



DEPARTMENT OF
**PUBLIC
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Appleton Health Department Procedures

Title: Tuberculosis Directly Observed Therapy				
Procedure: N_205_3_PRO				
Creation Date: 2/24/2025		Last Approved Date:		Reviewed Annually
Description:		Directly Observed Therapy (DOT) for Tuberculosis (TB) is a best practice where a trained healthcare worker observes a patient taking their TB medications.		
PHAB Domain/ Standard/ Measure:		2.1.4 A: Maintain protocols for investigation of public health issues. 2.1.5 A: Maintain protocols for containment and mitigation of public health problems and environmental public health hazards.		
Statutory Authority/ Evidence Base/ Links:		Chapter 252: Communicable Diseases (specifically, 252.07 Tuberculosis): https://docs.legis.wisconsin.gov/statutes/statutes/252/07		
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Procedure Approval Tracking				
Created/ Reviewed/ Revised Date	Legal Services Approval Date	Board of Health Approval Date	Council Approval Date	Health Officer or Designee Signature (Name/Title)
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Purpose

To ensure medication prescribed for Active and Latent Tuberculosis (TB) is taken as ordered and in accordance with clinical best practice. This allows for the best outcomes for treatment, including reduced side effects and higher completion rates of treatment.



Procedure

Directly Observed Therapy (DOT): Active TB Disease

In accordance with the American Thoracic Society (ATS) and Centers for Disease Control (CDC), DOT is the standard of care for all clients with confirmed or suspected TB Disease (pulmonary and/or extra pulmonary) from initiation through completion of therapy.

If a Public Health Nurse (PHN) feels they do not have the capacity to provide daily DOT to all clients with TB disease, the PHN will discuss the situation with the Public Health Nursing Supervisor to determine how referrals are prioritized, and resources are utilized to assure daily DOT is provided to clients with active TB Disease. Solutions can include utilizing Video Directly Observed Therapy (VDOT), DOT workers, or other staff.

Duration of DOT for Active TB

The City of Appleton Health Department (AHD) will provide a 7-day a week DOT by a PHN for a minimum of 2 weeks AND until initial drug sensitivity results are known. After a minimum of 2 weeks of daily DOT with a PHN, 3 negative smears, clinical improvement and initial drug sensitivity results, it is acceptable to move to a 5-day a week DOT by a PHN with self-administered therapy on weekends and holidays. Throughout the remainder of treatment, including treatment for extra-pulmonary TB, it is preferable to have a 5-day a week DOT. As an alternative, VDOT or a dosing schedule of 2 or 3 times a week is acceptable based on provider/client discussion and agreement.

For clients diagnosed with multidrug-resistant TB (MDR TB), the goal is to maintain consistent therapeutic drug levels, so further drug resistance is less likely to develop. Clients with MDR TB will have a 7-day a week DOT by a PHN until second line drug sensitivity reports are back, the client has been on a drug-sensitive second line regimen for a minimum of 4 weeks, AND 3 negative sputum cultures have been reported. For the remaining course of treatment of MDR TB, the goal is a 7-day a week DOT by a PHN. DOT 5 days a week may be acceptable based on PHN assessment, State TB program, client preference, and provider agreement.

Charting is completed for every visit. Sign and date the Medication Administration Recordⁱ and/or chart in the WEDSS record for each client and review side effects using the Active TB Disease Assessment Form.ⁱⁱ



DOT: Latent TB Infection

DOT will be provided for these select clients with latent TB infection:

- Once weekly 3HP regimen, when prescribed through the State TB Program
- When medications are filled through a private fill (i.e. client has insurance, no financial hardship and gets medications through local pharmacy) and there is a need for DOT (examples: high risk for breakdown to active TB; high risk for side effects from treatment; consult with prescribing provider and/or Public Health Nurse Supervisor, etc.)
- Alternate regimens that are not prescribed on a daily basis (ex: twice weekly Isoniazid (INH))
- Children less than 5 years of age with LTBI are at higher risk for TB activation: AHD will provide a 7-day a week DOT by a PHN for a minimum of 2 weeks, at that time a 5-day a week DOT may be acceptable based on PHN assessment, client preference, and provider agreement. When standard resources are insufficient to perform DOT with children less than 5 years old diagnosed with LTBI, AHD will attempt to enlist the use of DOT workers and/or make alternative DOT arrangements (see Alternative DOT Arrangement section). In cases where parents/guardians decline DOT for their child less than 5 years of age who are diagnosed with LTBI, AHD will continue to encourage DOT for children less than 5 years of age but will also be respectful of parent/guardian decisions. The PHN should document the parent/guardian declination of DOT and notify the provider.
- Charting is completed for each visit. Sign and date the Medication Administration Recordⁱ attachment and/or chart in the WEDSS record for each client, and review side effects using the 3HP Assessment Form.^{iv}

When standard resources are insufficient to perform DOT with clients diagnosed with TB infection, AHD will enlist DOT workers and/or make alternative DOT arrangements (see Alternative DOT Arrangement section).

