



CDPH/CTCA Joint Guidelines

***TB Case Management
Core Components***

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Preface

The following Guidelines have been developed by the California Department of Public Health (CDPH), Center for Infectious Diseases, Tuberculosis Control Branch (TBCB), and the California Tuberculosis Controllers Association (CTCA). These Guidelines provide statewide recommendations for tuberculosis (TB) control in California. If these Guidelines are altered for local use, then the logo should be removed and adaptation from this source document acknowledged.

Introduction

The Centers for Disease Control and Prevention (CDC), the California Department of Public Health, Tuberculosis Control Branch (CDPH/TBCB) and the California Tuberculosis Controllers Association (CTCA) have identified case management as a critical component of an effective Tuberculosis (TB) Control Program¹. The public health goals in the management of TB are to:

- Identify and treat suspected and confirmed cases of active TB
- Render the patient non-infectious
- Reduce disease transmission through prompt contact follow-up
- Ensure completion of adequate therapy and prevent the development of drug resistance
- Identify other urgent health and psychosocial needs

This guideline identifies the key components in TB case management and serves as a tool to assist public health workers in achieving these goals. Effective TB case management requires administrative commitment and support. This includes education, staff training, and ensuring adequate funding to maintain program activities.

It is recommended that a specific health department employee (case manager) be assigned primary responsibility and be held accountable for ensuring that each patient is educated about TB and its treatment, that therapy is appropriate and completed, and that contacts are examined and complete therapy for latent TB infection as needed. Some specific activities may be assigned or referred to other persons (e.g. outreach workers, health educators, social workers, and disease investigation/legal staff), but the case manager is ultimately responsible for ensuring that activities are performed and appropriate outcomes are achieved.

TB control programs should provide the case manager with the necessary authority and support to ensure he/she is able to assume the responsibilities outlined. This includes the ability to obtain necessary clinical and treatment information.

Although some patients may undergo most of their evaluation and treatment in settings other than the health department, the major responsibility for monitoring and ensuring the quality of

¹ Centers for Disease Control and Prevention. Essential Components of TB Prevention and Control Program: recommendation of the Advisory Committee for Elimination of Tuberculosis. MMWR 1995; 44 (No. RR-11): 6.

al TB-related activities in the community should be undertaken by the health department, as part of its duties to protect the public health.¹

This guideline is organized into five major parts: Receipt of a Case Report, Assignment of the Case Manager, Assessment and Planning Phase, Ongoing Follow-Up and Completion of Therapy. Please be aware that certain core activities such as assessment for non-adherence and patient education are on-going activities and are therefore included throughout different parts of the guideline.

It is recognized that health departments differ in their staffing and organization and no set of guidelines can cover all the situations that may arise relating to case management. Health departments may choose to tailor or expand upon these guidelines to encompass program differences.

PART I

Receipt of a Case Report

TB control programs must be aware of reporting requirements (CCR Title 17, Section 2500 and Health and Safety Code 121362). It is suggested that jurisdictions use standardized forms specific to their TB control needs. Jurisdictions may contact the CDPH/TBCB for examples of these forms. This will help TB control programs obtain all information necessary to initiate case management. Upon notification of a suspect from a lab or other source, or upon receipt of the case report, assigned staff shall review the report for completeness, assess risk of transmission and determine necessary control measures. The provider or institution should be contacted immediately for important missing information or if inappropriate treatment plans are noted.

1.1 Demographic, diagnostic, and treatment information:

Under the California Health and Safety Code, initial case report should include:

- A. Demographics: Patient name, address, phone number, date of birth/age, occupation/employer, ethnicity, social security number and sex.
- B. Clinical: date/status of diagnosis, tuberculin skin test (TST) or interferon gamma release assay (IGRA) results, radiographic findings, bacteriologic findings, pathology or cytology findings, information regarding the risk of disease transmission to others, list of antituberculous medications, including dosages/date started, and adherence assessment.
- C. Other: Name, address and telephone number of person making report.
- D. Any other information requested by the TB control program.

