Section 7: Care of Clients with Active TB

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Introduction

The *Public Health Protection and Promotion Act* requires that all cases of Tuberculosis (TB) be reported to the Medical Officer of Health (MOH). Notification is to be made by telephone as soon as a case is suspected or confirmed and is to be followed by a written report within 24 hours. The CDCN is responsible for notifying the MOH of all suspect or confirmed cases of TB.

Early detection of active TB and prompt initiation of appropriate treatment and isolation (for infectious cases) improves outcomes for cases and stops transmission of TB bacteria.

Active TB is almost always curable when appropriate treatment is prescribed and adhered to. In the Labrador-Grenfell Health Region, all cases of active TB are treated with Directly Observed Treatment (DOT). Although it is sometimes necessary for clients with active TB to begin TB treatment away from their home communities, most can return within two to three weeks.

There are two distinct phases in TB treatment: the initial phase (sometimes referred to as the 'intensive phase') and the continuation phase. There are important differences in monitoring requirements between the two treatment phases.

Care of clients with active TB might also include interventions for protecting the health of others such as airborne precautions, and contact investigations.

Steps in Caring for a Client with Active TB

Step 1: Prepare to Deliver TB Diagnosis

- Consult the CDCN to confirm **isolation requirements** and whether a **contact investigation and/or source case investigation** is needed.

  Isolation Requirements:

  Clients with **pulmonary TB** including TB laryngitis usually require isolation for **AT LEAST** two weeks from the start of treatment.

  Clients with **all forms of TB** might require isolation until concurrent respiratory TB has been ruled out with chest x-rays and sputum testing. In some situations, clients with

suspected or confirmed active TB might be admitted to hospital for isolation until it is determined that airborne precautions are no longer necessary.

Isolation requirements for **a child with suspected or confirmed active TB** (any form) are determined on a case-by-case basis by the treating physician in consultation with the CDCN and MOH.

NOTE: When medical evacuation is necessary, use the same processes used to arrange for other medical evacuations (see **Section 15: Infection Prevention and Control**).

See Newfoundland and Labrador Tuberculosis Guideline Section 7: Prevention and Control of TB Transmission in Health Care Settings page 50, for Information on airborne precautions.

https://www.gov.nl.ca/hcs/publichealth/cdc/infectionpreventionandcontrol/

Contact Investigation and Source Case Investigation

Contact investigations are done for cases with infectious TB. Source case investigations (also called **Reverse Contact Investigations**) are done to identify how a non-infectious case or TST converter became infected with TB bacteria (i.e. to identify a 'source case').

- Review the client's chart to familiarize yourself with the context in which the diagnosis was made, which can help you to anticipate questions the client might ask. Prepare yourself to provide the client (and/or his/her parents/guardians) with information about:
    - The diagnosis and the clinical picture (e.g., chest x-ray findings, sputum test results).
    - Isolation requirements (if any) and how to comply with airborne precautions/home isolation when these are indicated (see **Section 15: Infection Prevention and Control**).
    - The follow-up plan (e.g., further evaluations, treatment [including DOT], potential adverse effects, monitoring),
    - Limitations on travel during treatment.

Step 2: Deliver TB Diagnosis

The TB physician will deliver the TB Diagnosis to the client via video teleconference or in person, which is arranged by the CDCN.

- Maintain airborne precautions when indicated by the TB Physician or the CDCN (i.e. during in-person appointments with a client who has infectious or potentially infectious active TB).
    - If feasible, arrange for the client to attend at the end of the day to minimize exposure to others. Alert reception staff about the appointment so they can **ensure the client dons a SURGICAL/PROCEDURE type mask** upon arrival and is immediately placed in an appropriate area for the interview (rather than sitting in the waiting room).
    - If possible, perform the interview in a ventilated room away from other people and with the door closed**. Don a DISPOSABLE N95 PARTICULATE RESPIRATOR (commonly referred to as an N95 mask) and fit-check it before entering the interview room. Wear the respirator throughout the interview.**

    See **Section 15: Infection Prevention and Control** for Information on masks.

Step 3: Client Teaching

During this visit the nurse will discuss home isolation, contact tracing, routine monitoring, and the follow-up regime. The nurse will complete the **TB Case Interview Guide/Form** (See **Appendix D: List of TB Forms and Client Letters**).

The **Case Interview Guide** is intended for use with a recently diagnosed case of TB, to help review their life and lifestyle during the time they may have been infectious and to identify contacts and persons who might need additional evaluation and assessment. All information obtained is confidential and client will be informed of same.

Review the following **TB Fact Sheets (Appendix E)** with the client (and/or the parent/guardian):

- Tuberculosis
- Taking Medication for Active Tuberculosis
- Tuberculosis Medication (as appropriate for the client's prescription)
- Keep Your Family and Friends Safe from TB

- TB Medications and Alcohol
- TB Medications and Acetaminophen (Tylenol)
- TB Medications and Your Liver
- Tuberculosis (TB) and Smoking
- Home Isolation Guidelines

When airborne precautions are required, document the date the client (and/or the parent/guardian) was informed and what information was provided.

Clients with active TB diagnosis will require isolation for a minimum of two weeks. Isolation can be done in a client's home or they may require a hospital admission.

Isolation in the client's home is preferred. However, there are circumstances which will require a hospital admission, such as, the need for further investigation, lack of stable housing (i.e. couch surfing), or unfavorable housing environment.

Reinforce the following key messages:

- Compliance with isolation recommendations (when indicated) will protect others from becoming infected with TB bacteria and developing active TB.
- Active TB is almost always curable with adherence to appropriate TB treatment.
- Adherence to treatment will:
  - Quickly reduce the number of TB bacteria in the client's body, which will provide relief from symptoms and (for infectious cases) help to stop transmission.
  - Prevent development (or worsening) of TB drug resistance.

