A patient-centred approach to drug resistant tuberculosis treatment in the community: a pilot project in Khayelitsha, South Africa

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Photo: John Freeman

DR-TB patient at home with family

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Acknowledgments

The implementation of the decentralised drug resistant TB pilot project in Khayelitsha and its ongoing development is made possible through the efforts and cooperation of a number of organisations and individuals. These include the City of Cape Town Health Department, the Provincial Government of the Western Cape (Department of Health), and the health care staff working under difficult conditions in all Khayelitsha clinics.

Finally, and most importantly, we acknowledge our patients and their fortitude in confronting the numerous challenges they face living with drug resistant TB.

TAC demanding access to community based care

Summary

Increasing numbers of patients are being diagnosed with drug resistant tuberculosis (DR-TB) in Khayelitsha. Diagnosing and providing effective treatment to sufficient numbers of patients, the majority of whom are also HIV-positive, are central to reducing further disease spread, but these seemingly simple tasks have historically been complicated by long delays in diagnosis due to the absence of appropriately adapted diagnostic tools and many months of treatment with highly toxic drugs that are difficult for patients to tolerate.

This report describes the implementation of a pilot project providing decentralised, patient-centred care and treatment for patients with DR-TB in Khayelitsha. The project is based on the premise that more patients will be diagnosed and successfully treated if they are supported to follow treatment in their homes and communities, rather than being isolated in specialised hospitals. In addition, building capacity to manage DR-TB at the primary care level will enable the scaling up of treatment provision, so that more patients can access high quality care.

Key aspects of the pilot model of care include:

- Increasing DR-TB case detection through community awareness programmes, staff education and screening of household contacts
- Encouraging the rapid diagnosis of DR-TB and decreasing the delay in initiating appropriate treatment
- Applying lessons from HIV/AIDS treatment, including a patient-centred approach to adherence, by providing counselling, education and support to patients and their families to empower them to understand the disease, observe infection control measures and take responsibility for completing their treatment
- Providing training and ongoing support to health care workers to enable them to treat and support patients
- Implementing infection control measures in clinic settings, patients' homes, and in the community
- Improving access to treatment for complex cases through specialised outreach clinics for adult and paediatric DR-TB, and inpatient facilities in Khayelitsha
- Establishing a monitoring and evaluation system to measure programme impact and assist with programme management
- Disseminating lessons learned to contribute to patient care beyond Khayelitsha

The development of the model of care for decentralising DR-TB management in Khayelitsha is an ongoing process. By evaluating different approaches we hope to be able to provide valuable lessons for other resource-constrained settings struggling with high levels of HIV/DR-TB co-infection. Early results suggest some improvements, but due to the complex social and economic circumstances of many patients, maintaining treatment for the required two years remains a challenge.

Central to this project is the assumption that the majority of DR-TB transmission occurs before patients are diagnosed and started on effective treatment – again highlighting the urgent need for better rapid diagnostic tools to detect DR-TB – and that the benefits of offering a service that is attractive and conducive to seeking care outweigh the risks of further household and community transmission after diagnosis.

Such a long time to take treatment

"These drugs are so horrible to eat every day. After nearly a year and a half, I thought it was just too much; I couldn't keep taking all those pills. I thought it would be okay if I stopped taking them. But they told me if I didn't keep going I might get sick again and then I would have to start again from the beginning with all the injections. So, I kept going with the pills and now I am cured. It was such a long time."

DR-TB patient

Informal settlement in Khayelitsha

Photo: John Freeman

Introduction

Khayelitsha is the largest township in South Africa's Western Cape Province. It lies 40 kilometres from Cape Town and is home to at least 500,000 people, over half of whom are unemployed. Khayelitsha has one of the highest burdens of both HIV infection and tuberculosis (TB) in the country and globally. In 2007, antenatal HIV prevalence was 30% and the case notification rate for TB was at least 1,500 per 100,000 people per year – among the highest TB incidence rates in the world [1].

Médecins Sans Frontières (MSF) started working in Khayelitsha in 1999 supporting a pilot programme to prevent mother-to-child-transmission of HIV. In 2001, the first patient in Khayelitsha received antiretroviral therapy (ART) through a pilot programme supported by MSF that has been subsequently integrated into the Western Cape Province ART programme. By the end of 2008, more than 10,000 people have been successfully started on life-saving ART in Khayelitsha.

In Khayelitsha, HIV and TB care and treatment are provided through an integrated approach, enabling a "one-stop" service for co-infected patients. There is a relatively high level of treatment success – 81% of patients who have never had a prior TB treatment episode are reported to be successfully treated. This figure compares favourably with other TB programmes in South Africa. However, treatment outcomes for patients who have been previously treated are less encouraging – only 62% receive a successful treatment outcome [1].

In response to the growing number of patients with DR-TB, a plan was formulated by MSF and the City of Cape Town Health Department to develop a community-based pilot project for the treatment and support of people with DR-TB in Khayelitsha. The main components of this project are described in this report.

Photo: John Freeman

Protecting staff

Burden of DR-TB in South Africa and national policy for addressing DR-TB

The World Health Organization (WHO) estimates that there are more than 14,000 MDR-TB cases arising in South Africa each year [2], but these figures are dated; they are derived from the last national survey conducted in 2000-2001 [3] and are likely to be an under-estimate. Even so, although the percentage of MDR-TB among all TB cases is

Drug resistant tuberculosis definitions:

In this report, DR-TB refers to patients who are infected with TB bacteria that are:

- Resistant to at least two of the most important first-line anti-tuberculosis drugs (rifampicin and isoniazid), therefore defined as multidrug resistant or **MDR**
- Resistant to rifampicin alone, therefore defined as rifampicin mono-resistant
- Resistant to rifampicin, isoniazid and two of the most important classes of second-line anti-tuberculosis drugs, a fluoroquinolone (such as ofloxacin) and an injectable drug, either amikacin, kanamycin or capreomycin, therefore defined as extensively drug-resistant or **XDR**

Patients can be infected with strains with a wide range of possible combinations of resistance to different drugs. For this reason, we use the term drug resistant TB (DR-TB) throughout this report. The labels MDR and XDR are often limiting in terms of treatment regimens and their use encourages patients to be labelled and further stigmatised by their disease. In reality, they are all the same disease but require different medications in order to cure people.

