

# Mobilise Against TB

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**Statement by the Treatment Action Campaign, the HIV Clinicians Society of Southern Africa, Médecins Sans Frontières, SECTION27 (incorporating the AIDS Law Project), HIV i-Base, Wits Reproductive Health and HIV Institute (WRHI), Jhpiego and the Centre for the AIDS Programme of Research in South Africa (CAPRISA)**

## Summary

On 10 August 2011, the Treatment Action Campaign (TAC), Médecins Sans Frontières (MSF), the HIV Clinicians Society of Southern Africa (HIVSOC) and SECTION27 hosted a meeting of scientists, clinicians, policy makers, government and activists to ignite South Africa's response to the tuberculosis (TB) epidemic.

The meeting looked at the challenges of the epidemic, as well as opportunities to improve the country's response so that we can reduce new TB cases and improve the cure rate.

Recorded TB deaths tripled between 1997 and 2005 in South Africa. TB is the country's number one cause of death in adults. Yet despite the health crisis posed by TB, the disease is neglected. The participants agreed that political will, accountability, access to new drugs and diagnostics and expanded funding are urgently needed to strengthen the response.

We need bold approaches: new diagnostics like the GeneXpert must be rolled out while also investing much more money in research for highly sensitive and specific point-of-care tests; HIV co-infected patients should be initiated on antiretroviral treatment regardless of their CD4 counts; patients with drug-resistant TB should have access to experimental drugs like bedaquiline (formerly TMC207) and delamanid (formerly OPC-67683).

We need a different approach to finding and treating TB. We need a campaign encouraging TB screening, similar to the campaign for HIV testing. By treating people with active TB much earlier, we can reduce the time that people are infectious.

People co-infected with HIV should be treated by the same health-care team for both conditions. The paternalistic Directly Observed Treatment (DOTS) model must be phased out and replaced with adherence models similar to those used for HIV. Treatment for drug resistant (DR) TB must be decentralised and must respect the Constitutional rights of patients. Facilities treating TB must have working infection control and implement contact tracing.

As with HIV, there needs to be a TB budget. The government's response to TB can be adequately planned and funded if government develops a needs-based budget.

Miners and former miners are disproportionately affected by TB. It is critical for the mining industry to improve work and living conditions, including the replacement of hostels with decent housing and lowering dust levels. The industry has to assist with regular check-ups of former miners, because they remain at very high risk of developing lung disease.

Prisoners are also at very high risk of TB. A study will soon be published showing that this risk is mainly due to overcrowding. The Department of Correctional Services must therefore take steps to reduce overcrowding in prisons. The special needs of children at risk of TB are often neglected. Efforts to prevent, diagnose and treat TB in children in South Africa are poor. Diagnostics and drugs are seldom tested as well in children as they are in adults. Children's needs must be prioritised.

The South African National AIDS Council released the first draft of the new National Strategic Plan for HIV and AIDS, STIs and TB (NSP) on the day of the meeting. The deadline for submissions is 7 September 2011. The NSP is an excellent opportunity to turn the recommendations of this meeting into policy that can be implemented to save millions of lives.

## **TB: What needs to be done?**

### **1. Protect the rights of people with TB and reduce TB vulnerability**

Poor people are much more likely to become sick with TB. But it is also much more difficult for poor people to access quality health-care so that TB can be diagnosed and treated. People with TB also face stigma and discrimination. This is why the response to TB must be consistent with the protection and promotion of human rights. This must be reflected in the new NSP and all other Department of Health TB policies.

### **2. Expand screening for and diagnosis of TB**

By screening more people for TB and diagnosing them earlier, we can treat more people, reduce mortality and reduce new TB infections. Through the HIV Counselling and Testing (HCT) campaign, more people have been screened for TB. Referral and follow-up systems must be strengthened so that people are not lost to follow-up and those diagnosed with active TB start treatment. TB screening must be increased to the scale of HIV testing by launching a TB-specific testing campaign.

Contact tracing of TB patients is another essential intervention. During the 2011 Budget Speech, Health Minister Aaron Motsoaledi announced that the Department of Health has begun rolling this out in some areas. This must urgently be expanded to all health facilities that treat TB.

### **3. Implement the GeneXpert and invest in better diagnostics**

TB diagnostics are far inferior to diagnostic tools developed for HIV. Today the gold standard for diagnosing TB is to grow it in culture from a patient's sputum. This is an expensive process that takes weeks. Most TB diagnosis is therefore carried out by looking for TB bacilli in sputum under a microscope. The turnaround time for this is about a day, but it is not very accurate. Many people with active TB, especially people with advanced HIV disease, have very few bacilli in their sputum and are therefore not diagnosed.

The GeneXpert is able to detect TB in many of the false negatives given by smear microscopy. Also, unlike smear microscopy, the GeneXpert is able to diagnose both drug susceptible TB and resistance to rifampicin. Resistance to rifampicin is highly correlated with resistance to isoniazid in South Africa and therefore with Multi-Drug Resistant (MDR) TB.

