Note: This chapter presents a general overview of the basic ethical and legal considerations that clinicians and health care organizations may face when managing cases of drug-resistant TB. Laws and procedures vary across jurisdictions. The individual clinician is advised to consult with local legal and public health authorities when faced with questions or concerns about specific cases.
For a number of reasons, the public health control of tuberculosis (TB) must be treated differently than other communicable diseases:

- TB is spread through the air, leading to the potential for more casual transmission than diseases that require sharing of body fluids or other intimate contact for transmission.
- An individual with active TB can be contagious for a long period of time and infect many other people.
- The consequence of transmission to others can be very dire, with significant morbidity to infected persons.
- Except for rare strains of multidrug-resistant TB (MDR-TB), and unlike some other deadly communicable diseases, TB can be cured and transmission can be prevented. Public health interventions are proven to be very successful both for the individual and for those sharing the air with that person.

### Drug-resistant TB requires even more heightened medical and legal attention for at least 2 reasons:

1. It is more difficult to treat and cure, and therefore, any transmission of the infection to other individuals carries significant consequences.
2. Poor adherence to TB therapy can promote or amplify drug resistance and must be actively prevented.

All states have laws specific to the control of TB. The federal government is also authorized, through the Public Health Service Act (PHSA), to take measures to prevent the entry and spread of communicable diseases from foreign countries into the United States and between states (Title 42, United States Code Section 264; Section 361 of the PHSA). The Centers for Disease Control and Prevention (CDC), through its Division of Global Migration and Quarantine, is empowered to detain, medically examine, or conditionally release persons suspected of carrying a communicable disease. These include “Do Not Board” (travel by flight) and “Border Look-out” (crossing borders, not by flight) provisions defined by the U.S. Department of Homeland Security. These provisions restrict travel for those identified as having an infectious disease of public health significance or quarantinable disease.

The exercise of powers granted by statute to control the behavior of persons with TB must always be tempered not just by the question “Is it legal?” but also “Is it ethical?”

Inherent in the use of public health authority is a struggle to balance two important principles: individual autonomy and protection of the public’s health.
The Ethical Framework

The ethical context of public health differs from that of most of medicine. In medical ethics, one balances the risks to the individual patient of the proposed intervention with the benefit to that patient. In public health, however, while the risk, such as loss of privacy, is to the individual patient, the benefit is both to the patient and to society as a whole.

Examples of potential risks to the patient include:

**Loss of privacy**
- Reporting
- Contact identification

**Loss of liberty and self-determination**
- Court-ordered diagnostic procedures, evaluations, and directly observed therapy (DOT)
- Long-term isolation, possibly even indefinite, in some cases of MDR-TB
- Detention

**Loss of legal rights**
- Unequal imposition of restrictions/interventions
- Lack of notice of legal consequences or opportunity to object to health orders
- Lack of legal counsel due to unwillingness of legal representatives to come into close proximity to an infectious patient, especially MDR-TB

Risks to the patient can be minimized if TB control interventions are provided in the context of an ethical framework in which interventions:

- Are substantiated by individualized assessments based on science (sometimes lacking in the case of treatment and transmission of drug-resistant TB)
- Identify and minimize burdens to the patient using a range of interventions from least to most restrictive
- Are implemented fairly and minimize social injustice or discrimination
Legal Issues for Practitioners

TB control programs operate within a complex legal framework that balances the civil rights of individuals with society’s need for protection. A dialogue between medical and legal professionals is necessary to ensure that whatever legal steps are taken to address patient non-adherence strike the appropriate balance with modern constitutional guarantees of privacy, liberty, and non-discrimination. These issues are the same whether a patient has drug-susceptible or drug-resistant TB. However, the consequences are more dire if a patient with drug-resistant TB remains contagious or his/her strain’s resistance is amplified. For this reason, all legal tools may be necessary when managing a case of drug-resistant TB.

