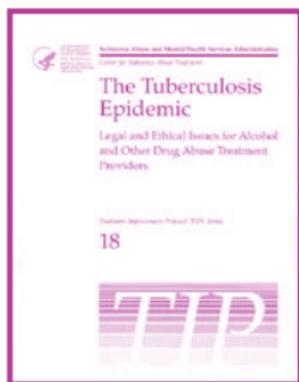


Quick Guide

For Clinicians

Based on TIP 18

The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Abuse Treatment Providers



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
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Quick Guide

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The Tuberculosis

Epidemic: Legal and

Ethical Issues for Alcohol

and Other Drug Abuse

Treatment Providers

This Quick Guide is based almost entirely on information contained in TIP 18, published in 1995 and based on information updated through approximately 1993. No additional research has been conducted to update this topic since publication of the original TIP.

WHY A QUICK GUIDE?

This Quick Guide was developed to accompany *The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers*, Number 18 in the Treatment Improvement Protocol (TIP) Series published by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration. This Quick Guide is based entirely on TIP 18 and is designed to meet the needs of the busy clinician for concise, easily accessed “how-to” information.

The Guide is divided into eight sections (**see Contents**). These sections will help readers quickly locate relevant material.

For more information on the topics in this Quick Guide, readers are referred to TIP 18.

WHAT IS A TIP?

The TIP series has been in production since 1991. This series provides the substance abuse treatment and related fields with consensus-based, field-reviewed guidelines on substance abuse treatment.

TIP 18, The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Abuse Treatment Providers

- Addresses the concerns of a broad range of readers including substance abuse treatment clinicians, social workers, medical personnel, program administrators, and policymakers
- Includes extensive research
- Lists numerous resources for further information
- Provides a reference for substance abuse treatment clinicians working with clients who have or might have tuberculosis

See the inside back cover for information on how to order TIPs and other related products.

INTRODUCTION

In 1992, Congress enacted a tuberculosis (TB) services mandate for all substance abuse programs that receive funding through the Substance Abuse Prevention and Treatment (SAPT) Block Grant. Department of Health and Human Services (DHHS) regulations require States to monitor, enforce, and facilitate program compliance with the mandate.

Substance abuse providers are obligated by Federal and State laws, and their own ethics, to

- Provide or arrange for TB screening and follow-up for their patients
- Report communicable diseases—including TB—to local or State public health officials
- Protect the confidentiality of their patients
- Provide a safe workplace for their employees and others, to include TB infection control

ATTENTION: To promote a safe workplace, substance abuse treatment providers should collaborate with public health officials and workplace safety specialists. Providers must be sure to exclude from the workplace any patients and employees who have active TB disease.

The Facts About TB

After declining steadily for nearly thirty years, the number of new cases of TB reported in the United States turned upward in the mid-1980s. From 1985 to 1993, the figure grew by approximately 14 percent, an increase the Centers for Disease Control and Prevention (CDC) attributes to at least four factors:

- The HIV epidemic
- Continuing immigration from countries where TB is common
- The transmission of TB in congregate settings, such as homeless shelters and correctional facilities
- The deterioration of the nation's health care infrastructure

The increase in incidence of TB has been accompanied by an increase in the prevalence of drug-resistant and multidrug-resistant strains of TB which can be very difficult to treat. Persons who develop drug-resistant TB tend to stay infectious longer. They are therefore apt to expose more people to infection.

For more detailed information, see TIP 18, pp. 1-4.

CAUSE AND TRANSMISSION

TB is caused by an organism called *Mycobacterium tuberculosis* or *M. tuberculosis*. The condition is spread primarily by tiny airborne particles expelled by someone with infectious pulmonary or laryngeal TB disease, typically through coughing or sneezing. These droplets can remain suspended in the air for several hours. If a person inhales them, he can become infected.