Anti-tuberculosis medications used to treat TB in South Africa

First-line drugs (for drug-susceptible TB):

- Rifampicin, isoniazid, ethambutol, pyrazinamide, streptomycin

Second-line drugs (for drug-resistant TB):

- Ofloxacin, kanamycin, ethionamide, terizidone (cycloserine), capreomycin, para-amino-salicylic acid (PAS)

suggested to be comparatively low (2.6%), given the extremely high overall TB incidence rate, the estimated incidence of MDR-TB is amongst the highest in the world (Figure 1). It is therefore of critical importance to diagnose and treat as many of these cases as possible in order to reduce transmission and control the emerging epidemic.

There were more than 24,000 cases of MDR-TB diagnosed over the five-year period from 2004-2008 in South Africa [4]. Of these, 7% were found to be infected with XDR-TB strains. Although extremely high, these figures are certainly a fraction of the estimated DR-TB in South Africa and suggest that large numbers of people are becoming ill and dying without ever being diagnosed.

In 2002, the national TB programme in South Africa adopted the WHO strategy of "DOTS-Plus" for the diagnosis and treatment of MDR-TB patients. The aim was to provide standardised treatment for all patients diagnosed with MDR-TB across the country. Under the protocol at the time, drug susceptibility testing (DST) to rifampicin and isoniazid (the minimum definition for MDR) was performed. If MDR-TB was diagnosed, then DST was performed against ethambutol. The standardised treatment for the intensive phase was five drugs for four months (kanamycin, ethionamide, ofloxacin, ethambutol and pyrazinamide) regardless of the time it took for a patient's positive sputum culture to become negative, followed by three drugs (ethionamide, ofloxacin and ethambutol) for 12 to 18 months. Pyrazinamide was continued for extensive cavitary disease. If ethambutol resistance was diagnosed, then ethambutol was replaced with terizidone.

Figure 1: Estimated MDR-TB incidence and proportion MDR-TB of all TB for South Africa, the Russian Federation and India [2]. Incidence figures are per 100,000 population per year.

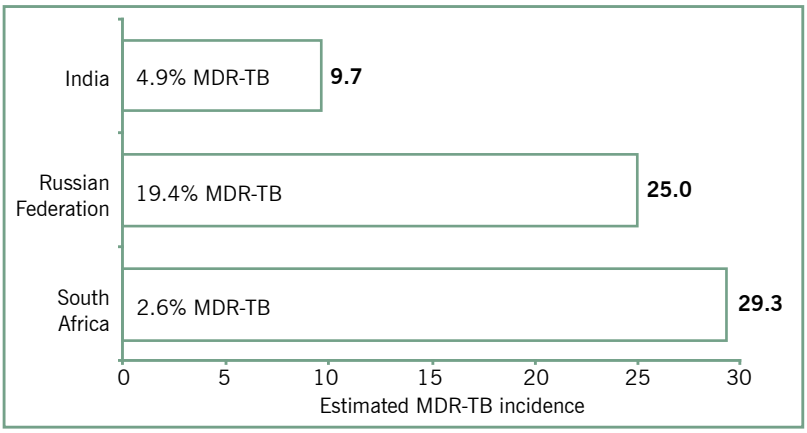


Photo: John Freeman

DR-TB patient just starting treatment

Although treatment outcomes were acceptable among those patients completing the full course of treatment, the high default rate led to relatively poor overall outcomes [5]. In addition, it now appears that substantial numbers of MDR-TB cases may have had resistance to other first-line drugs, including to ethambutol, for which conventional DST is often unreliable [3, 6, 7]. This means that a proportion of patients may have been treated with inadequate regimens containing insufficient 'active' drugs, thus inadvertently contributing to the development of further drug resistance.

A consultation process around the guidelines for treating DR-TB in South Africa was started in 2006 and led to a strengthening of the initial standardised regimen. It is now recommended that treatment consist of five drugs for six months, instead of four months (kanamycin, ethionamide, pyrazinamide, ofloxacin, and either terizidone or cycloserine) followed by a continuation phase of four drugs (instead of three drugs) for at least 18 months (ethionamide, pyrazinamide, ofloxacin, and either terizidone or cycloserine). This regimen includes either cycloserine or terizidone irrespective of ethambutol susceptibility testing. It is also recommended that the duration of the intensive phase, which includes the injectable drug kanamycin, continues for at least four months after negative culture of sputum [8]. Furthermore, there are plans to provide DR-TB testing for all patients diagnosed with TB in South Africa, with the rollout of a rapid line-probe molecular test for TB drug resistance. The moves to diagnose more cases earlier and to strengthen standardised treatment regimens will likely improve treatment outcomes for people with DR-TB.

The current national policy in South Africa is one of centralised care and treatment for DR-TB in regional, specialised treatment centres. Diagnosed patients are admitted to a centre for at least six months, usually into congregate wards. As these centres are often far from patients' homes, they are often cut-off from their families and feel abandoned. Consequently, there is commonly a high rate of default, with up to a third of patients refusing to remain in care [5, 9].

Photo: John Freeman

Mask wearing in clinic waiting areas

Hospitalisation or ambulatory treatment for DR-TB?

A number of arguments are put forward to support a centralised approach to DR-TB management. Hospitalisation allows for dealing with the complexity of treatment such as side effects, and the need to change regimens during the course of treatment. Also, adherence to treatment can be more closely monitored. The main argument is around the need to reduce community transmission by 'isolating' patients.

However, there is little evidence that prolonged hospitalisation improves adherence and prevents transmission, and there are even indications to the contrary. Specialised hospitals for DR-TB are often far away from patients' homes leading to feelings of isolation and neglect and resulting in high rates of default. Forcing DR-TB patients to stay in hospitals could have the unintended consequence of discouraging people from being diagnosed and therefore driving the epidemic underground, leading to increased community transmission [10]. Finally, there is now evidence that nosocomial transmission (within health facilities) of highly resistant TB strains occurs, even while patients are receiving second-line therapy [11, 12].

