

**NURSING DIRECTIVES/GUIDELINES**

**SUBJECT/TITLE: Tuberculosis Case Management**

**SECTION:** Standards of Care

**SUMMARY:** Oversight for the management of care for tuberculosis (TB) cases, suspects, contacts and those with latent TB infection (LTBI) in the community setting is the responsibility of the local health department nurse case manager in collaboration with health directors, nurse managers, clinicians, outreach workers and others. Clients may be managed in the private sector, by public health departments, or jointly. In all cases, the health department is ultimately responsible for ensuring that adequate, appropriate diagnostic and treatment services are available, and for monitoring the results of therapy.

**BRIEF BACKGROUND:** Case management is the preferred strategy for coordinating TB client care to ensure that the client’s medical and psychosocial needs are met through appropriate utilization of resources. The nurse case manager is responsible and accountable to ensure that the client completes a course of therapy, is educated about TB and its treatment, has documented culture conversion, and completes a contact investigation, if appropriate. The primary goals of TB case management are to render the client non-infectious by ensuring appropriate treatment; prevent additional transmission and development of additional disease; identify and remove barriers to adherence; and identify and address other urgent health needs. The health department role includes case management, contact investigation, determination of infectiousness (including release from isolation and return to normal activity/locations), and oversight of the treatment plan and outcome.

It is beyond the scope of this document to cover all situations that may arise during the course of treatment or investigation of any one individual or community. All nurses involved in the case management of TB clients should have immediate access to guidelines, policies and procedures published by the Centers for Disease Control and Prevention (CDC) and the Virginia Department of Health (VDH), Division of Disease Prevention, TB Control and Prevention program (DDP-tb).

