Case Management

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Case management is considered a critical component of effective TB control.

In the context of the tuberculosis (TB) program, case management refers to:

Assigning primary responsibility for coordination of patient care to ensure that the patient’s medical and psycho/social needs are met through appropriate utilization of resources. The case manager ensures that the patient is adherent with and completes an appropriate course of therapy until cure, and coordinates a regular, systematic review of the patient’s progress in therapy.

Roles and Responsibilities

Case management of drug-resistant TB is demanding and complex, so assigning a case manager to the drug-resistant TB patient is highly recommended.

The case manager is the “team leader” of the case management team. The case manager coordinates the case management efforts of the treating physician and consultants, and other caregivers such as outreach workers, directly observed therapy (DOT) workers, social workers, correctional facility nurses, school nurses, and contact investigators.

The case manager has primary responsibility for ensuring that:

- The patient adheres to treatment through completion via DOT
- The patient and significant others in his/her environment receive and understand education pertaining to drug-resistant TB disease, its transmission, and treatment
- The patient follows through with all medical evaluations, including clinical and toxicity monitoring
- Individuals in contact with the source case patient are identified, located, prioritized, evaluated, and treated as needed
- Response to therapy is evaluated regularly, and if not in accordance with expected outcomes, is further evaluated

Depending on the expertise, resources, and infrastructure of the clinic or medical provider managing the actual care of the patient, the case manager may have other roles and responsibilities. When primary clinical care is obtained through a private provider or when patients are hospitalized or incarcerated, the case manager may take on the role of liaison or coordination-of-care. In addition to the previously listed responsibilities, the case manager:

- Facilitates exchange of information between the family, medical providers, laboratories, pharmacies, insurance companies, and the public health infrastructure
- Builds relationships within all these systems to achieve the best results for the patient
- Ensures expert consultation has been sought and provides referral for consultation as needed
- Offers training, education, and resources to staff who will be providing patient care
It is encouraging that model programs utilizing a case management approach in community-based care of drug-resistant TB patients (see Figure 1) have been showing very promising results. Unfortunately, in areas where TB control programs are small with fewer resources, and in which public health nurses deliver a wide range of public health services, one drug-resistant TB case can put a huge strain on the system.

This chapter highlights some of the challenges surrounding the care of drug-resistant TB patients in the United States and the role of case management in addressing them.

**FIGURE 1.**

**Community-Based Model of MDR-TB Treatment**

Adapted with permission from *The Community Based Model of Multidrug-Resistant Tuberculosis Treatment*, Jaime Bayona, MD, MPH, Socios En Salud Sucursal, Peru
Ensuring Adherence to Treatment

The case manager must consider all potential barriers to adherence when structuring the plan of care for a patient’s treatment for drug-resistant TB. Anticipating and addressing potential barriers to adherence can not always prevent lapses in treatment or nonadherence; documentation of the interventions utilized will be important should legal orders need to be considered. A strong plan will include the following elements:

- Assessment of psycho/social and cultural needs
- Provision of education to the patient and patient’s family with the goal of obtaining commitment to the treatment plan
- Provision of treatment by DOT
- Monitoring and managing potential drug toxicities
- Use of incentives and enablers
- Use of culturally appropriate resources
- Use of legal orders

Directly Observed Therapy (DOT)

The consequences of treatment failure and further acquired drug resistance make DOT a high priority for cases of drug-resistant TB. DOT is so important to the treatment of drug-resistant TB that experts in the field of TB control around the world consider it a vital strategy. Achieving this standard of care, however, requires far greater time and commitment in the treatment of drug-resistant TB than for drug-susceptible disease:

- Several of the second-line drugs used to treat drug-resistant TB are better tolerated when introduced gradually and may require twice or 3-times-daily dosing.
- The use of injectable drugs requires a higher level of expertise, more time, and more technology than that required for observing the administration of oral drugs.
- Second-line agents require an extended treatment length and monitoring for adverse reactions.

The case manager must keep an open line of communication with the individual providing DOT and ensure that he/she can assess which signs and symptoms indicate potential medication toxicity. Any toxicity must be quickly identified, reported, and acted upon (see Chapter 6, “Monitoring Patients” and Chapter 7, “Adverse Reactions”). Use of standardized forms to record DOT doses and toxicities is crucial for these complicated patients. See examples of monitoring tools in Chapter 6 and on-line (www.currytbcenter.ucsf.edu/drtb).