From Transmission to Infection

Of those infected with TB, the following run an especially high risk of developing active TB disease:

- Persons with HIV
- Persons whose TB infection is relatively recent (within the previous two years)
- Injection drug users
- Those with a history of inadequately treated TB

ATTENTION: Only 10 percent of persons infected with TB who have normal responses, and are infected with TB, will develop active or contagious TB disease. The vast majority of TB infected persons—about 90 percent—will never develop active or infectious disease and will never pose a threat of transmitting TB to others.

Who Is at High Risk for TB Exposure?

Although anyone can be exposed to or get TB, some people are at higher risk of exposure (exposure does not necessarily result in infection).

These higher risk groups include

- The close contacts of someone who is infectious
- Immigrants from areas where TB is common, such as Asia, Africa, and Latin America
- The poor
- The medically underserved
- Racial and ethnic minorities
- Persons living in group settings, such as correctional facilities or substance abuse treatment programs
- Alcoholics and persons who inject drugs
- The homeless
- Persons with HIV infection
- Persons who are exposed to infectious TB on the job

Immunosuppressed Individuals

Between 10 and 25 percent of persons with TB do not react, or react only mildly, to tuberculin skin testing. Thus the fact that someone does not react to the test does not necessarily mean he

or she is not infected. The inability of some individuals to mount a response to tests such as the tuberculin skin test is known as “anergy.” Anergy can be caused by HIV infection, overwhelming miliary or pulmonary TB, severe or febrile illness, measles or other viral infections, Hodgkin’s disease, sarcoidosis, live-virus vaccination, and immunosuppressive drugs. Anergy can be detected by the administration (via the Mantoux technique) of at least two additional delayed-type hypersensitivity antigens when testing PPD. A person whose reaction to any three antigens measures 3 mm or more is not anergic and is not infected.

For more detailed information, see TIP 18, pp. 6–8.

DIAGNOSIS/TESTING

Programs unable to provide on-site TB testing should refer patients to a medical clinic or public health department for the following procedures. Programs that perform these functions on-site must ensure that the relevant staff members are properly trained.

The Mantoux Tuberculin Skin Test (PPD)

The preferred method for detecting TB infection—and the only way to diagnose TB infection before it progresses to active disease—is the Mantoux Tuberculin Skin Test (PPD Test). Please note, however, that all substance abuse treatment programs should obtain their patients' consent to TB testing beforehand.

Of course, some applicants may refuse to be tested, and would be within their rights to do so, but should be reassured that the test cannot transmit TB, that the results will not be reported except where required by public health law, and that the procedure is critical to the screening process.

The test involves the injection of a small amount of purified protein derivative (PPD) just beneath the surface of the skin of the forearm. The result of the PPD test can be read by a trained health

care professional within 48 to 72 hours of the time of injection.

Generally, a person with a normal immune response who is infected with TB for more than 2 to 10 weeks will produce a response to the PPD that manifests itself through the development of an induration—an area of raised, swollen, or hardened skin—at the site of the injection. A person not infected with TB will usually produce no induration in response to the PPD.

Reading and Classifying Reaction

In most cases, a positive reaction to a PPD test will show that a client is TB-infected. Whether a reaction is classified as positive will depend on the size of the induration and the risk factors for infection or disease of the person being tested. Indurations are measured and recorded in millimeters, and a reaction of 5 mm or more is considered positive in

- Persons whose chest x-rays suggest previous TB disease
- Persons who are HIV-positive
- Persons with risk factors for HIV infection
- Close contacts of persons with infectious TB
- Injection drug users whose HIV status is unknown

A reaction of 10 mm or more is deemed positive in

- Injection drug users who are HIV-negative
- Persons with known medical risk factors (other than HIV disease) for developing infectious TB (such as diabetes mellitus)
- Persons from medically underserved or low income populations, including high-risk minority group such as Asians, African Americans, Latinos, and Native Americans
- Immigration from countries where TB is common
- Residents of long-term health care facilities
- Health care workers in facilities where TB is present
- The homeless

All others will be considered to have a positive reaction to the skin test only if they develop an induration of 15 mm.

