Tuberculosis

Section VIII.

Case Management of Suspected Cases and Patients with Tuberculosis in the Field and Clinic

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Initial Case Management

In TB control, case management is the system by which an individual (case manager) or a group working together (case management team) has responsibility for the care of a patient. A case management assignment is made as soon as the patient is reported to the program. (See p. 140, Figure VIII-1.)

Objectives of Case Management

The objectives of TB case management are to:

- Render the patient noninfectious by ensuring an adequate course of treatment.
- Provide early intervention to promote continuity of care and treatment adherence.
- Prevent the development of resistant organisms.
- Identify and address other urgent health needs of the patient.
- Identify and remove barriers to adherence to a treatment regime.
- Prevent TB transmission by conducting timely and effective contact investigation.

Case management should begin as soon as a patient suspected of having TB is identified and reported to the local health department. It should not end until the patient completes treatment and is discharged from the clinic. The case manager conducts regular reviews of patient progress and makes plans to address any barriers to treatment adherence, follow-up appointments or referrals, and anticipates problems and plans interventions before problems occur.

Collecting information directly from the patient, the medical record and other sources is crucial to successful case management since appropriate treatment decisions cannot be made without this information. It is imperative that the case manger have as much information (both medical and social) about the patient as possible; information is also essential to deal with problems when they arise.

The Initial Interview

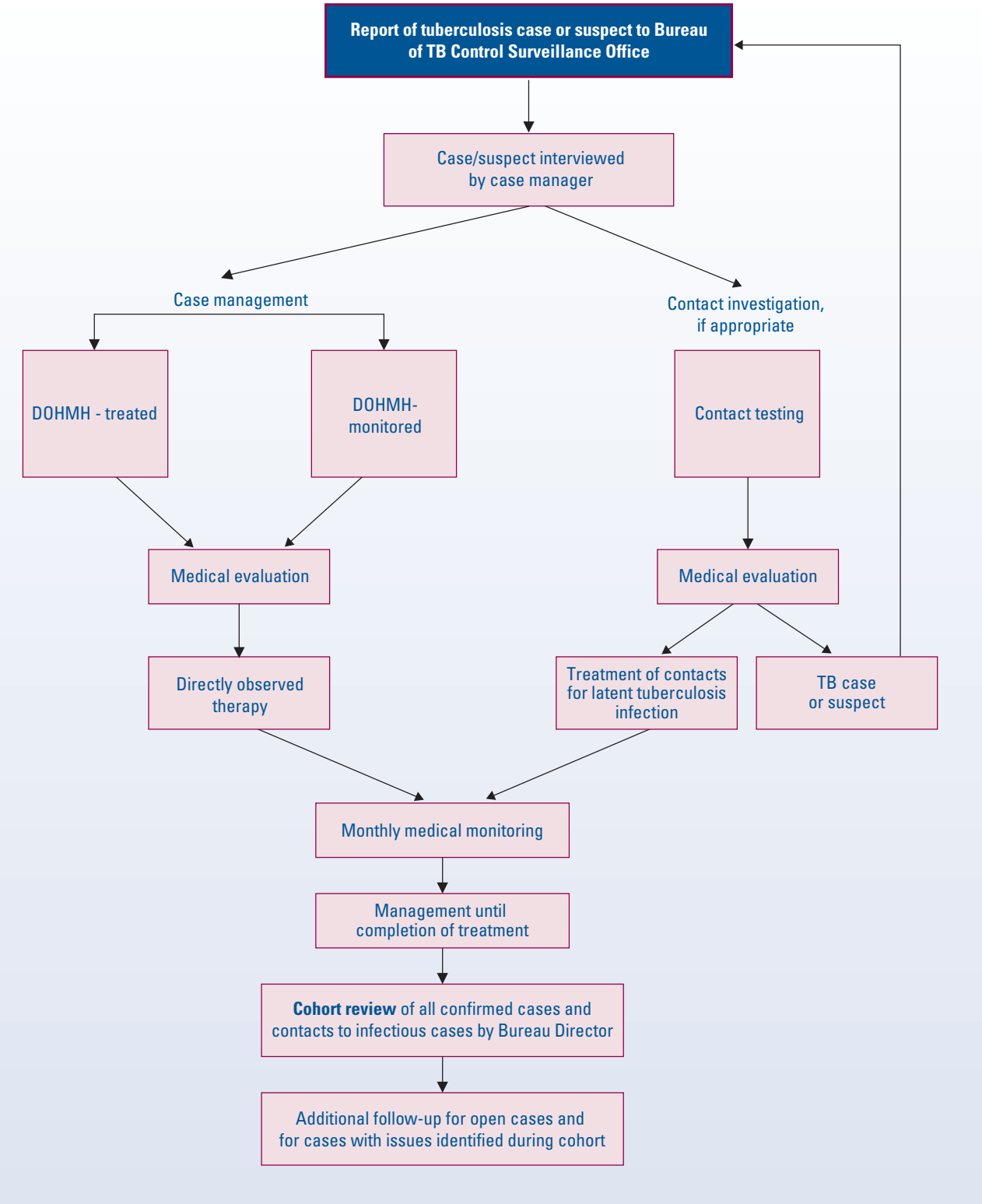
The case manager's initial interview with every patient who has suspected or confirmed TB should involve collecting as much information as possible. See Box on p. 141 for specifics about the initial interview.