Addressing Psycho/Social Needs

Be sure to assess the patient for strengths and barriers to adherence, and ensure that plans are in place for addressing issues such as mental illness, substance abuse, homelessness, and health insurance coverage. Costs associated with the treatment and management of patients with drug-resistant TB vary widely and are influenced by the amount and type of drug resistance as well as the extent of disease. For patients with limited or no health insurance coverage, charges associated with cost of drugs, diagnostic exams, and surgery may pose an extreme financial burden on individuals and families.
Many patients experience a period of prolonged unemployment associated with the period of contagiousness and due to employment discrimination. There is often a need for the case manager to intervene and educate employers and find alternative sources of income and other assistance for the patient and his/her family while he/she cannot work.

Undocumented immigrant patients with drug-resistant TB may be eligible for Medicaid or Medicare if they are able to obtain legal status in the United States. One avenue that might be explored is PRUCOL status (variably called Permanent Residence Under Color of Law, Persons Residing Under Color of Law, and Aliens Permanently Residing in the United States Under Color of Law). Organizations that provide pro bono immigration legal services can be very helpful in exploring options available to undocumented persons or low-income immigrants. Addressing these challenges early in the patient's course of treatment will go a long way in establishing a foundation of confidence and trust.

Consider community services that can assist you in addressing these challenges:

- Social services and programs for the medically indigent
  - Medicaid and any other third-party payer eligibility
  - In California, legal residents may be eligible for TB-MediCal, which may provide more outpatient benefits than other payer sources
  - In some jurisdictions, all TB care can be provided free of charge in the public health setting
- Immigration law counsel—National Immigration Law Center: www.nilc.org
- Drug and alcohol counseling
- Mental health programs
- Other community-based outreach services

Your key to successfully assisting patients with these challenges is to develop a trusting relationship with the patient and to be familiar with resources in your community. Ideally, case managers will have familiarity with and ongoing relations with valuable community resources prior to their first cases of drug-resistant TB.

**Bridging Cultural Barriers**

Over three-fourths of patients with MDR-TB in the United States are foreign-born, many of whom are recent arrivals.

**Barriers to diagnosis and treatment may include:**

- Cultural stigma about TB
- Fear of the cost of TB care and lack of eligibility for programs
- Concern that the illness might interfere with the immigration process
- Fear of deportation
- Hindered access to health care because of language or cultural barriers as well as the general difficulty of navigating complex health care systems in the United States
- Patient’s preference to seek traditional healing when ill
- Patient’s preference to seek out a physician from his/her own culture, who may not be familiar with diagnosis and treatment of drug-resistant TB
Engage the family in the patient’s care; encourage and praise their support. Do everything possible to get family members, especially spouses, to cooperate and support the treatment plan. An investment of time initially is well worth the benefits it often reaps.

Offer to evaluate family members for TB or latent tuberculosis infection (LTBI) and answer their questions.

**Patient Education**

In many respects, facing a diagnosis of drug-resistant TB can be likened to preparing for a marathon—the goal being to complete treatment with the fewest interruptions.

The case manager can play a key role in coaching the patient through the various phases of treatment by assisting the patient to set achievable interim goals. A standardized form can help the case manager document the many elements of patient education.

The following phases may not fit the treatment course for all drug-resistant TB cases, but hopefully will provide a context for case managers to anticipate their patients’ educational capacities and needs.
1. Initial Phase

The initial phase is likely to be quite intensive as the patient may be very ill, in respiratory isolation, and facing a barrage of very toxic drugs.

- **Keep information simple** with a focus on the following: minimizing transmission; achieving commitment from the patient to comply with the treatment plan; and sharing information about contacts and legal requirements.

- If the case manager is not the individual actually providing the DOT, **regular contact with the DOT provider and weekly contact with the patient will be important during this phase** to ensure that the patient is tolerating the medication and that side effects are quickly addressed. While most patients will experience mild complaints that can be managed without a change in the drug regimen (e.g., initiating adjuvant therapy, changing dosing time), some side effects warrant at least temporary discontinuation of the offending drug. Address all complaints, even if no change can be made. Make sure that the patient does not feel isolated during this phase.

- **If the patient is hospitalized, the case manager will need to provide support to the patient as well as to the hospital staff.** Hospital staff who do not care for TB patients routinely will need to be reminded to observe each dose of medicine (not to leave the medicine at the bedside) and may need to be educated about many aspects of drug-resistant TB care. If the patient’s medical needs are not given careful attention during this initial phase, the patient is at higher risk for becoming demoralized and discouraged. Hospital staff should be encouraged to seek expert consultation when necessary. Frequent and timely communication with the patient’s hospital-based treatment team regarding discharge planning should include: procuring second-line medications prior to discharge, coordinating infusion therapy services if the health department cannot provide them, and dealing with psychosocial issues (such as homelessness) prior to discharge.