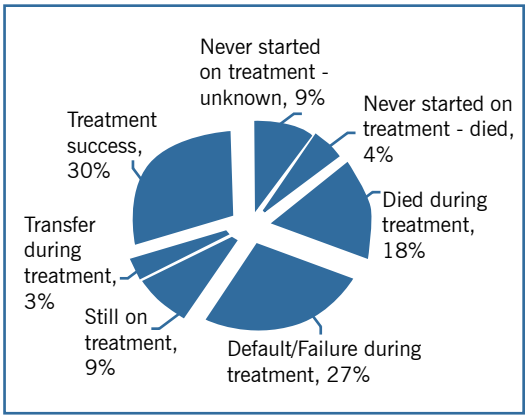
Arguments for centralised TB management (treatment is complicated, adherence must be monitored) are similar to those initially put forward to support the centralised management of HIV, particularly ART, but these have been dismissed due to both pragmatic reasons and human rights concerns [13]. Today, there is a broad consensus that in order to improve early health-seeking behaviour, promote adherence to medication, and minimise defaulting, HIV care is best provided in the primary care setting, as close as possible to patients' homes and communities [14]. These lessons for patient support are clearly applicable to DR-TB, all the more so because in South Africa, the majority of DR-TB patients are likely to be additionally HIV-infected and therefore require ART.

Drug resistant tuberculosis (DR-TB) in Khayelitsha

Situation analysis

In early 2007, MSF and the City of Cape Town Health Department conducted a review of DR-TB diagnosis and treatment in Khayelitsha. At the time, although patients were being diagnosed in Khayelitsha clinics, there were often long delays in accessing treatment, contributing to disease spread and mortality. Patients initially treated in hospital were discharged to clinics where there were limited clinical skills in managing the disease and infection control policies were not widely known or adhered to. Importantly, there was little support for patients to assist them in continuing their long and difficult treatment course. As the majority of patients with DR-TB in Khayelitsha are HIV-positive, any delay in the provision of appropriate second-line treatment increases the risk of morbidity and mortality, as well as the risk of transmission to the family and other contacts (who are often also HIV-infected).

Figure 2: Outcomes of patients diagnosed in 2005-2006 in Khayelitsha, based on a retro-spective review of incomplete clinic records.



As there was no systematic registration of patients diagnosed with DR-TB at that time, an accurate assessment of patient numbers and treatment outcomes is difficult prior to 2007. Nonetheless, of the 181 patients identified up to the end of 2006 whose records could be found, there were high rates of defaulting before and during treatment, and high rates of treatment failure and death (see Figure 2). Overall, 30% of patients were recorded as being successfully treated and 70% suffered a poor treatment outcome.

Current DR-TB burden

Of the nearly 6,000 people diagnosed with TB in Khayelitsha in 2008, 196 have been diagnosed with DR-TB to date, a substantial increase from previous years (Figure 3). While there may be a real increase in the incidence of DR-TB, the increased numbers are probably more a reflection of better case detection from year to year. Even so, given the lack of systematic testing, the real DR-TB burden may be substantially higher. Currently, only patients who have been previously treated for TB are eligible for TB drug resistance testing. Although only five cases were found to be infected with XDR-TB at diagnosis in 2008, this is also likely to be an under-estimate due to inconsistent second-line testing. Preliminary results from a survey now underway in Khayelitsha suggest that around 6% of all diagnosed TB patients may be infected with strains resistant to at least rifampicin. This would mean that close to 400 patients would be diagnosed with DR-TB each year if all those diagnosed with TB were to be tested.

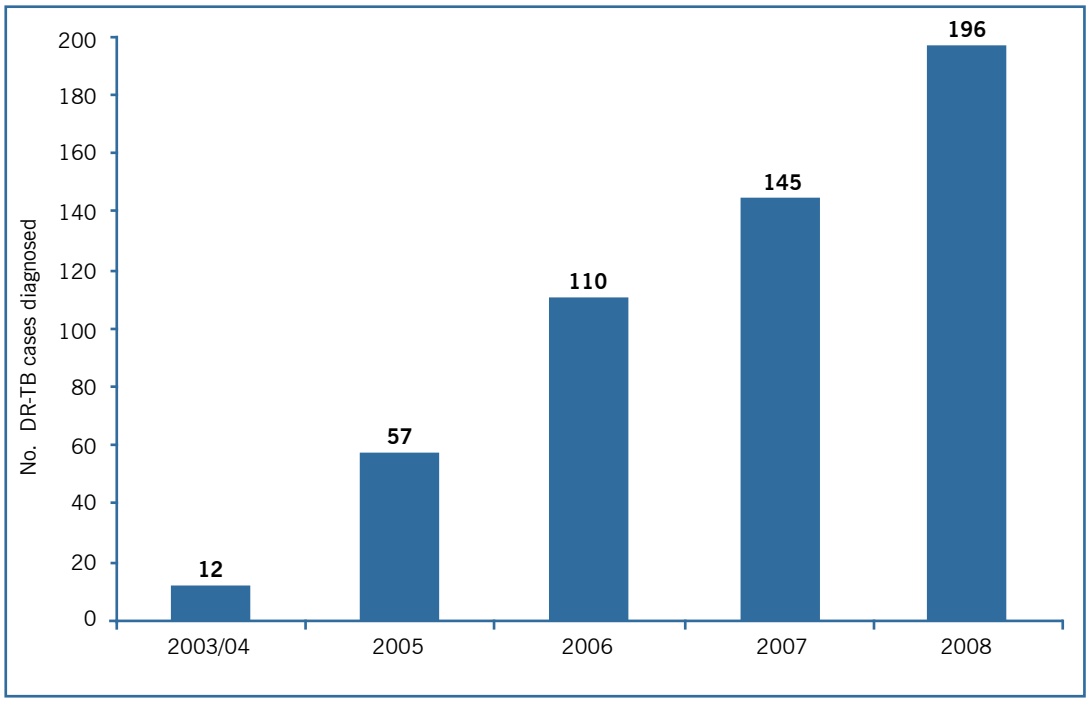
Photo: John Freeman

Clinic waiting area

Photo: John Freeman

In 2008, 74% of DR-TB cases diagnosed in Khayelitsha were also HIV-infected. This compares to 58% among DR-TB cases diagnosed prior to 2006, suggesting that more HIV-positive cases than before are being diagnosed, and presumably reflecting improved early mortality (i.e. prior to 2006, more HIV-infected patients were dying before being diagnosed with DR-TB).

