Turning the tide on TB:
Tackling DR-TB in Myanmar

Current practice and challenges involved in diagnosing and treating drug-resistant tuberculosis in Myanmar
Acknowledgements

We would like to pay tribute to all those patients with drug-resistant TB whose will to live healthy lives and whose courage in tackling the disease are an inspiration for health providers to continue improving and expanding care, and we would like to thank the Ministry of Health of the Republic of the Union of Myanmar, Médecins Sans Frontières, the World Health Organization and other partners for their efforts to develop much-needed care for drug-resistant TB in the country.

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Glossary

DOTS directly observed treatment short-course
DR-TB drug-resistant tuberculosis
DST drug susceptibility testing
MDR-TB multidrug-resistant tuberculosis
PMDT programmatic management of drug-resistant tuberculosis
MSF Médecins Sans Frontières/Doctors Without Borders
NTP National Tuberculosis Programme
PAS para-aminosalicylic acid
TB tuberculosis
WHO World Health Organization

Definitions

Drug-resistant tuberculosis (DR-TB): Describes all strains of TB that show resistance to one or more of the first-line drugs. The term is used in this pamphlet to include all of the possibilities listed below.

Monodrug-resistant tuberculosis (mono DR-TB): Describes TB that is resistant to any one first-line drug.

Polydrug-resistant tuberculosis (poly DR-TB): Describes strains that are resistant to more than one first-line TB drug, but not to both isoniazid and rifampicin.

Multidrug-resistant tuberculosis (MDR-TB): Describes TB that is resistant to at least both isoniazid and rifampicin, the most powerful first-line TB drugs.

Extensively drug-resistant tuberculosis (XDR-TB): Describes TB that is resistant to isoniazid and rifampicin, and also to second-line drugs, including at least one from the class of antibiotics known as fluoroquinolones, and at least one of the three injectable second-line drugs (capreomycin, kanamycin and amikacin).
Drug-resistant tuberculosis: A global emergency

Drug-resistant tuberculosis (DR-TB) is an airborne and highly infectious disease that is now a pandemic. Médecins Sans Frontières (MSF) projects across the globe are seeing unprecedented numbers of people with DR-TB, not only among patients who have previously failed TB treatment but also in patients newly diagnosed with TB — a clear sign that DR-TB is being transmitted in its own right. The most recent global data shows the highest rates of DR-TB ever recorded — an estimated 630,000 people. Yet this estimate is considered conservative and experts believe we are seeing just the tip of the iceberg due to limited diagnosis of drug-resistant forms of TB worldwide.

The best way to prevent DR-TB from occurring is to treat TB correctly so that drug-resistance does not develop in the first place. Once it has emerged, the best way to stop DR-TB from spreading is to start patients on treatment as quickly as possible, as the risk of infection drops rapidly as soon as patients start taking the right medication. To get the epidemic under control, many more people with DR-TB need to be diagnosed and put on treatment as quickly as possible, with the help of new, simple models of patient-centred care and rapid diagnostic tools which are available today.

However, the current drugs used to treat DR-TB are old, toxic and have to be taken for two years, including eight months of painful injections and up to 20 pills per day. These drugs have side effects ranging from debilitating nausea, vomiting and skin rashes to more serious side effects such as deafness, renal failure and psychosis.

There is clearly an urgent need for a shorter regimen to improve outcomes for DR-TB patients. A potential interim solution for certain contexts, including Myanmar, could be the ‘short course regimen for multidrug-resistant tuberculosis (MDR-TB)’ trialled on patients who had not previously been exposed to second-line drugs. The Van Deun study in Bangladesh described a treatment success rate of 87.9% and a default rate of 6%, which is significantly lower than default rates from standard regimens.

Such promising developments point toward the real challenge: to find a new, shorter, less toxic and more effective treatment regimen. Today, a historic opportunity exists to do so, with new TB drugs coming to the market for the first time in around half a century. As new drugs become available, more research is urgently needed to find the most effective combination of drugs that works best for patients.