Additional information programs should obtain include:

1. Patient's source of payment for medical care—this assists in the assessment of access to follow-up care and medications.
2. History of prior TB treatment—preventive therapy or treatment for active disease. Patients with prior treatment are at greater risk for drug resistance. Directly Observed Therapy (DOT) is indicated for patients with a history of prior TB treatment.
3. Weight—to ensure medication dosages are weight-appropriate. The case manager should contact the provider and resolve noted discrepancies.
4. Psychosocial issues—to assess potential compliance problems and initiate supervised therapy (DOT), as indicated.
5. Name of laboratory to which specimens have been submitted. The case manager will need to maintain follow-up on smear, culture and susceptibility status.
6. Other relevant medical conditions. It is important for the case manager/assigned staff to note any other medications that the patient is on that may have interactions with TB medications.
7. Ascertain if HIV testing was Determined. Document on RVCT use field 26.
8. Other locating information/address for patient.
9. Clarify designated TB care provider.
10. If the patient is in a correctional facility, obtain the booking number or inmate ID number.

1.2 Introduction/interaction with provider

Within one to three working days of receipt of report, the case manager/assigned staff should contact the provider/institution to:

- A. Equip the provider with the name and phone number of the contact person/case manager at the TB control program. And inform the patient's provider of the importance of coordinating care so the TB control program can fulfill their responsibilities to protect the public health.
- B. Review the initial case report information for accuracy and completeness; address questions about information provided on the case report, and any questions the provider may have.
- C. Familiarize the provider with the TB control program's role and services and the provider's responsibilities, including on-going reporting requirements, such as periodic treatment updates and discharge approval requirements.
- D. Assess adherence issues to determine the need for DOT. The case manager should explain the jurisdiction's DOT policies and services.

- E. Determine the patient's infectiousness and need for isolation, inquire about the household composition to assist in the initiation of the contact investigation. If infectious, assess if the patient is a candidate for voluntary isolation versus issuing a legal order of isolation.
- F. If patient is in a health care facility or institution, review the discharge care plan requirement. (Again it is suggested that TB control programs use a standardized form for the discharge approval process. Information pertaining to hours that approval may be obtained, provisions for evening, weekend and holiday periods, pager and fax numbers are important to include).
- G. Provide treatment recommendations and protocols (local, state and national guidelines) including recommendations for specimen collection and documentation of culture conversion. Discuss the availability of fixed-dose combination drugs.
- H. Inform the provider of the need for an HIV status determination if HIV status is not yet known. If a negative test has not been documented in the previous 6 months, an HIV test is recommended and represents the standard of care. Note that an HIV status will influence case management.

1.3 Reporting and notification requirements when TB suspects/cases are discharged, transferred or released

TB control programs require health department approval or notification, prior to discharge, transfer or release, depending on the institution (health care facility-vs-correctional setting). TB control programs must be familiar with the details of Health and Safety Codes 121361 and 121362. It is important for TB control programs to ascertain if the discharge setting is appropriate given the patient's infectious status and risk of transmission in that setting. It is suggested that TB Control programs have a standardized form for provider/institution use. These codes require that the discharge plan include:

- A. All pertinent and updated information required by the TB control program not previously included on initial or subsequent reports.
- B. Verified discharge location.
- C. Name of health care provider who has specifically agreed to provide TB-related care.
- D. Clinical information used to assess current infectious status.
- E. Any other information required by the TB program.

Additional information TB control programs may want to obtain would include:

- Patient's source of payment for medical care—this determines access to follow-up care and medications;
- Follow-up appointment date and time—the case manager should ascertain if there are funding or transportation barriers to attending appointment;

- The number of days of medications the patient is being discharged with and current drug dosages, and to note any medication changes that may have occurred during hospitalization/since initial case report;
- The household composition;
- Patient's need for DOT.

For discharges between jurisdictions, please see the CDPH/CTCA, “Interjurisdictional Continuity of Care Policy Statement”.

For more in-depth reading on these topics, case managers are encouraged to obtain the following resources:

- California State Health and Safety Code, Sections 121361 and 121362
- California Code of Regulations, Title 17, Section 2500
- CDPH/CTCA, “Guideline for the Treatment of Active Tuberculosis”
- CDPH/CTCA, “Oversight of Tuberculosis Care Provided Outside the Local Health Department TB Program”

PART II

Assignment of the Case Manager

A specific health department employee (case manager) should be assigned primary responsibility and be held accountable for ensuring that each patient is educated about TB and its treatment, that therapy is appropriate and completed, and that contacts are examined and complete therapy for latent TB infection as needed. Some specific activities may be assigned or referred to other persons (e.g. outreach workers, health educators, and social workers), but the case manager is ultimately responsible for ensuring that activities are performed and appropriate outcomes are achieved.