**PROCEDURE/DIRECTIVE:**

* Initial Steps to the reported TB case/suspect
  + Each health district should assign responsibility for receiving case reports for TB clients to a specific professional staff member or team. Contact information and the local process for reporting new TB cases/suspects should be communicated to appropriate health care facilities and providers within the district.
* All cases should be assigned to a nurse case manager within one business day of case report. Determine who will be the clinician of record for the client. Ensure that the clinician has access to appropriate treatment guidelines, legal and regulatory information pertinent to the control of tuberculosis and clinical information. Explain the role of the health department and nurse case manager, if necessary. Ideally, the first contact with the client and treating clinician by the nurse case manager (not office staff) should be within one business day, but no later than three days, after the initial report.
  + If the client is hospitalized, a hospital visit should be made prior to discharge, if possible, to facilitate a smooth transition to outpatient management and initiate the contact investigation.
  + All clients should be visited at home early in the initial follow-up period regardless of where the initial visit occurred.
  + Assess for client infectiousness potential. Determine need for isolation, use of surgical mask by client when leaving isolation, and use of N-95 or greater respirator by health department personnel when interacting with client. If the client is infectious, document findings in chart and complete Isolation Instructions form with client. Refer to Box 3 on page 9 of ***Morbidity and Mortality Weekly Report*** (MMWR) “Controlling Tuberculosis in the United States,” for current criteria for determining when client on therapy for pulmonary TB has become non-infectious.
  + Completion of the TB Treatment/Discharge Plan (2005A-TB-004), and approval by the local health director or designee, is required by the *Code of Virginia* prior to the release of clients from all medical care facilities (hospitals, long term care facilities, correctional facilities, etc.). The plan should include placement in an appropriate environment to prevent transmission to previously unexposed persons and also meet the client’s needs.
  + During the initial client and provider interview, obtain information including the following:
    - Current client demographics including: name, aliases, addresses, all phone numbers, date of birth, country of origin, immigration status at time of entry, length of time in US, if appropriate
    - Medical history and risk factors for either acquiring TB infection or for progression to active disease
    - Signs and symptoms of disease including initial onset is needed to determine period of infectiousness and for planning contact investigation.
    - Results of testing for TB infection, e.g., tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA), if done
    - Chest x-ray and CT scan results, if done
    - HIV test results, if done
    - Bacteriology results to include any or all that are currently available (smear results, culture results, susceptibility results and NAA results)
    - Pathology/histology results, if applicable
    - Current weight
    - Other hospital and medical records including records of other recent emergency room (ER) visits or hospitalizations for similar diagnoses such as pneumonia, bronchitis, etc. Review records carefully for treatment with a flouroquinolone. Flouroquinolones (e.g., Levoquin, moxifloxacin, etc.) have anti-TB activity and can impact sputum smear results.
    - Social factors (living arrangements, work/school, substance abuse, potential language/cultural barriers)
  + Obtain and place copies of all pertinent records (chest x-rays, bacteriology results, discharge summaries, etc.) in the VDH client record
* Assess the status of the diagnostic evaluation and arrange for additional examinations, if needed. For all cases of suspected extra-pulmonary TB, chest x-ray and sputum testing for AFB smear and culture should be obtained to assure that pulmonary disease is ruled out.
* Assess the current TB treatment plan for conformity to recommendations found in the MMWR “Treatment of Tuberculosis.”
  + - In Virginia, most cases should be started on the standard 4-drug regimen of isoniazid, rifampin, ethambutol and pyrazinamide. Medication dosages are based on weight, with adjustments, if needed, for altered renal and hepatic function or potential drug-drug interactions.
    - Notify TB Control if any client is started on a treatment regimen that does not contain a rifamycin (rifampin, rifabutin, rifapentine)
    - Re-calculate all medication dosages to assure appropriate dose for weight.
    - Review baseline CBC, liver and renal function tests and arrange for testing, if not done.
    - Review HIV test results and arrange for testing if not done.
    - Review records for a diagnosis of diabetes of any type. Arrange for therapeutic drug level monitoring within two (2) weeks of treatment initiation or as soon as possible thereafter for all cases/suspects with a diabetes diagnosis.
  + Review record for HgbA1c result and arrange for testing, if not done.
    - Review entire medication profile for potential drug-drug, drug-herbal and drug-food interactions. Follow VDH protocols for medication review.
    - Assess for known drug allergies.
    - Further information on correct dosages for TB medications and potential drug interactions can be found in MMWR “Treatment of Tuberculosis” (Vol 52/RR-11) pages 4 and 5.
      * If treatment plan does not follow recommendations found in the MMWR “Treatment of Tuberculosis,” contact the clinician of record within one (1) business day to determine reasons for deviation from standard TB treatment guidelines and any treatment issues. Involve nurse manager and health director, as appropriate, when deviations from the standard treatment plan cannot be resolved.
      * Report all cases of rifampin resistant or multiple-drug resistant tuberculosis, with the exception of isoniazid/streptomycin resistance, to VDH DDP-tb within 24 hours by phone (804-864-7906) or FAX (804-371-0248).
      * Non-resistant cases and suspects should be reported within seven (7) days by the submission of a completed Epi 1 form faxed to 804-371-0248.
      * Arrange for medical management if the client does not have a medical home.
      * Directly Observed Therapy (DOT) is the standard of care for the treatment of tuberculosis in Virginia.
        + The *Code of Virginia* (§ 32.1-50) requires a health director/designee approved treatment plan for all clients receiving treatment in the following categories regardless of source or location of care:
    - All cases with confirmed or suspected resistance to rifampin
    - All HIV-infected cases
    - All cases with a history of relapsed TB or prior treated or untreated TB and
    - All cases with a demonstrated history of non-adherence to a treatment regimen.
    - While not contained in the statute, pediatric cases should be considered part of this group.
    - DOT should be a requirement for approval of treatment plans for these clients.
      * Written health director acknowledgement is required for all categories of clients listed above who are not on DOT.
        + Refer to the VDH Nursing Directive on DOT.
        + Complete the DOT agreement with the client, filing a copy in the record and providing a copy to the client.
        + Complete the Isolation Instructions document with the client, if applicable, filing a copy in the record and providing a copy to the client.

If treatment is not provided by DOT, document reason in client record and initiate acceptable alternative to monitor client compliance such as monitoring of pharmacy pick-ups or pill counts. Written health director acknowledgement is required for all categories of clients listed above who are not on DOT.

Determine period of infectiousness and document dates with rationale for decision in client record. If appropriate, initiate contact investigation according to guidelines found in MMWR “Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis” and the VDH Contact Investigation nursing directive. High priority contacts should be contacted and evaluated within seven days of identification.