- Treatment is available in the client's home community and is supported with Direct Observed Treatment (DOT). The use of DOT:
  - Supports adherence,

- Ensures regular monitoring for medication side effects and other potential adverse reactions, and
- Provides opportunities for the client to stay informed about his/her progress and treatment.

Step 4: Prepare to Begin TB Treatment

- Ensure all baseline testing has been done, including:
  - Posterior/anterior and lateral chest x-rays (for clients on home isolation this will be completed when isolation is discontinued, if it has not already been done).
  - Three sputum specimens sent for AFB smear and culture.
  - Initiate **growth chart** if client is less than five years of age.
  - Confirm the client's weight and document it on the **Active TB DOT Record (Appendix D).** Compare the current weight against the prescription dosage to ensure the dosing is adequate Consult the CDCN if dosage adjustments are required. See the following tables located later in this section:
    - **Table 7.6**: **TB Treatment Regimens and Recommended TB Drug Dosages**
    - **Table 7.7: Recommended drug doses for daily and intermittent therapy in children (12 years of age and under)**
    - **Table 7.8: Recommended drug doses for daily and intermittent therapy in adolescents and adults**
    - **Table 7.9: Recommended doses of TB drugs in renal failure**
  - Blood tests: AST, ALT, total bilirubin, CBC, creatinine, uric acid, Hepatitis B surface antigen, Hepatitis C, and HIV.
  - Visual acuity and colour vision testing if Ethambutol is to be used.
- Consult the CDCN to obtain a prescription for TB treatment.
  - Put a copy of the prescription on the client's chart and send a copy of the prescription to the Regional Community Clinic.

- When TB treatment is to be provided at the school or day care, ask the parent/guardian to sign a **Medication Administration Consent Form (School or Day Care).** See **Appendix D: List of TB Forms and Client Letters.**

- Review the side effects with the client and/or parent/guardian prior to the administration of the medications.

- If the client refuses treatment, make every effort to educate the client on the disease, the risk to others and the consequences of not taking TB medication. Inform the CDCN. Carefully document every interaction with the client and all steps taken to try and initiate treatment.

Step 5: Begin TB Treatment

Once a prescription has been received, initiate an **Active TB DOT Record**. To avoid delays in treatment start, use stock medications rather than waiting for medications to arrive from the pharmacy. **Unless otherwise ordered, the prescribed TB drugs should be taken together at the same time, NOT spread over the course of the day.**

Before administering the first dose of TB treatment:

- Verify that the prescription matches what the TB physician prescribed.

- Ensure baseline blood test results are within normal limits for the client's age. Consult the CDCN about abnormal baseline results.

- If ethambutol is included in the treatment regimen, document baseline vision test results on the **Active TB DOT Record**. See **Visual Acuity and Red/Green Colour Vision Testing** for information on vision testing.

- Review information with the client (and/or the parent/guardian) on:

    - The treatment regimen.

    - Potential TB drug side effects/adverse responses to TB treatment (see **Table 7.1**), and how to contact CHN should any occur.

    - The need to ensure the CHN and the Regional Nurse are aware of all medications the client is taking or starts taking during TB treatment, so that potential drug-drug interactions can be identified (see **Table 7.2**).

- The importance of avoiding acetaminophen (Tylenol®) and/or alcohol during TB treatment.

- The importance of adhering to TB treatment.

Do not tell the client (or parent/guardian) that TB treatment will continue for a set period of time. A number of factors can influence the duration of treatment, including adherence and response to treatment, which cannot be known at treatment outset. Instead, explain that completing treatment requires a specific number of doses to be completed, and reinforce that the duration of treatment can be minimized with regular adherence.

After administering the first dose of TB treatment:

- Document the initial treatment dose on the **Active TB DOT Record**.

- Confirm a plan for the next DOT dose.

Preparation of doses of TB drugs is a nursing function. Community Health Aides (CHAs) ARE NOT authorized to prepare TB drugs or dispense doses from stock medication supplies.

See **Section 10: Guidelines for Working with Clients** for information on DOT, the use of incentives and enablers, and helpful information on administering TB drugs.

For a client whose TB Treatment began in Hospital:

- Ask the CDCN to obtain the client's **Medication Administration Record (MAR)** from the Hospital.

- Transcribe doses given in Hospital onto the **Active TB DOT Record** indicating the name of the facility (e.g. LHC) on the day the dose was given according to the MAR.

Table 7.1: Drugs included in the standard TB treatment regimen and associated side-effects

Adapted from Menzies R, Wong T. Canadian Tuberculosis Standards. 7th ed. Canadian Thoracic Society and the Public Health Agency of Canada; 2014

TB Drug	Common side effects/adverse reactions	Uncommon but important side effects /adverse reactions
Isoniazid (INH)	• Rash • Fatigue, drowsiness[1] • Drug induced hepatitis[2] • Headache • Neuropathy • Mild hair loss • Nausea/ vomiting[1,3] • Acne	• Central nervous system toxicity[4] • Anemia
Rifampin (RMP)	• Drug interactions • Rash • Saliva, urine, tears can become orange/red in colour (harmless, but could stain contact lenses)	• Drug-induced hepatitis[2] • Flu-like illness • Neutropenia • Thrombocytopenia
Pyrazinamide (PZA)	• Rash • Nausea/vomiting[1] • Hepatitis[2] • Arthralgia	• Gout[5] • Photosensitivity
Ethambutol (EMB)	• Visual toxicity (retrobulbar neuritis)[6]	• Rash

1. *Can also be a sign of drug-induced hepatitis.*
2. *Symptoms can include loss of appetite, nausea or vomiting, abdominal discomfort, unexplained fatigue, dark-coloured urine and scleral icterus or jaundice.*
3. *Especially with intermittent regimens administered in combination with rifampin.*
4. *Symptoms can include slurred speech, peripheral neuritis, dizziness, stupor, seizures and coma.*
5. *Although elevation in serum uric acid levels is common with pyrazinamide use, acute gout is rarely seen except in those with pre-existing gout.*
6. *Manifested by decreases in visual acuity, visual fields, or colour vision. More common with higher doses (e.g. 25 mg/kg), older age, and renal impairment.*

Table 7.2: **Some common and/or important drug-drug interactions associated with isoniazid and rifampin**.

