



# MANAGING MULTIDRUG-RESISTANT TUBERCULOSIS

## Legal implications

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### An urgent – and man-made – problem

South Africa faces one of the worst tuberculosis (TB) epidemics in the world. As a result of inappropriate or ineffective treatment, multidrug-resistant TB (MDR-TB) has arisen in all nine provinces, placing a severe burden on our health system.

#### High case load, despite low prevalence

- MDR-TB makes up 2,9% of TB cases.
- A recent MRC study showed that there are 6 000 cases of MDR-TB in South Africa per year.

#### High risk

- The infectious stage of MDR-TB (positive sputum smear) in actively coughing patients is very contagious.
- HIV-positive individuals (who have compromised immune systems) are at very high risk of developing active MDR-TB after infection.
- Children are at high risk of developing active MDR-TB once they are infected.
- On average, 10% of otherwise healthy individuals infected with MDR-TB will develop active disease in their lifetime.

#### Expensive treatment

- Drugs cost R30 000 per patient, compared to R300 for drug-susceptible TB.
- Treatment takes up to 24 months.
- Patients need to be hospitalised for 4–6 months.
- Laboratory investigations are extensive (monthly bacteriological cultures).
- Drug toxicity necessitates additional laboratory screening (eg. liver and kidney function, audiometry).

#### What is MDR-TB?

Multidrug-resistant TB (MDR-TB) is essentially a man-made problem.

In the majority of cases, it emerges when a TB patient receives inappropriate or ineffective treatment, which allows naturally-occurring resistant TB bacteria to survive and multiply.

Strains of MDR-TB can also be transmitted directly to susceptible individuals, such as children and those also infected with HIV.

## Active MDR-TB

When people with strong immune systems are exposed to MDR-TB, they can become infected, but won't normally become sick. The MDR-TB bacteria will remain in their bodies in a dormant state, and can't be passed on to others.

However, once an infected person's immune system is compromised – due to illness, a poor diet, stress or HIV – that person can develop active MDR-TB.

At a more advanced stage of the disease (when sputum tests detect organisms under the microscope), and once a patient develops a cough, they can infect others in their immediate environment.

## The human element

- The side effects of MDR-TB drugs are severe.
- Some drugs have to be given by painful injection every day for four months.
- Patients are away from family and work for extended periods.
- More than 30% of patients default on their treatment.
- If patients default too often, or treatment fails to work, a decision may have to be made to stop treatment.

**Patients who default on treatment, and those whose treatment fail, become chronic MDR-TB carriers and pose a significant threat to public health.**

## Dilemma: public vs. individual rights

**In order to protect communities, MDR-TB must be effectively treated, and patients with active MDR-TB must be prevented from infecting others. But doing so can violate the human rights of patients as protected in the Constitution. The responsibilities and powers conferred upon public health practitioners by health legislation need to be balanced with the rights of patients.**

## The public health approach: protecting communities

- The State has an ethical and legal obligation to protect communities against the consequences of an infectious disease.
- Current health legislation in South Africa (the Health Act) allows for public health interventions in order to contain infectious diseases that constitute a threat to public health.
- Without intervention, MDR-TB can be spread to large numbers of susceptible individuals (notably HIV+ persons and children).
- According to the Constitution, South Africans have a right to an environment that is not harmful to their health or well-being, and the right to be protected from infection.

## The Constitution: protecting individual rights

Health authorities are required to operate within the context of the Bill of Rights enshrined in the Constitution of the Republic of South Africa, affording individual rights to every person, which have to be promoted, respected and protected.