Figure 3: Number of DR-TB cases diagnosed in Khayelitsha by year (note: the number of cases in 2008 is likely to increase due to the delay in receiving results from the laboratory).



The decentralised model of DR-TB care in Khayelitsha

Objectives

The principal aim of the Khayelitsha DR-TB pilot project is to improve the care and treatment of people with drug-resistant TB in Khayelitsha through a patient-centred approach.

Primary objectives include:

1. Improving the diagnosis of DR-TB
2. Improving treatment outcomes
3. Decreasing DR-TB transmission

A secondary objective is to develop a model of care that may be applicable to other peri-urban settings and to document and disseminate lessons learned.

Objective 1: Improve the diagnosis of DR-TB

In Khayelitsha, as elsewhere in South Africa, patients who have previously been treated for TB are offered culture and drug susceptibility testing (DST) when they are screened for suspected TB again. Currently, 81% of patients in this category receive DST in Khayelitsha, a major improvement on the 56% receiving DST in 2007 [1]. In addition, any new patient who remains sputum smear positive at the end of the intensive phase of treatment is also offered culture and DST, along with suspected TB cases who are considered to be at high risk for DR-TB. This last category includes health care workers, anyone with exposure to a prison setting, and contacts of known DR-TB cases.

Strategies employed in Khayelitsha to improve case detection include the prompt screening and follow-up of household contacts of confirmed DR-TB cases and improving staff education and training in order to provide drug resistance testing to as many TB patients in high-risk groups as early as possible. By aiming to offer testing for likely DR-TB cases early, it is hoped that the number of patients who die between giving a sputum sample and being started on appropriate treatment can be reduced.

Since early 2008, DST is performed using a rapid polymerase chain reaction (PCR)-based method that detects DNA mutations contributing to resistance for isoniazid and rifampicin (Hain GenoType MTBDRplus). This method, which gives results within 24 hours, can be used directly on either sputum smear positive specimens or on positive cultures. Although this method is likely to have contributed to shortening the time between taking a sputum sample and starting a DR-TB patient on treatment, there are a range of other factors contributing to the delay in initiating treatment, apart from the time taken in the laboratory. These include difficulties in matching laboratory results to patients in clinics and locating and recalling patients to deliver the diagnosis. Work is underway to improve these areas.

Objective 2: Improve treatment outcomes

Improving the diagnosis of DR-TB through more rapid diagnosis and treatment initiation is likely to have a positive impact on treatment outcomes as people will start treatment when they are less sick. Other key strategies to improve treatment outcomes include:

- Education and counselling for patients and their families
- Early adherence counselling and defaulter tracing
- Education, training and support to health care workers
- Prompt identification and treatment of side-effects from DR-TB drugs
- Antiretroviral therapy for all HIV-positive DR-TB patients (irrespective of CD4 count)
- Adjustment of treatment regimens when DST indicates second-line drug resistance
- Maintenance of a detailed electronic register of diagnosed patients, their treatment, and outcomes.

Photo: John Freeman

DR-TB patient taking treatment in the clinic

The current model

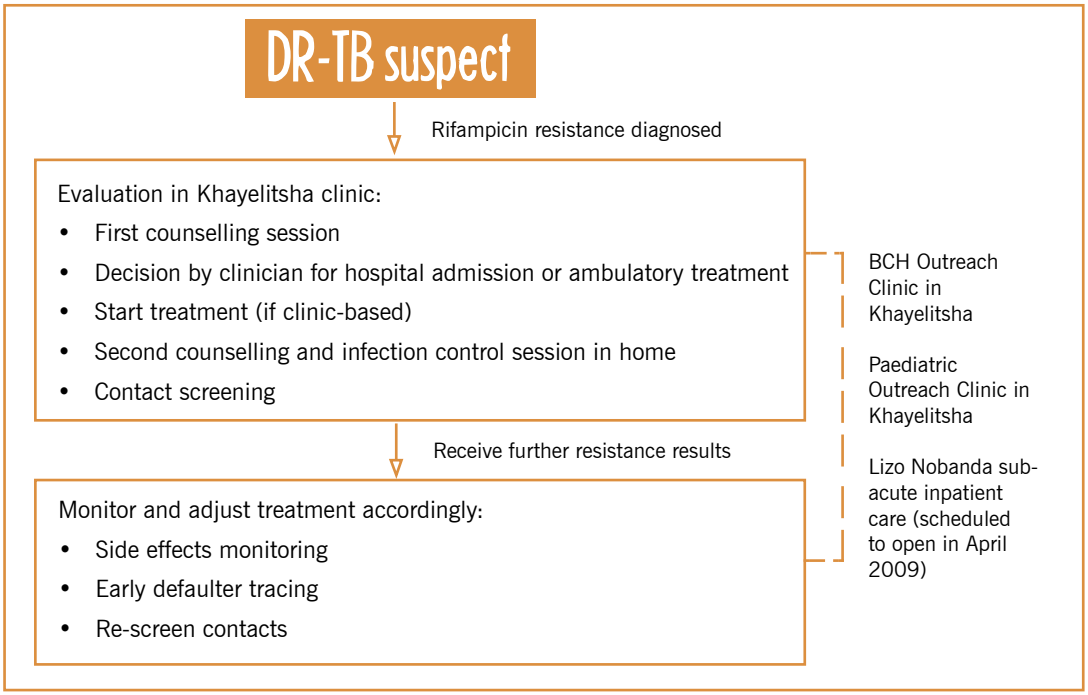
Patients diagnosed with DR-TB in Khayelitsha are given their diagnosis at the local primary health care clinic. They are then counselled by a dedicated DR-TB counsellor and treatment is started by the clinic TB medical officer. Patient data is sent to the referral DR-TB hospital, Brooklyn Chest Hospital (BCH), so the patient can be registered and prescriptions authorised. Patients who are severely ill and requiring hospitalisation are referred directly to BCH for admission by the clinic TB doctor. Hospitalisation is also recommended for patients who may find it difficult to attend the clinic every day to receive their treatment. Currently, any patient diagnosed with XDR-TB is also routinely admitted to BCH.

