NURSING DIRECTIVE

SUBJECT: Tuberculosis Case Management

SECTION: Standards of Care

SUMMARY: Oversight for the management of care for individuals with presumptive or confirmed tuberculosis (TB), contacts to individuals with infectious TB, and immigrants and refugees with TB classifications 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 by public health departments, or jointly with the private sector. 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. All nurses managing TB clients should be trained and have training documented on the VDH TB Training and Competency Assessment tool.

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 for ensuring that the client completes a course of therapy, is educated about TB and its treatment, has documented culture conversion, and that a contact investigation is completed, 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).

PROCEDURE/DIRECTIVE:

INITIAL NOTIFICATION

1. Each health district should assign responsibility for receiving case reports for individuals with TB to a specific professional staff member or team (commonly Senior TB Nurse or epidemiologist). Contact information and the local process for

reporting new individuals with presumptive or confirmed active TB should be communicated to appropriate health care facilities and providers within the district.

2. All new and presumptive 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 management of individuals with presumptive or confirmed TB. 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 business days, after the initial report.
3. Case manager should document on the Active TB Case Summary. Review information from the reporting source. Request medical records that provide the information needed to complete the Active TB Case Summary.
4. Case manager should provide guidance to reporting source regarding Airborne Infection Isolation precautions (AII). Presumptive and confirmed TB clients should be in AII if inpatient until standards for release from isolation are met. Estimate potential infectiousness (site of disease, bacteriology, symptoms).
5. Review the TB Nurse Clinical Pathway document to ensure completeness
6. Case manager should complete the initial notification to VDH TB Program of a new active TB case or presumptive case REDCap Form **within 3 days of initial notification**
7. Case manager should **initiate** the discharge plan if hospitalized. If discharge is imminent ensure the *TB Treatment/Discharge Plan* (2005A-TB-004) has been completed by the hospital provider, reviewed and signed by the Health District clinician of record or other designated clinician before discharge.
    a. If the clinician of record is offsite (Medical Officer, e.g.), the nurse case manager should coordinate for an electronic signature from the clinician of record using a secure signature platform (e.g. Adobe Pro).

FIRST THREE DAYS OF NOTIFICATION

Initial Visit Timeline

1. The client should be visited in person as soon as possible by the case manager, ideally within three days of notification. This visit may occur in a variety of settings such as in a hospital, congregate setting (e.g., correctional facility, long term care facility), or in the home.
    a. 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.

Initial Assessment

1. Assess for client infectiousness potential. Determine need for isolation. Health department personnel should use an N-95 or greater respirator when interacting with clients on isolation. Refer to Effect of Index Patient Characteristics and

Behaviors for criteria for determining when a client on therapy for pulmonary TB has become non-infectious.

   a. If the client is infectious, document findings in chart and complete the *Isolation Instructions* form with the client.

2. Determine the need for a contact investigation
   a. If appropriate, initiate contact investigation according to *Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis* and the VDH Contact Investigation nursing directive.
   b. Determine period of infectiousness and document in client record on 502.
3. Perform the initial client interview; confirm client medical/psychosocial/demographic information, and complete the TB and Newcomer Health History including:
   a. Current client demographics including name, aliases, addresses, all phone numbers, date of birth, country of origin, length of time in United States, if appropriate
   b. Medical history and risk factors for exposure to TB and/or progression to active disease
   c. Signs and symptoms of active TB including initial onset is needed to determine period of infectiousness and for planning contact investigation
   d. Results of testing for TB infection, e.g., tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA), if done
   e. Chest x-ray and CT scan results, if done
   f. HIV test results, if done
   g. Bacteriology results to include any or all that are currently available (smear results, culture results, susceptibility results and nucleic acid amplification test results)
   h. Pathology/histology results, if applicable
   i. Current weight
   j. 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 fluoroquinolone. Fluoroquinolones (e.g., levofloxacin, moxifloxacin, etc.) have anti-tuberculosis activity and can impact sputum smear results.
   k. Social factors (living arrangements, work/school, substance use, potential language/cultural barriers)
4. Obtain and place copies of all pertinent records (chest x-rays, bacteriology results, discharge summaries, etc.) in the VDH client record.