In the meantime, much more can be done to better tackle the crisis with the tools currently available. National TB programmes can scale up treatment programmes by utilising new diagnostics and patient-centred treatment approaches; while countries can show leadership in pushing for and supporting innovation, registering newly approved drugs, developing compassionate use programmes, and generally laying down the foundations for new treatment regimens as and when they become available.
New drugs

The drugs currently in phase II or later clinical trials are derived from four classes of compounds: nitroimidazoles, diarylquinolines, oxazolidinones and diamines.

Bedaquiline was registered by the US Food and Drug Administration (FDA) in December 2012 and has been recommended for use in adults with pulmonary MDR-TB by the World Health Organization (WHO).³

Delamanid has been submitted to regulatory bodies and is awaiting registration.

Potentially these two new drugs could be available for use in treating MDR-TB in the near future.

In addition, existing drugs not yet licensed for MDR-TB have shown promise, such as linezolid, clofazimine and moxifloxacin, as have those at an earlier stage in the drug development pipeline such as PA-824 and Sutezolid.⁴,⁵,⁶,⁷,⁸
Around the world:
A snapshot of MSF’s experience treating DR-TB

As the number of patients diagnosing positive for drug-resistant forms of TB increases in MSF’s projects around the world, the organisation is scaling up provision of DR-TB care, currently working in 21 countries.

Over the past three years MSF has treated around 4,000 people with DR-TB using a variety of treatment approaches with an emphasis on decentralised and patient-centred care.

However, this remains a fraction of what is urgently needed, and MSF is committed to advocating for increased DR-TB care worldwide, along with new and improved tools, notably a new treatment regimen.

Swaziland: One-stop service
Extremely high rates of HIV and DR-TB co-infection in Swaziland have resulted in MSF setting up ‘one-stop services’ where co-infected patients can be treated for both diseases at the same time. The focus is on integration, antiretroviral initiation and strong psychosocial support, due to the increased risk of adherence problems associated with a very high pill burden and unpleasant side effects.
Uzbekistan: Ambulatory from day one
In Uzbekistan, MSF’s innovative comprehensive DR-TB project provides ambulatory directly observed treatment (DOT) from day one. Having received the correct treatment, patients soon become less infectious. Hospital care is used only for patients who are seriously ill or whose side effects cannot be managed at home. This model of care was chosen for the context as it allows more patients to be treated with the resources available, while reducing the burden on the healthcare system as well as reducing the risk of nosocomial transmission. Generally patients in this programme are happier to be treated in their home environment. MSF plans to move from district to district, training TB specialists to support the continuation of the programme. However, convincing local people and medical professionals that ambulatory treatment works is challenging, while the logistics are complicated, requiring regular training and supervision.

India: Treating the most complicated cases
DR-TB is a huge problem in India, which has the second highest number of cases globally. While the government is making efforts to tackle the problem, many people remain unable to access treatment within the public health system. MSF’s joint HIV and DR-TB treatment programme in Mumbai focuses on those people with the most complicated forms of the disease. Most of MSF’s DR-TB patients are co-infected with HIV; an increasing number of patients have extensive forms of resistance to most TB drugs; a few suffer from chronic hepatitis B; and some are adolescents, for whom adhering to treatment is especially hard. The integrated care approach enables patients to access the range of medical care and support they need under one roof, and allows medical staff to best manage complex cases.

Uganda: Home is where the heart is
In rural northern Uganda, where the country’s only specialist TB hospital is a day’s travel away, MSF ran a successful decentralised, community-based DR-TB programme hand in hand with the Ministry of Health from 2009-12. While the number of patients in the programme was small (with just 17 patients), there were no defaulters, no treatment failures and no deaths. MSF put this success down to the fact that the patients received care within or near their homes, with volunteer village health team workers accompanying them to local clinics for injections, and other drugs taken under supervision at home. Patients expressed a strong preference for this model of care, which was seen to aid their recovery from the disease. Patients benefited from the support of trained counsellors and family and friends in coping with side effects and adhering to the treatment, while staying in their villages allowed them to farm their own land, earn money and stay involved in community life.
Myanmar: Achievements and challenges of treating drug-resistant TB so far

Myanmar is among the 22 countries with the highest TB burden in the world. The TB prevalence is twice the regional average and nearly three times the global average, with an estimated 300,000 people with the disease. The number of people with drug-resistant strains of TB is growing at an alarming rate, with an estimated 8,900 people contracting DR-TB in Myanmar each year. In 2007, with no treatment available, the outlook was bleak for the patients already diagnosed with DR-TB, not to mention the thousands undiagnosed, and it was clear that, unless urgent action was taken, the DR-TB crisis was not going to go away. The decision was made to set up a two-year pilot programme run by Myanmar’s National TB Programme (NTP) in collaboration with MSF and supported technically by the WHO. After some delays in obtaining approval from the Green Light Committee and importing the drugs, the pilot project was finally launched in July 2009.