Once a month, the medical officer from BCH conducts an outreach DR-TB clinic in Khayelitsha. Patients diagnosed in the previous month are reviewed jointly at this clinic by both the BCH medical officer and the local TB doctor. In most cases, only the patient medical record is reviewed – doctor consultations are reserved for patients requiring more complicated treatment regimens or with concomitant diseases (other than HIV). Generally, two to three patients are seen each month at the outreach clinic, while the remainder are discussed through medical record review. This process streamlines treatment initiation for patients while ensuring appropriate clinical care and encouraging sharing of clinical skills. (see Figure 4 on next page)

Education and training

One of the key findings of the initial review in Khayelitsha was the lack of training and capacity among clinic staff to manage DR-TB cases appropriately. Education, ongoing training, and support for difficult cases are therefore important components of the model of care in Khayelitsha. To date, more than 100 health care workers have been trained in the management and support of DR-TB patients. This includes nursing staff, TB clerks, assistants and counsellors. Knowledge of DR-TB treatment and management was assessed post-training through a written exam, which was passed by more than 95% of staff. Materials, in the form of training manuals and treatment protocols are also distributed widely and updated regularly. Medical officers in

Figure 4: Current model of care for DR-TB patients diagnosed in Khayelitsha.



Khayelitsha have also received additional intensive training in DR-TB management through both international training courses conducted by MSF and local courses conducted jointly by the City of Cape Town Health Department and MSF. To further build capacity among staff, monthly meetings to update knowledge and discuss programme issues and complex clinical cases are conducted in Khayelitsha.

DR-TB treatment

Patients with rifampicin-resistant TB are started on the standardised treatment regimen defined by the national South African guidelines. When second-line resistance results become available, often up to two months into treatment, the aim is to modify the treatment regime to provide at least three drugs to which the infecting strain is suspected to be susceptible. However, anecdotal data suggests that there is a high proportion of pre-existing resistance to ofloxacin among DR-TB patients in Khayelitsha. In this case, there is a chance that further resistance will have developed in the time between starting treatment and receiving second-line DST results. Consequently, it may be beneficial to strengthen the initial starting regimen still further by including a newer fluoroquinolone other than ofloxacin (moxifloxacin) along with terizidone or cycloserine. This would enable more treatment options if the infecting strain is found to be resistant to more drugs.

A difficult case for the medical team

A 39 year old man who is HIV-positive was diagnosed with pulmonary TB. Because he also had chronic hepatitis, he was treated for TB using a normal, but “liver-friendly”, regimen for drug susceptible TB. Six weeks later he was started on antiretroviral treatment (tenofovir, lamivudine, efavirenz) based on his CD4 count of 102 and hepatitis. Despite receiving treatment, his weight continued to drop, losing 7 kg in a month. A result was then received from the laboratory showing that he was infected with a TB strain resistant to both isoniazid and rifampicin (MDR-TB). The patient was then started on the standard DR-TB treatment regimen (kanamycin, ethambutol, ofloxacin, pyrazinamide and ethionamide).

However, due to deteriorating kidney function, the kanamycin injections were stopped and ethambutol was reduced to alternate days rather than daily. Tenofivir was also removed from the ART regimen as a potential contributor to renal dysfunction. Unfortunately, a routine hearing test showed significant hearing loss, most likely also caused by kanamycin injections. Despite a negative sputum culture at one month of DR-TB treatment, the two month sample was culture positive. The combination of concomitant hepatitis infection and side effects from currently available DR-TB medication leave the medical team with few options to provide effective DR-TB treatment for this man. This case highlights the complexities of providing concomitant HIV and DR-TB treatment and particularly the need for newer drugs to treat drug resistant TB.

Lizo Nobanda:

A community step-down care facility in Khayelitsha

The majority of patients with DR-TB do not require acute hospital care. They may, however, require support to take anti-tuberculosis medications, deal with side effects, or overcome other difficulties to receiving treatment at home. To provide sub-acute care, a small inpatient facility for DR-TB patients is being established in Khayelitsha. There is also a need for a facility to provide palliative care for those for whom no further treatment can be offered. Lizo Nobanda, a former HIV hospice in Khayelitsha, is currently under renovation and expected to open in April 2009 with capacity to accommodate 12 patients. It is expected that patients will mostly be admitted for short stays of a few weeks rather than months – the aim will be to provide options for both inpatient and outpatient treatment when needed in an environment that is closer to patient's family and friends.

Helping others with DR-TB

"I was not happy when they told me I had TB – I'd never had TB before. But I started taking the treatment anyway. But then it didn't seem to work, I was getting sicker and sicker. When they told me I had this drug resistant TB, I was so upset – I couldn't stop crying and I was so weak I couldn't really walk. They wanted me to go to hospital because I was so sick but I refused. I wanted to stay at home with my family. I started the treatment and they told me all about this disease and how to stop giving it to others. I have been on treatment now for 11 months and I feel much better. I am even working as a counsellor, helping other people with DR-TB to cope with the treatment. My family are very proud of me."