Ensuring Effective Case Management

Lack of effective supervision leads to marginal case management and hinders achieving TB control. There must be a systematic review of each case manager's activities and workload. At each review session, follow-up of outstanding issues must be addressed by a supervisor, including identifying barriers to patient adherence and plans must be implemented to counter those barriers. Supervisory reviews should also serve to answer a case manager's questions and address concerns.

Figure VIII-1

Case Management Flow Chart



Abbreviations: DOHMH = Department of Health and Mental Hygiene; TB = tuberculosis

Case Manager Initial Interview Topics

1. **Educate the patient about TB,** debunking any misconceptions about the disease. The case manager should determine the most appropriate educational intervention and provide appropriate literature. The educational content should include information about:
   - TB transmission and pathogenesis
   - Preventing TB
   - Distinguishing infection from disease
   - How drug resistance develops
   - Length of treatment needed for sensitive vs. drug-resistant TB
   - Standard TB medications, including names, dosages, actions and side effects
   - Directly Observed Therapy (DOT) program and free Department of Health and Mental Hygiene (DOHMH) services for TB
   - How to open prescription packaging and take medication
2. **Establish long-term plans for treatment** (in cases in which the patient will receive treatment/DOT).
3. **Determine whether the patient will stay in NYC** during TB treatment.
4. **Inquire about contacts** and emphasize to the patient why it is important that contacts be identified and evaluated **as soon as possible**.
5. **Establish a trusting relationship,** as this determines how well the patient views the role of the case manager and the health care establishment.
6. **Obtain and document locating information** and agree with the patient on a mode of communication (e.g., beeper, cell phone, home/work number, significant other). Identify who will always know where to find the patient.
7. **Assess understanding of TB** on the part of the family and identified contacts.
8. **Assess social needs** such as access to social services to resolve issues with child care, housing, employment, substance abuse and (if appropriate) legal or immigration issues (tell the patient that all services are provided irrespective of immigration status).
9. **If the patient is diagnosed with TB while in a hospital**, plans for follow-up care upon discharge must be initiated at the outset, and not on the day before discharge. These plans must address issues that will ensure adherence with the treatment regimen.

Case management meetings should be held regularly (once a week is ideal). These meetings must be attended by the physicians overseeing the patient's medical care, the case managers, individuals involved in the supervision of the case manager, individuals involved in contact investigation and others as necessary. Issues to be addressed by the case management team include:

- Mental, emotional and cognitive status (via referral to a social worker)
- Access to transportation
- Usual places of residence, where and how to locate the patient, impending plans to relocate or travel, housing needs and living situation
- Cultural and religious beliefs that may impact adherence
- Language and literacy barriers
- Substance abuse
- Ability to pay for medical care
- Work history/income source
- Support system
- Family dynamics

Ensuring Adherence

Improving adherence to treatment is one important goal of a patient-centered case management strategy—many patients lose the incentive to continue treatment when they start to feel well. Case managers and clinicians should continue to educate the patient about the importance of continuing to take medication longer than the patient thinks is necessary. This message should be restated throughout treatment, even if the patient has not explicitly questioned the need to continue taking medications. The case management team should obtain and document information that may indicate the patient's potential for non-adherence, and address barriers on an ongoing basis. See the Box that follows for information on nonadherence.

