

Disclaimer of Medical and Legal Advice: The following guidelines are for informational purposes only. These guidelines do not represent legal or medical advice.

Video Directly Observed Therapy for TB

General Information

Directly observed therapy (DOT) ensures the patient completes the entire course of medication. With DOT, a health worker observes the patient swallowing each dose of TB medication. Video Directly Observed Therapy (VDOT) may be used to observe DOT doses using videophones or video-enabled cellular devices.

Oregon Administrative Rule on Labeling and Dispensing Medication, Child Resistant Packaging, Med Paks

Local Public Health Authorities (LPHAs) should follow all applicable Oregon Board of Pharmacy Oregon Administrative Rules (OARs) regarding labeling and packaging medications. [OAR 855-041-1140 Customized Patient Medication Packages](#) provides specific guidance on requirements for patient “med paks”.

The TB Program, OHA recommends patients be provided with “med paks” for VDOT. A “med pak” is a package prepared for a specific patient containing two or more prescribed solid oral medications. Per OAR 855-041-1140, if the med pak “does not meet child-resistant standards (it) shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician, to dispense in a container not intended to be child-resistant, shall be obtained”.

Per Oregon Board of Pharmacy, the LPHA will comply with OAR requirements when dispensing med paks for VDOT if any of the following occur:

- 1- The patient signs a waiver stating child-resistant packaging is not needed.

Or

- 2- Med paks are placed into a child-resistant container. Child-resistant pouches may be obtained from the TB Program, OHA by ordering on the [Drug Order Form \(doc\)](#).

Or

- 3- The medical provider writes on the prescription that child resistant packaging is not needed. The patient should be made aware the med pak is not child-resistant and other accommodations should be considered if this poses a problem.

Obtaining Cellular Devices and Service for Patients

If a patient does not have a cellular device or service for VDOT, the LPHA may submit an application to the [Incentive and Enabler Instructions and Invoice Template \(doc\)](#) for assistance.

Policy

Evidence in [Recommendations for Use of Video Directly Observed Therapy During Tuberculosis Treatment — United States, 2023](#) demonstrated that VDOT is associated with a higher proportion of TB medication doses being observed, and similar proportions of cases with treatment completion and microbiologic resolution, when compared with traditional in-person DOT. The TB Program, OHA endorses utilizing VDOT for most patients who are on treatment for TB disease.

Eligibility

Consider the individual circumstances of each patient to determine if VDOT is appropriate. The following criteria may be helpful.

The ideal candidate:

- Accepts TB diagnosis is motivated and understands need for TB treatment.
- Can accurately identify each pill.
- Can demonstrate how to use the VDOT equipment and/or application.

Consider utilizing in-person DOT instead of VDOT when patient is:

- prescribed injectable medications.
- medically or psychologically fragile and needs close clinical monitoring.
- non-adherent to treatment.

Multidrug resistant TB (MDR TB):

TB patients with MDR TB should not be excluded from VDOT but may require in-person DOT for some time to assess for side effects. Contact TB Program, OHA for guidance as needed. LPHAs should use stricter adherence thresholds for reverting patients to in-person DOT and monitor these patients more closely.

Reasons to Stop VDOT and Return to In-Person DOT

Reasons to stop VDOT once started includes:

- Prescription of injectable medications
- Medically or psychologically fragile and needs closer clinical monitoring.
- Non-adherent to treatment.
- Patient wants to return to in-person DOT.

VDOT can be restarted at LPHA's discretion.

VDOT Initiation

- Assess patient for ability to use VDOT.
- Explain VDOT to patient and obtain agreement to participate.
- Review forms with patient and obtain signatures.
Forms may include:
 - Adherence requirements/expectations for VDOT
 - Confidentiality
 - Steps required by patient for VDOT
 - Patient responsibilities in case of technical failure
- Determine with patient a regularly scheduled time (for live video VDOT) or a regular frequency (for store-and-forward VDOT).
- Review the daily VDOT procedure with patient. A "practice session" is recommended.

VDOT Staff Responsibilities

VDOT staff are responsible for following all agency policies and procedures including:

- Following all OARs regarding packaging and labeling of medications.
- Regular (monthly at minimum) in-person visit to complete full assessment and provide medications to the patient.
- Documentation of each VDOT encounter.
- Completion of DOT in person in case of VDOT technical failure.
- Providing patient with instructions and training on use of VDOT application(s) and equipment.
- Providing patient with information about who to call with questions or in an emergency.

