

CHAPTER 1: INTRODUCTION

ABOUT THE FIFTH EDITION

This program manual describes activities and policies of the New York City (NYC) Health Department Bureau of TB Control (BTBC) and NYC Health Department TB Clinics related to the prevention, treatment, and control of tuberculosis (TB).

The first version of the manual was published in 1993 and was intended for the medical providers of BTBC as a reference guide for TB diagnosis, treatment, and prevention. With subsequent editions, the manual became more broadly used by other BTBC staff and healthcare providers in the community. Updated editions followed in 1997, 1999, and 2008.

This fifth edition of the manual is intended primarily as a reference document for BTBC staff. As an organization that provides direct clinical and public health services, BTBC has expanded the scope of activities discussed in the manual from previous versions to cover the full breadth of its work.

This manual is not intended to supersede clinical judgment. Instead, its purpose is to outline the functions and practices of NYC's TB Control Program and to provide updated policies, practices, and guidelines regarding TB prevention and care in NYC. Community providers who have questions regarding appropriate TB clinical practice should always contact the **NYC TB HOTLINE** at **(844) 713-0559**.

Guidelines in the manual are based on recommendations from the Centers for Disease Control and Prevention (CDC), the American Thoracic Society (ATS), the European Respiratory Society (ERS), the Infectious Diseases Society of America (IDSA), and the World Health Organization (WHO). Additional references and guidelines include the Curry Center’s *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians, 3rd Edition*, and the American Academy of Pediatrics’ *Red Book 2018-2021 Report of the Committee on Infectious Diseases*. Instances where BTBC practice differs from these recommendations have been noted in the text.

The fifth edition of the manual contains numerous tools intended to aid readers as they utilize the manual. These tools include:

1. **Callouts:** In each chapter, there are callouts highlighting resources, guidelines, cross-references, and sources of additional information on a topic.



Forms: Forms available for use by BTBC staff and partners



Clinical guidance: Key clinical recommendations



Laboratory-related information: Laboratory processes, services, and recommendations



Treatment-related information: Recommendations, dosing, side effects, and important drug interactions for TB medications



Links: Links to additional resources and information



Laws governing TB care in NYC: Information about the legal framework guiding TB policy and practice



Information and resources related to HIV: Considerations for TB testing, care, and treatment for persons with HIV infection



Contact BTBC: Guidance about when and how to contact BTBC

2. **Key Sources:** After each chapter, there is a comprehensive list of resources that can be referred to for additional information regarding that topic area.

- 3. Appendices:** At the end of the manual, there are additional resources to supplement the information discussed in each chapter. This includes a complete list of BTBC policies, instructions on how to induce sputum, and appropriate dosages for TB medications.
- 4. Tuberculosis Classification System:** BTBC uses a modified version of the international system for classifying TB patients. These classifications are based on the pathogenesis of TB and use a rating scale of zero to five. This system is used to ensure consistency in reporting across BTBC's surveillance and electronic medical record (EMR) systems and is referenced throughout the manual. The classification of each patient is informed by laboratory data, clinical judgment, and case management. (See *Appendix A: International Classification of Tuberculosis*.)

ABOUT TUBERCULOSIS

TB is an airborne disease caused by *Mycobacterium tuberculosis* (*M. tuberculosis*). TB transmission occurs when a person with active pulmonary or laryngeal TB disease expels droplet nuclei containing tubercle bacilli from their respiratory system into the air by coughing, singing, yelling, or speaking. A susceptible individual may inhale the bacilli and become infected.

TB has two stages: latent TB infection (LTBI) and active disease. An individual is diagnosed with LTBI when they have TB bacteria in their body but their immune system keeps the bacteria from proliferating. These individuals do not feel sick, do not have symptoms consistent with active disease, and cannot transmit TB to others. It is estimated that one-quarter of the world's population has LTBI.