Patients should be educated about the causes and effects of TB, the dosing and possible adverse reactions of their medication, and the importance of taking their medication according to the treatment plan. To facilitate adherence, the plan should use short-course treatment regimens and, for patients whose therapy is not directly observed, fixed-dose combination tablets. A welcoming and respectful atmosphere within the clinic setting is vital to encouraging adherence.

Common Problems with, and Early Indicators of, Poor Adherence

- DOT failure
- Slow sputum conversion or delayed clinical improvement
- Marginal or no acceptance of TB diagnosis
- Clinical deterioration while on TB therapy
- Inability of the case manager to verify pharmacy pick-up
- Failure to attend monthly follow-up appointments
- Pregnancy
- Substance abuse
- Malabsorption of TB medications
- Complaints that TB medications taste bad or make the patient sick.

All patients should be offered directly deserved therapy (DOT) as the standard of care. In some cases, electronic cap monitoring may be appropriate; however, it is not a substitute for DOT. Intermittent regimens facilitate DOT for both the provider and the patient, and should be used for most patients on standard TB regimens.

Incentives should be readily available to enhance adherence to therapy. These can range from simple overtures (e.g., offering a cup of coffee or food discount coupons; talking to a patient while waiting in the clinic) to tackling complicated issues (e.g., obtaining food and housing for a homeless patient). Providing transportation to the clinic is also important in promoting adherence.

Clinicians with TB patients who have demonstrated an inability or unwillingness to adhere to a prescribed treatment regimen should consult the Bureau of Tuberculosis Control (BTBC), which provides assistance in evaluating patients to determine causes

of non-adherence. If the patient still fails to adhere, the BTBC may take appropriate legal action, which could entail seeking court-ordered DOT or detention.

Return-to-Supervision Activities

Immediate follow-up is essential for patients who are non-adherent. Chest center staff should initiate the first follow-up contact; patients who cannot be located by chest center staff must be referred to field staff for further return to supervision (RTS) activities.

Follow-Up for Patients with Tuberculosis Who Have Missed Visits and for Suspected Cases Not on Directly Observed Therapy

A telephone call should be made to the patient within 1 working day of a missed appointment and the chart should be reviewed for appropriate action. A new appointment can be mailed to a DOHMH chest center patient if:

- The patient has enough medication to last at least until the new appointment and confirms by phone that he or she is taking the medication.
- The patient is at a low priority level compared with other TB clients requiring home visits.
- The patient specifically requests not to be visited.
- The only means of contacting the patient is a mailing address (i.e., post office box).

For all DOHMH patients, a home visit should follow the telephone call within 3 working days. If the patient has no telephone number and does not fall into the above categories, a home visit **must** be made within 3 working days. Patients who cannot be located by chest center staff must be referred to field staff for further RTS follow-up.

Follow-Up for Missed Directly Observed Therapy Visits

DOT patients should be called within 1 working day of a missed appointment. If the phone call is unsuccessful, or if the patient has no phone number, a home visit should be made within 1 working day of a missed appointment. Daily DOT patients are considered nonadherent after missing 3 daily doses, or 1 to 2 doses per week, for 2 consecutive weeks. DOT patients on intermittent therapy are considered nonadherent after 2 or more doses are missed within 2 weeks. The primary care physician and case manager must be informed of any DOT nonadherence within the week of occurrence.

Patients who cannot be located by chest center staff must be referred to field staff for further RTS follow-up.

Prioritizing Patients for Further Return to Supervision

Several factors must be considered when deciding how to prioritize finding patients lost to follow-up. (See Box on p. 144). The first consideration is whether the patient has enough medication. Patients who are estimated to have sufficient medication and who report by telephone that they are taking the medication should be a lower priority than those who have run out of medication. In general, patients recently diagnosed with TB are a higher priority than older cases.

Cohort Review

Quarterly cohort review meetings were established by the BTBC in 1992 as a quality assurance tool for improving case management. This was one of several initiatives established at that time to help control the TB epidemic.