Evaluation of Test Conversions

A conversion is a change of between 10 and 15 mm—depending on the individual’s age—in the size of an induration resulting from a PPD skin test. Programs must be sure to evaluate patients or employees who convert from PPD-negative to PPD-positive, since test conversions may indicate

that TB is being transmitted within the facility. Where such transmission occurs, the program should call on a public health specialist to help it review its risk assessment, determine the cause, and prevent further transmission.

Chest X-Rays

Chest x-rays are the traditional method for detecting pulmonary TB disease in a person with positive PPD and/or symptoms such as a persistent cough, fever, or chills. However, since a person with both HIV infection and active TB disease may have an apparently “normal” film, chest x-rays are not necessarily definitive. Also, an annual chest x-ray is required by people who are infected with TB and work in health care facilities to rule out active disease.

WARNING: For some people (such as immunosuppressed individuals) interpretations of PPD testing and the determination of active TB are more complex. See TIP 18 for more details.

For more detailed information, see TIP 18, pp. 8–9.

THERAPY OPTIONS

The following will assist in making diagnosis/ referrals and address the concerns of prospective therapy patients:

Preventive Therapy

- Clinical studies have shown that 6 to 12 months of isonicotinic acid hydrazide (INH) preventive therapy can reduce the odds of TB infection becoming active TB by 69 to 90 percent.
- High-risk preventive therapy patients who are likely to have been exposed to an organism resistant to INH should receive an alternate anti-TB drug, e.g., rifampin (RIF).
- High-priority candidates for preventive therapy include: persons who are or may be HIV positive, close contacts of persons with infectious TB, persons whose chest x-rays suggest previous TB, injection drug users, persons infected within the preceding two years.
- Others who should be evaluated for preventive therapy include those under 35 who have reacted to the PPD test with an induration of 10 or more millimeters and are any of the following: foreign-born, poor, medically underserved, members of a minority group, homeless, or live in long-term care facilities.

Active Therapy

- The initial treatment regimens will usually consist of multiple drugs (such as INH, RIF, pyrazinamide, and either ethambutol or streptomycin) and will last six months.
- Drug-resistant TB should be treated through an individualized treatment plan based on the drug-susceptibility patterns of a patient's particular strain of *M. tuberculosis*.
- The CDC recommends that treatment be administered by means of directly observed therapy (DOT). This means that a health care worker or public health employee will watch the patient to see that he or she takes prescribed medication.
- Whether they use DOT or not, all programs providing TB treatment should promote adherence by: developing individualized treatment plans, trying to provide culturally and linguistically appropriate outreach staff, educating patients about TB and TB treatment, using incentives, simplifying access to health and social services.
- In cases on non-adherence, programs should coordinate with local public health and medical providers to determine why a patient is non-adherent and to make sure that the patient resumes treatment.
- Staff and patients with active disease may not return to their program while infectious.

For more detailed information, see TIP 18, pp. 9–10.

ADMISSION AND DISCHARGE ISSUES

Exclusion/Discrimination

Substance abuse treatment programs may not discriminate against persons who have, have had, or are suspected of having TB unless such persons pose a significant risk to the health or safety of others.

The Federal Rehabilitation Act of 1973 and the Americans With Disabilities Act of 1990 (ADA) protect individuals from disability-based discrimination. Under these statutes, substance abuse treatment providers may not

- Deny treatment on the basis of a disability to any individual who meets the essential eligibility requirements of the program
- Establish eligibility criteria that screen out or tend to screen out people with disabilities, unless such criteria are necessary for the provision of the services the program offers or are necessary for safe operation
- Provide services to a disabled person that are different, separate or not equal to those offered to others, unless doing so is necessary to provide the individual with services that are as effective as those provided to others
- Engage in acts or practices that discriminate against people who are disabled

Pre-Admission Screening

Programs should have a pre-admission protocol that includes a questionnaire that focuses on TB signs and symptoms, PPD results, past TB diagnoses, and TB treatment and therapy, if any. The pre-admission protocol should include PPD skin testing for high-risk applicants. Applicants with TB symptoms should be referred immediately for a medical evaluation and admitted only after being cleared as non-infectious by a physician.