Menzies R, Wong T. Canadian Tuberculosis Standards. 7th ed. Canadian Thoracic Society and the Public Health Agency of Canada; 2014.
Rifampin and Isoniazid Product Monograph. E-Therapeutics. Canadian Pharmacists Association. Accessed November 2014.
Isoniazid and Rifampin. Lexicomp Online. Accessed November 2014.

NOTE: List does not include all possible interactions; consult a pharmacist for further information.

Isoniazid (INH)	Rifampin
• Acetaminophen • Antacids • Anticonvulsants (Carbamazepine, Phenytoin) • Antidepressants (Citalopram) • Beta-blockers (Metoprolol) • Clopidogrel • Diazepam • Doxorubicin • Haloperidol • Pimozide • Tamoxifen • Theophylline • Thioridazine	• Antiarrhythmics (Diltiazem, Verapamil, Digoxin) • Anticoagulants (Warfarin, Apixaban, Dabigatran) • Anticonvulsants (Phenytoin, Valproic Acid) • Antifungals (Ketoconazole) • Antipsychotics (Aripiprazole, Clozapine, Quetiapine) • Barbiturates • Beta-blockers • Calcium Channel Blockers (Amlodipine, Nifedipine) • Clarithromycin • Cyclosporine • Estrogens (including hormonal contraceptives) * • Glucocorticoids • Methadone • Protease Inhibitors • Sulfonylureas

**Women using hormonal contraceptives should be advised to use alternate forms of birth control while taking rifampin.*

Step 6: Continue TB Treatment

Clients (and/or parents/guardians), Community Health Aides (CHAs), and all nurses managing the care of clients on TB treatment share responsibility for:

- Preventing and identifying TB drug side effects/adverse responses to treatment.
- Identifying worsening or recurrence of TB signs/symptoms, such as weight loss or fever, that could indicate suboptimal response to treatment.
- Ensuring the CHN and/or the TB physician and/or the Regional Nurse are aware of all medications the client is taking (or starts taking) during TB treatment.

- Ensuring potential interruptions in, or barriers to, treatment adherence (e.g. travel) are identified and addressed (or minimized).

Monitoring Requirements

- Monitor clients taking standard TB treatment as per **Table 7.3** or as directed by the CDCN and/or the TB physician.

- Monitor clients on extended standard treatment as per **Table 7.4**. Monitoring requirements for clients taking non-standard TB treatment (e.g. for drug-resistant TB) are determined by the TB physician.

NOTES:

  - Monitoring requirements are also determined by the TB physician for clients:

    - With abnormal baseline blood test results,

    - At increased risk for hepatotoxicity or other adverse effects, and

    - Who develop side effects/adverse effects.

  - Blood tests after baseline are **NOT** routinely required during standard TB treatment for clients under 13 years of age.

  - In some situations, a clinical evaluation by a physician or nurse practitioner may be requested by the TB physician or the CDCN during the course of treatment; for example, pediatric clients or clients that are considered higher risk because they have underlying liver disease, are pregnant, or are experiencing treatment related issues.

- Document assessments on the **Active TB DOT Record**. Consult the CDCN or the TB physician about abnormal results.

- Clinical monitoring of any client whose TB treatment is provided by a CHA must include a face-to-face assessment by a nurse or a physician **AT LEAST WEEKLY** (more frequently if there are any concerns).

The CHN retains the ultimate responsibility for ensuring that the treatment regimen is followed, adverse reactions are monitored, and necessary lab work is done. Because of this, frequent meetings with the Community Health Aide, and at least WEEKLY meetings with the patient are required.

Key Aspects of Monitoring during Active TB Treatment

- **Hepatotoxicity**

Severe and potentially fatal hepatotoxicity can occur during TB treatment. Hepatotoxicity is defined as liver enzyme (AST/ALT) levels **FIVE** times the upper limit of normal *without symptoms* **OR THREE** times the upper limit of normal *with symptoms*.

Clients at increased risk for hepatotoxicity during TB treatment include:

- Pregnant clients and clients who are up to three months postpartum.
- Those with a history of previous drug-induced hepatitis.
- Those with current cirrhosis or chronic active hepatitis of any cause.
- Those with hepatitis C.
- Those with hepatitis B and abnormal transaminases.
- Those who consume alcohol daily or who are undergoing concomitant treatment with other hepatotoxic drugs (e.g. methotrexate).

If signs/symptoms consistent with hepatotoxicity are present:

- **Hold treatment.**
- Consult the CDCN or the treating physician.
- Refer to the Regional Community Clinic or Hospital Laboratory for bloodwork as ordered by the TB physician.

Signs/symptoms consistent with hepatotoxicity:

- Loss of appetite

- Nausea and/or vomiting
- Abdominal discomfort
- Unexplained fatigue
- Dark-coloured urine
- Scleral icterus or **jaundice**
- Fever and chills

- **Potential for other Adverse Effects/Concerns**
  - Use clinical judgment to determine whether the CDCN should be consulted or whether the client should be referred to the regional community clinic for assessment.
  - **Monitor clients taking anticonvulsants closely** as both INH and rifampin can affect the metabolism and serum levels of anticonvulsants.
  - Complete vision tests monthly for clients taking ethambutol. Document results on the **Active TB DOT Record**. Consult the CDCN or the TB physician should visual disturbances or changes to be noted.

- **TB Symptoms**
  - TB symptoms usually improve substantially once effective TB treatment is started. Consult the CDCN if symptoms do not improve, or if they worsen/recur as it could reflect suboptimal response to treatment or development of TB drug resistance.

- **Sputum Testing for TB**
  - Testing of sputum (or other respiratory specimens) is done at key points during treatment (sputum for AFB, as ordered by the physician). Results are used to determine level of infectiousness and response to treatment.
    - Cases who are **smear positive** should have:
      - One weekly smear examination to assess response to therapy and contagiousness until smear negative.