The cohort review consists of quarterly meetings for all staff responsible for patient care. This includes all case managers and their supervisors in BTBC chest clinics and in the field, all treating physicians and nurses, and any epidemiologists involved in case management. The cohort review is the BTBC's most important method of program evaluation as it provides a multi-disciplinary forum to review the management of each case and ensures accountability at all levels. It allows clinicians, managers and public health advisors to consult on difficult cases, especially nonadherent patients, those with MDRTB or cases with numerous contacts in several settings.

Cohort reviews take place 5 to 8 months after the patient is diagnosed with TB, allowing for

Prioritization for Locating Nonadherent Patients

1. Any patient with multidrug-resistant TB (MDRTB) with current positive bacteriology (smear or culture), regardless of the site of their disease
2. Newly diagnosed patients, or reactivated patients, who have had AFB-positive sputum smears with no documentation of conversion to negative within the last 9 months
3. Any child younger than18 years of age with less than 6 months of treatment, regardless of site of disease
4. Any patient who is HIV-positive with current sputum AFB-negative smears, but whose culture has not converted to negative
5. MDRTB patients with negative bacteriology (smear and culture) who have received less than 18 months of therapy
6. HIV-positive contacts of MDRTB patients (if they are known)
7. Patients with single drug-resistant TB who remain culture positive
8. Patients with drug-sensitive TB who have negative smears but remain culture positive
9. Patients with drug-sensitive TB who have negative smears and cultures but who have received less than 6 months of treatment
10. Patients with only drug-sensitive extra-pulmonary TB

most patients to complete treatment. During these meetings, all confirmed cases of TB diagnosed during a particular quarter are presented in a standardized format to the Bureau Director by the case manager responsible for them. The Bureau Director reviews each case, verifying details such as the patient's clinical status, appropriateness of the treatment regimen, treatment adherence, treatment completion and outcome of the contact investigation. As each case is presented, the cohort epidemiologist enters the information into a spreadsheet, while another epidemiologist systematically documents the issues or problems identified for each patient during the meeting. Individual staff is required to follow up on all issues identified.

Objectives of the cohort review process are to:

- Ensure the implementation of comprehensive case management procedures for all TB patients in NYC
- Improve promptness of appropriate interventions
- Maintain reliability of data on the TB registry
- Provide immediate analysis of treatment outcomes and contact investigation efforts, measured against previous cohorts
- Assess NYC's efforts compared to local and national TB control targets
- Identify, track and follow up on important case management issues
- Provide ongoing training and education for staff
- Provide staff with a forum for open discussion with BTBC management

These objectives provide the technical rigor needed to comprehensively assess program experience, provide feedback to staff and continually improve the TB control program.

Nonadherent Patients Who Should Be Referred for Detention

- The patient has missed chest center appointments for 2 or more months and has refused voluntary center or field DOT.
- The patient is nonadherent to, or considered inappropriate for, self-administered treatment by the treating physician and is unwilling or unable to start or continue BTBC chest center or field DOT.
- The patient has exhibited adherence to self-administered therapy monitored with a MEMS cap of less than 80%.
- Pharmacy checks show insufficient medications being picked up by the patient.
- The barriers to treatment adherence were addressed to the extent feasible and possible, but the patient continues to be nonadherent.
- A range of DOT options (e.g., including DOT at a worksite or methadone maintenance program) were offered to the patient; however, the patient continues to fail to maintain more than 80% adherence to DOT.
- Appropriate referrals to address chemical dependency issues were provided and patient remains non-adherent.
- Appropriate referrals to address mental health problems were provided and patient remains non-adherent to treatment.
- The patient was referred to a social worker for assistance because unstable housing arrangements interfered with adherence to TB treatment. However, the patient refuses placement and/or continues to fail treatment even following housing placement.

Regulatory Intervention Options

Nonadherent patients who have, or are suspected of having, TB must be referred to the Regulatory Affairs Unit for evaluation for regulatory actions. This should be done when customary interventions fail to result in patient evaluation and adherence to an anti-TB regimen. All efforts and interventions made to facilitate adherence to prescribed TB treatment regimens must be documented in detail in TB control records and forms. For nonadherent patients referred to Regulatory Affairs, field efforts to return patients to medical supervision must continue until a decision is made and executed. Legal intervention should be considered when all reasonable efforts to assist the patient in completing the entire course of TB treatment regimens have failed (see Box above).