DR-TB patient

Photo: John Freeman

Clinic consultation

Improved treatment outcomes can also be achieved through appropriate treatment of patients with concomitant HIV infection. Lack of ART is clearly a major contributor to early death from DR-TB [15]. Of the 115 DR-TB patients diagnosed in 2008 who were also HIV-positive, only one-third were receiving ART at the time of diagnosis. Of those not on ART, one-half had CD4 levels below 200 cells/mm^3. The recommendation in the Western Cape is that all HIV-positive DR-TB cases are eligible for ART irrespective of immune status, and should start one to two months after initiating anti-tuberculosis therapy.

Patient support and counselling

Treatment for DR-TB is long and difficult for patients. Many of the second-line anti-tuberculosis drugs used to treat DR-TB have significant side-effects. Some are common and although debilitating are relatively manageable, such as nausea and vomiting, while others are more severe and lifelong, such as deafness. Taking these drugs continuously for up to two years therefore requires an enormous commitment from patients. Supporting patients through education and counselling is of paramount importance in improving adherence to treatment and reducing default from treatment.

In Khayelitsha, DR-TB patients are offered counselling as soon as possible after diagnosis. Currently, this is done by a dedicated MSF DR-TB counsellor supported by a peer educator. Both are former DR-TB patients and, as with ART adherence by HIV-positive lay health workers and peer educators, are therefore able to counsel patients based on first-hand experience. Patients also receive a second counselling session, preferably in their home and

DR-TB patient support group

Photo: John Freeman

A child waiting for treatment at Site-B TB clinic in Khayelitsha

The power of the support group

"I didn't know much about MDR before, all I knew was that you have to go hospital and that this hospital is a place that people never come back from – they die there. So, I thought I was going to die too. After I talked to the counsellor, I went to the support group at my clinic and I saw all these people taking treatment and looking good. Now I am thinking I will be okay. I was very worried about my baby at this time – that she would have the same disease as me. She was tested and was negative. Now I sleep in a separate room from my baby and I am very careful about not giving my disease to my family."

DR-TB patient

with their family members present. The aims of this session are threefold:

- To educate patients and families about DR-TB and its treatment
- To assess the risk of transmission of DR-TB in the household and develop strategies to minimise this risk
- To counsel household members and close contacts about the need for screening to establish if other family members are also suffering from tuberculosis and offer preventative treatment to children who may be at risk

The DR-TB counsellor is also available to counsel patients who are having difficulties adhering to treatment or who miss clinic appointments. A significant number of Khayelitsha DR-TB patients are hospitalised at some point, in either Brooklyn Chest Hospital or DP Marais Hospital. In order to support patients in these facilities and reduce feelings of abandonment and neglect, the DR-TB counsellor visits each of these facilities at least once every two weeks. The aim is to act as a link between patients and families and to provide additional counselling to hospitalised patients as required.

Patients are invited to attend peer support groups conducted weekly in a number of Khayelitsha clinics. Either the DR-TB counsellor or peer educator attend these sessions in order to answer questions about side-effects, treatment regimens, infection control, or other issues that may arise in discussions. These fora are also excellent for encouraging patients just starting on treatment – they can see and talk to people who have been on treatment for much longer, and learn how others cope with taking their treatment. Currently, at least 40 patients are attending support group meetings each week in Khayelitsha.

Objective 3: Decrease DR-TB transmission

In addition to improving treatment outcomes for individuals, the decentralised pilot project aims to reduce the risk of transmission of drug-resistant strains of TB in the community. Because TB is spread by the airborne route, anyone breathing air containing TB bacteria is at risk of infection. As the provision of appropriate treatment reduces infectiousness of individuals, it is assumed that most TB transmission occurs prior to infectious patients being diagnosed and receiving treatment. The early diagnosis of patients with DR-TB is therefore a key strategy in reducing transmission. However, even though treatment will reduce infectiousness, there remains a significant risk of ongoing transmission from patients starting treatment and those for whom

treatment is failing. Infection control is therefore important to implement in patients' homes, in health care facilities, and in the community at large.

In addition, screening and monitoring of close contacts of diagnosed TB cases for active TB disease is done to ensure that people at high risk for DR-TB are tested as soon as possible. Similarly, but on a much broader level, providing information to the community at large regarding the risk of DR-TB aims to stimulate people who think they may have TB to seek a diagnosis. The Treatment Action Campaign (TAC) and other community groups play a key role in mobilising community awareness about the signs and symptoms of TB, including DR-TB, as well as the importance of infection control.

Reducing the risk of DR-TB transmission in patients homes

The patient-centred approach to DR-TB treatment aims to allow patients to be in their own homes and, to the extent possible, resume a normal, autonomous life. In order to minimise the risk to other household members, an initial assessment is conducted and a plan developed that will result in a safer home environment. The assessment considers factors such as the vulnerabilities of household members – young children, people with HIV and other chronic illnesses, along with space available in the home and ventilation. From this assessment a risk-reduction plan is drawn up that will include providing education about TB transmission and the need for cough hygiene, and may include plans to provide separate sleeping arrangements for the patient and strategies to reduce contact with vulnerable household members. Paper masks are also distributed to be worn by the patient when they are in overcrowded and closed conditions with others.

To date, more than 100 homes have been assessed. In the majority of cases, households have been able to make arrangements for the patient to sleep separately and have been able to minimise contact between the patient and vulnerable household members. Sometimes young children are able to stay elsewhere until the patient becomes culture negative (usually within two months). Families are instructed on the need to maximise air flow and ventilation and occasionally additional windows have been installed in homes to increase ventilation. Ironically, given that the majority of DR-TB patients in Khayelitsha live in corrugated iron shacks in informal settlements, ventilation through the many gaps in building materials is often considered adequate. In a few rare cases, the project has resolved to build an additional room on the shack to provide sufficient space for the patient.

While these interventions are unlikely to reduce the risk entirely in households, they will reduce risk

Patient information leaflet on infection control in the home

Difficult to continue taking treatment

"When I started treatment, they told me it would be difficult and I would have to take the pills for 2 years. But, I didn't realise it would be as hard as it was. The injections were really painful – after about 2 months I was so tired of going to the clinic and getting the injections that I stopped going. They came to see me and ask why I wasn't coming anymore, I told them I'd had enough. Then they explained that this was the only way to get better and that if I stopped taking treatment I could make my family sick as well. Now, I've been on treatment for a year and a half, the injections have stopped and I feel much better."