Several human rights of patients – as protected in the Constitution – could be violated by efforts to protect the community and to treat the infected person:

- Freedom and security of the person: violations of this right arise from enforced detention or treatment
- Life: the right to receive treatment, and the right of those not infected to

be protected from infection

- Health care: the right to health care services and emergency medical treatment
- Just administrative action: the right to be heard before action is taken affecting individual rights
- Human dignity: the effects of detention and treatment on an individual's dignity
- Privacy: disclosure of a patient's health status to others
- Equality: discriminating between those who will receive treatment or be detained and those who will not
- Freedom of movement and residence: the effect of enforced detention and conditions of release
- Freedom of trade, occupation and profession: the effect of enforced detention and conditions of release.

## The legislative framework

The South African Department of Health is legally responsible for control of TB, including MDR-TB, as a public health problem.

The department is required to operate within the context of the Bill of Rights enshrined in the Constitution of the Republic of South Africa, which affords individual rights to every person that have to be promoted, respected and protected. The Bill of Rights also balances competing rights and communal interests.

Relevant legislation that provides a legal framework for the management of MDR-TB includes the following:

- The Constitution of the Republic of South Africa, 1996
- The National Health Act 61 of 2003
- The Health Act 63 of 1977 and its Communicable Diseases Regulations of 30 October 1987
- The Promotion of Administrative Justice Act 3 of 2000
- The Occupational Health and Safety Act 85 of 1993
- The Compensation for Occupational Injuries Diseases Act 130 of 1993
- The Employment Equity Act 55 of 1998
- The Labour Relations Act 66 of 1995
- Basic Conditions of Employment Act 75 of 1997.

## Key issues and imperatives

**The recommendations contained in this policy brief are based on the systematic analysis of real-life MDR-TB case studies. This process identified the key issues – with their potential legal implications – arising out of the management of MDR-TB. These were assessed independently by two advocates with Constitutional law expertise and experience. The process also identified four key imperatives that would influence test cases in court.**

## Key issues

### Patient-related issues

- Patients refusing treatment
- Patients refusing hospitalisation
- Patients discharging themselves from hospital
- Infectious patients requesting discharge from hospital
- Termination of treatment in patients who:
  - o habitually interrupt treatment
  - o fail to respond to treatment
  - o experience drug adverse effects that may cause permanent harm
  - o have a concomitant terminal disease

### **Community-related issues**

- Disclosure of MDR-TB status to close contacts and communities
- Infectious patients continuing employment
- Discharge of chronic patients back to communities
- Protection of vulnerable populations (eg. children, HIV-infected individuals)

### **Labour-related issues**

- Protection of health care workers
- Refusal of health care workers to provide care for MDR-TB patients
- Compensation for health care workers contracting MDR-TB
- Extended sick leave for health care workers with MDR-TB

### **The need for test cases**

The inherent contradiction posed by the need to address MDR-TB using conventional public health intervention strategies like confinement, coercion, detention or quarantine, while protecting individual patient rights, needs to be tested for Constitutional validity.

Potential conflict in the legislation is evident, as is the lack of adequate procedural safeguards within current public health legislation.

The relevant provisions of the Health Act and the Communicable Disease Regulations issued under the Act, read with the National Health Act, have also not yet been tested for Constitutional validity.

The abovementioned directly applicable sets of legislation also need to be tested within the context of public health.

Test cases in court are therefore to be welcomed and encouraged.

### **Key imperatives**

1. MDR-TB represents a failure of public health attempts to treat TB adequately.
2. MDR-TB treatment comes at an exceptionally high cost when compared to drug-susceptible TB.
3. MDR-TB represents an unacceptably high risk to vulnerable populations, notably young children and HIV-infected individuals.
4. The risk posed by smear-positive MDR-TB patients with a productive cough is unacceptably high and available infection control mechanisms are inadequate to prevent MDR-TB transmission.

## **Policy recommendations: a legal compromise**

**The threat of MDR-TB to public health provides a legal basis for Government to intervene in decision-making regarding an individual's health care. However, the responsibilities and powers conferred upon public health practitioners by health legislation need to be balanced with the rights of patients.**

These recommendations are based on legal validity, not medical ethics, and are subject to the use of lawful procedures.