Substance abuse treatment providers can easily incorporate items regarding TB symptoms and history into existing admission/intake questionnaires. Such questionnaires must be developed using language that will be easily understood by the patient, and should pay special attention to the following symptoms:

- A cough that lasts for three weeks or more
- Persistent fever
- Night sweats
- Unexplained weight loss (more than 10 percent of body weight over a 90-day period)
- Coughing up of blood

The questionnaire should help to establish whether the prospective patient is a member of a group that is at high risk for TB, or is on any TB medications that may need monitoring.

Reasonable Accommodation

A blanket refusal to hire or admit—or a policy of firing or refusing treatment to—anyone who is infectious but willing to undergo appropriate treatment is illegal. Where any person, disabled or not, poses a significant risk to the health or safety of others, the provider must determine whether there are reasonable accommodations (or modifications) that can be made to eliminate the risk of transmission.

An accommodation is reasonable as long as it eliminates the risk of transmission without imposing an undue burden on the provider or requiring fundamental alterations in program services. For instance, since a person with infectious TB can be rendered non-infectious in a relatively short time, an employer might give an employee an extended leave of absence or delay the start date for a new employee.

For a patient, one possibility is deferred admission, contingent on treatment and a medical determination that he or she is free from infectious TB and poses no significant risk of transmitting TB to others.

For more detailed information, see TIP 18, pp. 13–21.

CONSENT, DISCLOSURE, AND CONFIDENTIALITY

Many States reinforce the 1992 Congressional mandate with laws that require a large percentage of their substance abuse treatment providers to report cases of communicable disease (including TB) to local or State officials, and cooperate with them in follow-up.

Sample consent forms are located on pp. 43–48 of TIP 18.

Disclosure

A disclosure is a communication that identifies an individual as having participated in, participating in, or seeking to participate in drug or alcohol abuse treatment.

Regulations prohibit substance abuse treatment programs from either explicitly or implicitly disclosing the identities of the individuals they serve or have served. However, a communication that does not reveal an individual's status as a patient in substance abuse treatment is not a disclosure for purposes of the regulations.

Patient Disclosure Consent

A valid consent allows a program to disclose a significant amount of relevant information about a

patient. To be valid, a consent must be in writing and must include all of the following elements:

- Name of the program authorized to make the disclosure
- Name of the person or organization that is authorized to receive the information
- Name of the patient/subject
- Purpose of the disclosure
- Description of the information to be disclosed (which must conform as narrowly as possible to the purpose of the disclosure)
- A revocation provision, which states that the patient may revoke his or her consent at any time except to the extent that action has already been taken in reliance upon the consent
- Expiration date (or the specification of an event which will cause the consent to expire)
- Date
- Patient's signature

To protect patients who consent to the release of confidential information to public health officials, substance abuse treatment providers should

- Explain to patients that a consent to certain disclosures can facilitate both substance abuse and TB treatment

- Emphasize that the program will disclose only information that is relevant to treatment
- Reassure patients about the continuing confidentiality of the released information
- Ensure that substance abuse treatment and public health officials who are provided with such information thoroughly understand the importance of confidentiality
- Respect the patient's right to refuse or withdraw consent
- Develop strict guidelines for dealing with breaches of confidentiality

Qualified Service Organization Agreements

A Qualified Service Organization Agreement (QSOA) is a fairly simple contract that permits a substance abuse treatment provider to share patient-identifying information with an outside service provider where

- The outside service provider needs that information to provide services for the program or its patients
- The outside service provider agrees not to re-disclose that information

In effect, a QSOA extends the orbit of a substance abuse treatment provider to include the services of the outside agency. Patient consent is not

required for disclosures made between the two agencies under such an agreement.

Medical Emergencies

Confidentiality regulations allow programs to disclose patient-identifying information, even without a patient's consent, to public or private medical personnel who "have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention." The medical emergency exception can only be invoked on a case-by-case basis, after a program has determined through an individualized assessment of every particular person's case that circumstances justifying a disclosure exist.