The purpose of regulatory intervention is to:

- Ensure that nonadherent TB patients complete an adequate course of TB treatment
- Ensure that patients suspected of having TB undergo appropriate evaluation
- Ensure that the public is protected from infectious TB patients who have refused to voluntarily agree to isolation
- Prevent the development of an epidemic of acquired drug resistance among TB patients who are unwilling or unable to adhere to an interrupted course of treatment

Commissioner's Orders

Section 11.47 of the NYC Health Code authorizes the Commissioner of Health to exercise a range of compulsory options to control TB (i.e., to issue "any orders he or she deems necessary to

protect the public health") from someone who is a danger to the public health, including, but not limited to sections (d) (1) through (d) (5) orders in the current Health Code (see Box on p. 147).

The Commissioner has long been empowered to detain patients with TB whose presence in the community constitutes a danger to the public health. As amended, §11.47 of the Health Code expanded that authority and mandated constitutional due process safeguards for detainees. Section 11.47 emphasizes that involuntary detention should generally be considered a measure of last resort.

The Commissioner continues to have general authority to issue any orders deemed necessary to protect the public (or an individual's) health [Health Code §11.47 (d)] and is given specific authority to detain nonadherent TB patients who represent a public health threat.

Less restrictive orders may also be requested by providers treating patients for whom adherence to anti-TB medication is an issue. The provider may request, and the Commissioner may order, that a person with TB complete an appropriate prescribed course of medication [11.47 (d) (2)] and/or that a patient's ingestion of medication be monitored through DOT [11.47 (d) (3)].

1. The Department conducts an intensive evaluation of the medical and TB treatment histories of patients referred for detention, which includes:
   - Analysis of all relevant Department and hospital records to verify past TB-related behavior
   - Documentation of providers' efforts to promote adherence to treatment
   - Description of the patient's present circumstances
2. All applicable clinical and social service records are reviewed in detail, both to determine whether the patient can reliably maintain pertinent contagion precautions and whether he/she can comply with voluntary treatment. The Department must be able to demonstrate that less restrictive treatment alternatives were identified, attempted and failed, or were considered and ruled out.
3. Patients detained pursuant to Commissioner's orders may request release at any time after an order is served. They are entitled to representation by a private or city-appointed attorney. When the detainee requests release, the city has 3 business days to file an application in Supreme Court seeking a court order authorizing continued detention also known as an order to show cause.

The order to show cause requests the court to schedule an expedited hearing at the facility where the patient is being detained.

Patients who do not request release may be held for up to 60 days by Commissioner's order. If longer detention is anticipated, the Department must apply for a court order authorizing continued detention. All court orders must be reviewed by the court issuing the order every 90 days thereafter.

The burden of proof supporting the detention of an individual with TB rests with the Health Department, which must provide clear and convincing evidence that the continued presence in the community of the individual with active TB presents a danger to the public health and that there is no measure short of detention that can be reasonably applied.

Documentation in the form of hospital, clinic and other clinical records constitutes the Department's evidence that detention is necessary. Certified copies of hospital and other records are required. The records include, but are not limited to:

- All TB-related admissions and clinic visits
- Incident reports for elopement (leaving the hospital without notice)
- Leaving the hospital against medical advice
- Records of visiting nurse and other-provider home visits for DOT
- Notes or memoranda from psychiatric, medical, nursing, social worker or other provider staff

The records require documented observations of a patient's past TB compliance history and other factors that appear to rule out reliance on voluntary completion of prescribed TB therapy. The Department's access to such records is authorized by applicable city, state and federal law, and a Department representative will request them in writing.

Tuberculosis-Related Regulatory Interventions Sections of the Current Health Code

Health Code 11.47 d (1) authorizes removal and/or detention in a hospital of individuals who have or are suspected of having active TB and who are unable or unwilling to submit to voluntary examination. An additional order pursuant to 11.47 d (4) or d (5) must be issued if circumstances warrant continued detention after examination confirms active TB disease.