- **Prepare the patient to expect some side effects** so that when they occur, the patient does not fear that the treatment is doing more harm than good. Close monitoring is needed to ensure side effects are responded to promptly, particularly when treatment is initiated in an outpatient setting.

- **Assist the patient in coordinating ongoing care of co-morbid conditions,** such as HIV, diabetes mellitus, and renal disease.

In many respects, facing a diagnosis of drug-resistant **TB can be likened to preparing for a marathon – the goal being to complete treatment with the fewest interruptions.**

**Information to reinforce during the initial phase:**

- **Simple infection control practices,** such as covering the mouth when coughing and disposing of tissues properly. Discuss the patient’s plans regarding work, travel, or moving.

- **Strategies for keeping the home well-ventilated** with fresh air and adhering to visitor restrictions if isolated at home.

- **Expected side effects** and plan for addressing minor complaints should they occur.

- **Potential consequences of nonadherence to treatment** and respiratory isolation.

- **Maximizing nutritional intake.**

- **Sharing information** to assist in the identification and evaluation of contacts.

- **Emphasizing the importance of keeping scheduled clinical appointments.**

- **Understanding the criteria for noninfectiousness** (i.e., when home isolation can be discontinued and the patient will be allowed to return to work or school).
2. Second Phase

This period begins once the patient is deemed non-infectious and continues until the injectable agent is discontinued. During this phase, the focus should be on helping the patient understand the disease and working together to identify barriers to achieving completion of treatment without interruption. Drug toxicity can occur at any phase in treatment and should continue to be closely monitored. If surgical intervention is indicated, it might occur during this phase.

- **Consider incentives and enablers that might aid adherence to treatment.** (See “Use of Incentives and Enablers.”)
- **Reevaluate the patient’s knowledge and understanding of the disease** and the potential serious side effects of treatment; reinforce information as needed.
- **Regularly assess for serious side effects** such as increasing depression, changes in vestibular function, etc. (See Chapter 6, “Monitoring Patients” and Chapter 7, “Adverse Reactions.”)
- **Monitor care for co-morbid conditions.**
- **Reinforce importance of monthly sputum collection, good nutrition, and physical activity** as tolerated.
- **Monitor monthly for signs of continued clinical improvement.**
- **Discuss management of injection site(s)** (care of IM/IV sites).
- **Review the patient’s plans concerning work, travel, or moving.**
- **Ensure that the patient understands that a non-infectious state is not equivalent to being cured.**
- **Serially and continually reassess the status of the contact investigation** and the sharing of information regarding contacts not previously identified.

3. Third Phase

If continued clinical response is achieved, the third phase begins when the parenteral agent is discontinued and lasts until the end of treatment. While this may sound much like nearing the home stretch, it is really closer to passing the halfway point. The patient may well have to take oral medications for another year or more before reaching the finish line.

- **Ensure vigilance in ensuring DOT and clinical response monitoring.**
- **Revisit the patient’s commitment to the treatment plan and the need to complete treatment to prevent relapse.**
- **Reassess the patient’s understanding of the consequences of nonadherence to treatment; reinforce information and address barriers as needed.**
- **Revisit the patient’s plans concerning work, travel, or moving.**
4. Final Phase

The final phase begins once treatment is completed. The marathon is over, yet the patient will require clinical monitoring for the next several years to ensure that if a relapse occurs, it will be identified and acted upon quickly.

- Ensure that the patient is knowledgeable about signs and symptoms of TB and what to do should he/she experience them.
- Schedule follow-up appointments and arrange for reminder notification.
- Revisit the patient’s plans concerning work, travel, or moving.

Use of Incentives and Enablers

Patient motivation commonly wanes once the patient begins to feel better and may affect the patient’s commitment to the treatment plan. The use of incentives and enablers is another strategy reported to be effective in assisting patients in maintaining adherence to treatment. Incentives are “small rewards” given to patients to encourage them through the lengthy treatment and monitoring period. Enablers refer to things that assist a patient to overcome a barrier, such as the provision of taxi or bus fare to attend a clinic appointment when a patient is without a means of transportation. The following resource addresses the use of incentives and enablers and gives many examples for the case manager to consider:


Use of Legal Orders

Legal measures are sometimes required when a patient with infectious, drug-resistant TB remains nonadherent despite interventions to overcome barriers and gain the patient’s cooperation. The case manager should be knowledgeable about the process for referring such patients and must ensure that documentation of all lesser restrictive measures that have been employed has occurred. Local, regional, and/or state TB control programs can provide additional information on the state laws and regulations pertaining to TB when persistent nonadherence is occurring. See Chapter 9, “Ethical and Legal Issues.”
Clinical Response Monitoring