In individuals with active TB disease, *M. tuberculosis* bacteria overcome the body's immune defenses, actively reproduce, and cause illness. These individuals have symptoms and can potentially infect others if their site of disease is respiratory (i.e., pulmonary or laryngeal). Symptoms of respiratory TB include a persistent cough, hemoptysis, chest pain, loss of appetite, weight loss, chills, fever, or night sweats. People can develop TB disease anywhere in their body. However the most common site of disease is the lungs. People infected with TB bacteria have a five to 15% lifetime risk of developing TB disease. Persons with weakened immune systems—such as those with untreated human immunodeficiency virus (HIV) infection or other immunosuppressive conditions—have a much higher risk of becoming ill.

TB is treatable and preventable, but in the absence of effective treatment, TB disease may lead to serious illness and death. Globally, TB is a leading cause of death by an infectious disease, killing more people each year than HIV, malaria, or influenza. The United States (U.S.) is considered a low burden country, with a TB incidence of approximately three cases per 100,000 persons. Within the U.S., however, NYC has a much higher burden of disease—approximately seven cases per 100,000 persons annually.



A detailed description of TB epidemiology, surveillance data, and trends in NYC can be found in the Health Department's **ANNUAL TUBERCULOSIS SUMMARY**, available online at www.nyc.gov/health

INNOVATIONS IN TUBERCULOSIS CARE IN THE LAST DECADE

DIAGNOSIS

» Interferon Gamma Release Assays

When testing for TB infection, there are two categories of tests: interferon gamma release assays (IGRA) and tuberculin skin tests (TST). IGRAs are a newer blood-based test that are more specific for TB infection than the TST. IGRAs are the preferred test for TB infection in NYC Health Department TB clinics and investigations in the community. (See *Chapter 2: Diagnosis and Treatment of Latent Tuberculosis Infection.*)

» Nucleic Acid Amplification Testing

Nucleic acid amplification (NAA) tests use molecular methods to detect the presence of *M. tuberculosis* complex. The NYC Public Health Laboratory (NYC PHL) and hospital and commercial laboratories use these molecular tests to rapidly confirm the presence of TB, determine if there are genetic mutations that suggest drug resistance, and assist in determining if patients can be released from isolation. (See *Chapter 4: Laboratory Testing for Tuberculosis Disease* and *Chapter 12: Tuberculosis Genotyping and Cluster Investigation.*)

» Whole Genome Sequencing

Whole genome sequencing (WGS) utilizes genetic information from the entire TB genome and can be used to identify *M. tuberculosis* complex and species within it, detect genetic mutations associated with drug resistance, and identify the presence of single nucleotide polymorphisms (SNP) to characterize and compare TB strains. (See *Chapter 4: Laboratory Testing for Tuberculosis Disease* and *Chapter 12: Tuberculosis Genotyping and Cluster Investigation.*)

» United States Preventive Services Task Force Grade B Recommendation for LTBI testing

Testing for LTBI among adults at high-risk for TB is now recommended by the new United States Preventive Services Task Force (USPSTF) guidelines at a Grade B level. This means that there is a high certainty of moderate benefit of this service and it should be provided. By identifying persons with TB infection and connecting them to LTBI treatment, future TB cases can be prevented. (See *Chapter 2: Diagnosis and Treatment of Latent Tuberculosis Infection.*)

TREATMENT

» Update to Clinical Practice Guidelines for Treatment of Drug-Susceptible Tuberculosis

The 2016 ATS/IDSA/CDC treatment guidelines for drug-susceptible TB recommend comprehensive care for all patients with active TB disease, noting that case management, including directly observed therapy (DOT), is essential to ensure effective TB treatment outcomes. These updated guidelines recommend use of daily therapy during the intensive phase and daily or thrice-weekly intermittent therapy during the continuation phase. Biweekly therapy during the continuation phase is no longer recommended. Furthermore, the new guidelines recommend that patients who have TB disease and HIV infection begin

antiretroviral therapy (ART) while being treated for TB, and offer updated recommendations on the timing of initiation of treatment for both diseases. (See *Chapter 5: Treatment of Drug-Susceptible Tuberculosis Disease in Adults.*)

» Bedaquiline

A new drug, bedaquiline (BDQ), has been approved for use in patients with multidrug-resistant TB (MDR-TB). The addition of a new drug from a novel class of compounds has led to the development of new all-oral regimens for the treatment of MDR-TB, as recommended by the WHO, CDC, ATS, ERS, and IDSA. The use of this new drug is explained in detail in this manual. (See *Chapter 6: Treatment of Drug-Resistant Tuberculosis Disease in Adults.*)