Education and Forms

1. Initiate client education. Topics should include but are not limited to: the difference between active TB and TB infection; transmission of TB; signs and symptoms of TB; infection control for the client/home and prevention of spread; medications and potential side effects to medications; diagnostic procedures; monitoring and follow-up during treatment; meaning of test results; roles and

responsibilities of client, case manager, and health department; how to contact case manager; and how to deal with side effects/problems during treatment.
    a. Provide language and literacy appropriate TB educational materials in patient preferred language: TB educational materials
2. Provide an overview of the TB treatment plan including monthly nursing/clinician visits. Provide contact information for clinic and case managers. Note this review in nursing progress notes.
3. Obtain signatures on HIPAA required forms - Notice of privacy practices, Authorization to Release PHI
4. Read, explain and obtain signature on the Patient Isolation Instructions
5. Read, explain and obtain signature for Directly Observed Therapy Agreement. Arrange for time and place for DOT. Notify the Outreach Worker
    a. File a copy in the record and provide a copy to the client.
6. Complete the *Isolation Instructions* with the client, if applicable, filing a copy in the record and providing a copy to the client.

Medications

1. Consult with clinician and provide a drug interaction checker to determine any drug/drug interactions with TB treatment regimen after obtaining a list of current medications. Give drug interaction report to clinician for review. Document all medications on the Medication List.
2. Prior to discharge, coordinate with discharging clinical team to ensure continuity of TB meds until medications can be ordered from Central Pharmacy.
    a. See VDH implementation guide for more information on medication billing and ordering

Labs and follow up tests within first three days

1. Place TST, or draw an Interferon Gamma Release Assay (IGRA) if not done and M.tb not confirmed
2. Do baseline diagnostic testing: Ishihara and Snellen for vision. Audiometry and Rhomberg testing are not needed if initiating standard RIPE treatment, needed for second line drugs only
3. Do AST, ALT, bilirubin, alkaline phosphatase, platelet count, creatinine, HIV, if not done within the last month. Document results on Lab Flow Sheet
4. Do HgbA1c, whether the client has a history of diabetes or not, if not done in the prior 3 months
5. Do Hepatitis B and Hepatitis C screening if client has risk factors (IV drug use, birth in Asia or Africa, HIV +)
6. Collect observed #1 sputum specimen. Assure GeneXpert (NAAT) on all initial smear positive specimens. Provide sputum containers for collection over next two days or schedule an induction if needed. Provide instructions for how to collect a sputum. Induce if necessary.
    a. Document date collected on Bacteriology Flow sheet.

7. Assess the status of the diagnostic evaluation and arrange for additional examinations, if needed. For all cases of presumptive extra-pulmonary TB, chest x-ray and sputum testing for acid fast bacilli (AFB) smear and culture should be obtained to assure that pulmonary disease is ruled out.

Treatment Plan

1. Assess the current TB treatment plan for conformity to recommendations found in the TB treatment guidance, *Treatment of Drug-Susceptible Tuberculosis* (2016).
2. In Virginia, most cases should be started on the standard 4-drug regimen of rifampin, isoniazid, pyrazinamide, and ethambutol unless there is suspicion or concern of resistance. Medication dosages are based on weight, with adjustments, if needed, for altered renal and hepatic function or potential drug-drug interactions.
3. Notify the VDH TB Program if any client is started on a treatment regimen that does not contain a rifamycin (rifampin, rifabutin, rifapentine). Notification can be through email (tuberculosis@vdh.virginia.gov), calling nurse consultant or indicate on initial notification (REDCap)
    a. Re-calculate all medication dosages to assure appropriate dose for weight.
    b. Review baseline CBC, liver, and renal function tests and arrange for testing, if not done.
    c. Review HIV test results and arrange for testing, if not done.
    d. Review record for HgbA1c result and arrange for testing, if not done.
4. Review records for a diagnosis of diabetes of any type. Arrange for therapeutic drug level monitoring within **two weeks** of treatment initiation or as soon as possible thereafter for all clients on treatment for active TB with a diabetes diagnosis and/or an elevated HgbA1c (≥6.5). Request serum drug level monitoring via REDCap here.
    a. Review entire medication profile for potential drug-drug, drug-herbal, and drug-food interactions. Follow VDH protocols for medication review.
    b. Assess for known drug allergies.
    c. If treatment plan does not follow recommendations found in the TB treatment guidance, *Treatment of Drug-Susceptible Tuberculosis* (2016) contact the clinician of record within one 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.
    d. Arrange for medical management if the client does not have a medical home.
5. The *Code of Virginia* (§ 32.1-50) and *Virginia Administrative Code* (12VAC5-90-225) requires a health director/designee approved treatment plan submitted no later than the time when anti-tuberculosis drug therapy is started or modified for all clients in the following categories, regardless of source or location of care:

a. Individuals, whether inpatient, incarcerated, or outpatient with the following conditions:
    i. HIV infection
    ii. Confirmed or suspected active TB disease resistant to rifampin, rifabutin, or other rifamycin
    iii. History of prior treated or untreated active TB disease, or a history of relapsed active TB disease
    iv. Demonstrated history of nonadherence to any medical treatment regimen

Discharge

1. Complete the *TB Treatment/Discharge Plan* (2005A-TB-004), with approval by the clinician of record, as 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 while also meeting the client's needs. If the client is hospitalized, arrange for the home assessment.
2. Assess for potential barriers to care such as language, cultural barriers, homelessness, substance use, etc. and develop plan to address them
    a. Arrange for language/interpretation support as needed.
    b. Arrange for housing and subsistence support as needed.
    c. Refer to social service agencies for support as appropriate.
3. If housing or food support is anticipated access all local avenues for assistance before submitting a request for AHIP funds. Requests should be submitted through REDCap.