The GeneXpert provides test results in two hours. However the planned rollout of the GeneXpert is largely at district-level laboratories and not decentralized at primary health care facilities where people with TB present. Slow laboratory turnaround times and reliance upon transport systems will continue to delay results.

A costing in South Africa demonstrated that placing the GeneXpert in health facilities will increase the costs of rolling out the GeneXpert by 70%. (Source: [G Meyer-Rath](#)) But the test will only realise its true value if it is decentralised. While it is therefore essential to put pressure on the manufacturer, Cepheid, to reduce costs further, the roll-out to primary care facilities must still be budgeted for.

Diagnosing TB in infants and young children is very difficult and under-researched. Many children cannot produce a sputum sample. Private care facilities and NGOs generally use a nebuliser (mist machine) to produce a sputum sample from a child. Nebulisers are urgently needed in public health facilities to scale up diagnosis of TB in infants and children. Nebulisers can also help adults to produce sputum.

Finally while we must rapidly roll out the GeneXpert, which is possibly the best available TB diagnostic tool, we still need an affordable, rapid, electricity-free point of care TB diagnostic tool. Further investment in the development of such tools is strongly needed.

#### **4. Treat all people with drug resistant (DR) TB and decentralise DR TB care**

South Africa is failing to diagnose many cases of DR TB. According to Médecins Sans Frontières, in Khayelitsha only 54% of cases of DR TB are detected. (Source: [Presentation by Eric Goemare](#)) This figure is likely lower elsewhere in the country. Of those diagnosed nationwide, we are failing to retain and initiate many of them onto treatment. Beyond that, treatment targets are far lower than the number of patients diagnosed.

In 2010, nearly 10,000 cases of DR TB were diagnosed but only a little more than 5,000 were started on treatment. By the end of 2011, the Department of Health estimates it will treat 6,500 DR TB patients. (Source: [Norbert Ndjeka, Department of Health](#))

Without treatment, most patients with DR TB will die. Delaying treatment also increases the risk of transmitting DR TB. With the rollout of the GeneXpert, we can predict a large increase in the number of patients diagnosed with DR TB and therefore save many lives. It is estimated that the rollout of the GeneXpert will lead to the detection of 21,250 new cases of DR TB by 2013. (Source: [G Meyer-Rath](#)) But in order to save these lives, it is essential to set ambitious treatment targets to provide treatment to all people diagnosed.

With ambitious treatment targets, treatment must be decentralised to reach all people in need. Currently there is not enough space in clinics to treat all patients and treatment is highly centralised. The Department of Health estimated that as of April 2011, there was a shortage of over 750 beds for DR TB patients. (Source: [Norbert Ndjeka, Department of Health](#)) A properly costed and budgeted-for Community Health Worker policy is needed to scale up decentralised DR TB treatment.

#### **5. Improve access to second-line TB medicines**

Treating patients with DR TB is expensive and costs are expected to rise. In South Africa the average cost of treating an MDR TB patient is R1,200 per month during the injectable phase and R900 per month during the continuation phase. For XDR TB patients the prices rise to R6,000 per patient per month during the injectable phase and R4,000 per month during the continuation phase. (Source: Email Communication, Department of Health)

The shortage of suppliers of active pharmaceutical ingredients and finished DR TB medicines drives up the costs of these medicines and makes them vulnerable to shortages.

Capreomycin, an injectable used in South Africa to treat XDR TB, provides an example of some of the cost drivers in the TB medicines market. There is currently a worldwide shortage of the medicine as there is only one supplier of the active pharmaceutical ingredient.

Another problem is delayed regulatory approval of TB medicines. Para-aminosalicylic acid (PAS) is used to treat XDR TB, costing an average of R2,000 per patient per month. The medicine was not registered until 8 August 2011 and was being purchased via Section 21 authorisations. The price is expected to drop by around 20% now that the medicine is registered, but will remain extremely expensive. (Source: Email communication, Department of Health)

For most DR TB medicines, South Africa is paying higher prices than are available through the Global Drug Facility (GDF), which is the procurement arm of the WHO for DR TB medicines. South Africa should consider procuring medicines at lower prices through the GDF. It is vital that government take steps to reduce the costs of DR TB treatment.

There have been several stock-outs of standard first-line TB drugs. Breaks in the drug supply-line endanger the lives of patients and cause drug resistance. They must be prevented.

## **6. Compassionate access to experimental TB medicines**

There are a number of new TB medicines in the pipeline. They need further testing and are not yet ready to be registered. However, patients with MDR and XDR TB have to take treatment for approximately two years and they have a poor prognosis. They should be offered compassionate access to promising experimental medicines.

Bedaquiline (formerly TMC207) is the most advanced in clinical trials. It has been in development since at least 2004 and must be made available for compassionate use.

A phase II trial demonstrated that the addition of bedaquiline to MDR treatment regimens resulted in more patients converting much quicker to sputum-negative culture.

Clinicians in South Africa must apply to the Medicines Control Council for Section 21 authorisations to use bedaquiline. These authorisations are already being used to procure PAS, a far less effective and harder to tolerate medicine.