DR-TB patient

for the relatively short period of time between the patient receiving a diagnosis and becoming non-infectious through treatment. Home visits also aim to empower patients and households to reduce their own risk and to have more control over their disease.

Reducing the risk of DR-TB in Khayelitsha clinics

Patients not admitted to hospital currently attend clinics daily to receive medication and therefore may be seen as a risk. However, the majority of DR-TB transmission in clinics probably occurs prior to patients being diagnosed with DR-TB. As a result the focus should be on providing a safe clinic environment for all staff and patients, based on the assumption that anyone may be infectious, regardless of a DR-TB diagnosis. This is important not only to reduce the risk of nosocomial transmission, but also to lessen stigma and discrimination against people living with DR-TB.

To this end, infection control policies have been drafted for each clinic in Khayelitsha. These include the three levels of TB infection control: administrative, environmental, and personal protection controls. To date the implementation of these policies has been variably successful: implementation has contributed to improving natural ventilation in some clinics (for example, through the installation of waiting areas with improved ventilation) and ensuring provision of paper masks for all clients sitting in waiting areas. However, significant challenges remain, including improving patient flow through clinics and empowering health care staff to take responsibility for infection control.

Photo: John Freeman

Preventing the spread of TB in clinics

Community involvement

In South Africa, media reports have painted a picture of drug-resistant TB as a killer disease for which there is no cure, requiring virtual quarantining of patients who are widely blamed for having the disease based on an incorrect assumption that they have not taken their first-line TB drugs correctly [16]. Not surprisingly, these reports have encouraged community fear and stigmatisation of those suffering from DR-TB. There has been a general view that these patients should be removed from the community to reduce the risk to others. Unfortunately, this view is likely to exacerbate the problem by leading to high rates of defaulting from treatment, and discouraging people from testing for fear of the result.

To encourage community acceptance and support for ambulatory treatment, the pilot project aims to educate community groups about the risk posed by DR-TB, about what can be done to reduce that risk, and about the fact that most DR-TB patients can be cured provided they are supported to take their full treatment course, despite the long duration and toxicity of the drugs currently available.

To date, a number of community organisations, such as TAC, the Khayelitsha Health Forum, and other groups providing home-based HIV care and HIV peer support, have received a two-hour interactive training session conducted in the local language, Xhosa. Feedback from these sessions has been excellent and it has often been difficult to keep up with demand. More recently, the pilot project has started to engage with the taxi owners associations and taxi drivers to communicate about the risk of TB transmission in crowded taxis with closed windows. The focus has been on encouraging taxis to keep windows open and to encourage cough hygiene among taxi users.

The next steps in the community campaign will be to try to reduce the risk of TB transmission in other specific settings such as shebeens (local bars) and community halls, and encourage community acceptance of mask-wearing in public, and awareness of TB symptoms to encourage early health-seeking behaviour.

Contact tracing

Given the often crowded living conditions in Khayelitsha, household transmission is likely to contribute substantially to the overall burden of DR-TB. Active case-finding among household contacts may therefore be an effective strategy to identify more cases and get them started on treatment earlier.

All adult household and close contacts of diagnosed patients are screened for symptoms suggestive of TB. Those that are symptomatic are encouraged to give a sputum sample and are offered culture and drug resistance testing. Young children aged five and under are all routinely screened through a specialist paediatric outreach clinic held monthly in Khayelitsha. Screening aims to diagnose active TB disease that may be drug resistant and to assess children who may benefit from preventative treatment to reduce the risk of active DR-TB disease from developing. When an active DR-TB case in a child is confirmed bacteriologically, the child is treated according to their resistance profile. Otherwise a treatment regimen is devised according to the resistance profile of the index case. Preventative treatment regimens are also designed according to the resistance profile of the index case.

DR-TB stigma

"As I am a teacher I am very worried about what other people will think. When I was told I was HIV-positive and needed treatment, I wanted to get my medications from my own doctor and not go to the clinic in front of everyone. But then, my doctor told me I had this MDR and that I had to go to the clinic. I didn't want to take treatment; I didn't believe I could get this disease. Then they talked to me for a long time and I went to the support group at the clinic. Now I go to the clinic every day to get my pills – even the pills for HIV. My family help me a lot too."