The case manager is responsible for ensuring that all necessary monitoring for both toxicity and clinical response occurs and that abnormal results are brought to the attention of the treating physician. (See Chapter 6, “Monitoring Patients” and Chapter 7, “Adverse Reactions.”) To keep the confidence of the patient, healthcare providers, and DOT workers, the case manager must be detail-oriented, anticipate problems and manage them as they occur. Helpful tools and strategies include:

- Scheduling regular visits with the patient, initially weekly and then monthly, to perform a thorough nursing assessment until completion of therapy.
- The “Care Plan” and the “Drug-O-Gram” are documents that can be customized for the case manager’s own needs and patient’s circumstances (see Chapter 6, “Monitoring Patients”, and Monitoring Tools 1 and 2).
- Monitoring flow sheets to track progression of bacteriology results, blood work, audiograms, and vision/vestibular screening (see Chapter 6, “Monitoring Patients,” and Monitoring Tools 3, 4, and 5).
- Real-time reminders on the computer or “Palm,” a tickler system, Post-it notes on the desk, highlighted messages on the desk calendar, a hanging file system, etc.
- Seeking expert consultation from regional resources such as state TB control programs and Regional Training and Medical Consultation Centers (RTMCCs). The learning curve is very steep during case management of the first case or two of drug-resistant TB, and use of the resources included in this book and discussions with experts will help with the rapid acquisition of information required.

The case manager will be instrumental in assessing:

1. Conversion of sputum smear and culture
2. Resolution of symptoms
3. Weight gain and stabilization
4. The need to adjust medication as weight changes or as renal function changes

Bacteriology

- Obtain 3 sputa for AFB smear every 2 weeks until smears become negative.
  - Sputum specimens should be collected at least eight hours apart.
  - At least 1 specimen should be an early morning specimen. Some patients will be able to collect higher quality specimens if all of them are collected first thing in the morning.
  - Consider supervision of collections and/or sputum induction.
- Collect 2 to 3 sputum samples monthly until cultures become negative.
- Repeat susceptibility testing if cultures remain positive after 3 months of treatment.
- Once the culture has consistently converted to negative, obtain at least 1 specimen of sputum for AFB smear and culture monthly if clinically improving, and more frequently if indicated. Once the patient is no longer able to spontaneously produce sputum, sputum induction may be required.
- Obtain sputum for AFB smear and culture at the end of treatment.
- A critical activity of the case manager is coordination of microbiologic evaluation for the patient’s cultures. Specimens should be of good quality and at least 5 to 10 ml...
in volume. Specimens need to be routed to the appropriate reference labs, specific detection of drug resistance tests need to be requested, and results communicated as quickly as possible to the treating physician.

**Therapeutic Drug Monitoring**

- The case manager also frequently coordinates collection and transport of blood samples for therapeutic blood monitoring. Few reference labs perform these levels, and factors such as cost and a patient’s insurance status require the experience of the case manager. For details, see Appendix 12, “Therapeutic Drug Monitoring.”

**Symptoms**

- Assess symptoms of TB monthly throughout treatment and document resolution of symptoms that were present at diagnosis. Monitor symptoms of drug toxicity.
- Conduct post-treatment symptom review during regularly scheduled follow-up appointments for 2 years after treatment completion.

**Weight**

- Weight is a key marker for evaluating clinical improvement. Check weight monthly until stable, and then periodically (every 2 to 3 months) throughout the course of treatment and follow-up. Some case managers will find it more convenient to develop a routine of monthly, rather than intermittent weight checks.
- When the patient has sustained substantial weight loss, or if the drug-resistant TB patient is an infant, monitor weight more frequently as a measure of clinical response to therapy and to ensure dose adjustments are made as weight increases.

**A Word about Nutritional Supplements**

Nutritional supplements such as Ensure and multi-vitamins are an important aspect of drug-resistant TB care, but they may impact the absorption of certain drugs commonly used in the treatment of drug-resistant TB (such as fluoroquinolones). Refer patients with co-morbidities impacted by nutritional intake (such as diabetes) for dietary consultation.
Continuity of Care

The role of the case manager becomes increasingly important when the drug-resistant TB patient is being treated in the private sector and/or changes providers during the course of his/her treatment. When the drug-resistant TB patient moves between facilities (such as a hospital or jail) and the community during the course of treatment, the case manager must ensure that appropriate treatment, monitoring, and education of the patient continues. This may require:

- Re-establishing relationships with a whole new group of staff
- Providing training and/or information on drug-resistant TB to staff caring for the patient
- Establishing processes for sharing information

If the patient moves out of the case manager’s jurisdiction, concrete plans for transfer of care need to be in place before the move. Even if the patient moves out of country, an accepting provider and responsible jurisdiction need to be identified and apprised of the patient’s disease and treatment history. The patient should be provided with only enough medications to last through the travel period until they can reestablish DOT in the new jurisdiction. Contact information for family and friends, both in your area and in the destination, may be helpful if the patient does not arrive at the destination in a timely manner.