Directly Observed Therapy

1. Directly observed therapy (DOT) is the standard of care for the treatment of active TB in Virginia.
2. Refer to the VDH Nursing Directive on DOT for additional guidance on DOT.
3. Document on DOT Log
4. Refer to the Delegation of Nursing Tasks to Unlicensed Personnel Dispensing and Delivering Medications in Health Departments directive for additional guidance on delegation.

ONGOING MONITORING AND ASSESSMENT

All clients receiving one or more anti-tuberculosis medications should receive a monthly in-person clinical assessment by a physician, DO, NP, PA, or nurse case manager. Case manager should work with business staff to ensure eligibility screening is completed within first 30 days of treatment. See VDH Eligibility Guidelines for more information.

Ongoing Monitoring Tests

1. Follow TB treatment guidance, *Treatment of Drug-Susceptible Tuberculosis (2016)* and district protocol for blood work frequency. Clients on second-line drugs may require additional laboratory monitoring tests.
2. 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 business day.**
3. **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.
4. 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.
5. For clients on second line TB drugs (e.g., fluoroquinolones, bedaquiline, pretomanid, clofazimine, cycloserine, linezolid, etc.) assure appropriate monitoring for drug-specific side effects and additional laboratory tests required for drugs included in the regimen.

Side Effect Monitoring

1. Monitor for adverse reactions and side effects to medications. Document any reactions in the client record.
2. 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 or medical officer 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.
3. 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.

Drug susceptibility results.

1. Obtain drug susceptibility results
2. Report resistance to any drug to the clinician within **one business day.**
3. Report all cases of rifampin resistant or multi-drug resistant TB to the VDH TB Program within one business day.

4. Unless stoppage is due to side effects, ethambutol and pyrazinamide should not be discontinued until drug susceptibility results are received.
5. 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:
    a. Notify the clinician and health director
    b. Take appropriate actions in consultation with clinician, health director, and VDH TB Program to determine cause, e.g., drug resistance, malabsorption.

Infectiousness Monitoring

1. Monitor for changes in infectiousness
2. Follow VDH TB Program guidelines for frequency of sputum collection for smear and culture conversion until individual is culture negative. Document on Bacteriology Flow sheet.
3. For clients with multi-drug or extensively drug resistant TB, one sputa sample should be collected monthly after culture conversion. Collection of sputum will continue following completion of treatment as outlined by a TB nurse consultant and/or medical consultant, if indicated. Occasionally alternative sputum collection frequency and duration may be needed for clients with drug resistance or extensive findings in radiography. Consult with VDH TB Program. Follow standard procedures for sample collection, e.g., first morning sample, if possible, rinse mouth before collection, refrigerate specimen until transport to lab.
4. If client is unable to produce an expectorated sample, an induced collection should be attempted using hypertonic saline (3%, 5%, 7% or 10%) solution.
    a. If inducing sputum, indicate that in WebVision when submitting sample.
5. Maintain isolation until the client is no longer infectious. Refer to current VDH guidelines for criteria for release from isolation for clients on treatment.

Treatment Monitoring

1. Monitor for changes to treatment plan.
2. Continue DOT or other strategies to monitor client treatment compliance.
    a. Immediately assess for reasons to any adherence problem.
    b. Take appropriate corrective actions based on causation.
    c. Involve clinician, nurse manager, health director, and VDH TB Program as appropriate for assistance in the management of ongoing adherence issues. Recurring multidisciplinary rounds are useful to coordinate patient care and should be considered.
    d. Consider actions outlined in *Virginia TB Control Laws Guidebook*, as necessary. Consult with VDH TB Program.
3. Assure appropriate dose count before any standard regimen changes.
4. Assure correct number of pyrazinamide (PZA) doses before drug is discontinued.
5. Notify VDH TB Program immediately if the rifamycin (rifampin, rifabutin, rifapentine) is discontinued from the treatment regimen for any reason.