» Treatment for Extensively Drug-Resistant Tuberculosis

The Food and Drug Administration has approved a six-month regimen of BDQ, pretomanid, and linezolid for use in patients with extensively drug-resistant TB (XDR-TB), treatment-intolerant TB, or non-responsive pulmonary TB. (See *Chapter 6: Treatment of Drug-Resistant Tuberculosis Disease in Adults.*)

» Electronic Directly Observed Therapy

Directly observed therapy (DOT) is the standard of care for treating patients with active TB disease in NYC. During DOT, a patient is observed by a trained healthcare worker while ingesting anti-TB medications. BTBC now offers electronic DOT (eDOT) to remotely monitor patients ingesting anti-TB medications in addition to in-person DOT. Live video eDOT (LVDOT) is conducted via video conferencing; with recorded VDOT (RVDOT), the patient submits a recording of themselves taking the medication, which is then reviewed by a DOT worker. eDOT offers increased convenience for both patients and staff. (See *Chapter 10: Case Management for Patients with Tuberculosis.*)

» Short Course Regimens for Latent Tuberculosis Infection

Short-course rifamycin-based regimens for LTBI are recommended due to increased safety, tolerability, and treatment completion in comparison to INH. Rifampin for four months and the 12-week regimen 3HP are the preferred regimens in NYC Health Department TB clinics. 3HP consists of a 12-week regimen of once-weekly isoniazid and rifapentine. (See *Chapter 2: Diagnosis and Treatment of Latent Tuberculosis Infection.*)

» Treatment of Tuberculosis and Human Immunodeficiency Virus

Guidelines for the treatment of HIV are rapidly evolving. New recommendations for the treatment of TB patients with HIV infection include the recognition that, for the majority of patients, earlier initiation of HIV treatment decreases mortality. While a complete guide for all possible treatment regimens for patients with HIV infection is beyond the scope of this manual, BTBC provides guidance for treating patients with TB disease who have concomitant HIV infection. Physicians should always coordinate treatment with an HIV provider and refer to the most recent HIV guidelines. (See *Chapter 5: Treatment of Drug-Susceptible Tuberculosis Disease in Adults.*)

NEW YORK CITY HEALTH CODE

There have been several changes to the NYC Health Code since the last publication of the manual.

- In 2009, the NYC Health Code was amended to require that healthcare providers submit a discharge plan for all patients with infectious TB disease prior to release from the hospital.
- In 2012, the Health Code requirement to test new entrants to a NYC secondary school was eliminated.
- As of 2017, providers and laboratorians are now required to report any child younger than five years of age with a positive test for TB infection along with the result of their chest radiograph (CXR) and any LTBI treatment regimen initiated. (See *Chapter 17: Laws Governing Tuberculosis Care in New York City*.)
- In 2019, the NYC Health Code was amended to require laboratories to report all results of blood-based tests for TB infection, including negative results.