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<td>2007</td>
<td>Myanmar adopts Stop TB Strategy</td>
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<td>July 2009</td>
<td>Two-year pilot programme starts with 309 patients</td>
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Pilot project (2009-11)
MSF constructed specialised DR-TB wards in the grounds of Yangon’s Aung San hospital (a specialist TB referral facility), while UNITAID/Expand TB/FIND supported the set up of a bio safety level-3 laboratory capable of doing solid and liquid culture, linked to the supranational laboratory in Bangkok. A national DR-TB committee, including experts from the hospital, medical school and retired clinicians, decided which patients to enrol. The NTP enrolled 240 patients and MSF enrolled 69 patients, 31% of whom were HIV-positive.

The model of care initially involved two months in hospital, followed by 21-22 months of ambulatory treatment either in township health centres or patients’ homes. Counselling and psychosocial support were an important element of the approach.

A number of adaptations and improvements were made during the pilot phase, including:
- The NTP shifted its policy to hospitalise only severely ill patients and/or patients with social problems.
- The national DR-TB committee meetings to discuss enrolments were increased in frequency from every two to three months to a theoretical once a month.
- The geographical entry criteria were expanded from 10 to 22 townships.
- In this particular context, home-based care was found to be labour-intensive, inflexible and often unpopular with patients, so patients were given the choice between receiving DOTS at home or in MSF clinics. Patients under NTP care received DOTS in township health centres.

Programmatic Management of DR-TB (2011-present)
Begun in July 2011, and largely funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Programmatic Management of DR-TB (PMDT) has built on the experience of the previous two years, enrolling a further 558 patients (as of first quarter of 2013), with treatment now provided by the NTP in 38 townships with technical support from the WHO.

Model of care:
- **Ambulatory** – with no hospitalisation period, except for severe cases or clinical investigations.
- **Decentralised and community-based** – with patients receiving DOTS in township health centres, regional HIV/TB clinics or at home.
- **Integrated TB/HIV care** – with medical staff trained to provide care for both diseases.

Outcomes
The NTP enrolled 861 patients between 2009 and the first quarter of 2013. From the cohort (3rd Q 2009-4th Q 2010), the outcomes of the 184 patients were: 131 (71%) cured; 31 (17%) died; 20 (11%) defaulted; and 2 (1%) failed.

One hundred new patients were enrolled in MSF’s programme between July 2009 and May 2013. Of these, 25 (25%) were cured, 16 (16%) defaulted, one (1%) failed and 35 (35%) are still under care. Eight patients (8%) died before treatment could begin and 15 patients (15%) died during the course of treatment.
Challenges

- The number of patients defaulting from treatment is high, especially in the MSF cohort, while success rates are low. The following section (Components of programme) highlights how the current model of care attempts to tackle these significant challenges.
- More flexibility and adaptations in treatment provision are needed for key populations such as intravenous drug users, men who have sex with men, commercial sex workers, migrants, and conflict-affected populations.

Components of programme

Case finding

People suspected of having DR-TB are identified by screening patients at risk of catching the disease. These include retreatment cases, especially failures; HIV-positive TB patients; and contacts of known DR-TB patients.

Challenges

- It can be difficult to identify DR-TB suspects who live outside the catchment areas.
- There is currently a lack of HIV testing and counselling within NTP services (although systematic counselling and testing is planned in the near future).

Diagnosis

The GeneXpert MTB/RIF device, which can diagnose resistance to rifampicin in less than two hours, has been available in Myanmar since March 2012. The NTP plans to expand its use to more than 20 facilities. Confirmation is by Hain test, available in Myanmar since 2012, which takes two to three days. Samples are also sent to the National TB Reference Laboratory for liquid culture and drug susceptibility testing (DST). Future plans include putting all rifampicin-resistant patients diagnosed with GeneXpert MTB/RIF who are HIV co-infected or severely ill on empirical treatment while waiting for their DST results.