When DOT workers are utilized, the PHN is responsible for monitoring symptoms and side effects with the client and/or client's guardian monthly, at minimum.

Video DOT (VDOT) Guidance

Video DOT (VDOT) has proven to be a cost efficient and effective method to observe DOT in clients that may not or cannot receive it face to face with a health care worker. The following are recommendations for the use of VDOT.



Active Disease VDOT

Active Disease VDOT Inclusion Criteria:

- Client has pan-sensitive TB disease
- Client accepts the TB diagnosis, is motivated, and understands the need for TB treatment
- Client has completed in-person DOT for a minimum of 2 weeks with 100% compliance
- Client is 18 years old or older or parent is present during VDOT visits if client is under 18 years old
- Client has not experienced any adverse medication reactions during the in-person DOT phase of treatment
- Client can demonstrate how to properly use the VDOT equipment and/or application
- Can be served by a health care worker that speaks the same language or can use an interpreter
- No current history of mental illness that would affect adherence to treatment (i.e., psychiatric hospitalizations, personality disorder, severe depression, etc.)

Latent TB Infection VDOT Guidance

Latent TB Infection VDOT Inclusion Criteria:

- May be used with any regimen
- Monthly clinical assessments (in person or video), by a PHN must be done for Isoniazid (INH) and Rifampin (RIF) daily regimens. Weekly clinical assessments (in person or video) by a PHN must be done for 3HP (isoniazid-rifapentine regimen to treat LTBI, once weekly for 12 weeks or any other non-daily regimen)
- Client has completed in-person DOT for a minimum of 2 weeks with 100% compliance.
- Client accepts the latent TB diagnosis, is motivated, and understands the need for treatment
- Client is 18 years old or older or parent is present during VDOT visits if client is under 18 years old
- Client has not experienced any adverse medication reactions during the in-person DOT phase of treatment
- Client can demonstrate how to properly use the VDOT equipment and/or application.
- Can be served by a health care worker that speaks the same language or can use an interpreter



- No current history of mental illness that would affect adherence to treatment (i.e., psychiatric hospitalizations, personality disorder, severe depression, etc.)

Confidentiality during VDOT

- Clients must be aware (see language below) these video platforms are not HIPAA compliant, and their use and acceptance of a non-HIPAA compliant platform must be documented in the client record.
- The use of this video application may present privacy risks for the information being discussed, which means that information may not be protected from potential review by others. AHD is not responsible for any disclosures of health information while the video is being transmitted.
- Educate clients to use private space while performing VDOT, utilizing ear buds when in settings where others may hear their conversation.
- PHN/DOT workers should use a private space when performing VDOT. Ear buds must be used if others are able to hear the conversation between you and your client.
- Recordings of the client taking pills should only be done in rare circumstances (travel, religious holidays, weather, etc.). Sending these recordings may present privacy risks for the information being discussed, which means that information may not be protected from potential review by others. AHD is not responsible for any disclosures of health information sent via this method.

Alternative DOT arrangements

Alternative DOT providers may include, but are not limited to:

- Health care providers at a private clinic or federally qualified community health center.
- Home health agencies.
- School nurses.
- Other individuals or entities as deemed appropriate per PHN/client agreement.
- **NO** family members living in the same household as the client may provide DOT.

PHN Responsibilities for Alternative DOT Arrangements

- Develop an individual treatment plan for each client.
- Educate the client regarding TB medications, side effects, need for laboratory tests and provider follow-up, and DOT plan.



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- Assure medication adherence and client safety with the medications, including training and observing parent/guardians or DOT workers involved with medication administration (e.g., medication crushing, splitting, and/or drawing up in liquid form).
- Enlist DOT workers who are trained, oriented, and fit-tested with a respirator as needed.
- Complete a Client Profileⁱⁱⁱ sheet or WEDSS Patient Tab and route to the DOT worker(s) and/or PHN's involved with client's care. Update as needed. Remove when treatment is complete.
- Provide orientation regarding client health status, DOT setting, medications, and medication side effects to the DOT worker involved with client care.
- Coordinate at least one joint visit with the DOT worker in order to introduce client and orient to the client's needs.
- Attend at least one face-to-face meeting (such as DOT visit) each week with clients with active TB disease receiving daily DOT to monitor client's status, assess for side effects, and answer client questions.
- Attend at least one face-to-face meeting (such as a DOT visit) monthly for Latent TB clients.
- Fill medication boxes for DOT worker on a weekly or monthly basis. Clearly and promptly, communicate to the DOT worker any necessary precautions and/or any changes to client status and/or treatment plan.
- Document medication adverse reactions, side effects, and status changes in client record.
- After the weekly client assessment, if there are one or more issues noted (side effects, symptoms, etc.), identifying further follow-up or education, the PHN has the discretion to continue performing DOT until client is stable in their treatment (side effects are managed or not present, symptoms have subsided or are stable, etc.).
- If the client has complex medical needs (e.g., living with HIV, multiple medical conditions, poorly controlled diabetes, etc.), the PHN may continue DOT until they determine the client's situation is stable enough for a DOT worker to perform DOTs.