Protocol for Live Video VDOT

1. Activate the application at the scheduled time.
2. Confirm the identity of the patient.
3. Assess the patient for any adverse medication reactions before the patient takes the medications. Hold medications, if indicated, per existing protocol.
4. Patient shows each pill separately and identifies medication.
5. Patient places pills in mouth after identification and swallows medication in full view of camera.
6. Patient opens mouth to show pills were swallowed.
7. Confirm time and date for the next VDOT.
8. Complete required documentation.

Protocol for Store-and-Forward VDOT

1. Patient activates video application at the agreed upon frequency (daily, etc.).
2. Patient identifies himself or herself and the day's date to the camera and remains in camera view for the duration of video recording.
3. Patient shows each pill separately and identifies each medication.
4. Patient places pills in his or her mouth after identification and swallows medication in full view of camera.
5. Patient opens mouth to show pills were swallowed.
6. Patient uses the application to send the video to the LPHA.
7. Staff review the store-and-forward videos and complete required documentation daily. If daily review is not possible, staff will review and document on a weekly basis at minimum.

Ensuring Patient Confidentiality

Use of VDOT must conform to all applicable legal provisions regarding the protection of patient information, regardless of the type of VDOT technology used. LPHAs are responsible for determining what is legally permissible.

Technology Options for Video Directly Observed Therapy (VDOT)

The following options are for informational purposes only. This is not a complete list of allowable products. These products have NOT been evaluated for compliance with state or federal privacy laws.

Telemedicine-Specific Products

The following products are designed for use in telemedicine or medication adherence monitoring and are HIPAA-compliant. These products are available for purchase; total cost may include license fee plus a fixed per patient, per month cost. Products can be used on computers, tablets or smart phones.

- AiCure: AiView (<https://www.aicure.com/index.php>) Store-and-forward video (asynchronous).
- Emocha: miDOT (<https://www.emocha.com/>) Store-and-forward video (asynchronous). Developed by Johns Hopkins University.
- SureAdhere (<http://sureadhere.com/>) Store-and-forward video (asynchronous). Developed by University of California, San Diego.
- Zoom for Government (<https://zoomgov.com>) Encrypted live video conferencing.

Other Products

The following are commercially available products that have been used for VDOT but are not specifically intended for medication adherence monitoring. **These products may not be HIPAA compliant.** Consultation with local legal counsel is advised before use. These products are free and/or low cost, and can be used on computers, tablets, or smart phones to complete medication monitoring via video.

- FaceTime (<https://apps.apple.com/us/app/facetime/id1110145091>) Live video conferencing. Available on Apple products.
- Skype and Skype for Business (<https://www.skype.com/en/>) Live video conferencing with translator feature that can provide simultaneous interpretation during video calls.
- Zoom (<https://zoom.us/>) Live video conferencing.

References on VDOT

Centers for Disease Control and Prevention. Supplemental Information for Video Directly Observed Therapy (VDOT) Recommendations.

Retrieved January 8, 2023 from:

<https://www.cdc.gov/tb/topic/treatment/vDOT.htm>

Mangan, J.M., Woodruff R.S., Winston, C.A. et al. Recommendation for Use of Video Directly Observed Therapy During Tuberculosis Treatment – United States, 2023. MMWR Morb Mortal Wkly Rep 2023; 72:313-316.

Retrieved January 8, 2023 from:

https://www.cdc.gov/mmwr/volumes/72/wr/mm7212a4.htm?s_cid=mm7212a4_w.

Minnesota Department of Health TB Prevention and Control Program (2023). Video Directly Observed Therapy Toolkit.

Retrieved January 8, 2023 from:

<https://www.health.state.mn.us/diseases/tb/lph/vdot/index.html>

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Reference on Legal Issues

The Network for Public Health Law (January 2016). Video Directly Observed Therapy Legal Brief. Legal Considerations Relevant to Video Directly Observed Therapy (VDOT) in

Minnesota. Retrieved from: <https://www.networkforphl.org/wp-content/uploads/2020/05/VDOT-Fact-Sheet.pdf>