Challenges

- Diagnostic capacity is currently limited, with just two laboratories (in Yangon and Mandalay) able to carry out DST using liquid culture. This method theoretically takes three weeks to produce results, but the heavy workload and processing time means that diagnostic turnaround often takes longer. Additionally, human resources and structural constraints limit the diagnostic capacity at a peripheral level. However, a third lab is currently being renovated.
- A number of patients were diagnosed so late that they died before being able to start treatment, having potentially infected others before diagnosis.
- An agreed algorithm for the early start of treatment needs to be developed. Eligibility for DST (including for second-line drugs) and treatment enrolment also needs to be included in expansion plans.
- Significant numbers of diagnosed DR-TB patients are waiting for treatment due to delays in the supply of second-line drugs.

Enrolling patients

Decisions about which patients to enrol were previously made by the national DR-TB committee, but since June 2013, this has been decentralised to smaller committees at the regional level.

Challenges

- The frequency of committee meetings – which in theory happen once a month –depends in reality on the availability of DR-TB drugs in Myanmar. In 2012, a total of five meetings were held, while during the first half of 2013 only two such meetings took place.
- Only people with MDR-TB are eligible for enrolment in the programme. The management of monodrug-resistant and polydrug-resistant TB cases are not included in the current guideline.
“I really thought I was going to die before the treatment began”

“I started suffering from this illness in 2006, so it’s taken five years for me to get treatment and overcome it. During that time I had to wait a year from being diagnosed with MDR-TB to getting on the treatment programme. I remember I kept being told, ‘The programme will start soon, the programme will start soon’. And all that time, I was feeling worse and getting weaker by the day.

Towards the end of the wait, I was bedridden, coughing all the time and with constant shortness of breath. I’m a hairdresser, but I had to stop working in the salon — I didn’t have the strength even to sweep the floor. I really thought I was going to die before the treatment began.

See this tattoo on my hand? It means ‘perseverance’. I got it at a pagoda festival when I was 15. But during the wait, and then during the treatment, it took on a new meaning for me. It reminded me that I had to hold on, have courage and not give up. I really needed that, because when I was finally admitted to the treatment programme, the side effects were so bad I almost wished I wasn’t being treated.

In the mornings I used to hate having to take all the drugs – there were so many. Seventeen tablets plus a lot of smaller ones, and that’s not including the drugs for numbness and dizziness.

It was tough. Eighteen patients started at the same time as me, and of those five died, including one who killed himself; another died at the end of treatment. At the beginning, they told me there were no guarantees, but I was determined I was going to be one of the ones who survived. I just kept looking at my tattoo to remind myself of what I had to do. I feel like a much stronger person now. In the future I know I can face anything, no matter how hard, because of the experience I’ve been through with MDR-TB.”
Social care package
To assist and motivate patients to adhere to their treatment, patients receive:

- 20,000 kyats (US$22-23) per month
- Dry food rations (with support of the World Food Programme)
- Transport costs
- Accommodation (for those patients unable to live at home)

Challenges
- Provision of a social care package is not yet common practice within the NTP and is dependent on funding availability.
- Even when a social care package is provided, social and financial problems still cause some patients to abandon treatment.

Treatment support
Counselling and psychosocial support are vital in helping patients adhere to the long and difficult course of treatment. MSF employs two counsellors and has provided training in counselling for NTP staff, including nurses, medical doctors and social workers (in Yangon, Lashio, Saggai and Mandalay). Two cured DR-TB patients are also employed by MSF to share their experiences and provide psychosocial peer support.

Self-help patient groups have been shown to be helpful in providing support and motivation in MSF's HIV programme, and plans are underway to set up similar groups for DR-TB patients. The experience of World Vision Myanmar with self-help groups for drug-susceptible TB will also be considered.

Challenges
- With just one social worker per NTP hospital, not all patients have the opportunity to receive psychosocial support from a trained counsellor.
- Community volunteers have not yet been involved in DR-TB treatment.