As appropriate, consider referral to programs such as CureTB or TBNet. Both programs are available at no cost to patients or clinicians. These programs can work with patients who are considering moving prior to completion of therapy.

- CureTB is a binational referral program based out of San Diego, California, for patients with TB who move between the United States and Mexico. Patients will be linked to care in Mexico and educated about the differences in services that can be expected. **Note:** Availability of second-line medications, acid-fast bacilli (AFB) cultures, and DOT is limited in many parts of Mexico. Telephone: 619-542-4013.
- TBNet is a comprehensive tracking and referral network within the Migrant Clinicians Network. TBNet helps provide continuity of care services for mobile populations with active TB or LTBI who move throughout the United States. Telephone: 800-825-8205.

Interface With Private Providers

If the patient is managed by a private provider:

- Make an appointment to meet the provider and the office staff as soon as possible.
- Make it clear through your actions and words that you are an ally and will be very helpful in the complicated management of the patient.
- Explain your legal responsibility to monitor the patient throughout the course of treatment.
- **Explain the regulations** in your state or jurisdiction regarding the provider’s responsibility to provide information to the health department.
- Explain the absolute necessity of DOT and that it is not in any way punitive. Patients frequently take their cues from their physicians; enlist the provider’s support in encouraging the patient to accept DOT.
- Relay the benefits of case management and DOT in the efficient treatment of drug-resistant TB.
• Explain the infection control practices required to keep office staff and other patients safe.

• Ensure that the office staff has been appropriately evaluated if unprotected exposure to the patient has occurred.

• Offer resources to help manage the patient’s co-morbid conditions, such as diabetes, malnutrition, and HIV.

• **Share this Survival Guide and a list of consulting resources** with the provider. Stress the importance of an expert in drug-resistant TB being involved throughout the course of treatment. In some areas, ongoing consultation with the regional experts is routine (see Appendix 1, “List of Expert Resources for Drug-Resistant TB”).

• If the provider and staff have the infrastructure and resourcefulness to problem-solve for the patient (i.e., interfacing with insurance companies; seeking supplies of hard-to-get medications; making sure that the patient follows through on all monitoring; ordering and following through on detection of drug resistance testing, blood levels, etc.), stay actively involved in order to ensure that **everything** gets done and is followed up on appropriately.

• Touch base with the office staff regularly. Continue to offer yourself as a resource, problem-solver, and advocate. Anticipate staff needs, such as an audiologist who takes the patient’s insurance or an interpreter who the patient trusts.

**Infection Control**

In order to halt the transmission of *M. tuberculosis*, the correct diagnosis must first be considered, the appropriate treatment must be initiated, and appropriate infection control measures must be instituted. Contagious or potentially contagious TB patients should be housed within a negative pressure room in the hospital setting or separated from family or friends in the outpatient setting.

When dealing with suspected or confirmed infectious drug-resistant TB, even greater emphasis should be placed on strict adherence to infection control standards, as there are limited options and scant data defining effective measures for preventing drug-resistant TB in exposed contacts. Unfortunately, infection control practices and isolation are a significant hardship for the patient and family and may unnecessarily perpetuate and exaggerate stigmatization of the patient with drug-resistant TB. The safety of the public and the patient’s family and contacts must be weighed against the mental health and morale of the patient as well as the utilization of resources required to isolate a patient beyond the necessary and appropriate time frame.

