BACKGROUND GUIDES

BACKGROUND GUIDE 2:
CASE MANAGEMENT AND DIRECTLY OBSERVED THERAPY FOR LTBI

Case management is an essential part of an effective LTBI treatment program. Using a case management strategy means that the staff works as an interdisciplinary team to facilitate the patient's ability to adhere to a lengthy course of treatment.

The Case Management Society of America defines case management as "a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates options and services to meet an individual's health needs through communication and available resources to promote quality, cost-effective outcomes." This approach provides the patient with the strong support he or she needs in order to understand and follow medical recommendations. For patients with TB disease, directly observed therapy (DOT) is an essential component of case management. DOT occurs when a health worker or other medical team member provides each dose of medication directly to a patient, as prescribed by the treating physician. The assigned staff member must observe the patient swallowing each dose and document that this has occurred.

For more than two decades, TB disease has been effectively treated by systematic DOT, which is now considered standard practice. However, the strategy of providing DOT for LTBI has only recently come to the forefront. It is proving to be a useful methodology for reducing the progression to TB disease among high-risk individuals.

WHY ARE CASE MANAGEMENT AND DOT RECOMMENDED FOR THE TREATMENT OF LTBI?

Infected individuals who are at highest risk for developing active TB disease often are challenged with difficult life circumstances—such as homelessness, drug or alcohol use, or HIV infection—that can impede their ability to adhere to LTBI treatment. This

difficulty in adherence is especially true if they must self-administer their medication. Case management that includes DOT is considered the best way to address the barriers and challenges these patients face so that they can complete their full treatment course. DOT for LTBI high-risk clients, especially those who are co-infected with HIV or have HIV risk factors, has the potential to dramatically decrease the number of future TB cases.

WHAT TREATMENT REGIMEN IS PROVIDED TO LTBI PATIENTS?

To prevent the development of TB disease in individuals who have TB infection, the standard treatment regimen is isoniazid (INH). This medication is given daily or twice weekly for an extended period (for example, six or nine months), depending on such factors as the patient's age and HIV status.

For patients who have contraindications for INH or who are contacts of an individual with INH-resistant TB, rifampin is an alternative for preventive treatment. Refer to the American Thoracic Society and Centers for Disease Control and Prevention guidelines for current treatment recommendations. The Tools section includes a sample copy of the ATS/CDC Statement: Targeted Testing and Treatment of LTBI guidelines, as well as Update: Adverse Event Data and Revised ATS/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection. To locate additional guidelines or to check for updates, see the CDC listing under the "Internet Resources" section of the Resource Guide in the Tools section.

A detailed sample from an LTBI treatment program, NYC DOHMH Protocols for LTBI (Source: New York City Department of Health and Mental Hygiene), is included in the Tools section.

WHAT ARE THE OTHER COMPONENTS OF THE CASE MANAGEMENT APPROACH?

An effective LTBI program for hard-to-reach, high-risk LTBI patients requires more than observing and recording medication doses. It often requires the following activities and approaches that are fundamental to case management. Implementing these activities will help patients complete their course of treatment and will increase your program's rate of success.

Assign each patient to an individual case manager. A newly enrolled patient is assigned to the caseload of a particular individual on the staff. This case manager has the primary responsibility for establishing a supportive relationship and helping the patient meet the challenges of adherence to treatment. The case manager educates the patient about TB and the importance of treatment, works with him or her to plan when and where to provide doses, and provides a consistent point-of-contact linking the patient with the program.

Encourage trusting relationships and good communication between patients and staff. The staff, in particular the case manager, needs to be skilled at both conveying messages to patients and eliciting information from them. Good communication is key to treatment completion and is the primary means the staff has to convey concern and build trusting relationships.

The case manager needs to learn from the patient:

- The patient's understanding of TB infection, treatment recommendations, and reactions to medication
- The patient's beliefs about TB status, appropriate healthcare practices (which vary among cultural groups), and the healthcare system
- Information about his or her medical, psychological, and social needs
- Locating information

In turn, the case manager needs to make sure the patient understands:

- The purpose of the treatment and the importance of completing it
- The staff's expectations of the patient once treatment begins
- The limits to program incentives and other benefits

Since this population of patients can be sensitive to inconsistency in messages, staff members need to be clear on policies and to convey them accurately to patients.

Back up good patient relationships with clear clinical and administrative protocols. Well-defined policies and clearly stated written protocols will help the team achieve efficiency, consistency, and fairness in its dealings with patients. This is especially important when you are dealing with patients who are likely to test staff members and "shop around" among staff until they obtain the answers they want. Your policies, guidelines, and procedures need to be clearly communicated to the LTBI team and repeated regularly at staff conferences.

At the same time, it should be understood that flexibility is also essential in dealing with persons in your target groups, and that the good judgment of your team members should be respected.

Coordinate activities and communicate with staff about patients and problems. Supervisors and staff members must work together to ensure that the entire team is well informed about the current status of patients, that issues and problems are addressed, that each team member has an adequate caseload, and that all patients are covered if their assigned case manager is absent. The case manager must be able to provide clear and accurate information to other team members who are involved in patient care, such as the identity of:

- The physician who assesses the patient's medical status and prescribes LTBI treatment

- The nurse who prepares treatment doses, monitors medical status throughout the treatment course, and refers the patient as his or her status changes over time

- Other outreach staff, administrative support personnel, and supervisors who should be alerted of any special conditions when the patient comes for care

Hold regular case conferences. The most efficient way to keep everyone on the team up-to-date is to schedule case conferences on a regular basis, preferably weekly. The case conference also provides an opportunity for building trust among staff through sharing frustrations and receiving support.

