

PROTOCOL FOR VIDEO DIRECTLY OBSERVED THERAPY

Background

Directly observed therapy (DOT) is when a trained health care worker or other designated individual (excluding a family member) provides the TB medication and watches the patient swallow every dose. This is done to ensure that the entire course of medication is taken. Video Directly Observed Therapy (VDOT) may be used to observe the DOT doses using videophones or video enabled electronic devices. VDOT is useful for selected patients to minimize travel burden and provide a convenient patient-centered approach to care. VDOT may be used for treating active TB disease patients or latent TB infection (LTBI) patients.

Eligibility for VDOT

The first dose of all medication should always be done in person so that the Local Health Department (LHD) Nurse can monitor for any adverse effects. After that the LHD Nurse should assess each patient for eligibility of VDOT. Consider the individual circumstances for each patient to determine if VDOT is appropriate.

Eligible patients for VDOT

- A patient who understands the need for TB treatment and accepts the TB diagnosis.
- A patient who can accurately identify each medication that is prescribed.
- A patient who can use the VDOT equipment properly and is able to run the VDOT application.
- A patient who can communicate effectively via video conferencing.
- A patient who has reliable internet connection with sufficient video quality.

Ineligible patients for VDOT

- A patient with multi drug-resistant (MDR) TB or extensively drug-resistant (XDR) TB.
- A patient with a high risk of drug-drug interaction.
- A patient with a high risk of adverse drug reactions.
- A patient with risk factors or history of poor compliance with treatment.
- A patient that speaks a language that VDOT cannot accommodate.

Reasons to stop VDOT and to in-person DOT

Once VDOT has been started there may be some unforeseen circumstances that would cause it to be discontinued and in-person DOT to resume.

(Please note that VDOT can be restarted again if the reasons that caused VDOT to be stopped have been resolved, and it is mutually agreeable between the LHD and the patient)

Reasons to stop VDOT

- A patient has an adverse drug reaction to TB medication.
- A patient that would like to return to in-person DOT.
- A patient who can no longer accommodate use of VDOT in a confidential setting.
- A patient who misses 2 LHD calls via VDOT and/or VDOT doses of medication.
- A patient who defaults 2 twice on other aspects of adherence (labs, appointments, etc.).
- A patient that the LHD or TB doctor feels would benefit more with in-person DOT.

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Process to begin VDOT

Initiation of VDOT

All of the following must be completed before initiating VDOT

- The first dose of medication was done in person and there was no noted adverse reaction after the dose.
- The LHD staff has assessed the patient for eligibility criteria.
- The LHD must discuss the option of VDOT with the patient.
- The patient must agree to participate in VDOT and sign and initial the proper WV TBEP VDOT consent form to participate in VDOT.
- The patient and LHD must agree on a regularly scheduled time and frequency that VDOT will be done.
- The LHD must review the procedure for completion of VDOT by the patient and the patient is able to demonstrate how to properly use the equipment and application.

VDOT LHD responsibilities

LHD staff are responsible for following all WV TBEP policies and procedures for VDOT

- The LHD must do a monthly in-person visit with the patient to complete a full in-person assessment, do the proper lab work and provide the medication to the patient.
- The LHD must do VDOT documentation and record it on the proper DOT record form.
- The LHD must be able to provide in-person DOT should there be an equipment or application failure.
- The LHD must be able to provide the patient with instructions and training of use of VDOT equipment and VDOT application and document this training was completed.
- The LHD must provide the patient with information about who to call with questions or in an emergency.
- The LHD must provide the patient with a list of side effects that can be caused by the patient's medication regimen and answer any questions the patient may have about these side effects and document that this was done.

Types of VDOT

There are two types of VDOT that can be done. Live video VDOT or Store-and-forward VDOT.

Protocol for Live Video VDOT

Live video VDOT is where the patient and LHD will get on the same agreed upon type of device application at the same time and the LHD will watch live video of the patient taking their medication in real time.

The following steps must be taken to ensure that live video VDOT is done properly:

1. The LHD and the patient must activate the application at the agreed upon scheduled time, the frequency of the VDOT is determined by the WV TBEP Treatment Protocol requirements for DOT.

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2. The LHD must confirm the identity of the patient.
3. The LHD must assess the patient for any sign or symptoms of adverse drug reactions prior to observing the patient taking medication. **IF THERE ARE ANY SYMPTOMS OF ADVERSE DRUG REACTIONS THE MEDICATION MUST BE HELD AND THE LHD MUST CONTACT WV TBEP.**
4. The patient must show the LHD each pill separately and the identification of the medication must be made and acknowledged by the LHD.
5. The patient must place the pills in their mouth after identification and swallow the medication in full view of the camera for the LHD to see.
6. The patient will then open their mouth to show that the pills were swallowed.
7. The LHD and patient will confirm the date and time for the next VDOT.
8. The LHD will complete the required documentation.

Technology Options* for Live VDOT

FaceTime (<https://support.apple.com/en-us/HT204380>)

Skype (www.skype.com/en)

****This list does not constitute an endorsement for any particular product or application. These options are provided for review and consideration. ****

Protocol for Store-and-Forward VDOT **(NOT CURRENTLY AVAILABLE)**

Store-and-forward VDOT is a special device application that records the patient taking their dose of medication and then that image is uploaded via the internet to a storage server where the LHD can later view the image. This is NOT a real-time application.

The following steps must be taken to ensure that store-and-forward VDOT is done properly:

1. The patient must activate the video application at the agreed upon frequency which is determined by the WV TBEP Treatment Protocol requirements for DOT.
2. The patient must identify their self and the day's date to the camera and must remain in view of the camera for the duration of the video recording.
3. The patient must show and identify each pill separately.
4. The patient must place the pills in their mouth after identification and swallow the medication in full view of the camera.
5. The patient will then open their mouth to show that the pills were swallowed in full view of the camera.
6. The patient uses the application to send the video to the LHD.
7. The LHD will review the store-and-forward video and complete the required documentation, this is to be done the same day that the patient submitted the video.

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8. The LHD will contact the patient and the WV TBEP with any issues that are observed with the recording.

Ensuring Patient Confidentiality

The use of VDOT must conform to all applicable legal provisions regarding the protection of patient private information, regardless of the type of VDOT technology used. If there are any questions in determining what is legally permissible, please contact WV TBEP.