PART III

Assessment and Planning Phase

3.1 Establish contact with the patient—home/facility visit

The case manager should conduct a face-to-face visit with the patient within three to seven days of receipt of report of suspected or confirmed TB, depending on risk of transmission, and at least monthly thereafter. If the patient is in a correctional setting, the face-to-face means a visit to the correctional facility by the case manager or the correctional liaison. Prior to the initial visit, the case manager should determine necessary respiratory precautions.

The purpose of the initial visit(s) is for assessment and development of a treatment plan. Explain the role and responsibilities of the health department, as well as the patient's responsibility.

3.2 Verify patient medical history

Obtain, verify, and document the patient's medical history, including the following information:

- A. Chronological history of presenting signs and symptoms and events leading to diagnosis;
- B. Prior exposures to TB or individuals with prolonged cough (include when, relationship, and did the person have MDR-TB);
- C. Prior TB disease, treatment, or preventive therapy;
- D. Hospital admissions;
- E. Other health conditions affecting TB treatment;
- F. Results of lab tests if not previously reported;
- G. All prescribed medications and their dosages; (Verify by visual inspection or contact pharmacy.)
- H. Ensure the patient has started appropriate TB drug regimen promptly (either by self-administered therapy (SAT) or by DOT);
- I. The patient's HIV status:
 - 1. The case manager should educate the patient about the importance of HIV testing. HIV testing is recommended for all patients unless their status has been documented and is the standard of care.
 - 2. Routine HIV screening of all TB patients with active TB, regardless of age is recommended by CDC.
 - 3. The opt-out approach is the current standard, in which the HIV testing approach mirrors other lab tests, such that the patient is informed that the HIV test will be performed with the rationale for the test unless the patient declines.

3.3 Conduct symptom review

Assess patient for current symptoms of TB. Implement TB isolation if indicated;

- Document clinical signs and symptoms including frequency, characteristics and duration of any productive or nonproductive cough or hemoptysis;
- Notify provider of respiratory isolation;
- Assess if the patient is appropriate for voluntary isolation or if there is a need for a legal order of isolation;

- Ensure and document the patient's adherence to home respiratory isolation.

3.4 Assess adherence issues

Perform a comprehensive assessment of the strengths and barriers to treatment adherence. In particular, address the following psychosocial issues:

- Mental, emotional, and cognitive status
- Access to transportation
- Usual places of residence, where and how to locate patient, impending plans to move or travel, housing needs and living situation
- Cultural and religious beliefs that may impact adherence
- Language and literacy abilities
- Excessive use of alcohol and drugs
- Patient's source of payment for medical care
- Work history/source of income
- Support system
- Family dynamics

Obtain additional information that may indicate patient's potential for non-adherence. The case manager should document the presence or absence of risk factors for non-adherence. Refer to the CDPH/CTCA joint guidelines for "DOT Program Protocols in California", which describes high priority groups who should be considered for DOT.

3.5 Education patient and family education.

Assess the patient, family and identified contact's understanding of TB and determine the most appropriate educational intervention. Provide brochures, written instructions or other helpful items as appropriate. The education content shall include:

- A. How TB is transmitted to others and transmission prevention
- B. Infection vs. disease
- C. Mechanism of disease process and length of treatment
- D. TB medications: names, dosage, actions, side effects and what actions the patient should take when experiencing signs and symptoms of a drug side effect. Ensure patient can demonstrate how to open packaging and take medication.

3.6 Initiate contact investigation

Using the most recent version of the CDPH/CTCA “Joint Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis”, initiate an investigation using the concentric circle method. Assess the home environment for children, other high-risk contacts and ventilation.

- A. Determine and document infectious period to establish priorities for the contact investigation. Establish duration, frequency, and intensity of exposure based on the index case, environmental factors and contact characteristics.
- B. Begin contact investigation as soon as possible. The priority, speed, and extent of a contact investigation should be influenced by the likelihood of transmission and possible consequences of infection (especially for HIV-infected contacts or contacts who are young children). The case manager should consider contacts in the home, work, social settings and personnel from agencies that may provide ancillary services in the patient’s home.
- C. Refer contacts for evaluation for infection and disease. Ensure contacts are placed on appropriate treatment.
- D. Confer with the contacts’ health care provider(s) as necessary.

3.7 Plan for ensuring access to care and adherence

Develop a plan and identify interventions for addressing barriers to care/adherence. Document the outcome of interventions.

- Assist patient with concurrent health and psychosocial problems.
- Use incentives and enablers to promote/ensure adherence.
- Initiate legal action as indicated (i.e. DOT orders, orders of examination).