6. 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.
7. Continue assessment of barriers to treatment and adherence and take corrective actions as appropriate.
8. Monitor for psychosocial issues that may directly impact TB case and make referrals as appropriate.
9. If the client is on a regimen that does not include a rifamycin (rifampin, rifabutin, rifapentine), the TB regimen should not be stopped until a TB nurse consultant or medical consultant verifies completion.
10. 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 with information on DOT doses. Email the *TB Case Closure* form with encryption to tuberculosis@vdh.virginia.gov or fax it to 804-416-5178 within seven days.
11. If Therapeutic Drug Monitoring is indicated by clinician, follow protocol here
12. Assure appropriate dose count before treatment is discontinued entirely.
    a. See Recommendations for Determination of Completion of Treatment

Continuity of care during relocation to other jurisdictions.

1. For clients moving out of state, complete an interjurisdictional notification form and email it with encryption to tuberculosis@vdh.virginia.gov or fax it to 804-416-5178 for processing. For clients moving internationally, complete a Cure TB Transnational Notification Form and email it with encryption to curetb@cdc.gov and to tuberculosis@vdh.virginia.gov.
    a. For TB cases who remain in the United States, the case manager is responsible for periodically contacting the receiving jurisdiction to monitor treatment progress and to obtain final treatment completion information. VDH TB Program can assist with obtaining information from other states if needed.
    b. For clients who relocate within Virginia, contact the receiving local health district directly to assure continuity of care and transfer of appropriate records.
2. The TB case manager is not responsible for monitoring treatment progress for TB cases that permanently leave the United States.
3. Recommended additional action includes direct contact by the 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.

Recordkeeping:

1. A client record is needed for all encounters with the TB program.

2. Contact investigation forms and documentation should be filed in a separate pronged folder adjacent to the client record. The folder should be labeled "Contacts of [*Case Name*]."
3. A *TB Risk Assessment* form or *Contact Investigation* form alone may be appropriate for some clients.
4. 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.
5. A case management record is needed for
    a. All clients with presumptive and confirmed TB – regardless of source of care
    b. All clients who meet one or more of the following criteria
        i. Referred for chest x-ray
        ii. Sputum collected
        iii. Presumptive or confirmed TB regardless of the source of medical care or site of disease.
        iv. 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.
            a. Documentation by Exception chart forms are not appropriate for inclusion in the TB case management record. Standard VDH TB Program record forms should be used for all clients receiving TB services. Refer to VDH TB Program *Recommendations for Tuberculosis Record and Form Use*.
            b. VDH TB Program record forms, test results, and other medical records should be filed in the client record according to VDH TB Program, agency, or local district guidelines for assembling client records.
            c. *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.
            d. Record Retention Information

Forms used in TB case management are available in multiple languages on the VDH TB Forms for Local Health Departments site. Please contact the VDH TB Program if additional translations are needed.

EVIDENCE BASE:

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Code of Virginia (§ 32.1-50. Examination of persons suspected of having active tuberculosis disease; reporting; report forms; report schedule; laboratory reports; and required samples. https://law.lis.virginia.gov/vacode/title32.1/chapter2/section32.1-50/

Code of Virginia (§ 32.1-50). Treatment plan; submission of plan and mediation of disagreements; determination of cure. https://law.lis.virginia.gov/vacode/title32.1/chapter2/section32.1-50.1/

Virginia Administrative Code (12VAC5-90-225) Additional data to be reported related to persons with active tuberculosis disease (confirmed or suspected). https://law.lis.virginia.gov/admincode/title12/agency5/chapter90/section225/

Virginia Department of Health. (2022). *Needed Communication between Local Health Departments and the TB and Newcomer Health Programs.* Virginia Department of Health TB Program. https://www.vdh.virginia.gov/content/uploads/sites/175/2021/05/Needed-Communication-between-Local-Health-Departments-and-the-TB-and-Newcomer-Health-Programs.pdf

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Virginia Department of Health. (2022). *Recommendations for Determination of Completion of Treatment for Active Tuberculosis.* Virginia Department of Health TB Program. https://www.vdh.virginia.gov/content/uploads/sites/175/2022/12/Recommendations-for-Determination-of-Completion-of-Treatment-2022.pdf

Virginia Department of Health. (2022). *Recommendations and Procedures for the Use of Therapeutic Drug Monitoring in Clients.* Virginia Department of Health TB Program. https://www.vdh.virginia.gov/content/uploads/sites/175/2020/05/TDM-May-2020.pdf

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Virginia Department of Health. (2019). *Recommendations for Tuberculosis Record and Form Use.* Virginia Department of Health TB Program. https://www.vdh.virginia.gov/content/uploads/sites/175/2023/02/Recommendations-for-TB-Record-and-Form-Use-updated-9-12-19-1.pdf

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Directive Comments and Feedback

Comments and feedback regarding this directive should be directed to the Director, Public Health Nursing (804) 864-7014.