### **1. Enforced hospitalisation is allowed for high-risk MDR-TB patients**

Current health legislation empowers authorities to detain patients with communicable diseases until the disease no longer poses a public health threat, thereby allowing quarantine restrictions to be enforced for a limited period.

However, enforced hospitalisation of MDR-TB patients would seriously infringe on the right to freedom and security of the person, given that treatment is prolonged (up to 24 months) and bound to fail in a considerable proportion of patients (up to 10%).

The infringement is viewed to be justifiable for high-risk MDR-TB patients only (those who are smear-positive and have a productive cough), in the light of the right of members of the public, many of whom may have compromised immune systems, to be protected from exposure.

The following is recommended:

- High risk MDR-TB patients may be committed to a health facility.
- Enforced hospitalisation of high-risk MDR-TB patients applies irrespective of whether treatment has commenced, whether they are already in a medical facility or whether they have absconded from treatment.
- Committing a patient to a medical facility must be done in accordance with lawful procedures.

### **2. Enforced treatment of MDR-TB patients is not allowed**

The enforcement of MDR-TB treatment represents a most severe invasion of the right to freedom and security of the person, in particular, the right to bodily integrity. Given the toxicity of MDR-TB treatment, the potentially severe side effects, the lower success rate of treatment, and the reduced life expectancy of MDR-TB patients, there is not sufficiently strong justification for coerced treatment.

The following is recommended:

- Treatment should remain voluntary.
- Adequate counselling should be provided in order for patients to make an informed decision about treatment.

### **3. Informed consent is required for MDR-TB treatment**

MDR-TB treatment is voluntary, but because of the potential risks to the patient (and, if the patient is pregnant, to the foetus), full knowledge regarding the treatment as provided in Sections 6, 7 and 8 of the National Health Act must be communicated to the patient. This will enable the patient to make a more informed decision about whether or not to consent to treatment.

The following is recommended:

- Full knowledge regarding the treatment must be communicated to the patient.
- Written consent must be obtained from MDR-TB patients prior to treatment.

### **4. Discharge of MDR-TB patients is to be based on risk assessment**

#### **Low-risk patients**

- Low-risk (smear- and/or culture-negative) MDR-TB patients must be discharged on request.

#### **High-risk patients**

- MDR-TB patients who are smear-positive and who refuse treatment, or for whom treatment has been terminated, may be discharged, provided they do not have a productive cough.
- They should be warned to return for regular check-ups if they develop a cough, failing which they should be collected and committed to a health facility (albeit without enforced treatment).
- They should also be adequately counselled regarding preventive

measures and safety procedures, and the risks they could present to persons with whom they have close contact, the need for disclosure of these risks, and the potential legal liability for failure to disclose or to take precautionary measures.

### **Terminally ill patients**

Terminally ill MDR-TB patients might have to remain in a medical facility until death. In such cases suitable counselling and visitation rights would be appropriate, as well as notification of family members. As an alternative, where circumstances permit the patient to be cared for by family (or the equivalent) and with the consent of the family, the patient may be discharged, provided that:

- He or she stays within the confines of the home
- No young children or persons with known HIV infection are put at risk
- The necessary measures are taken to prevent the spread of infection
- Access to the patient by outsiders is restricted or controlled.

### **General**

A discharge report as required by Section 10 of the National Health Act should be given to all MDR-TB patients.

## **5. Termination of treatment is legally justifiable in some cases**

MDR-TB patients should be counselled at the onset of treatment on their responsibility to adhere to the treatment regimen and the consequences of interruption and/or default. Limited drug availability and the best use of scarce resources need to be taken into account when decisions on restarting MDR-TB treatment after interruption or default are taken.