3.8 Establish good communication with the patient’s health care provider

Send the health care provider an introductory letter identifying the case manager and services provided by the TB control program and outlining the provider’s responsibilities. This letter should also equip the provider with the necessary information, such as phone, FAX, and pager numbers, to reach the case manager.

PART IV

Ongoing Follow-Up

4.1 Ensure and document patient’s adherence to TB medications

Poor patient adherence to TB medications can result in treatment failure, ongoing disease transmission, and the development of drug resistance. Therefore, monitoring adherence is essential for successful curative treatment.

A. For patients on DOT

The case manager should ensure that patients are receiving TB medications and that DOT is documented in the patient's chart(s). DOT documentation should differentiate between visits during which the medication ingestion was observed by the DOT worker, visits during which the medication is delivered but not observed, or neither observed nor delivered. TB control programs should have policies and procedures detailing roles and responsibilities for follow-up or missed DOT doses. For person's non-adherent with DOT, the case manager should assess the situation, consult with the provider and provide:

1. Patient education and counseling;
2. DOT at the patient's convenience – by changing the time, place or frequency (intermittent therapy) of DOT visits;
3. Use of incentives and enablers – ensure cost to the patient is not a barrier;
4. Referral for social services, housing and drug and/or alcohol services as needed;
5. Legal orders - if less restrictive measures are utilized, documented and unsuccessful.

B. For patients on pill counts—case managers are cautioned on the reliability of pill counts since indirect measures of adherence are less effective and depend on patient's report or history.

1. Documentation of pill count to be placed in patient's chart(s) on weekly or monthly basis and reviewed by the case manager to ensure that the patient is receiving adequate therapy.
2. For persons with poor adherence and incorrect pill count, case manager should consult with the provider and initiate DOT. Case manager may also consider:
 - a) Patient and family education;
 - b) Urine testing;
 - c) Use of incentives and enablers;
 - d) Legal orders—for DOT/complete medication.

C. For patients on self-administered therapy (SAT)

1. Fixed-combination drugs are recommended.
2. Visit to home setting to check medication supply. Confirm refill with pharmacy, if indicated.

3. Confirm patient's compliance with follow-up appointments and clinical improvement including culture conversion to negative, radiographic improvement, and symptom review.
4. Should the case manager determine that the patient demonstrates poor adherence to SAT, consult provider and initiate DOT.

4.2 Monitoring of adverse effects and toxicity

- A. The case manager reinforces prior patient teaching and continues to educate the patient and family about TB medications, signs and symptoms of adverse effects, importance of continued treatment and uninterrupted drug therapy. Case managers should be familiar with all TB medications, their side effects, contraindications and drug interactions. Educate patient to report side effects.
- B. For patients on self-administered therapy, the case manager ensures that patients are assessed for adverse effects to TB medications at least monthly and at each visit. If a patient is on DOT or pill counts, staff should assess the patient for adverse effects on each visit by performing a symptom review. TB control programs should develop standardized forms/flowsheets for this purpose, particularly when patients are on DOT. The TB control program is responsible for ensuring that outreach staff providing DOT is properly trained about how to interview and elicit patient information. The case manager should be aware of complications by maintaining close communication with outreach staff.
- C. The following signs and symptoms suggesting side effects, including hepatotoxicity, should be reported immediately to the patient's provider, and in consultation with the provider, the case manager should instruct patient to stop TB medications until evaluated by the provider*:
 - Jaundice
 - Dark urine
 - Vomiting
 - Abdominal pain
 - Fever
 - Oboxicity
 - Visual changes
 - Vestibular changes
 - Marked clinical rash

- D. Less severe signs and symptoms should be reported to the patient's provider within 24 hours*:
- Anorexia
 - Nausea
 - Malaise
 - Peripheral neuropathy—tingling or burning sensation in hands or feet
 - Rashes
- E. Assess and document results of baseline and ongoing liver function tests in order to monitor for hepatotoxicity. TB control programs should develop procedures for planned frequency of tests and define the responsibilities of the case manager for responding to abnormal results.
- F. Monitor and document other baseline and ongoing tests for toxicity monitoring.

*These lists are not all inclusive.

4.3 Medication changes

Ensure changes in TB medication are carried out as appropriate and are documented.