Criteria for issuing:

- Diagnosis of TB likely, based on the clinical picture, a chest radiograph consistent with TB and /or sputum smear results positive for acid-fast bacilli (AFB).
- Individual persistently refuses medical evaluation for active TB.
- Individual is in close physical contact with others.

Health Code 11.47 d (2) authorizes the Commissioner to require that persons having or suspected of having active TB complete an appropriate prescribed course of medication for TB.

Criteria for issuing:

- Patient leaves the hospital against medical advice (AMA), refuses anti-TB treatment or fails to attend TB-related clinic appointments.
- Sputum cultures pending or awaiting confirmation

Health Code 1147 d (3) or "CoDot" authorizes the Commissioner to require that persons with active TB who are unable or unwilling to complete an appropriate prescribed course of medication for TB follow a course of DOT.

Criteria for issuing:

- Sputum culture was positive for *M. tb* during the past year.
- Individual has not completed treatment and is unreliable to self-medicate.
- Individual is consistently < 80% adherent despite voluntary clinic, home or field DOT.

In some cases:

- History of violation of isolation precautions and/or being impossible to locate.
- Individual refused anti-TB medications or stopped treatment without valid reason.

Health Code 11.47 d (4) authorizes removal and/or detention in a hospital or other health care facility of persons having or suspected of having active infectious TB who are considered substantially likely to transmit the disease to others because they are unable or unwilling to observe appropriate anticontagion precautions. The detention order may be lifted if circumstances change indicating that the patient is either no longer infectious and/or is able or willing to comply with respiratory isolation or other necessary contagion precautions.

Criteria for issuing:

- Individual refuses hospitalization or threatens to leave the hospital AMA.
- Despite education, individual cannot or will not be separated from other persons who are at risk of becoming infected with TB.

Health Code 11.47 d (5) authorizes the Commissioner to remove and/or detain in a hospital or other health care facility individuals which active TB (infectious or noninfectious) that, based on past or present nonadherent behavior, cannot be relied upon to complete the appropriate TB treatment regimen and/or to maintain anticontagion precautions. This section allows long-term detention for patients who require it.

Criteria for issuing:

- Sputum culture was positive for *M. tb* during the past year.
- There is no evidence of treatment completion.
- History and/or risk of individual being impossible to locate.
- All reasonable DOT options, including CoDOT (d3), have failed or are failing.
- In some cases, individual refuses to accept the diagnosis of active TB.

Procedures for Infectious or Potentially Infectious Patients Who Want to Leave the Hospital

Once a provider has grounds to believe that a patient may leave the hospital without authorization, the BTBC should be contacted immediately. Patients deemed infectious and who do not meet discharge criteria should not be allowed to leave by signing out against medical advice.

As it can take some hours to gather and review all pertinent records to issue a Notice of Obligation to Isolate, once the Bureau is notified, the hospital is obligated to hold the patient, with a guard if necessary, and prevent him or her from leaving until the actual Notice is sent to the facility. (10NYCRR2.27)

Upon receiving the Notice, the hospital must monitor the patient's activity and take all necessary measures to prevent him or her from leaving the hospital. A signed Commissioner's order for detention [a d(1)or d(4) order] will be faxed to the hospital within 24 business hours of the issuance of a Notice of Obligation to Isolate.

Upon receiving a request for a detention order, BTBC staff will conduct an assessment of the patient's risk to the public health. Based on hospital and other clinical records, the patient's TB treatment-related behaviors will be evaluated. Additionally, the Bureau will assess documentation pertaining to case management efforts to identify and address barriers to patient compliance. This assessment determines whether a Commissioner's detention order should be issued (see Box on p. 147).

The patient who is to be detained is personally served with the Detention Order by BTBC or hospital staff. When the patient is served, he or she is informed of the legal authority for the order and his/her rights, which include the right to request release at any time and the right to an attorney. The Order includes the BTBC and other Health Department telephone numbers that the patient may call to request legal representation and/or release. The City of New York will assign a lawyer to the patient upon request by the patient.

To facilitate the Commissioner's Order, DOHMH must provide clear, convincing evidence of nonadherence. The evidence must sustain the need of a regulatory action for detention of an individual with active TB who is unable or unwilling to adhere to treatment and DOT.

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