Exceptions to the Regulations

Despite their strictness, Federal substance abuse treatment confidentiality regulations contain a number of exceptions. Some specific disclosures permitted are

- Where authorized by patient consent
- Under a QSOA
- To report a medical emergency
- Where they do not reveal that the patient is in treatment for substance abuse

- To report a crime on the program's premises
- To report child abuse or neglect
- Where authorized by a court order
- For an audit or evaluation
- For research
- For use of internal program communications

Addressing Patient Mistrust

Consent and confidentiality situations often give rise to the larger issue of patient mistrust, which can cause substance abusers to walk away from treatment. To reassure their patients, substance abuse treatment providers should always strive to

- Address patient concerns about sanctions related to TB services
- Address concerns about the availability of needed services
- Address concerns about confidentiality
- Change any negative perceptions that substance abuse treatment counselors may have of public health, since counselors can influence patient attitudes and perceptions
- Use outreach programs and drop-in centers to reach difficult populations and develop patient trust

- Make it clear to undocumented aliens that health officials will not contact immigration authorities or investigate their immigration status

For more detailed information, see TIP 18, pp. 13–21 and pp. 49–50.

A TB INFECTION CONTROL POLICY

Substance abuse programs must have and implement a TB infection control policy for the early detection, isolation, and treatment of patients or employees with active TB. An effective TB infection control policy will need to be in writing, will identify the person or persons responsible for supervising the implementation of the necessary controls, and will explain and emphasize the hierarchy of controls, to include

- Administrative controls
- Engineering controls (where possible)
- Masks or respirators (where necessary)

Only properly qualified individuals should be designated to oversee TB controls. A program without such an individual on staff should explore the possibility of obtaining appropriate training through local public health or occupational safety agencies.

Record Keeping

The following information should be recorded for all patients and employees:

- Dates and results of PPD skin testing (including size of induration in millimeters)
- Date and results of chest x-ray

- Name of clinician
- Date and place of TB diagnosis
- Treatment recommended
- Medical clearance for non-infectiousness
- Date treatment was completed
- Date and place of referral and follow-up evaluation
- Results of follow-up evaluation

All referrals should be documented as well, including the nature of referral, the results, and the progress of treatment follow-up. If DOT was administered, the dates of each dose given should also be recorded. Local or State public health departments can help design an appropriate record-keeping system.

Review of Agreement

The Cooperative Agreement must be reviewed periodically for effectiveness.

Contact

Each party to the Cooperative Agreement must have a list of key contacts in the other party's organization.

Use of Masks (or Respirators)

Assuming that effective administrative controls are in place, masks are the least important of the

three components of the recommended hierarchy of controls, at least for the typical substance abuse treatment program (since, generally, masks protect only the wearer). Masks are required only when interacting with someone who is or may be infectious (e.g., when in the same room with such a person, or when transporting such a person in an enclosed vehicle).

Employees who require masks to protect themselves must be instructed in their proper use. Infectious persons should also be instructed to wear masks, and should be isolated and asked to observe other precautions before and during transfer to a medical facility. Unless the program functions as a full-service health care facility, employees should not attempt to counsel potentially infectious persons until infectiousness has been ruled out.

Educating Your Program

Substance abuse treatment programs should seek the assistance of State and local public health departments in establishing a TB training program. In exchange, the program might offer to train the latter in substance abuse issues.

Education of Staff

All staff should be trained in the basics of TB, including prevention, transmission, diagnosis,

treatment, and follow-up. Such training should address staff concerns about infection and disease. Intake personnel should be able to recognize the symptoms of TB. Optimally, a program should also have an employee trained to administer and read PPD skin tests or even provide DOT.

Counselors will need to be trained to field patient questions about TB, and should therefore be familiar with issues such as PPD skin testing, the importance of chest x-rays for individuals who react positively to PPD tests or have HIV infection, the basic symptoms associated with TB, and the dangers of non-adherence to treatment regimens. Counselors should also be familiar with the health and social services network so as to be able to refer patients appropriately to TB and other services.