- A. Case manager ensures that orders for medication changes are noted and placed in patient's chart(s) within 24 hours of notice of change, and that changes are implemented.
- B. Within 24 hours of notice of change, case manager must confirm appropriateness of regimen with sensitivities, patient's weight, and length of treatment. Case manager should consult with the TB Controller or designee as necessary.
- C. If a change in medication is inappropriate, the case manager's supervisor must be notified within 1 working day. Case manager contacts provider with recommended treatment regimen within 1 working day and verifies that these recommendations have been implemented and documented in the patient's chart(s).
- D. If provider continues with inappropriate regimen:
- The case manager's supervisor, TB Controller and clinician must be notified within 1 working day of recommendation to provider to change regimen, so that they can intervene in resolution of inappropriate regimen.

4.4 Monitoring bacteriologic improvement

- A. If a patient is sputa smear negative, lab reports are to be placed promptly in patient's chart(s). If previously sputa smear positive and now smear negative (x3) on separate, consecutive days, discontinue isolation.
- B. If a patient is smear positive and

1. Had a prior positive, then place report in chart;
 2. The new smear positive is pulmonary TB, then notify the TB Controller and provider and initiate isolation;
 3. Repeat sputa smears at appropriate intervals, at least every 2 weeks, until 3 consecutive negative sputa smears have been documented from different days, then all results are to be placed in patient's chart(s).
 4. If the patient is isolated or quarantined, then the patient and appropriate staff are to be notified the same day when non-infectiousness is documented to discontinue isolation.
 5. Ensure and document patient's adherence to respiratory isolation.
- C. For patients with culture-positive pulmonary TB, two or more sputa should be collected monthly for smears and cultures until persistently negative cultures are documented and placed in the patient's chart.
- D. Patients should be evaluated for treatment failure if sputa specimen(s) remain bacteriologically positive after 2 months of treatment or become bacteriologically positive after initially converting to negative. Case manager should initiate evaluation of patient and notify supervisor within 1 working day. Case manager should:
1. Review and confirm patient's medication compliance;
 2. Place patient on DOT, if not already on DOT;
 3. Reconfirm appropriateness of medication regimen, based on the patient's sensitivity report and other considerations;
 4. If additional anti-TB drugs are added to the treatment regimen, ensure that at least 2 new drugs that the patient has not been treated with previously are used;
 5. Consider serum drug levels;
 6. Repeat culture now, with repeat drug sensitivity testing.
- E. Case manager should monitor/evaluate patient's clinical response to treatment. Some indicators are:
1. Lessening or resolution of TB symptoms;
 2. Weight gain;
 3. Progressive improvement in the chest x-ray, if pulmonary disease.

4.5 Culture negative/no specimens collected

If patient is culture negative or no specimens collected:

- A. Review medications client was on at the time TB medications were started – particularly other antibiotics.

- B. Obtain follow-up chest x-ray reports to determine improvement, if applicable.
- C. Review patient's symptoms for improvement, if applicable.
- D. Review patient's TST information- retesting may be appropriate if initially negative OR test if not initially done – discuss with provider.
- E. Review information with provider regarding his/her reasons for continuing TB medications.
- F. Discuss the above findings with the TB Controller or TB control clinician to determine if the patient is to be reported as a case.
- G. If the patient is not to be reported as a case, the provider is to be notified that the patient is closed to TB control program services. The patient can then be closed to TB Registry.

4.6 Verify drug susceptibility studies

- A. The case manager should obtain and promptly document all positive cultures and respective drug sensitivities.
- B. The sensitivity report should be forwarded to the appropriate TB control staff for submission of RVCT follow-up report #1.
- C. If the patient's TB organism is pan-sensitive, provider is to be notified for adjustment of medication.
- D. If the patient is drug-resistant:
 1. Provider is to be notified for adjustment of medications.
 2. Case manager is to confirm appropriateness of regimen within 2 working days of provider notification.
 3. DOT must be initiated.
 4. If INH-resistant or MDR-TB; case manager must refer to Contact Investigation and Treatment of TB guidelines, so that identified contacts are placed on appropriate preventive therapy regimens.
 5. If regimen is inappropriate, TB Controller and clinician are to be notified immediately.
- E. If patient is MDR-TB, case manager's supervisor, TB Controller and patient's provider are to be notified the same day that MDR findings are reported/known.
- F. Case manager is to confirm initiation of appropriate regimen within 1 working day. If provider is unwilling to institute an appropriate regimen, the supervisor and TB Controller are to be notified the same day so they can intervene with provider. Case manager should:

1. Ensure that provider has experience in treating MDR-TB or access to this level of expertise.
 2. At the direction of the TB Controller/clinician, confer with provider and arrange transfer of care to a provider with experience/expertise in the management of MDR-TB. Case manager must document transfer of care and ongoing follow-up.
 3. Ensure appropriate medications are obtained.
 4. Initiate DOT.
- G. If patient is non-adherent with DOT, case manager must document attempts to correct situation and notify supervisor. Case manager should:
1. Provide patient education, including information regarding second-line TB drug;
 2. Attempts to provide DOT at a mutually agreed upon place and time;
 3. Use incentives and enablers;
 4. Serve legal orders if approved by the TB Controller;
 5. Maintain accurate DOT records or drug o gram.