MDR-TB treatment can be terminated in the following cases, provided that appropriate counselling has been offered to the patient, and the patient has been heard before a final decision is made:

- **Where the patient no longer consents to receiving treatment.** This may include situations where the patient becomes pregnant, or suffers from severe side effects, or the likelihood of severe side effects increases significantly.
- **Where there is a negligible chance of success, even where the patient wishes the treatment to continue.** This may include situations where the patient has another terminal disease which has reached an advanced stage, where the treatment has been interrupted too often to remain effective, or where treatment has completed its full course without resulting in cure.
- **Where, due to interruption and recommencement of treatment, there is an unacceptable risk that amplification of resistance will lead to strains of MDR-TB for which no treatment is available.**
- **Where a patient interrupts treatment more than once.** However, in compelling circumstances, such as those beyond the patient's control, a further course of treatment should be allowed. Discretion should be exercised appropriately.

## **6. Disclosure of patient information is not generally permissible**

- Although TB (and therefore MDR-TB) is a notifiable disease, the main purpose of notification of communicable diseases is to generate a public health response by the responsible health authority. This is entirely different from disclosing a patient's medical information to the community, which constitutes a breach of individual privacy.
- The issue of disclosure currently presents one of the most pressing dilemmas in MDR-TB management as, in terms of sections 14 and 15

of the National Health Act, confidential information concerning a health care user may only be disclosed if it is in the interests of the user or if the user consents in writing. Although disclosure in another person's interest might arguably be justified by a law of general application, there is no such law at present and therefore disclosure of a patient's MDR-TB status to the community (including, for example, employers, spouses, co-workers, etc.) is not presently permissible.

- Current regulations require that a parent/guardian of a pupil at a teaching institution discloses to the principal if the pupil has been infected or exposed to TB (and by implication also MDR-TB). This may well be justifiable as a law of general application. The principal may require the pupil to stay away until a suitable medical certificate permits his or her return. Disclosure to a teaching institution may not be made by the health authority.

## **7. Defaulting patients must be followed up**

MDR-TB patients who interrupt treatment must be traced and notified to attend for treatment. They must be advised of the implications of interruption and that treatment may be terminated if they do not comply.

## **8. Health care workers have the right to be safe**

- TB (and MDR-TB) is an occupational disease and health care workers have the legal right to a safe working environment where adequate protection should be provided against infection.
- The onus rests on employers to provide safe or alternative employment for health care workers with HIV infection, or with medical conditions leading to compromised immunity, who are therefore at greater risk.
- The Hazardous Biological Agents Regulations (27 December 2001 under the Occupational Health and Safety Act) should be in place in all workplaces where MDR-TB is present.
- Health care workers should be counselled about the risks of working with MDR-TB patients, the taking of necessary precautions, and the substantially increased risks if they are, or become, HIV positive. Voluntary HIV counselling and testing should be offered to health care workers on the basis that alternative working environments will be sought for those who are HIV positive and who wish to minimise their risk of infection with MDR-TB.
- HIV testing is not compulsory, nor is transfer to a lower risk environment. Requests to be transferred do not have to be accompanied by disclosure of HIV status; however, those who voluntarily disclose their positive HIV test results should receive preference in being transferred to lower risk environments.
- Any disclosure of HIV status should be voluntary, made to a designated health care provider, and held in the strictest confidence.
- Compensation claims for health care workers contracting MDR-TB should be lodged in terms of the Compensation for Occupational Injuries and Diseases Act 130 of 1993, where MDR-TB is presumed to have been contracted during work involving the handling of or exposure to MDR-TB.
- As a general rule, health care workers who contract MDR-TB through work should not be dismissed on the basis of incapacity at the expiry of their paid sick leave. A fair procedure should be followed, including an investigation into the nature and extent of the incapacity, the effects of treatment, and alternatives to dismissal. This would usually result in extended sick leave being granted. The provision of extended sick leave to an employee, at least on an unpaid basis or at less than full pay, in order to undergo treatment for MDR-TB would be regarded as fair. Fairness can only be tested in the circumstances of each particular case, and factors such as disability insurance and ill-health retirement benefits as alternatives would be relevant.