        - Three sputum samples tested at two months whether smear negative or not.
        - Three sputum specimens each month from month three to six until all three are culture negative.
        - Three sputum specimens at six months regardless of previous results.
        - As ordered by the physician.

    - Cases who are **smear negative** should have sputum testing at two months and six months or as ordered by the physician.

    - The CDCN shall notify the CHN if:

        - AFB sputum smear or TB culture results change from negative to positive, i.e. if a positive AFB smear or TB culture result is reported for a client whose sputum smear results were AFB smear or TB culture negative previously, **OR**

        - Any of the TB cultures on the sputum specimens collected at Week 4 **or afterward** are reported as 'positive'.

- **Changes in Weight**

    - Document weight on the **Active TB DOT Record** monthly.

    - Maintain a weight and growth chart for clients five years of age and under.

    - Ensure adequate dosing is maintained by comparing the client's current weight against the last month's weight, and against the prescription dosage (see **Table 7.6: Recommended treatment regimens for fully susceptible (or expected to be fully susceptible) active TB**). Consult the CDCN when dosage adjustments are required. See the following tables later in this section:

        - **Table 7.6**: **Recommended treatment regimens for fully susceptible (or expected to be fully susceptible) active TB**
        - **Table 7.7: Recommended drug doses for daily and intermittent therapy in children (12 years of age and under)**
        - **Table 7.8: Recommended drug doses for daily and intermittent therapy in adolescents and adults**
        - **Table 7.9: Recommended doses of TB drugs in renal failure**

NOTE: Notify the CDCN immediately about weight loss in any client or failure to gain weight in a growing child as this could reflect an adverse response to treatment or development of active TB.

- **Adherence**

  - Consult the CDCN if **three** doses in a row are missed and/or if adherence falls below 80% in a calendar month.

    To calculate adherence as a percentage, divide the number of DOT doses taken by the number of DOT doses due. Multiply the result by 100. Example: seven DOT doses taken divided by nine doses due (i.e. two doses missed) = 78% adherence.

NOTE: Ask about travel plans during each DOT visit. Consult the CDCN when arranging for continuation of TB treatment during travel (see **Travel during TB Treatment**, page 31).

  - Refer to **Section 10: Guidelines for Working with Clients** for non-compliance/ non-adherence to treatment.

- **Pregnancy**

  - Consult the CDCN or the TB physician for guidance on management of clients that become pregnant during TB treatment.

Major Monitoring Milestones

- **After TWO WEEKS of treatment:**

  - Draw AST, ALT, and bilirubin for clients 13 years of age and older and/or at increased risk for hepatotoxicity;

  - Consult the CDCN for guidance on discontinuation of home isolation. **DO NOT advise the client to discontinue home isolation without prior approval from the CDCN and/or the TB physician.**

- **After ONE MONTH of treatment:**

- Send the **Active TB DOT Record**, along with an updated growth chart for clients five years of age and under to the CDCN to review for adherence and treatment issues.

- **Once results from Drug Susceptibility Testing (DST) are received (typically four to six weeks after treatment start):**
  - Consult the CDCN and/or the TB physician to confirm whether adjustments to the prescription are needed. Ethambutol is usually discontinued once DST results confirm the isolate is sensitive to INH, Rifampin, and PZA. **DO NOT adjust the treatment regimen without consulting the CDCN and/or the TB physician.**

- **After TWO MONTHS of treatment:**

  - Send three sputum specimens for TB testing (if possible). Consult the CDCN if:

    - The client is unable to produce a sputum specimen as these test results are needed to determine whether extended treatment is necessary.

    - AFB sputum smears or TB cultures go from negative to positive.

    - Any of the TB cultures on the sputum specimens collected at Week 8 are reported as 'positive'.

  - **For clients with respiratory TB:**
    - Refer client for TB clinic follow-up.

  - **Once all doses prescribed for the initial phase of treatment have been observed,** PZA is usually discontinued and most clients are changed to three times-weekly DOT (Monday, Wednesday, and Friday) for the continuation phase of treatment. Consult the CDCN to obtain a prescription for the continuation phase of treatment from the TB physician or community physician (where applicable).

    - **DO NOT change to the continuation phase of treatment until all doses prescribed for the initial phase of treatment have been observed AND an updated prescription has been received.**

    - **DO NOT stop TB treatment while waiting for the updated prescription or medication supply. To avoid interrupting treatment, use stock**

medications rather than waiting for medications to arrive from the pharmacy.

- **At the end of MONTHS THREE THROUGH FIVE of treatment:**
    - Ensure all routine monitoring has been completed and recorded on the **Active TB DOT Record**;
    - Send the up-to-date **Active TB DOT Record** to the CDCN, along with the updated growth chart for clients five years of age and under.
    - For clients with pulmonary TB:
        - Send three sputum specimens for TB testing (if possible) each month until **all three** are TB culture-negative. Consult the CDCN if:
            - AFB sputum smears or TB cultures go from negative to positive, **OR**
            - Any of the TB cultures on these sputum specimens are reported as 'positive'.
- **After SIX MONTHS of treatment:**
    - Ensure all routine monitoring has been completed and recorded on the **Active TB DOT Record**.
    - Send the up-to-date **Active TB DOT Record** to the CDCN, along with the updated growth chart for clients five years of age and under.
    - Send three sputum specimens for TB testing (if possible). Consult the CDCN if:
        - AFB sputum smears or TB cultures go from negative to positive, **OR**
        - Any of the TB cultures on these sputum specimens are reported as 'positive'.

For clients with respiratory TB:

- Refer client to TB Clinic follow-up.

