TB infection or disease. Therefore this test is not included at PMB level of care for adults but maybe used for diagnosis in children.

Adjunctive tests

- Chest X-rays are a non-specific test and therefore may be difficult to interpret. For instance, lung tissue scarring from old PTB is difficult to differentiate from active PTB. Sometimes the PTB may not be apparent on chest X ray.
- Computerized Tomography (CT scan) and Magnetic Resonance Imaging (MRI): The use of CT scan and MRI are not widely recommended because they are expensive but they have proved useful for imaging tuberculosis lesions in:
  - Children and immune compromised people suspected to have TB but without any positive findings
  - Patients with normal or inconclusive chest x-ray where TB complications are suspected
  - Patients with extra-pulmonary TB
- Adenosine DeAminase (ADA): ADA is an enzyme found in most cells, it is elevated in TB effusions (>30µl). This test may therefore be useful in confirming the cause of an effusion when it doubt.

Other tests used to determine drug resistance, TB in people who also suffer from other diseases, and TB not located in the lungs are available but will not be discussed in this edition.

Other investigation methods, other than the ones mentioned, may also be done in order to identify possible conditions that may have an impact on the treatment provided. These baseline tests are mostly performed on the first contact but may be repeated on specific intervals. The national guidelines specify these as follows in the table below.

Investigations		Recommended frequency
Microscopy	All patients	Baseline, 7 weeks and 23 weeks
Height	All patients	Baseline
Weight	All patients	Baseline and monthly
Body mass index	All patients	Baseline
HIV test	Patients with unknown HIV status or have not tested in the past year	Baseline
Blood glucose	Urine glucose and ketones (All patients)	Baseline
	Blood glucose (symptomatic patients)	Baseline and monthly for diabetic patients
Pregnancy test	Women of child bearing age, presenting with history of amenorrheoa and not on contraception	Baseline
Alcohol use screening	Patients with a history of alcohol use	Baseline
Liver function tests	In patients with a history of liver disease, excessive alcohol use	Baseline,
Serum creatinine	In patients with a history of kidney disease	Baseline, monthly
Chest x-ray	Patients with concomitant lung disease and those with a history of working in the mines	Baseline, end of treatment

It is however important to note that all tests and diagnostic tools available to the state sector qualifies as PMB level of care and must be available to the member in the private sector.

Treatment

The aims of TB treatment as per the National Tuberculosis Management Guidelines 2014 are to:

- Cure the patient of TB
- Decrease transmission of TB to others
- Prevent the development of acquired drug resistance
- Prevent relapse
- Prevent death from TB or its complications

TB drugs have different properties in the way that they prevent resistance and act against the actual bacteria.

The standard treatment regime for all newly diagnosed and previously diagnosed patients is made up of an Intensive Phase lasting 2 months and a Continuation Phase lasting 4 months.

In the intensive phase 4 drugs i.e. isoniazid, rifampicin, pyrazinamide, and ethambutol are used to rapidly kill the bacteria. Infectious patients become less infectious within approximately 10-14 days of starting treatment and symptoms decrease. The majority of patients with sputum smear-positive TB will become smear-negative within 2 months.

In the Continuation Phase, 2 drugs (isoniazid, rifampicin) are used, over a period of 4 months. The sterilizing effect of these drugs eliminates the remaining bacteria and prevents subsequent relapse.

Different treatment regimes exist for children younger than 8 years who also weight less than 30kg and for patients who also have other health conditions such as HIV, Diabetes Mellitus etc.

The treatment regimens for MDR and XDR TB will not be discussed in detail but are specified in the National Tuberculosis Management Guidelines 2014.

As TB is a PMB condition, treatment must be provided as per the published national guideline.

If the treatment is provided to you in the private sector, the medical scheme is still obliged to fund this as per the requirements of the PMB regulations.

It is important to remember that your medical scheme may still use managed care principles such as designated service providers. Please ensure that if you are diagnosed with TB your medical practitioner is familiar with the national guidelines.

Care

The care component of the PMB diagnostic treatment pairs provide for continuous funding of ongoing pathology tests and consultations after treatment has started. Should further conditions or complications and side-effects from TB treatment be diagnosed, it is included in the PMB level of care.

References

1. National Tuberculosis Management Guidelines 2014 – Directorate TB DOTS Strategy Coordination, National Department of Health
2. http://www.santa.org.za

REGIMEN 1: FOR ADULTS AND CHILDREN OLDER THAN 8 YEARS OR WEIGHING MORE THAN 30KG

Pre-treatment body weight	Intensive Phase 7 days a week for 2 months	Continuation phase 7 days a week for 4 months	
	RHZE (150,75, 400,275)	RH (150,75)	RH (300,150)
30-37 kg	2 tabs	2 tabs	
38-54 kg	3 tabs	3 tabs	
55-70 kg	4 tabs		2 tabs
>70kg	5 tabs		2 tabs

Table as published in the National Tuberculosis Management Guidelines 2014

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information@medicalschemes.com
Hotline: 0861 123 267
Fax: 012 430 7644