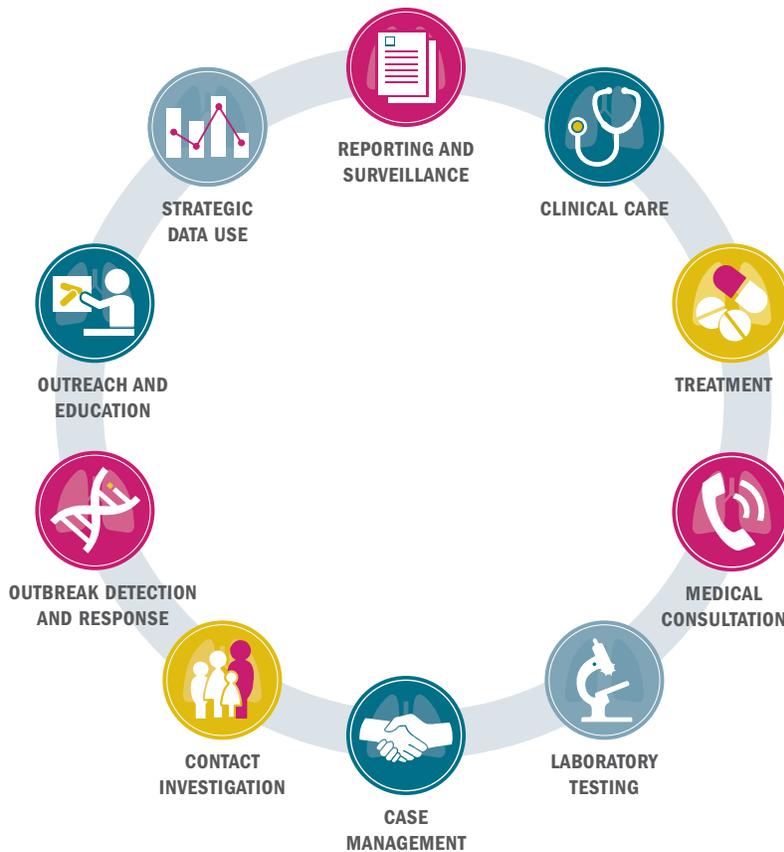
NON-STIGMATIZING LANGUAGE

BTBC is committed to promoting patient-centered, non-stigmatizing language in this manual and beyond. From a patient perspective, common TB-related terminology such as "defaulter," "suspect," or "non-compliant" may be viewed as negative and judgmental, or evoke a sense of blame or shame for the patient with respect to their TB status. In this manual—excluding instances in which references are made to specific local laws and policies—the terms "person lost to follow-up," "person with signs and symptoms consistent with TB disease," and "non-adherent" are used instead. By moving towards patient-centered terminology, BTBC aims to empower patients, recognize their individual personhood, and fight the stigma associated with TB.

THE ROLE OF THE BUREAU OF TUBERCULOSIS CONTROL IN TUBERCULOSIS CARE AND PREVENTION IN NEW YORK CITY

BTBC functions through an integrated and dynamic model of core activities and services. These include surveillance, case management, contact investigation, direct patient care, medical consultation, outbreak detection and response, education, training, outreach, research, and program evaluation. With a focus on the public health and clinical care needs of patients, their families, and NYC communities—and consistent with local, state and national laws, regulations, and mandates—BTBC works to ensure effective TB care, prevention, and control in NYC.

The NYC Health Department operates four TB clinics located in the Bronx, Brooklyn, Manhattan, and Queens. These clinics serve as key TB referral centers for a variety of entities including community healthcare providers, homeless shelters, social service providers, and drug treatment centers. They also evaluate immigrants and refugees who arrive in NYC with a Class B status based on notifications from the CDC Division of Global Migration and Quarantine. Health Department clinics provide comprehensive TB diagnostic and treatment services, including testing and treatment for TB disease and LTBI, sputum



induction, medical evaluation, CXRs, HIV testing, and DOT services. All services and medications at the TB clinics are free of charge to all patients regardless of immigration or insurance status.

TB is a reportable condition in NYC, and staff review all TB reports received by BTBC for timeliness, completeness and accuracy, and to ensure prompt, appropriate, and effective TB diagnosis and treatment for reported individuals. Surveillance for TB disease also enables BTBC to quickly initiate case management and other public health interventions, monitor TB trends, identify and interrupt ongoing TB transmission, and inform programmatic initiatives and policy decisions.

BTBC provides case management services to every patient with TB disease in NYC, persons with clinical suspicion of TB disease, and contacts to infectious TB patients regardless of where they receive clinical care. These services include patient education, patient interviews, medical chart reviews, contact identification, contact evaluation, DOT, and medical consultation. Together, these services ensure that every patient is able to complete TB evaluation and treatment in a timely fashion.

Through community and provider-based outreach efforts, BTBC actively works to detect, treat, and prevent TB in high TB burden populations. Culturally and linguistically appropriate TB educational materials are utilized to raise awareness about TB and engage populations most at risk for developing TB.

Altogether, BTBC weaves clinical and public health practices to provide the best possible TB care to all individuals and communities affected by TB in NYC.

KEY SOURCES

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