Consult the CDCN to confirm the treatment plan. **DO NOT discontinue treatment without consulting the CDCN and/or the TB physician.**

Table 7.3: Routine monitoring during standard treatment for Active TB (unless otherwise directed)

Monitoring	End of Week 1	End of Week 2	End of Week 3	End of Week 4	End of Week 8	End of Month 3	End of Month 4	End of Month 5	End of Month 6
Weight (kg.)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Check dose against current weight	✓	✓	✓	✓	✓	✓	✓	✓	✓
Assess side effects	Ask about side effects and possible hepatoxicity prior to each dose of medication.								
Assess for TB signs and symptoms	Consult CDCN if there is worsening or recurrence of TB signs or symptoms								
AST, ALT, Bilirubin, Serum creatinine, uric acid	Repeat after baseline if ordered by the Physician								
CBC		✓		✓	✓	✓	✓	✓	✓
HgbA1c		If 13 yrs or older							
Sputum for smear and culture (Smear +ve Respiratory TB only)	X1*	X1*	X1*	X1*	X3 (All TB clients)	Repeat 3 specimens each month until culture-negative.			X3 (All TB clients)
Sputum for smear and culture (Smear -ve Respiratory TB only)					X3 (All TB clients)				X3 (All TB clients)
PA and lateral CXR					✓				✓
Pregnancy	Ask women of childbearing age about possibility of pregnancy monthly.								
Snellen and Ishihara colour tests	Repeat monthly while Ethambutol is being taken.								
Travel	Ask about travel plans during each DOT visit.								

Notes:

*Blood tests after baseline are **NOT** routinely required during standard TB treatment for clients under 13 years of age.*
Signs and symptoms of hepatotoxicity include loss of appetite, nausea and/or vomiting, abdominal discomfort, unexplained fatigue, dark coloured urine, scleral icterus or jaundice.
**For AFB smear positive cases, continue to collect one weekly sputum specimen for TB testing until negative.*

Step 7: Extend or Discontinue TB Treatment

Decisions on length of treatment are made by the treating physician, in consultation with the CDCN.

TB treatment is usually discontinued once:

- The prescribed number of doses have been taken, and
- The end-of-treatment examinations have been ordered (e.g., chest x-rays, sputum tests for TB), and
- The file (including Active TB DOT records) has been reviewed by the CDCN and/or the treating physician and s/he has confirmed that an adequate course of treatment has been completed.

If it is determined that TB treatment can be discontinued, proceed to **Step 8**.

If treatment beyond six months (extended treatment) is required:

- Consult the CDCN to confirm:
    - Whether an updated prescription is needed (to maintain the client's TB drug supply).
    - Monitoring requirements. Routine monitoring for most cases on extended standard treatment is described in **Table 7.4.**

  NOTE: Monitoring requirements for clients whose treatment is extended beyond 12 months and/or who are receiving non-standard treatment (e.g. for drug resistant TB) are determined on a case-by-case basis by the treating physician.

- Initiate an **Active TB DOT Record-Extension of Treatment Form (Appendix D)**

Table 7.4: Routine monitoring during extended treatment for Active TB (unless otherwise directed)

Monitoring	End of Month 7	End of Month 8	End of Month 9	End of Month 10	End of Month 11	End of Month 12
Weight (kg.)	✓	✓	✓	✓	✓	✓
Check dosing against current weight	✓	✓	✓	✓	✓	✓
Assess side effects	Ask about side effects and possible hepatoxicity prior to each dose of medication.					
Assess for TB signs and symptoms	Consult CDCN if there is worsening or recurrence of TB signs or symptoms					
CBC, AST, ALT, Bilirubin	✓	✓	✓	✓	✓	✓
Serum creatinine, uric acid	Repeat after baseline if ordered by the Physician					
Sputum for smear and culture (Smear +ve Respiratory TB only)	Repeat three specimens each month until all three are culture negative		X 3 (all clients)	X 1	X 1	X 3 (all clients)
Sputum for smear and culture (Smear -ve Respiratory TB only)			X 3 (all clients)			X 3 (all clients)
PA and lateral CXR			✓			✓
Pregnancy	Ask women of childbearing age about possibility of pregnancy monthly.					
Snellen and Ishihara colour tests	Repeat monthly while Ethambutol is being taken.					
Travel	Ask about travel plans during each DOT visit.					

Notes:

Blood tests after baseline are NOT routinely required during standard TB treatment for clients under 13 years of age.

Signs and symptoms of hepatotoxicity include loss of appetite, nausea and/or vomiting, abdominal discomfort, unexplained fatigue, dark coloured urine, scleral icterus or jaundice.

**For AFB smear positive cases, continue to collect one weekly sputum specimen for TB testing until smear negative.*

Step 8: Document TB Treatment Outcome

For a client with 'Complete' TB treatment:

- Review TB signs/symptoms with the client (**Table 7.5**). Remind the client (and/or the parent/guardian) to remain alert for TB signs/symptoms, and to report to a health care provider quickly should any develop. **It is possible for people who have completed TB treatment to develop active TB again (relapse).**

Table 7.5: Signs and Symptoms of TB

Systemic TB signs/symptoms	Signs/symptoms of respiratory TB disease	Signs/symptoms of non-respiratory TB disease
• Fever* • Night sweats* • Weight loss or failure to gain weight (i.e. failure to thrive) • Fatigue • Loss of appetite	Systemic TB signs and symptoms **AND:** • Cough >3 weeks (dry or productive) • Chest pain • Shortness of breath • Bloody phlegm (hemoptysis)	Systemic TB signs/symptoms **AND** pain or dysfunction at the involved site, e.g.: • Swollen lymph nodes (TB lymphadenitis) • Headache, irritability, photophobia, stiff neck (TB meningitis)

****Can be absent in the very young and the elderly***

Complete the **Active TB Treatment Outcome Form**. Include in the record:

- Which TB drugs were taken
- Number of doses taken
- Start date and end date of treatment
- Document completion of TB treatment in the 'Progress Notes' and on the **Active TB Treatment Outcome Form (Appendix D)**

If treatment was 'incomplete', record why treatment was stopped.