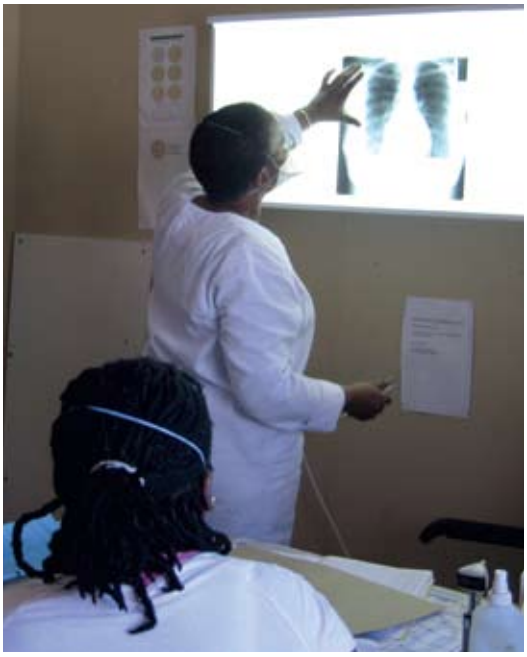
DR-TB patient

Photo: John Freeman

TB infection control in the clinic waiting area

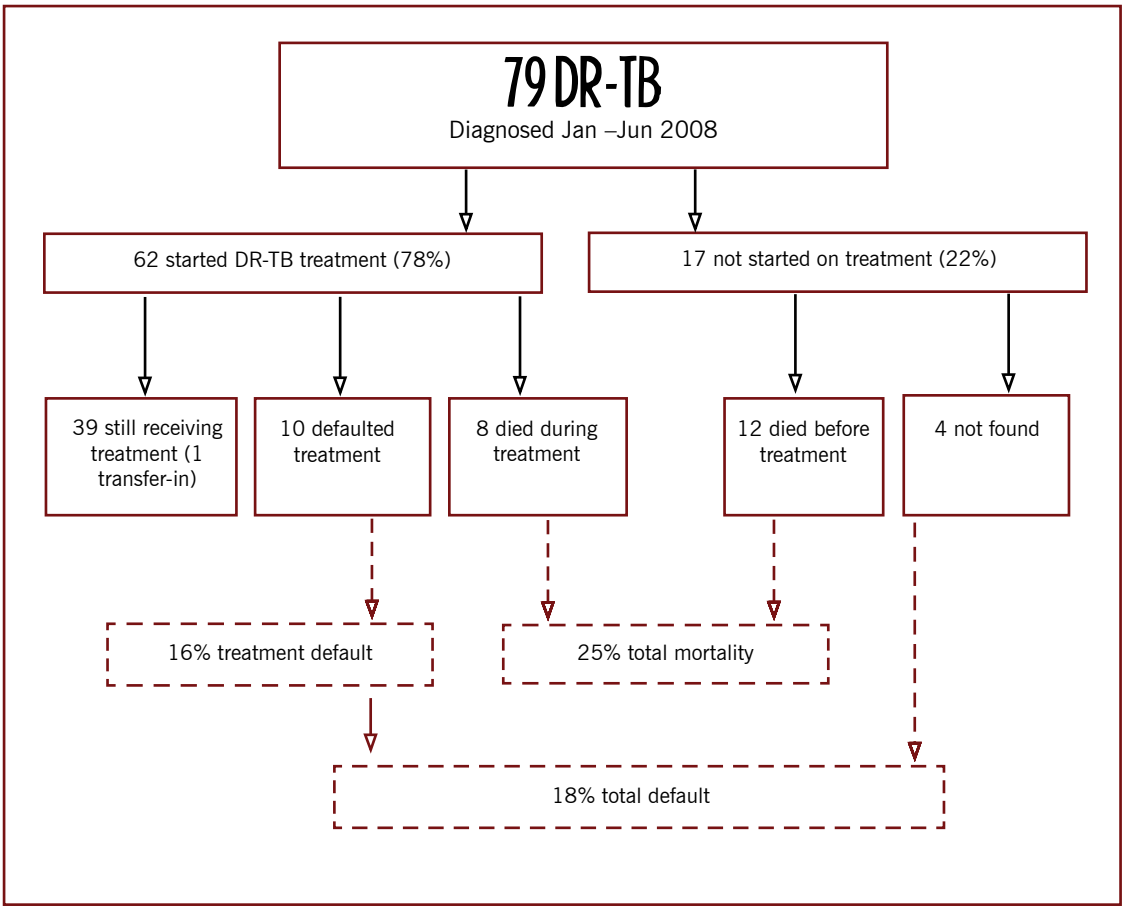
Early results

While the implementation of the Khayelitsha DR-TB pilot project remains in its early phases, we hope that the interventions will result in improved treatment outcomes for individuals and contribute to mitigating the effects of the epidemic of DR-TB in this setting. Early results suggest that we have some way to go to see significant improvements. From the 79 patients diagnosed in the first half of 2008, we can see that mortality before treatment remains high – 15% died before treatment could be started at a median of only 29 days after sputum sampling (Figure 5). As the majority of these patients died before the lab result was received, HIV status remains unknown for many. Default before treatment has improved, as has default during treatment, although it remains high at 16%. This may reflect the greater proportion of patients starting treatment, including those who perhaps would not have started treatment without extensive counselling. Given that most patients who default treatment do so within the first year of treatment, we are hopeful that this figure will not increase substantially over time.



Specialist DR-TB outreach consultation in Khayalitsha

Figure 5: Early outcomes for DR-TB patients diagnosed between January and June 2008 in Khayelitsha.



Challenges

Clearly, while significant progress has been made in some programme areas, there is no magic bullet for radically improving treatment outcomes for DR-TB patients, particularly those who are diagnosed late and those who are HIV co-infected. Significant challenges to the scale up and implementation of a patient-centred model of care for DR-TB remain. Our premise is that the benefits gained in terms of improved case detection and improved treatment outcomes will outweigh any further transmission risks in the community. Although this is difficult to assess, any approach that is more patient-centred is likely to result in more cases diagnosed and more patients completing the full course of treatment.

Given the dearth of new drugs that may shorten treatment for drug resistant tuberculosis, treatment will remain lengthy and difficult for patients for the foreseeable future. These inherent difficulties, combined with the complex social and economic circumstances of many patients in a setting like Khayelitsha, suggest that DR-TB treatment will remain problematic for years to come: patients will wait too long for a diagnosis, will have difficulties in adhering to treatment, and may default from treatment. Challenges also remain in implementing infection control practises in Khayelitsha clinics. Novel approaches are required, particularly in relation to ensuring infection control in homes and reducing stigma in the community.

The development of the model of care for decentralising DR-TB care in Khayelitsha is an ongoing process. Through evaluating different approaches and determining what works and what does not, we hope to arrive at a model that may be applicable and replicable in similar settings elsewhere. Included in these adaptations are the level of staffing required, different approaches to infection control, and the development of better tools to monitor and evaluate progress. Innovation is key to developing models of care adapted to local contexts and to the burden of DR-TB in different settings and to encouraging the development of better diagnostic tools and drugs to enable earlier detection and more tolerable treatment for patients.

While not cost-free, the investments required to support decentralised DR-TB treatment at the primary care level are far below those needed to support the centralised model of patient isolation in hospital wards. And most importantly, this approach shows some evidence of increasing earlier diagnosis of DR-TB, improving treatment outcomes, and promoting awareness and openness about the disease.

Photo: John Freeman

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Cough Hygiene

Cover your mouth and nose when you cough. There are three ways of doing this:

Use your upper arm

Use a tissue

Use a surgical mask