4.7 Complex case management issues

Patients with complex case management issues should be discussed at team meetings and case conferences, and these discussions should involve ancillary staff with specialized expertise.

A. Poor adherence—common problems/early indicators are:

1. Incorrect pill counts
2. DOT failure
3. Slow sputum conversion or delayed clinical improvement
4. Poor or non-acceptance of TB diagnosis
5. Clinical deterioration while on TB therapy
6. Pharmacy errors
7. Appointment failure
8. Pregnancy

B. Use of disease investigators/staff intervention/legal orders to ensure treatment adherence. It is important for the case manager to document less restrictive interventions taken and their outcomes before proceeding with legal intervention.

1. Patients who need Disease Investigator/Staff intervention/legal orders include:
 - Lost to follow-up—locate;

- Failure of appointments—Legal Order of Exam; provide transportation if needed;
 - Failure to treat – Legal Orders for Treatment; Legal Order for DOT; consider incarceration;
 - Voluntary DOT contract failure—Legal Orders for DOT.
2. Document Disease Investigator/Staff referrals and review interventions/outcome.
- C. Other medical issues which require closer case management include:
- Hemodialysis
 - Drug-drug interactions
 - Adverse TB drug reactions
 - Substance abuse
 - HIV infection
 - Diabetes

4.8 Compliance with medical follow up

Verification of compliance with medical appointments. The case manager must ensure and document in the chart the patient's compliance with medical appointments every month. If the patient is non-compliant with appointments, case manager should address potential barriers and consider:

- Patient education
- Provider education
- Transportation issues
- Attempt to provide reminder system to patient
- Use of enablers and incentives
- Legal orders (i.e. order of examination)

4.9 Coordination of services

The case manager assists in the ancillary needs of the patient in order to promote compliance, while maintaining confidentiality, between the patient, provider and agencies. Potential referrals include: AIDS Case Management, Social Services, dialysis, work sites, schools, home health, rehab and probation. Document interactions between TB control program and services/agencies utilized. Note information received and actions taken/outcome of intervention.

TB control programs should develop protocols and time lines that designate the frequency of interactions/reports with providers. Situations for which these protocols should be developed include:

- Provider update of potential drug reactions.
- Provider update regarding compliance issues.
- Provider update of overall patient progress via written report.
- Use of treatment updates.

4.10 Treatment Updates

Initiate and review quarterly treatment updates for patients whose care is provided outside the health department. Compare these updates to case manager/TB control program record. Updates allow the case manager to provide assurance and assistance in treatment completion. Updates may be required more frequently in complex/high risk patients.

A. Treatment updates need to include:

1. Current provider name
2. Patient name, D.O.B., current address
3. Last and next provider appointments
4. Medication start and stop date/medication changes
5. Bacteriology reports, including sensitivity reports
6. Radiology reports
7. Projected treatment completion date
8. Comments section—issues including compliance, clinical improvement, pathology or cytology findings can be addressed here
9. Provider signature and date

Note: TB control program may choose to request additional information.

B. TB control programs should document the date Treatment Updates are sent to providers, date returned to TB control program, document information received and this information should be compared to case manager/TB control program record.

4.11 Change in TB care provider

If a patient's care provider changes, the new provider's name, address and telephone number must be verified by the case manager and documented in the chart promptly.

The case manager contacts the new provider and assesses/documents appropriateness of care.

If care is inappropriate, staff must attempt to correct the situation and notify supervisor within 1 working day.

4.12 Continuity of care during relocation

Ensure continuity of care when patient relocates – the case manager should communicate with the patient and with ancillary staff visiting the patient’s home to be alert for indications of potential relocation (early indicators include: loss of job, housing crisis, divorce, sudden changes in the family).

- A. If the patient plans to relocate, a new address should be obtained by the case manager and documented immediately. Provide patient with information on how to access the case manager (in case the transfer does not occur or patient has questions).