**Infection Control Guidelines**

The following resources reflect current standard practices regarding TB and infection control:

• CDC’s **Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings**, MMWR 2005; 54 (No. RR-17), available online at: [www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm)

• Curry International Tuberculosis Center **2011 Tuberculosis Infection Control: A Practical Manual for Preventing TB**, available online at: [www.currytbcenter.ucsf.edu/TB_IC](http://www.currytbcenter.ucsf.edu/TB_IC)

• Your local health jurisdiction is an important resource and may have specific guidelines...
Discontinuation of Isolation

When is it safe to discontinue isolation for multidrug-resistant TB patients? There are several times during the treatment regimen when this issue will need to be addressed:

- In the hospital environment, when discontinuation of negative-pressure isolation is contemplated
- When travel or transport to another facility is desired
- When discharge to the home environment is considered
- When transfer to a high-risk environment such as a congregate setting is the only option
- When home isolation may be discontinued

While there are no clear-cut guidelines for these decisions, the following information may be helpful:

- Studies have shown that most transmission of TB occurs before drug treatment has been initiated and that smear-positive cases transmit more efficiently than smear-negative cases. A recent molecular epidemiology study concluded that 17% of secondary cases of TB in San Francisco were transmitted from smear-negative TB cases.
- For drug-susceptible TB, a patient receiving TB treatment is deemed to be non-contagious when he/she has produced 3 consecutive smear-negative sputa, has started an appropriate treatment regimen, and is clinically improved.
- Outbreaks of MDR-TB have been reported in hospitals, jails, and congregate settings. Transmission has been documented in households and in communities. The dramatic decline in MDR-TB cases in the U.S. since 1993 is attributable both to improved awareness and better drug regimens, but also to more aggressive infection control measures.
- MDR-TB takes a terrible toll on individuals and their families, and secondary cases should certainly be avoided whenever possible. Unfortunately, the aforementioned transmission studies primarily included drug-susceptible cases. The current guidelines reduce risk to contacts, but do not eliminate it. Patients with smear-negative, culture-positive sputum on treatment certainly could still transmit TB.
- Because the consequences of MDR-TB are so much more dire, and there are no proven regimens for window prophylaxis or treatment of LTBI, it is appropriate to be more cautious about returning MDR-TB patients back to their homes, schools, work sites, and congregate settings.
  - Particular care should be taken when considering if patients can return to settings where there are young children, immunocompromised individuals, and people who have not previously been exposed to the patient.
  - Some experts would consider MDR-TB patients potentially contagious as long as their sputum cultures remain positive. These experts recommend isolation while hospitalized and would not release MDR-TB patients to congregate settings until their sputum cultures become negative.
  - World Health Organization guidelines consider patients with MDR-TB to be contagious until their sputa are culture-negative, and forbids travel in public airplanes or other public transportation until their sputa are culture-negative.
Discontinuation of Isolation—
Management at Home

A number of factors should be taken into account when considering management at home:

- Extent of disease, cavitation, and smear status (reflect the bacillary load)
- Extent of the drug resistance (susceptibility to first-line drugs and fluoroquinolones increases likelihood of early sterilization)
- Clinical and microbiologic response to treatment regimen
- Physical environment (is the home very small and crowded with little air flow?)
- Medical risks of household members (young children, immunocompromised?)
- Treatment status of household members (on window prophylaxis or LTBI treatment?)
- Stability of household (relative likelihood that no new members will enter)
- Anticipated adherence by case and contacts
- Safety and protection of service providers in the home

While TB patients cannot be excluded from their families and homes indefinitely, every effort should be made to ensure the safety of contacts.

Decisions about home management should be made in consultation with the local health officer/TB controller and experts in drug-resistant TB.

Special precautions will be required if there are young children in the home, immunocompromised contacts, or a risk of persistent contagion.

Healthcare and other service providers entering the home to deliver DOT and/or other healthcare services (e.g., patient interviews) must comply with current infection control measures to prevent occupational exposure when caring for drug-resistant TB patients who are considered potentially infectious. For information that is essential to consider when preparing for the care of infectious TB patients in the home setting, consult with national (National Institute for Occupational Safety and Health [NIOSH]) and state occupational health and safety programs, your state TB program, or your Regional TB Training and Medical Consultation Center (RTMCC).

Long-term hospitalization in negative-pressure isolation is exceedingly expensive. Safe options should be explored once the patient is medically stable and tolerating the full drug-resistant TB regimen. In some cases, management at home will not be possible while a patient is still potentially contagious because of young children or previously unexposed individuals living in the home, or the physical layout or small space prevents the patient from having a private space for home isolation. In these cases, consider:

- Patients can sometimes be housed in a motel room which has an air supply that vents to the outdoors.
- A mobile home or trailer may be rented or purchased and used to house the patient until they are non-contagious.
Transportation

Considerations for transporting the infectious drug-resistant TB patient:

- **Private car:** Have windows down, mask patient if possible, eat outdoors at stops.
- **Ambulance:** Identify an ambulance company that has negative pressure and high efficiency particulate air (HEPA) filtration. Patient should still wear surgical masks, and providers and drivers should wear N-95 masks.
- **Air ambulance:** Contact the patient’s insurance company, your hospital social worker or case manager, or your expert resources to identify an air ambulance company or private flight arrangements to safely transport your patient. WHO and International Air Transport Association have published guidelines regarding transporting potentially contagious tuberculosis patients by airline (see “References.”)