Legal Priorities

Priorities for TB control programs include ensuring that:

- Active cases of TB are identified, do not further transmit TB, and receive appropriate treatment
- Persons at risk of having been infected due to recent exposure are identified, evaluated for the presence of infection, and receive treatment as needed
- Persons at high risk of having TB infection or disease are appropriately screened and provided access to care

Although there are variations among state TB control statutes, in general, laws specific to the control of TB deal with the first and second of these priorities. Among the legal powers usually delegated to public health authorities are reporting requirements, orders for persons to appear when and where directed, and orders for persons to remain isolated and/or detained for treatment.

Reporting Requirements

Examples of public health reporting requirements include the requirement for health care providers, institutions, and laboratories to:

- Report known or suspected cases of TB
- Report when persons with TB self-stop the prescribed treatment (including being lost to follow-up)
- Provide clinical and treatment updates upon request
- Provide a treatment plan and obtain approval from the local TB controller prior to discharging or transferring a patient from a health care institution

Health care providers caring for TB patients should be familiar with the reporting requirements in their jurisdictions.

Reporting requirements are designed to provide the public health authorities with information necessary to ensure that persons with TB obtain timely, adequate, and appropriate treatment and are not lost to follow-up.
Orders to Appear and Comply

Public health authorities are granted legal power to “order” persons with or suspected of having TB to comply with directions. These “Health Officer Orders” often have the force of law in that violation of such an order is generally a misdemeanor and may lead to further legal action. Examples of Health Officer Orders include:

- Order to appear for examination to rule out active TB
- Order to complete treatment
  - Usually does not include the ability to force persons to take medications against their will
- Order to comply with DOT and other medical instructions, including infection control
- Order for admission into a health facility
  - Often for nonadherent patients with voluntary home isolation

Orders to Isolate or Detain

Perhaps the most intrusive power vested in local health authorities is the power to isolate or detain a nonadherent patient involuntarily if that individual is believed to represent a risk to the public’s health.

Two such types of orders are relatively commonplace in TB control:

- Order for an infectious patient to be isolated in his/her home or other facility as designated
- Order for a persistently nonadherent patient to be civilly detained at a health facility until the patient has completed a course of treatment

While involuntary detention of nonadherent persons with contagious TB has long been used, the increase of drug-resistant TB has added a new dimension to the issue of detention. Persons who are nonadherent with their anti-tuberculosis regimens, even after they are no longer contagious, may develop or amplify drug-resistant TB, leading to treatment failure and transmission of a difficult or even impossible-to-treat infection. The possibility for nonadherence, followed by the development of drug-resistant TB, has led to the institution of laws allowing the detention of patients until they are cured, rather than just until they are no longer contagious. For nonadherent patients with MDR-TB, this could lead to detention for many years.

Because of the degree of restriction of individual liberty inherent in the detention of nonadherent patients, every reasonable effort should be made to identify and address the patient’s barriers to adherence and to pursue the least restrictive alternatives that may allow the patient to achieve adherence to the treatment regimen. The decision to detain a patient must be made based on an individualized assessment of that patient.
Least restrictive alternatives that should be pursued prior to detention:

- Education/counseling (linguistically appropriate)
- Removing cost as a barrier
- Voluntary DOT
- Use of incentives/enablers
- Provision of stable housing
- Referral to social services
- Alcohol and drug rehabilitation
- Health officer orders: isolation, DOT, radiographs, sputum

**Summary**

- Many physicians are uncomfortable with discussions of the use of legal powers to “force” patients to adhere to treatment regimens.
- MDR-TB patients may have more difficulty adhering to prolonged, complex TB regimens than do drug-susceptible patients.
- TB patients, and drug-resistant patients in particular, present a risk to others in the community with whom they may come into contact.
- While the physician’s primary focus is the individual patient, the public health department must also consider its legally mandated responsibility to protect the public’s health. Fortunately, the two are rarely in conflict.
- Public health authorities rely heavily on healthcare providers to notify them of TB cases and to provide appropriate evaluation and treatment of persons with or exposed to TB.
- Physicians often do not have the same resources as the health department to fully address a patient’s psycho/social needs and barriers to adherence to TB care. By working together, the physician and health department can meet the needs of most patients.
- For those few patients who, for whatever reasons, continue to pose a risk to the public despite all efforts to address their barriers, ethical and legal options are needed to ensure that these patients do not continue to put others in the community at risk.
References