Initiate client education. Topics should include but are not limited to: the difference between TB disease and TB infection; transmission of tuberculosis; signs and symptoms of tuberculosis; infection control for the client/home and prevention of spread; treatment plan, medications and potential side effects to medications; diagnostic procedures; monitoring and follow-up during treatment; meaning of test results; roles of client, case manager, and health department; how to contact case manager; and how to deal with side effects/problems during treatment.

Assess for potential barriers to care such as language/cultural barriers, homelessness, substance abuse, etc.

Arrange for language/interpretation support as needed.

Arrange for housing and subsistence support as needed.

Refer to social service agencies for support, substance abuse treatment, etc. as appropriate.

* Ongoing Monitoring and Case Management
* All clients receiving one or more anti-TB medications should receive a monthly clinical assessment by a physician or nurse case manager.
* Perform monitoring tests as appropriate for treatment plan.
  + Follow guidelines in MMWR “Treatment of Tuberculosis” and district protocol for blood work frequency. Clients on second-line drugs may require additional laboratory monitoring tests.
  + All clients receiving ethambutol or other drugs that might impair vision should receive baseline and monthly visual acuity and color vision screening while on the drug. All changes in results from previous screening should be reported to the clinician within one (1) business day.
  + Baseline and monthly hearing screening should be performed for all clients receiving ototoxic drugs (injectable agents such as capreomycin, streptomycin, etc.) while the client is receiving the medication. Abnormalities should be reported to the clinician within one business day.
  + If clients are started on ethambutol or injectable medications prior to the local health district becoming aware of the client, baseline vision and hearing screening should occur before any continued treatment is initiated by the local health district.
  + For clients on second TB line drugs (e.g., flouroquinolones, capreomycin, amikacin, ethionamide, PAS, linezolid, etc.) assure appropriate monitoring for drug-specific side effects and additional laboratory tests required for drugs included in the regimen.
* Monitor for adverse reactions and side effects to medications. Document any reactions in the client record.
* Potentially serious adverse reactions should be reported to the clinician immediately, e.g., within 1-2 hours. Potentially serious reactions include: jaundice, dark urine, vomiting, abdominal pain, fever, visual changes or a marked clinical rash. In consultation with the clinician, hold medications until the client is evaluated by the clinician. If unable to contact the clinician, consult with the health director or a back-up clinician prior to holding the medications. Anti-tuberculosis medications should not be stopped without clinician order unless the situation is extremely serious or life threatening. In the event of a very serious reaction the client should seek medical care immediately.
* Less severe side effects and reactions should be reported to the clinician within 24 hours. Less severe side effects may include: anorexia, nausea, malaise, peripheral neuropathy (tingling or burning sensation in hands or feet), and rashes.
* Obtain susceptibility results.
  + Report resistance to any drug to the clinician within 12 hours.
  + Unless stoppage is due to side effects, ethambutol and pyrazinamide should not be discontinued until drug susceptibility results are received.
* Monitor client during treatment for clinical improvement such as improved appetite, weight gain, cessation of fevers, improving or cessation of productive cough, etc. If there is no improvement or a worsening in clinical condition:
  + - Notify the clinician and health director
    - Take appropriate actions in consultation with clinician, health director, and DDP-tb to determine cause, e.g., drug resistance, malabsorption.
* Monitor for infectiousness and test of cure – sputum specimens should be collected according to the following schedule until individual is culture negative.
  + - Follow DDP-tb guidelines for frequency of sputum collection for smear and culture conversion.
* After smear conversion, sputa should be collected every 7-10 days, with a maximum of three (3) samples a month, until two (2) negative culture results are received for clients with pansensitive TB disease.
* For clients with multi-drug or extensively drug resistant TB, one sputa sample should be collected monthly after culture conversion. Collection of monthly samples should continue for six (6) months after the completion of treatment.
  + - Occasionally alternative sputum collection frequency and duration may be needed for clients with drug resistance or extensive findings in radiography. Consult with DDP-tb. Follow standard procedures for sample collection, e.g., first morning sample if possible, rinse mouth before collection, refrigerate until transport to lab.
    - If client is unable to produce an expectorated sample, an induced collection should be attempted using hypertonic saline solution.
    - Maintain isolation until the client is no longer infectious. Refer to Box 3 on page 9 of MMWR “Controlling Tuberculosis in the United States” for criteria for release from isolation for clients on treatment.
* Continue DOT or other strategies to monitor client treatment compliance.
  + - Immediately assess for reasons to any adherence problem.
    - Take appropriate corrective actions based on causation.
    - Involve clinician, nurse manager, health director, and DDP-tb as appropriate for assistance in the management of ongoing adherence issues.
    - Consider actions outlined in Virginia TB Control Laws Guidebook, as necessary. Consult with DDP-tb.
* Monitor for changes to treatment plan.
* Assure appropriate dose count before any standard regimen changes.
* Assure correct number of PZA doses before drug is discontinued.
* Notify TB Control immediately if the rifamycin (rifampin, Rifapentine, rifapentine) is discontinued from the treatment regimen for any reason.
* Assure appropriate dose count before treatment is discontinued entirely.
* Review all changes within 24 hours for appropriateness of drug selection and dosage. Initiate action to correct inappropriate changes within 24 hours. Involve nurse manager and health director, as appropriate.
* Continue assessment of barriers to treatment and adherence and take corrective actions as appropriate.
* Assure continuity of care during relocation to other jurisdictions.
  + For clients moving out of state or internationally, complete an appropriate referral form and fax it to DDP-tb at 804-371-0248 for processing.
* For TB cases who remain in the United States, the TB case manager is responsible for periodically contacting the receiving jurisdiction to monitor treatment progress and to obtain final treatment completion information.
* The TB case manager is NOT responsible for monitoring treatment progress for TB cases that permanently leave the United States.
  + For clients who relocated within Virginia, contact the receiving local health district directly to assure continuity of care and transfer of appropriate records.
  + Recommended additional action includes direct contact by the nurse case manager with receiving jurisdiction unless located outside of the United States and provision of follow-up plan and contact/locator information for new health department to client.
    - Monitor for psychosocial issues that may directly impact TB case and make referrals as appropriate.
    - When TB medications are stopped for any reason such as treatment completion, determination that the case was not active TB, moved out of country or lost to follow-up, a TB Case Closure form should be fully completed. Information on DOT doses must also be included on the TB Case Closure form. The form should be faxed within seven (7) days to the TB Program at 804-371-0248.
    - If the client is on a regimen that does not include a rifamycin (rifampin, rifabutin, rifapentine), the TB regimen cannot be stopped until reviewed by a Virginia TB Medical Consultant and DDP-tb.