DOT Worker Responsibilities

- Before medicine is taken: if client reports potential side effects or illness, immediately notify the case managing PHN so a determination can be made about medication administration. If unable to reach the PHN, call other AHD PHNs or Nursing Supervisor.
- Observe any necessary precautions as determined by the PHN.
- Immediately notify the PHN if the client is un-locatable or declines medication.



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- Take a cellular telephone on all visits.
- Use an interpreter as needed (in-person or telephone) and sign interpreter invoices after interpreter use.
- Assure correct medication based on:
 - number of pills and dosage of medication the client should take.
 - size and color of each type of pill.
- Deliver filled pill boxes and DOT forms to the client visit, as directed by the PHN.
- Witness a parent/guardian splitting, crushing or mixing medicine in foods as needed.
- Observe the client swallowing the medication and monitor for adherence.
- If the PHN indicates this is necessary, check client's mouth to assure the medication was swallowed.
- Sign and date the Medication Administration Recordⁱⁱ and/or chart in the WEDSS record for each client; the applicable side effect assessment form needs to be completed as well, either Active TB Disease Assessment Formⁱⁱ (Active TB Disease) or 3HP Assessment Form (for LTBI).^{iv}
- Deliver client incentives as needed, per direction of PHN.
- Adhere to client-centered principals of care, allowing for flexibility in medication administration date, time, and/or location as needed (e.g., client has a provider appointment during usual DOT time).

DOT Worker will NOT:

- Be responsible for assessment of a client or determining whether a client is having an adverse reaction or side effect
- Fill pillboxes
- Tell any client to not take medicine, unless directed by a PHN

Inclement weather or staff illness during scheduled DOT visit

If the PHN or DOT worker is unable to make it to the client's DOT visit due to inclement weather and VDOT cannot be utilized:

- The PHN case manager or Nursing Supervisor will decide whether the client may take medications over the phone (if client has medications at their home) and will call the client with instructions.



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If the PHN or DOT worker is unable to make it to the client's DOT visit due to illness:

- Call the PHN case manager or Nursing Supervisor to notify of illness.
- The PHN case manager or Nursing Supervisor will decide whether the client may take medications over the phone (if client has medications at their home) and will call the client with instructions.

Definitions

3HP: isoniazid-rifapentine, regimen to treat LTBI

Active TB Disease: Active tuberculosis (TB) disease happens when the immune system cannot keep TB germs from multiplying and growing in the body. People with TB disease feel sick and can spread TB germs to others. TB disease can almost always be treated and cured with medicine. Without treatment, it can be fatal.

AHD: Appleton Health Department

DOT: Directly Observed Therapy for TB is a best practice where a trained healthcare worker observes a patient taking their TB medications.

IGRA: Interferon-Gamma Release Assay, is a blood test used to diagnose tuberculosis infection.

INH: Isoniazid, regimen to treat LTBI

Latent or Inactive Tuberculosis (LTBI): Tuberculosis (TB) germs can live in the body for years without making you sick. This is called inactive TB or latent TB infection. People with inactive TB do not feel sick, do not have symptoms, and cannot spread TB germs to others. Without treatment, inactive TB can develop into active TB disease at any time and make you sick.

PHN: Public Health Nurse

RIF: Rifampin, regimen to treat LTBI

TST: Tuberculin Skin Test, a two-step screening test for TB bacteria.



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VDOT: Video Directly Observed Therapy

WEDSS: Wisconsin Electronic Disease Surveillance System

Attachments

[Wisconsin State Statutes Chapter 252: Communicable Diseases](#)

[Wisconsin Administrative Codes Chapter DHS 145: Control of Communicable Diseases](#)

ⁱ Medication Administration Record

[City of Appleton\Shared Documents\Nursing\Communicable Disease\Tuberculosis](#)

ⁱⁱ Active TB Disease Assessment Form

[City of Appleton\Shared Documents\Nursing\Communicable Disease\Tuberculosis](#)

ⁱⁱⁱ Client Profile

[City of Appleton\Shared Documents\Nursing\Communicable Disease\Tuberculosis](#)

^{iv} 3HP Assessment Form

[City of Appleton\Shared Documents\Nursing\Communicable Disease\Tuberculosis](#)