Education of Patients

Rather than relying exclusively on staff to convey this information, programs might employ methods such as peer education, group education, and joint staff and patient training. Peer counseling is a particularly effective means of bridging barriers to cooperation. A program might wish to give certain patients special training and responsibilities with respect to training other patients in the basics of TB.

For more detailed information, see TIP 18, pp. 29–32.

GLOSSARY

Anergy: Absence of ability to generate a sensitivity reaction in a subject to a substance expected to be antigenic (immunogenic, allergenic) in that individual.

Cooperative Agreement: An interagency agreement that sets out in detail the roles and responsibilities of each partner in the screening, treatment, and follow-up of mutual patients.

Directly Observed Therapy (DOT): Any therapy—whether preventive or to treat an active condition—in which a health care worker or public health employee watches the patient to see that he or she takes the prescribed medication.

Immunosuppression: Prevention or interference with the development of immunological response; may reflect natural immunological unresponsiveness, may be artificially induced by chemical, biological, or physical agents, or may be caused by disease.

Induration: An area of raised, swollen, or hardened skin. Measured in millimeters, an induration of a certain size following a PPD test can be an indication of TB infection.

INH: Abbreviation for isonicotinic acid hydrazide, the primary antibiotic/antibacterial agent used in treatment of TB. Also used as an abbreviation for the brand name drug Isoniazid.

Mantoux Tuberculin Skin Test: The preferred test for detecting TB infection, and the only way to diagnose TB infection before it progresses to active disease.

Mycobacterium tuberculosis (or *M. tuberculosis*): A genus of aerobic, nonmotile bacteria (family Mycobacteriaceae) which cause tuberculosis.

PPD: Abbreviation for pure protein derivative. Another name for Mantoux Tuberculin Skin Test.

Program: A Federally-assisted entity that, in whole or in part, specializes in individualized drug or alcohol abuse diagnosis, treatment, or referral for treatment. A program may be an individual or an organization. Federal assistance is defined as receiving Federal funds in any form, even if they do not directly pay for alcohol or drug services. Any such program is subject to Federal confidentiality laws related to alcohol and other drug information about patients or clients.

Qualified Service Organization Agreement

(QSOA): A contract that, under certain conditions, permits a substance abuse treatment provider to

share patient-identifying information with an outside service provider.

Reasonable Accommodation: In regard to infectious diseases, an accommodation made for a patient or employee that eliminates the risk of transmission of an infectious disease without imposing an undue burden on the provider or requiring fundamental alterations in program services.

Rifampin: An antituberculosis drug used in treatment of TB, typically referred to as RIF.

TB Disease, Active TB, Active TB Disease, or Infectious TB: These terms indicate infection by *M. tuberculosis*, active disease, and the ability to infect others. In contrast to simple TB infection which is used to denote only the presence and immune response to *M. tuberculosis*.

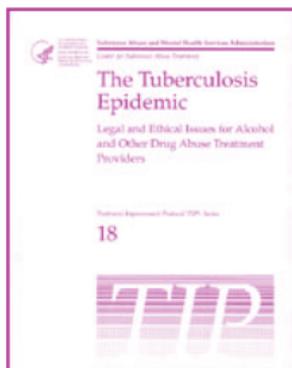
TB Infection: This term is used to denote the presence of (and usually an immunological response to) *M. tuberculosis*, but it does not necessarily mean there is TB disease or active TB. Once someone has been identified as having a TB infection, it remains to be determined whether or not there are the requisite additional signs or symptoms indicative of active TB disease.

Ordering Information

TIP 18 *The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers*

TIP 18-Related Products

KAP Keys for Clinicians based on TIP 18



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Easy Ways to Obtain Free Copies of All TIP Products

1. Call SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) at **800-729-6686**, TDD (hearing impaired) **800-487-4889**
2. Visit CSAT's Website at **www.csat.samhsa.gov**



Other Treatment Improvement Protocols (TIPs) that are relevant to this Quick Guide:

TIP 6, *Screening for Infectious Disease Among Substance Abusers (1993)* **BKD131**

See the inside back cover for ordering information for all TIPs and related products.