If relocation involves change in jurisdiction, the sending Local Health Jurisdiction (LHJ) should obtain as much information as possible including the new address, the telephone number of new provider, and emergency contact. The national “Interjurisdictional TB Notification” form should be faxed/mailed to the receiving jurisdiction. Phone contact between jurisdictions is encouraged to ensure uninterrupted treatment during transition. This also applies to patients moving out of the country, and patients who travel frequently between the U.S. and Mexico. Temporary medications may be provided for continuity of care.

- B. If patient is unable/unwilling to provide a new address, supervisor and TB Controller are to be notified immediately, and may issue legal orders, as indicated. Case manager should consider providing:
- Education of need for relocation information and continuity of care, receiving jurisdiction’s TB control program telephone number, for patient’s use in the event patient leaves and establishes a new residence without notification.
 - A temporary supply of medications until follow-up care is established. Supply of medications must be approved by clinician/TB Controller.

4.13 Continued education

Continue to educate patient, family, and identified contacts.

- A. Reassess patient, family, and contacts understanding of tuberculosis.
- B. Identify and address concerns

Patient

1. Disease/healing process—review natural course of the disease;
2. Treatment plan—culture and susceptibility results; medication changes; monthly sputa collection (if applicable) to document culture conversion and then at least monthly (x2) for verification of negativity; if culture negative –chest x-ray and/or symptom/clinical improvement; length of treatment;

3. Uninterrupted drug therapy —review;
4. Weight changes—medication adjustment, as indicated;
5. Drug interactions—notation of drugs that include potential adverse drug interactions;
6. Document patient concerns and action taken; record test results (Ishihara, Visual acuity, Audiometric/Vestibular).

Family and other contacts

1. Review preventive measures against developing disease;
2. Treatment plan—prophylaxis per CDPH/CTCA Contact Investigation Guidelines and/or ATS/CDC Guidelines;
3. Uninterrupted drug therapy—review;
4. Weight changes (particularly in children)—medication adjustment;
5. Side effects—symptom review for hepatotoxicity, neuropathy, etc;
6. Drug interactions;
7. Document contacts' concerns and action taken.

4.14 Psychosocial issues

Assess, address and document patient's psychosocial issues. Assess needs for potential and currently identified problems that may have a direct impact on a patient's TB care.

Potential problems and suggested strategies could include:

- Substance abuse—Recovery programs; DOT;
- Homelessness—Social services/housing referrals; DOT;
- Violent behavior—Legal order for completion of treatment; DOT; Incarceration
- HIV status—Testing and/or AIDS Case Management
- Pregnancy—Medical care
- Memory or cognitive disorder—DOT
- Language barriers/cultural beliefs—Interpreters; DOT; culturally competent staff
- Compliance with appointments—Social services referral; transportation
- Medication supply—Social services referral; funding

Document issues identified, strategies for resolution, and patient outcomes.

4.15 Completion of contact follow-up evaluation

The case manager should ensure documentation of on-going contact investigation following contact investigation guidelines. TB control programs should have policies and procedure in place to address the following:

- Determine which cases should trigger contact investigation;
- Criteria for assigning priority level – high, medium or low;
- Use of standardized forms to document contacts. These will be utilized to review number of contacts, relationship to index case, and status of contact investigation;
- Medical management of high, medium and low priority contacts;
- Location and assessment of non-compliant contacts.

PART V.

Completion of Therapy

Verification of completion of therapy and a completed contact investigation is the responsibility of the case manager.

5.1 Verification of adequate course of treatment

Most cases of active TB can be successfully treated using standard short course (6 month) therapy; see the most recent CDPH/CTCA “Guidelines for Treatment of Active Tuberculosis” for specific treatment regimens. The case manager is responsible for considering the following conditions to ensure that the patient has received an adequate course of therapy:

- A. If culture remains positive beyond 2 months of treatment, reasons for persistent positive cultures should be examined and treatment adjusted/prolonged. Ideally, in these cases, treatment should be continued at least six months after culture converts to negative, or, in culture negative disease when there is documented clinical improvement.
- B. Military TB or TB involving the central nervous system, bones or joints. Treatment is extended to 12 months.
- C. Relapse of TB following treatment for TB with pan sensitive organisms. Treatment may be prolonged to 9 months or more. (Current drug susceptibility testing must be performed and the regimen adjusted if resistance has developed.)
- D. Co-infection with HIV. A six month regimen is considered acceptable by the American Thoracic Society (ATS)/CDC guidelines: however most clinicians will prolong treatment to 9 months or more or until 6 months beyond the last positive culture. If a patient has had the TB treatment regimen altered to allow the use of protease

inhibitors, the case manager/TB Controller/provider should discuss and agree upon the regimen and duration.