Infection control
Once patients start treatment, their potential to infect others reduces significantly, so getting as many patients on treatment as soon as possible is vital. Other measures to control TB infection in Myanmar include:

Township health centres
- Cough triage helps to identify patients with TB symptoms so they can be kept separate from other patients.
- Environmental controls (open windows, standing fans) maximise the flow of fresh air and natural light into buildings.
- Separate waiting areas and appointment times reduce contact between patients with drug-susceptible and drug-resistant TB.
- Patients are provided with surgical face masks.
- Staff are provided with N95 respirators.
- Patients are given health education and instructed in cough etiquette.

In the community
- Patients, family members and caregivers are counselled on how to minimise the spread of infection (cough etiquette, sleeping in separate rooms, improving ventilation).
- Caregivers are provided with N95 respirators.

Challenges
- Stigma is a major issue in Myanmar, so patients may be unwilling to wear masks for fear of being identified as having TB.
- While Myanmar’s two specialist TB hospitals (in Yangon and Mandalay) have separate areas for DR-TB patients, there is no such provision in township hospitals, where infection control measures (including providing staff with N95 respirators) are frequently inadequate.
Patients often live in overcrowded accommodation with little light or ventilation, making it difficult to control the spread of infection within the community.

Working in partnership
A key element of the approach to treating DR-TB in Myanmar is working in partnership with other health entities accountable for TB care, with clear divisions of responsibility in line with expertise and resources.

The NTP and MSF work collaboratively and enjoy a relationship of trust, holding regular case discussions in Yangon’s Aung San hospital, and holding joint trainings of medical doctors and counsellors. The NTP refers HIV-positive cases to MSF and provides first and second-line drugs, while MSF provides ancillary drugs for treating opportunistic infections.

Challenges
Collaboration between the NTP and MSF needs to be extended to other parts of the country where MSF works and where it has identified an urgent need to start DR-TB treatment within existing medical programmes.

Other organisations with the capacity to support universal access to DR-TB treatment need to become engaged in the push to scale up treatment in Myanmar.

Drugs supply
The drugs for treating DR-TB are ordered by the United Nations Office for Project Services (UNOPS) and the Global Drug Facility (GDF), after approval from the Global Fund.

Challenges
- Long lead times for drug procurement (including forecasting, identifying funding, ordering and delivery) has affected the number of patients put on treatment. The situation is improving gradually: in 2011 and 2012, the drugs did not arrive until the final quarter of the year; in 2013 they arrived in June. This has delayed treatment for people diagnosed with the disease and increased the risk of their infecting others.
- There is insufficient access to drugs for managing side effects.
- No buffer stock of drugs currently exists.
- Apart from capreomycin, there are no alternative second-line drugs available for patients with toxicity, while there is a lack of access to new drugs (for example for compassionate use).

Resources – staff and training
The skill level of staff involved in DR-TB care is crucial, as having poorly trained staff may increase the risk of patients interrupting treatment, provoking further drug-resistance. Staff training is therefore prioritised, with both MSF and the NTP running joint trainings for TB clinical management and counselling.

Challenges
- With the geographical expansion of DR-TB care to 38 townships, general health staff within the NTP are at risk of becoming overstretched. Currently staff are incentivised to visit those patients receiving home-based care twice a day, but if patient numbers increase, this may become increasingly difficult to manage.
The way forward: Turning the tide on drug-resistant TB

As a result of hard work and commitment by everyone involved, all the fundamental elements required to treat DR-TB are now in place and the programme is up and running. The next step will be to strengthen the basics, to address the challenges highlighted and to make improvements that will allow DR-TB treatment and care to be scaled up throughout Myanmar, using all the means currently available. Meanwhile, as more patients are encouraged to access treatment, and more people believe that a cure is possible, the stigma of seeking treatment is also likely to be reduced.

However, the current 24-month regimen presents a major challenge to scaling up treatment. From the perspective of patients, two years of toxic treatment with serious side effects is a huge personal challenge. It also presents a significant socio-economic burden for the many patients who find themselves unable to work and support their families for extended periods while on treatment. From a public health perspective, the cost of scaling up Myanmar’s DR-TB programme is simply unfeasible without a major injection of funds from donors. Putting 8,900 new patients on DR-TB treatment would cost Myanmar in the region of US$44.5 million per year.