NOTE: For a client who had/has long periods of non-compliance, consult the CDCN immediately when the client returns to the community or when his/her location becomes known. **DO NOT resume TB treatment without consulting the CDCN.**

- Once the **Active TB Treatment Outcome Form** is complete send it to the CDCN along with an updated growth chart for clients under five years of age.

- After consulting the TB Physician, the CDCN will complete **Part 3: Treatment Outcome and Surveillance Recommendations** and return it.

- Review the **Active TB Treatment Outcome Form** for the surveillance recommendation when it is returned by the CDCN.

    - If surveillance **WAS NOT** recommended, file the **Active TB Treatment Outcome Form** in the client's chart and write a note. Send a copy of the form to the Regional Community Clinic or Medical Records Department as appropriate.

    - If surveillance **WAS** recommended initiate the **Tuberculosis Surveillance and Outcome Form (Appendix D**) and follow the steps in **Section 13: TB Surveillance**. File the **Active TB Treatment Outcome Form** in the client's chart and send a copy to the Regional Community Clinic or Medical Records Department as appropriate.

Follow-up after TB Treatment

Follow-up after TB treatment is determined by the TB physician. In general, follow up post active TB treatment is as follows:

- Cavitary or smear-positive confirmed active TB adequately treated: follow up every 6 months for two years.

- Non-cavitary AND smear-negative active TB confirmed or diagnosed clinically and adequately treated: no follow up required.

- Active TB inadequately treated: follow up every six months for two years.

- See **Section 13: TB Surveillance** for the surveillance protocol.

NOTES:

- A client whose TB treatment was discontinued prior to completion is at **HIGH RISK** for relapse of active TB.

- A history of prior TB treatment does not provide protection against re-infection with TB bacteria. Clients who are exposed to active TB after TB treatment should

undergo routine contact follow-up assessments (see **Section 12: Contact Investigation, Window Period Prophylaxis and Source Case Investigation**).

TB Treatment Regimens and Recommended TB Drug Dosages

The tables on the next few pages indicate the recommended treatment regimens as well as the doses for each drug for adults, including those with renal insufficiency, and children.

NOTES: See **Table 7.9** for clients with renal insufficiency. Some forms of active TB require an extended continuation phase (e.g. bone TB, TB meningitis). All doses must be taken as directly observed therapy (DOT). Use of pyrazinamide (PZA) in the intensive phase during pregnancy is individualized. When PZA is not included in the initial phase or when PZA is discontinued before the initial phase has been completed (e.g. due to drug intolerance), an extended continuation phase is required to reduce risk of relapse of active TB.

Table 7.6: Recommended treatment regimens for fully susceptible (or expected to be fully susceptible) active TB

Adapted from: Menzies R, Wong T. Canadian Tuberculosis Standards. 7th ed. Canadian Thoracic Society and the Public Health Agency of Canada; 2014,
American Thoracic Society, Infectious Diseases Society of America, Centres for Disease Control. Treatment of Drug-Susceptible Tuberculosis. CID 2016:63 (1 October).

	Initial Phase	Continuation Phase
	Standard Treatment Regimen Option 1 - PZA INCLUDED in Initial Phase	
Regimen 1	INH, RMP, PZA, EMB*,** taken **daily** (or five days a week, Monday to Friday) for **two months – 56 daily doses (minimum 40 daily DOT doses)**	INH, RMP for **four months**, taken: **Daily** (or five days a week, Monday to Friday) **OR** **Three times a week – 54 doses** (Monday/Wednesday/Friday) †
	Standard Treatment Regimen Option 2 - PZA NOT INCLUDED in Initial Phase^	
Regimen 2	INH, RMP, EMB*, ** taken **daily** (or five days a week, Monday to Friday) for **two months (minimum 40 daily DOT doses)**	INH, RMP for **seven months**, taken: **Daily** (or five days a week, Monday to Friday) **OR** **Three times a week – 93 doses** (Monday/Wednesday/Friday)

**Ethambutol is not necessary in children when the source case strain is fully susceptible. Refer to Canadian Tuberculosis Standards, Chapter 9 (2014) for detailed recommendations on TB treatment in children.*
***Consult the CDCN and/or the treating physician re: discontinuing EMB as soon as drug susceptibility test results confirm there is no drug resistance.*
^Recommended for clients over 65 years and those with other risk factor(s) for hepatotoxicity. Risk of toxicity should be managed on a case-by-case basis in children as there is little supporting pediatric data.

†Three times weekly is preferred over twice weekly because if clients miss a single dose while receiving three times weekly therapy, they effectively receive twice weekly therapy, which is adequate. If clients miss a dose of twice weekly therapy, they effectively receive once weekly therapy, which is inadequate. In general, daily therapy is definitely preferred over intermittent regimens in children.

Table 7.7: Recommended drug doses for daily and intermittent therapy in children (12 years of age and under)

Adapted from: Menzies R, Wong T. Canadian Tuberculosis Standards. 7th ed. Canadian Thoracic Society and the Public Health Agency of Canada; 2014,
Blumberg HM, Burman WJ, Chaisson RE, et al. American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Societies of America. Treatment of tuberculosis. Am J Respir Crit Care Med 2003; 167(4):603-62.,
American Academy of Pediatrics. Tuberculosis. Red Book: 2012 Report of the Committee on Infectious Diseases (29th Ed.) Elk Grove Village, IL: American Academy of Pediatrics, 2012.

