

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) is a treatment strategy that 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 that 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](#).

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 program](#) for assistance. Instructions and forms can be found under the Reimbursement Forms tab on the TB Program, OHA web site.

Policy

VDOT may be used for carefully selected patients to minimize travel burden and provide a convenient patient-centered approach to care. VDOT may be used for treating TB disease or latent TB infection with regimens requiring DOT.

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.
- Is able to demonstrate how to use the VDOT equipment and/or application.
- Can communicate effectively over the phone.
- Has a reliable internet connection (for internet-based VDOT)

Exclude if patient has:

- Possibility of severe drug-drug interaction.
- Risk factor(s) for poor adherence (e.g., under 18 years old, homeless, substance abuse, non-adherence to prior TB treatment, psychiatric illness, memory impairment).

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:

- Change in inclusion or exclusion criteria status.
- Patient wants to return to in-person DOT.
- Adverse reaction to TB medication.
- Patient ingests less than 90 percent of scheduled VDOT medication doses.
- Patient defaults on other aspects of adherence (e.g., missing medical appointments, not returning calls).

(Note: VDOT can be restarted at LPHA's discretion)

VDOT Initiation

- Assess VDOT inclusion and exclusion criteria.
- 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, biweekly).
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 local public health authority (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). Application uses facial recognition feature that requires no video review by the medical provider. Available for Apple and Android.
- HipaaBridge (<http://www.hipaachat.com/>) Encrypted live video conferencing and text features. Available for Apple and Android.
- Emocha: miDOT (<https://www.emocha.com/>) Store-and-forward video (asynchronous). Developed by Johns Hopkins University. Available for Android.
- SureAdhere (<http://sureadhere.com/>) Store-and-forward video (asynchronous). Developed by University of California, San Diego. Currently available on Android; Apple application is under development.
- VSee (<https://vsee.com/>) Encrypted live video conferencing and text features. Information is not stored on or intercepted by VSee servers. Local file storage allows users to record and store videoconferences and chat history on user's computer, not accessible to VSee. Recorded conferences or chat histories may be securely uploaded to an electronic health record system.

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 strongly 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://support.apple.com/en-us/HT204380>) Live video conferencing. Available on Apple products.
- Fuze (<https://www.fuze.com/>) Live video conferencing. Available for Apple and Android.
- Skype and Skype for Business (<https://www.skype.com/en/>) Live video conferencing with translator feature that can provide simultaneous interpretation during video calls. Available for Apple and Android.
- Zoom (<https://zoom.us/>) Live video conferencing. Available for Apple and Android.

References on VDOT

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Reference on Legal Issues

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