***Recordkeeping:***

* A client record is needed for all encounters with the TB program. A TB Risk Assessment

form or Contact Investigation form alone may be appropriate for some clients.

* Contact investigation forms and documentation should be filed in a separate prong folder adjacent to the client record. The folder should be labeled “Contacts of [*Case Name*].”
* A TB Risk Assessment form or Contact Investigation form alone may be appropriate for some clients. Only a summary document detailing the findings of the contact investigation should be placed in the case record. Contact investigation records containing contact names, addresses and other HIPAA protected information should be stored elsewhere.
* A case management record is needed for:
  + - All cases – regardless of source of care
    - All clients who meet one or more of the following criteria
      * Referred for chest x-ray
      * Sputum collected
      * Identified as a suspect or active case of TB disease regardless of the source of medical care or site of disease.
      * Recommended for treatment for LTBI as a contact to an active case regardless of the source of medical care. The record should contain final treatment completion outcome.
      * Recommended for treatment for LTBI as a reactor or convertor by the local health department
        + An appropriate TB Service plan should be included in all TB records. This document can be tailored to each individual client’s needs and should be updated during the course of care.
        + Documentation by Exception chart forms are not appropriate for inclusion in the TB case management record. Standard VDH TB Control record forms should be used in all classes of TB client records. Refer to DDP-tb guidelines for “Use of the TB Case Management Record. Case records and records for suspects on a trial course of treatment for presumed active disease should be filed in a six (6)-prong folder. A folder with fewer sections may be used for other records.
        + VDH TB Control record forms, test results and other medical records should be filed in the client record according to agency or local district guidelines for assembling client records, but in such a way that bacteriology, blood and radiography results are filed together in orderly fashion to facilitate ongoing monitoring.
        + Directly Observed Therapy (DOT) logs may be maintained in a separate folder to facilitate prompt documentation for the current month only. At the end of each month, the DOT log and any progress notes should be filed appropriately in the client record.

**EVIDENCE BASE:**

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*Code of Virginia* (§ 32.1-50) Treatment plan; submission of plan and mediation of

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