TB Drug	Daily Dose (Range)		Three Times a Week Doseˆ (Range)	
	By Weight	Maximum	By Weight	Maximum
Isoniazid (INH)	10mg/kg (10-15 mg/kg)†	300 mg	20-30 mg/kg	600-900 mg
Rifampin (RMP)	15 mg/kg	600 mg	10-20 mg/kg	600 mg
Pyrazinamide (PZA)	35 mg/kg (30-40 mg/kg)	2000 mg	70 mg/kg (60-80 mg/kg)	*
Ethambutol (EMB)	20 mg/kg (15-25 mg/kg)	**	40 mg/kg (30-50 mg/kg)	***
Vitamin B6 (Pyridoxine)	1 mg/kg	12.5 mg	1 mg/kg	12.5 mg

ˆIntermittent doses should be prescribed only when directly observed treatment is available. In general, daily treatment is definitely preferred over intermittent regimens in children.
† Optimal dose range for children under 13 years of age that weigh less than 35 kg. For children 13 years of age and older that weigh between 35 and 60 kg, the optimal dosing of isoniazid is an area of uncertainty (refer to Canadian Tuberculosis Standards, Chapter 9 [2014]).
**For pyrazinamide: maximum three times a week dose for children is 3000 mg according to the American Thoracic Society (ATS) and 2000 mg according to the Red Book.*
***For ethambutol: maximum daily dose for children is 1600 mg according to the ATS and 2500 mg according to the Red Book.*
**** For ethambutol: maximum three times a week dose for children is 2400 mg according to the ATS, and 2500 mg according to the Red Book.*

Table 7.8: Recommended drug doses for daily and intermittent therapy in adolescents and adults

American Academy of Pediatrics. Tuberculosis. Red Book: 2012 Report of the Committee on Infectious Diseases (29th Ed.) Elk Grove Village, IL: American Academy of Pediatrics, 2012.
Adapted from: Menzies R, Wong T. Canadian Tuberculosis Standards. 7th ed. Canadian Thoracic Society and the Public Health Agency of Canada; 2014.

NOTE: *The treating physician will determine whether dosing is daily or intermittent. In general, DAILY DOT (or DOT five days a week, Monday to Friday) is prescribed during the INITIAL PHASE of treatment.*

TB Drug	Daily		Three Times a Week	
	By Weight	Maximum	By Weight	Maximum
Isoniazid (INH)	5 mg/kg	300 mg	10 mg/kg	600 mg
Rifampin (RMP)	10 mg/kg	600 mg	10 mg/kg	600 mg
Pyrazinamide (PZA)	20-25 mg/kg	2000 mg	30-40 mg/kg	4000 mg
Ethambutol (EMB)	15-20 mg/kg †	1600 mg	25-40 mg/kg	2400 mg

† Ethambutol dosing: optimal dosing is unclear. Eye toxicity is dose-dependent; risk is higher at 25 mg/kg than at 15 mg/kg.

Table 7.9: Recommended doses of TB drugs in renal failure

Adapted from: Menzies R, Wong T. Canadian Tuberculosis Standards. 7th ed. Canadian Thoracic Society and the Public Health Agency of Canada; 2014.

TB Drug	Clearance by Kidney	Normal Dose	Creatinine clearance less than 30%* or hemodialysis†
Isoniazid (INH)	NO	5 mg/kg daily	No Change
Rifampin (RMP)	NO	10 mg/kg daily	No Change
Pyrazinamide (PZA)	Metabolites	20-25 mg/kg daily	25-35 mg/kg **three times per week**
Ethambutol (EMB)	YES	15-20 mg/kg daily	15-25 mg/kg **three times per week**

**Insufficient data if creatinine clearance >30% but <60%. Give standard doses but monitor closely.*

† No data on pharmacokinetics if patient is undergoing peritoneal dialysis. Give doses as for hemodialysis but monitor closely.

Visual Acuity and Red/Green Colour Vision Testing

Clients taking Ethambutol (EMB) are at risk for ocular toxicity. Failure to detect early signs of ocular toxicity and/or to discontinue EMB can result in permanent damage to the optic nerve and blindness.

- Document visual acuity and colour vision test results on the DOT record at baseline and monthly **THROUGHOUT** treatment with **EMB.**
- **Prior to each dose of EMB:**
    - Ask the client whether s/he has any of the symptoms listed below or has noticed any other changes in his/her vision. If there are any concerns, consult the CDCN and/or the TB physician **immediately.** Changes to the treatment might be necessary, for example, the EMB might need to be withheld until further vision testing can be done.

Symptoms associated with ocular toxicity can affect one or both eyes, and include:

- Sudden loss of vision (partial or complete)
- Blurred or foggy vision
- Changes to colour vision and/or visual acuity
- Pain with eye movement
- "Blind spots" in the field of vision (scotomata)

Visual Acuity Testing

Understanding Visual Acuity Test Results

Example: 20/40

The top number (20) refers to the distance (in feet) the client was standing from the chart when the test was done. The bottom number refers to the distance (in feet) at which a person with normal eyesight could read the same line the client read correctly. Thus, a result of 20/40 means the line the client read from 20 feet away could be read by a person with normal vision from 40 feet away.

Testing Procedure

- Use a Snellen chart with numbers or pictures if a client cannot read letters (see **Figure 7.1**). When using a Snellen chart that features "E's", ask the client to use finger/hand gestures to identify the position of the characters.

Figure 7.1: Examples of types of Snellen eye charts for visual acuity testing

NOTE: DO NOT USE THESE IMAGES FOR TESTING

Adults and Children Over Five Years of Age

- If the client usually wears eye glasses or contact lenses, these should be worn during the test.

- Have the client sit or stand 6.1 metres (20 feet) from a Snellen eye chart.

- Test each eye individually. To do so, ask the client to keep both eyes open, and to cover one eye with the palm of his/her hand.

- Begin with the **TOP** line (largest). Ask the client to identify the characters on the first line, moving from left to right. Change lines downward, one at a time, until you reach the line on which the client can identify **LESS THAN** four of the six characters. Record the numbers adjacent to that line (e.g. 20/25) in the area provided at the bottom right-hand corner of the client's DOT record.

- Repeat the process for the other eye.