Contact Investigation

One of the primary responsibilities of the case manager is to identify, locate, and evaluate contacts.

In general, the process of performing a TB contact investigation is the same whether a case is drug-resistant or not, and includes:

- Review of the index case’s medical history and history of present illness
- Interview of the case to identify contacts
- Performance of a field investigation
- Risk assessment for TB transmission
- Prioritization of contacts for evaluation
- Evaluation of contacts
- Provision of treatment for LTBI and essential follow-up of contacts
- Evaluation of contact investigation outcomes and decision of whether to expand the investigation

To determine whether the TB infection you find among contacts represents exposure to the recent drug-resistant TB case or exposure to a previous and possibly drug-sensitive case, consider the transmission risk assessment findings and the individual contact’s TB exposure history.

TB Transmission Risk Assessment

The risk assessment focuses on the route of transmission, which in cases of TB is almost exclusively airborne. Assessing the risk of transmission helps determine which contacts should be given high priority for testing and evaluation.
The risk of TB transmission is contingent on 3 main factors:

1. **Infectiousness of the TB patient:**
   - Symptoms, sputum smear status, site of TB, presence of cavitary disease

2. **Environment where transmission likely occurred:**
   - Size of room, amount of ventilation, presence of air cleaning systems

3. **Characteristics of the contact's exposure:**
   - Frequency of contact and duration of the exposure

**Indications of transmission include:**

- High infection rate among contacts
- Infection in a young child
- Presence of converters*
- Identification of a secondary case

*According to the American Thoracic Society (ATS), a skin test “converter” is someone who has an increase in reaction size of 10 mm or more within a period of 2 years.

**Contact TB Exposure History**

A very thorough TB history of contacts with LTBI will help you to assess the likelihood of recent infection and to make treatment decisions.

Include these essential factors in your assessment:

- Prior tuberculin skin test (TST) history and baseline TST. Taking the time to look for prior TST history is time well spent in a drug-resistant TB investigation. Sources of this information include:
  - Employment or immigration health record
  - Primary care provider medical record
  - School/immunization health record
  - Military health/immunization records
  - Other programs that the patient may have accessed, such as CureTB, TBNet, or programs such as foster care that have a health screening component on entry into the program
- History of previous exposure to TB—was it a pan-sensitive case? Was previous treatment for LTBI or active disease taken?
- Information on the contact’s country of birth, year of arrival (if foreign-born), and travel history is helpful and may give clues to prior exposure potential.
- History of incarceration (a situation in which TST is often performed).

For detailed information, see: Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC, **MMWR** 2005; 54 (No. RR-15, 1-37); available on-line: www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm
Drug Supply

Drug Availability

Second-line anti-tuberculosis drugs are sometimes hard to find. Creativity and perseverance will be required.

- Contact the nurse consultant at the state health department (TB elimination section) or the state TB controller. If your state TB program supplies TB medications, its central pharmacy may carry or have access to second-line drugs.
- If your local pharmacy does not carry the drug, ask them to order it and ask them how long it will take to get it.
- If the local pharmacy cannot obtain the drug in a timely fashion, call your local hospital or a neighboring TB clinic and ask if you can borrow a quantity of the drug.
- Try to identify a patient in the area who has recently been taking the drug and see how that person’s case manager obtained the drug.

Drug Shortages

Some second-line drugs have pre-established production quotas that make access to the drug difficult when demand suddenly increases. If your state does not have a central pharmacy that stocks and distributes drugs used to treat drug-resistant TB, order and keep on hand a several-month supply of drugs to prevent treatment interruption due to supply shortages. If you are told a required drug is on back order, unavailable, or out of stock, report this immediately to your state TB control program. The Food and Drug Administration (FDA) is also a potential resource and can be contacted at: www.fda.gov/cder/drug/shortages; drugshortages@cdr.fda.gov; telephone: 301-796-4570

Some insurance companies will limit the number of days or weeks a pharmacy can supply certain medications. Fluoroquinolones and macrolides in particular, may require special treatment authorization from the insurance company. Ask the pharmacy to help you anticipate any such restrictions on the patient’s prescription plan. A simple treatment authorization request (TAR) letter explaining the medical condition, duration of anticipated use of the drug, and need for that particular drug over another formulary drug will usually suffice. For most efficient processing, include the patient’s name, date of birth, insurance ID and policy numbers as well as the subscriber information.