To ease this situation, a shorter regimen, as previously highlighted in this paper, could be explored in parallel with current programmes. The shorter regimen, which has the support of the WHO, would need to be tested in Myanmar through a pilot project under proper conditions. If the outcomes of such a project turned out to be as positive as those in other countries where the regimen has been applied, the NTP would be in a much stronger position to scale up its treatment of DR-TB countrywide.

Meanwhile, new drugs coming to the market for the first time in nearly half a century provide an unprecedented opportunity, offering the potential for developing new regimens that are patient-centred,
shorter, more effective, with fewer side effects, and also affordable. The drug pipeline for TB is the best it has ever been, with 10 drugs in clinical testing (see ‘New drugs’ on page 5). Both bedaquiline and delamanid are completely new classes of antibiotic with no reported resistance and could be game-changers in tackling the DR-TB epidemic.

The TB community must urgently work out how best to use the new drugs in a new and much improved treatment regimen – ideally without an injectable component, so that care can be undertaken in the community. Access to the new drugs will depend to a large extent on the manufacturers making the new drugs available for research, and on countries like Myanmar swiftly registering the drugs once they have been approved. In the meantime, Myanmar should explore compassionate use programmes, support innovation, and push for affordable access to new drugs.

**Recommendations:**

A treatment approach should be adopted and promoted based on the principles below in order to accelerate universal access to DR-TB treatment and care.

1. **Model of care:**
   - Ambulatory, with patients receiving care as outpatients.
   - Decentralised, with patients receiving care close to their homes.
   - Comprehensive, with DR-TB care integrated with HIV services.
   - Patient-centred, the sharing of responsibility between the healthcare provider and patient with regards to the treatment and care.

   This should include provision for: effective case finding strategies; rapid diagnosis; patient support packages; context-specific home-based care; and psychosocial and peer support.

2. **An improved treatment regimen should be validated in Myanmar – in the short-term using current second-line drugs, and in the long-term ensuring access to new drugs as and when they become available.**

3. **Current WHO recommendations should be adopted on treating all forms of DR-TB, and guidelines should be drawn up for treating groups of patients with specific needs, such as pregnant women.**
Specific recommendations:

Diagnostics: The current time lag between patients being diagnosed and put on treatment should be reduced. Algorithms should be reviewed to allow for treatment to start earlier, even when cases have not yet been completely confirmed.

Infection control: All efforts should be made to achieve early diagnosis and treatment – the best form of infection control.

Measures to control nosocomial infection should be strengthened in both township health centres and regional hospitals.

Drugs: A new, shorter, less toxic and more effective treatment regimen is crucial to turning the crisis around both in Myanmar and globally. New drugs coming to the market for the first time in nearly half a century offer a historic opportunity to find an improved regimen – requiring urgent research. New drugs must be made speedily available to patients in Myanmar as soon as they become obtainable.

Sustainable funding should be put in place and increased efforts should be made by the donors and the agencies involved in supply management for an uninterrupted supply of WHO prequalified TB drugs, including buffer stock.

Domestic funding should be increasingly pursued for first-line drugs, going hand in hand with strengthening national drug regulatory mechanisms.

Drugs should be made available, free of charge, for the treatment of side effects.

Partnerships: All non-governmental organisations with capacity (such as the TB Union and MSF) should provide continued support in strengthening health systems at all levels, as well as providing technical support.

Knowledge should be shared both regionally and internationally.

Human resources: Medical students should be trained in the prevention and management of DR-TB as part of overall training in the public health aspects of TB.

More counsellors should be trained to provide psychosocial care.

Funding: Myanmar is one of the five early applicants to the Global Fund’s new funding model and the only country that submitted successful concept notes for the three diseases (TB, HIV and malaria). Within the US$82 million allocated by the Global Fund to the NTP for TB control in Myanmar for 2013-16, it is essential that sufficient funds are accorded to tackling DR-TB, along with the necessary implementation support and expertise. Whilst the Global Fund, USAID and the Three Millennium Development Goals Fund will support the government’s ambitious plans to expand HIV/TB and MDR-TB care, all parties, both national and international, must maintain a sense of urgency for reliable and consistent funding in the future.
References