Children Three to Five Years of Age

- If the child usually wears glasses, these should be worn during the test.
- Have the child stand 3.1 meters (10 feet) away from a Snellen eye chart.
- Test each eye individually. To do so, ask the child to keep both eyes open, and have an adult cover one of the child's eyes.
- Begin with the **BOTTOM** line on the chart (smallest). If the child cannot identify **AT LEAST** four of the six characters correctly, move up the chart to the next larger line until you reach the line on which the child can identify **AT LEAST** four of the six characters. Record the numbers adjacent to that line (e.g. 20/25) in the area provided at the bottom right-hand corner of the child's DOT record.
- Repeat the process for the other eye.
- Refer to the **Nunatsiavut Public Health Manual F-40** for more information.

Children under Three Years of Age

- Do the test when the child is alert.
- Evaluate the child's ability to fixate on an object, maintain fixation, and then follow the object in various gaze positions.
- Perform the test for each eye individually, and then repeat the evaluations with both of the child's eyes uncovered.
- Record findings in the area provided at the bottom right-hand corner of the child's DOT record.

Red/Green Colour Discrimination Testing

Testing Procedure

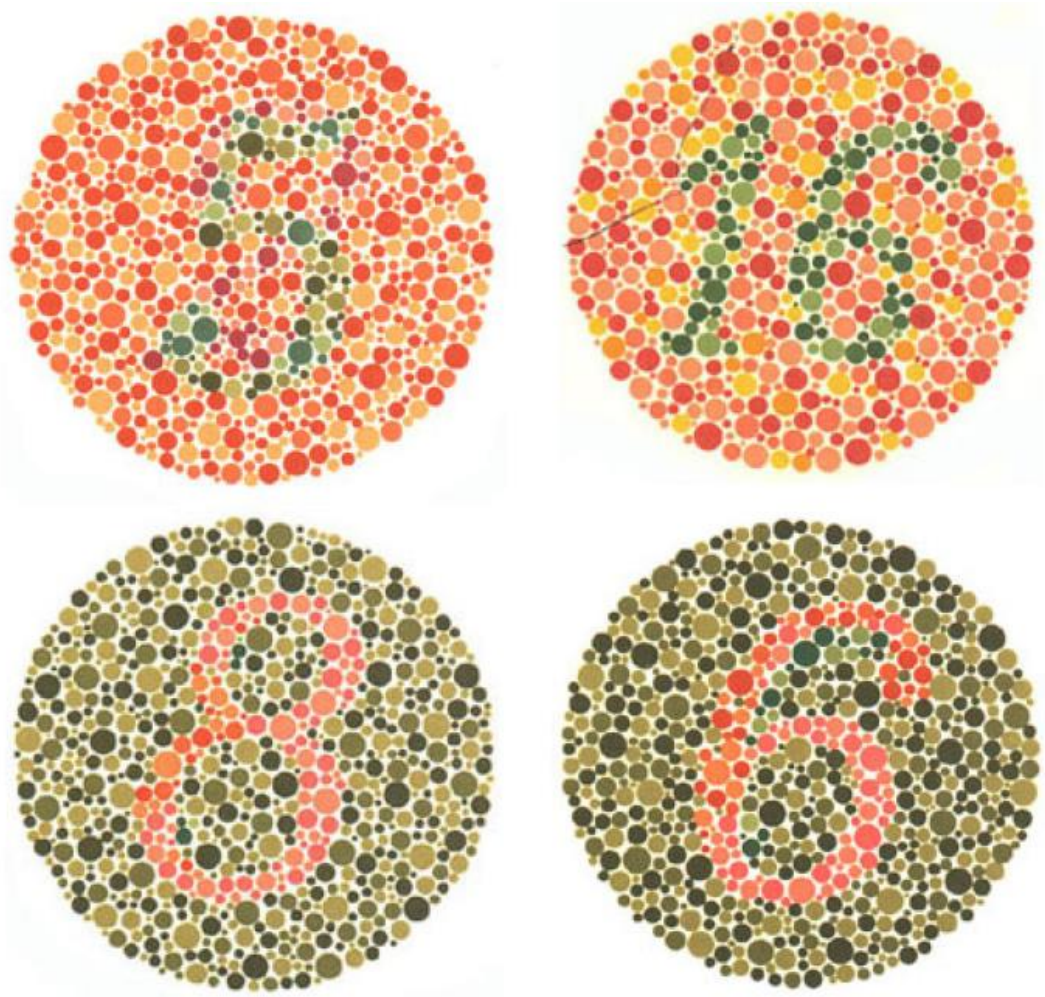
- Use Ishihara plates (**Figure 7.2**) or the red/green lines on a Snellen eye chart (**Figure 7.1**).

- Ask the client to identify red and green within the images. If the client cannot name the numbers on the Ishihara plates, ask that s/he trace the outline of each number with his/her finger.

- Record results in the area provided at the bottom right-hand corner of the client's DOT record.

Figure 7.2: Ishihara plates for red/green colour discrimination testing

NOTE: WHEN PRINTED IN COLOUR, THESE IMAGES MAY BE USED FOR RED/GREEN COLOUR DISCRIMINATION TESTING.



Source:

American Academy of Ophthalmology Preferred Practice Committee
http://one.aao.org/CE/PracticeGuidelines/PPP_Content.aspx?cid=64e9df91-dd10-4317-81426a87eee7f517. Accessed March 20, 2014.

Travel during Active TB Treatment

Consult the CDCN as soon as a client indicates s/he plans to travel. Be prepared to discuss:

- Anticipated travel dates,
- Reason for travel,
- Arrangements for continuation of treatment (e.g. prescriptions, DOT provider, ongoing monitoring),
- Whether treatment should be held at any point during the anticipated travel period,
- Whether TB drugs should be sent with the client, **AND**
- Complete a **TB Travel/Transfer Form (Appendix D)**

When a client is travelling within the LGH Region:

- Send the completed **TB Travel/Transfer Form** to the Community Health Office, and Regional Community Clinic or Health Center of the destination community.
- Notify the CDCN and call the local Community Health to notify transfer and review the follow-up.

When a client is travelling outside the LGH region:

- Send the CDCN the completed **TB Travel/Transfer Form**, who will arrange transfer to the receiving community. Include all relevant paperwork.