Drug Storage and Safety

Most of the drugs used to treat drug-resistant TB can be stored at room temperature (59° to 86°F; 15 to 30°C); however, some require refrigeration.

- Keep the following medications refrigerated:
  - Paser granules—store below 59°F (15°C); can also be stored in freezer
  - Streptomycin sulfate—store between 36° to 46°F (2° to 8°C)
- Work with the agency providing parenteral medications to make sure the suspended forms do not exceed their safe shelf life.
- Ensure safety of needle handling and disposal.

See Chapter 4, “Medication Fact Sheets” for more details about each drug.
Patient Assistance Programs (PAPs)

The distribution of drugs used to treat drug-resistant TB varies throughout the country, with some states maintaining central purchasing and distribution. The cost of these drugs is also variable, but in general, they are expensive, particularly when you factor in the length of treatment. Patient assistance programs (PAPs) may be helpful in offsetting costs. Table 1 displays some drugs used to treat drug-resistant TB that are known to be included in PAPs.

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
<th>Manufacturer</th>
<th>Eligibility criteria</th>
<th>PAP telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treactor-SC</td>
<td>Ethionamide</td>
<td>Wyeth Pharmaceuticals</td>
<td>U.S. resident, without resources</td>
<td>800-568-9938</td>
</tr>
<tr>
<td>Levaquin</td>
<td>Levofloxacin</td>
<td>Ortho-McNeil Pharmaceuticals</td>
<td>Without resources</td>
<td>800-652-6227</td>
</tr>
<tr>
<td>Avelox</td>
<td>Moxifloxacin</td>
<td>Schering Plough</td>
<td>Without resources</td>
<td>SPCares: 800-656-9485</td>
</tr>
<tr>
<td>Zyvox</td>
<td>Linezolid</td>
<td>Pfizer</td>
<td>Without resources</td>
<td>888-327-7787</td>
</tr>
<tr>
<td>Augmentin</td>
<td>Amoxicillin/ clavulanate</td>
<td>GlaxoSmithKline</td>
<td>U.S. resident, without resources</td>
<td>866-PATIENT 866-728-4368 <a href="http://www.bridgestoaccess.com">www.bridgestoaccess.com</a></td>
</tr>
<tr>
<td>Lamprene</td>
<td>Clofazimine</td>
<td>Novartis</td>
<td>MDR-TB</td>
<td>301-443-1240 FDA, single patient Investigational New Drug (IND)</td>
</tr>
</tbody>
</table>

The AIDS Drugs Assistance Program (ADAP), funded by Ryan White CARE Act dollars, provides HIV-positive individuals with low- or no-cost prescription medications to treat HIV/AIDS and related conditions. In October 2007, ADAP announced that 8 drugs used to treat MDR/XDR-TB were added to the ADAP formulary: Moxifloxacin, capreomycin, ethionamide, cycloserine, para-aminosalicylate, imipenem/cilastin, linezolid, and levofloxacin. The ADAP formulary now includes most if not all of the drugs used to treat pan-sensitive MDR- and XDR-TB. Providers who wish to inquire about their patients’ eligibility for this program should contact the local ADAP coordinator at their state’s health department.
Summary

The assignment of a case manager for cases of drug-resistant TB is highly recommended. The case manager coordinates activities of many team members and is responsible for ensuring that all details of treatment and monitoring are completed.

The case manager:

• Ensures adherence to treatment by coordinating DOT
• Addresses psycho/social needs and facilitates treatment of substance abuse and mental health programs
• Bridges cultural gaps by use of community resources and appropriate interpreters
• Provides aggressive and ongoing education to patients, families, and other care providers
• Coordinates clinical response and toxicity monitoring as well as communication of results to providers
• Coordinates medical care given by private providers, medical consultants, and the TB clinic
• Interfaces between families, providers, and institutions regarding infection control practices
• Performs contact investigations and follows through with treatment of contacts
• Works with providers, pharmacies, third party payers, and drug companies to ensure consistent drug supply

The case manager might be the first team member to detect “red flags” that might suggest increased risk of treatment failure. The case manager should alert the treating physician and team if the following are observed:

• Nonadherence with treatment
• Nonadherence with infection control
• Missed clinical appointments
• Failure to gain weight
• Failure to convert cultures, etc.
References


• Centers for Disease Control and Prevention. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings. MMWR 2005; 54 (No. RR-17).

• Centers for Disease Control and Prevention. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. MMWR; 2005; 54 (No. RR-15, 1-37).