## **7. Scale up infection control measures**

Infection control is crucial if we are to address the TB epidemic, particularly the prevention of transmission of TB in health facilities. New facilities must be designed to reduce nosocomial transmission. All health care facilities must be provided with the resources for effective infection control. There must be an uninterrupted supply of N95 masks and this must be budgeted for. Patients and visitors should be educated on the importance of infection control. Community education programmes must be strengthened.

Health care workers exposed to nosocomial TB infection should be supported by the trade unions, the Department of Health and the Department of Labour to ensure they are properly looked after and receive the compensation they are entitled to.

## **8. Addressing the TB/ HIV co-epidemics**

In South Africa, TB/HIV co-infection is estimated at 73%. On 12 August 2011, Deputy President Kgalema Motlanthe announced that all patients with CD4 counts at or below 350 cells/mm<sup>3</sup> will now be eligible for antiretroviral treatment (ART). Expanding ART eligibility is important for reducing the number of active TB cases and government should be congratulated on taking this step. However the WHO recommends that all people co-infected with HIV and TB should be offered ART regardless of CD4 count. The Department of Health should implement this measure to improve TB cure rates.

Isoniazid preventative therapy (IPT) is now available in public health facilities for people living with HIV. IPT can reduce a person's risk of developing active TB. However, concerns were raised that IPT is being implemented in South

Africa without the condition that it only be offered to patients who are tuberculin skin test-positive (TST-positive). There is abundant evidence that IPT only benefits such patients. Moreover, it is potentially harmful to give IPT to TST-negative patients. As there were conflicting views on the use of IPT there needs to be further consultation involving clinicians and people living with HIV on its use and roll-out.

## **9. Reduce TB in the mines**

Miners are at very high risk for active TB because of their exposure to silica (causing silicosis) and heavy dust levels, as well as the crowded living conditions that many miners experience. The risk of contracting TB is 2 to 5 times higher if you have silicosis. The risk of contracting TB is 3 to 5 times higher for people living with HIV. An HIV positive miner with silicosis is 16 times more likely to develop TB than a miner without these risk factors. (Source: [Rodney Ehrlich](#))

For miners with silicosis or exposed to heavy dust levels, the increased risk of contracting TB is life-long. The high prevalence of TB in the mining population also exposes their families and communities to TB infection.

SANAC must convene a stakeholders' summit to consider solutions to the crisis of TB in the mines. The mining industry should take responsibility for improving living and working conditions, reducing this group's risk of contracting TB and supporting better access to health care. All miners should have access to decent, lifelong health surveillance and health care.

## **10. Address the barriers to scaling up access to antiretroviral therapy**

Expanding decentralised TB treatment that is integrated with HIV care effects human resources. Policies addressing specific groups of health care workers, such as the [Nurse Initiation and Management of ART](#) (NiMART) and the Community Health Worker policies, must be consistent and monitored taking into account the state's aim to revitalize primary care.

NiMART is a necessary intervention that will improve patient access and quality of care if our health systems are simultaneously strengthened. While much progress has been made in the past year, there are still significant barriers to standardised, efficient, effective expansion of HIV services in South Africa.

Barriers to the expansion of NiMART must be addressed urgently by finalising regulations governing scope of practice of all cadres of nurses, clarifying minimum standards for training and mentorship related to NiMART as well as clarifying standards for determining competency, relieving nurses of other time-consuming tasks that can be shifted to community health care workers, disseminating information on government decisions relevant to health care workers' roles and removing the barriers to nurses prescribing ART and for pharmacists and pharmacy assistants to dispense their prescriptions.

## **11. There needs to be political will from all government departments to deal with TB**

TB is intimately linked to poverty. The government departments responsible for improving access to safe drinking water, adequate nutrition and housing are also essential to the response to TB.

We need budgets that are evidence-based. There needs to be better accountability for TB spending at all levels of government, especially national and provincial. We currently do not know how much we are spending on TB. A conditional grant would be beneficial for monitoring TB expenditure. But the reporting mechanisms for TB expenditure must be improved.

The Department of Health and the National Treasury should work closely together, while co-operation between other Departments should be improved. People must be identified who would take responsibility for TB in their respective

departments.

All policies, whether for the decentralised treatment of MDR-TB or for the integration of HIV and TB services, should be costed and budgeted. All policies should be properly communicated so that they are understood and complied with.

## Presentations from the meeting

- Lihle Dlamini: [Living with TB](#)
- Francois Venter: [Why we need to be angry about TB](#)
- Kerrigan McCarthy: [The TB/HIV integration new national policy: Progress and challenges](#)
- Nesri Padayatchi: [Implementing TB/HIV integration: A practical experience](#)
- Stacey Stender: [NiMART, a key to integration: slow progress despite large training initiatives](#)
- Norbert Ndjeka: [The new MDR TB national policy and the state of implementation](#)
- Eric Goemaere: [Foreseeable problems with future 2nd line drug supply](#)
- Doug Wilson: [Dealing with MDR TB in the field](#)
- Rodney Ehrlich: [TB in the mines](#)
- Peter Bailey: [Union perspective on TB in the mines](#)
- Gary Maartens: [IPT](#)

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