- E. Children < 4 years of age. Some clinicians will prolong treatment to 9 months.
- F. Documented non-adherence or inability to tolerate the treatment regimen. Length of treatment will be determined on a case by case basis.
- G. Drug resistance/MDR-TB. Length of treatment will be determined based on the sensitivity report. Clinical, bacteriology, and radiographic findings must also be considered.

If possible, two sputa smears and cultures should be performed at the completion of therapy and final chest x-ray taken to document response to therapy.

5.2 Closures other than completion of therapy

- A. Moved: All attempts should be made by the case manager (utilizing other disciplines as necessary) to obtain a new or forwarding address. If this new address is within the original jurisdiction, the case should be transferred as per the local health jurisdiction protocol. If the new address is in another jurisdiction, the new jurisdiction should be notified and the “California Confidential TB Referral Form “submitted to the new jurisdiction as per the “Interjurisdictional Continuity of Care Policy Statement”. Cases should only be closed as “moved” if a new address is obtained.
- B. Lost: If all attempts to locate the patient fail, the case should be closed as “Lost”. TB control programs should have standardized procedures outlining what efforts must be made before a patient is closed as “Lost”.
- C. Not TB: If the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated and another diagnosis is established, the case is closed as “Not TB.”
- D. Died: If the patient expired prior to completion of treatment, the case is closed as “Died”. Contact investigation should be continued.
- E. Uncooperative or Refused: After pursuing legal options, if the patient refused to complete therapy (e.g., the patient refused to take medication and remained culture negative for a specified period of time) the case is closed as “Uncooperative” or “Refused”. The case manager will ensure all efforts to have the patient comply with therapy have been initiated. Closure of this type should have prior approval of the TB Controller/clinician. Patients should be placed in a surveillance registry for follow-up chest x-ray and sputa at 6 and 12 months after medications are discontinued.
- F. Other: If therapy was discontinued for another reason, the case is closed as “Other”.

5.3 Final review of the contact investigation to ensure completion

The case manager shall review the contact roster to ensure all higher risk contacts have been identified, have had an initial and follow-up TSTs/IGRA (if indicated), have had a chest x-ray (if indicated), have been clinically evaluated, and have been offered

appropriate therapy (preventive therapy or therapy for active disease). The case manager will ensure all higher risk contacts have received TB education and are able to verbalize understanding of their current TB diagnosis (TB Class I, II, III, IV or V).

The case manager shall review the contact roster to ensure all lower risk contacts have been identified and completed appropriate screening. (Note: follow-up of low priority contacts who do not come in voluntarily should be determined by the local health jurisdiction.

The final contact investigation should be summarized and then reviewed with the case manager's supervisor. Summary should include number of contacts tested, number of contacts converted, and number of new Class III's, problems identified and addressed.

5.4 Submit final RVCT information

The case manager will ensure all data necessary to complete the final RVCT is available. (RVCT Follow-Up Report 2). This will include:

- Lab reports to support sputum culture conversion (if indicated);
- Date therapy stopped;
- Reason therapy stopped;
- Type of outpatient health care provider;
- Directly Observed Therapy information (total, partial or self administered; who administered the DOT; number of weeks of DOT);
- Final drug susceptibility results.

5.5 Closing TB control services

The case manager will complete any TB control program paperwork required to officially close the case to the LHJ as well as send a letter to the health care provider (if indicated) notifying them that the case has been closed to TB control program services and the reason for closure. (Sample closure letters are available from the CDPH TB Control Branch). Patients should be given documentation of treatment completion.

Note: No set of guidelines can cover all individual situations that can and will arise. When questions arise on individual situations not covered by these guidelines, consult with your local TB Controller or the CDPH, TBCB.

Suggested Reading

1. CDPH/CTCA, “Guidelines for the Treatment of Active Tuberculosis”
2. CDPH/CTCA, “Guidelines for Oversight of Tuberculosis Care Provided Outside the Local Health Department Tuberculosis Control Program”
3. CDPH/CTCA, “Directly Observed Therapy Program Protocols in California”
4. CDPH/CTCA, “Interjurisdictional Continuity of Care Policy Statement”
5. CDPH/CTCA Joint Addenda “Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis”
6. BRN Nurse Practice Act, 2010.
7. California Code of Regulations, Title 17, Section 2500.
8. California Health and Safety Codes, Sections 121361, 121362, 121364, 121365.