The entire treatment team should attend the case conference, including the physician, nursing staff, outreach staff members, social workers, and the TB control program officer. Choose a non-clinic time for case conference meetings so that as many team members as possible may attend. Every effort should be made for case managers to be present to discuss the patients under their care.

At the case conference, each case manager should update the team on his or her assigned patients. Subjects for discussion include:

- *Problems with individual patients.* If a case manager is experiencing difficulty, the team can offer support and solutions.

- *Location changes.* The team can be brought up to date on who is in jail, who has moved, or who is out of town temporarily.

- *Medical information.* Staff with medical and nursing expertise can help the team learn more about TB diagnosis and treatment, symptoms of adverse reactions to medications, and other medical conditions or co-diagnoses that might complicate LTBI treatment.

- *Social services information*. Social workers can alert the team to benefits, housing, and treatment options available for the patients.

- *Group strategies for outreach, treatment, and scheduling*. For example, the team might use this opportunity to develop a targeted screening schedule for homeless shelters or a TB training for staff of community-based organizations (CBOs).

HOW IS COMPLETION OF TREATMENT DEFINED?

Every LTBI treatment program must define treatment completion so that the staff and the patient have benchmarks against which to measure progress toward the agreed-upon goal. The treatment goal is set on an individual basis for each patient according to the physician's decision, based on appropriate standards of care, regarding the regimen and duration of treatment that will be most suitable for that individual. For example, in San Francisco's Tuberculosis Outreach Prevention Services program, typical treatment goals are:

- Completion of 180 daily doses or 52 twice-weekly doses (equivalent to six months of doses) of INH within nine months, *or*

- Completion of 270 daily doses or 76 twice-weekly doses (equivalent to nine months of doses) of INH within twelve months

HOW CAN YOUR PROGRAM HELP PATIENTS COMPLETE THEIR COURSE OF TREATMENT?

Because of high-risk lifestyles, the patients receiving LTBI treatment often have difficulty adhering to an ideal course of treatment. It is not necessary to take every dose of prescribed treatment in order to acquire protection from progression to TB. However, the more closely the patient can adhere to the treatment, the more likely it is that he or she will receive an adequate course.

The first step in promoting adherence is to make sure that patients understand the purpose of the treatment, why it is important, and what is expected of them. When the patient begins treatment, and at intervals thereafter, explain what the physician has ordered and ask the patient to repeat back what he or she understands about the medication, the number of doses needed, the length of treatment, the anticipated completion date, and symptoms of adverse reactions. In addition to maintaining close staff-patient relationships, as described above, strategies that LTBI programs have found helpful in increasing adherence include:

- Understanding the realities of the individual patient's daily life
- Offering incentives and enablers
- Making it easier to take treatment, for example, by providing fast-track drop-in dosing or tailored dose administration in the field
- Providing twice-weekly treatment doses, which allow flexibility in days the patient needs to present for treatment. For example:

  If the patient has a Monday/Thursday dose schedule but is not available on a particular Monday, he or she can take the dose on Tuesday and still meet the schedule of two observed doses in a week.

Dosing responsibilities can be divided between agencies that work with the patient, so that each week the LTBI program staff provides the medication on one scheduled treatment day (e.g., Monday) and another agency provides it on the next treatment day (e.g., Thursday).

HOW DO YOU HANDLE PATIENTS WHO MISS APPOINTMENTS?

Missed appointment can be expected from all but the most highly motivated patients. If a patient fails to come to the clinic for a treatment dose or to present for treatment at an agreed-upon time or place, team members need to take action by documenting

the missed appointment in program records, ensuring that the full team is alerted to the situation and ready to respond, and initiating a search to locate the patient.

In the last pages of this background guide, Table A summarizes the specific steps to be taken in the event of a missed appointment. You should develop protocols for your program to guide decisions about treatment interruptions. Questions to be resolved include:

- What constitutes treatment interruption?
- What conditions will determine whether an interrupted treatment regimen can be resumed or whether the earlier doses should be disregarded and the treatment regimen begun anew?
- How many "re-starts" will be attempted for sporadically adherent patients?
- Under what circumstances will the program abandon efforts to have a particular patient complete his or her treatment regimen?

REMEMBER: Helping patients adhere to treatment is a group responsibility. Everyone must work together when helping patients throughout the healing process. (Adapted from San Francisco Department of Public Health, Tuberculosis Control Section.)

TABLE A: AN INTERDISCIPLINARY APPROACH TO ADDRESSING NONADHERENCE

Anytime a dose is missed	All team members should: • Ask the patient what happened and record the reason for missed dose • Encourage the patient to adhere to treatment by motivational counseling and problem solving
When a patient misses one dose	The case manager and/or appropriate team members should: • Document the missed dose in the clinic records • Phone or otherwise contact the patient, reminding him or her to come into the clinic • Contact the patient with a second reminder if he or she fails to appear within a reasonable time (define this time interval in your program protocols) • If the patient misses a second deadline to appear or was scheduled to have a dose delivered and did not present for treatment, attempt to redeliver the dose to the patient • Make necessary adjustments in incentives and enablers
When there has been no communication and the patient misses the second consecutive dose	The case manager and/or appropriate team members should: • Attempt to make a delivery and, if possible, find out the reason why the patient is not adhering to treatment or honoring his or her contract for incentives and enablers • Initiate a search, using the locating information obtained when the patient enrolled: 1. Phone, send letters, or make home visits to known places of residence 2. Contact relatives and friends, if known 3. Check with: – Places where the patient is known to hang out – Shelters, soup kitchens, or other facilities the patient is known to use – Other programs or agencies that work with the patient (HIV program, parole officer, etc.) – Jails, if the patient has a history of incarceration – Hospitals, if patient has significant risk factors for hospitalization