Division of Disease Control and Health Protection		Procedure Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 1 of 12
	IOP 360-02-19	

Table of Contents

Section

I.		ose	Page 2
II.	Auth	nority	2
III.	Sco	ре	2
IV.	Defi	initions	2
V.	Intro	oductory Procedures	3
	Α	Store and Forward	3
	В	Live Streaming	3
	Ċ	Device Options	3
	D	Determining Client Eligibility	4
	E	Exceptions	5
	F	Building Consensus for VDOT	5
VI.	Оре	erating Procedures	5
	A.	Requesting State-owned Mobile Devices	5
	B.	VDOT User's Personal Device	6
	C.	Using Store and Forward VDOT	6
	D.	Using Live Streaming VDOT	8
	E.	Criteria for Remaining on VDOT	9
	F.	Retrieving the Mobile Device from the Client	9
VII.	Doc	cumentation	10
VIII.	Trai	ning	10
IX.	Sup	portive Data and References	10
X.	Hist	ory	11
XI.	Sigr	nature Block with Effective Date	11
XII.	Appendix 1 – VDOT Participant Agreements		12

Division of Disease Control and Health		Procedure
Protection		Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 2 of 12
	IOP 360-02-19	

Video Directly Observed Therapy (VDOT)

- **Purpose:** The provision of an efficient, less restrictive method of treating tuberculosis (TB) until cure that satisfies the physician's order for directly observed therapy (DOT) in the patient's treatment plan as required by law.
- II. Authority: Section 392.64, Florida Statutes, Tuberculosis Control
- III. Scope: Registered Nurses (RN), Licensed Practical Nurses, Disease Intervention Specialists (DIS), TB Program Managers, Regional TB Coordinators, Medical Doctors, Doctors of Osteopathy, Physician Assistants, Advanced Practice Registered Nurses, Aides/Techs, or other trained and authorized county health department (CHD) staff under the direction of the State TB Medical Director or his designee.

IV. Definitions:

- A. **CHD TB Program staff:** This includes the TB physician (if available locally), the servicing member of TB Physicians Network or TB Control Section Medical Director (if no local physician), TB Program Manager (if applicable), TB Clinical Manager (if applicable), Nurse Case Manager (NCM), and DIS (if applicable).
- B. **Co-morbid:** TB case with an additional medical, mental health or substance use condition, for example, HIV, diabetes or uncontrolled alcohol use.
- C. **Mobile Device:** May be a smartphone or tablet appropriately configured and utilized to facilitate VDOT.
- D. **Polycom RealPresence® Client:** Teleconferencing application used to perform all iterations of VDOT and secured with DOH-approved software to guard against unwanted breaches of confidentiality during electronic transmission.
- E. System Administrator (Sys Admin): Information technology personnel at the CHD
- F. **TB Control Section (TBCS):** State TB program located in Tallahassee.
- G. **VDOT:** Video directly observed therapy is the process of observing the ingestion of anti-TB medications by means of a secure, electronic video link and/or application as proof that a client is taking his or her medication as prescribed.
- H. **VDOT Observer:** Any person trained to observe ingestion of anti-TB medication, screen for adverse reactions to medications, document the process, and provide limited clinical and programmatic technical support to VDOT clients.
- I. **VDOT User:** Any client who agrees to, and is assigned to, VDOT

Division of Disease Control and Health Protection Bureau of Communicable Disease		Procedure Video Directly Observed Therapy (VDOT)
Tuberculosis Control Section		Page 3 of 12
	IOP 360-02-19	

- J. **Video Conferencing Team (VCT):** State information technology (IT) unit in Tallahassee responsible for the rollout and maintenance of the Polycom secured conferencing platform.
- V. Introductory Procedures: Two methods of VDOT are currently available:
 - A. Store and Forward: VDOT User records the medication-taking session for viewing later by the VDOT Observer. "Store and Forward" is the most commonly used method for VDOT and works best for VDOT Users who must take medication outside CHD business hours or must split doses due to adverse reactions. IT facilitates client's ability to work, travel or attend school, and provides both the VDOT User and VDOT Observer maximum flexibility.

The VDOT User dials into the Polycom server and records the ingestion of medication. Once the VDOT User disconnects, the video is transcoded into a video file which is viewable until deleted, up to 30 days after creation. The VDOT Observer is sent an email alert when the video is available for viewing, usually within minutes of video creation.

Detailed instructions for video retrieval is available on the TB SharePoint home page, along with all VDOT documents at: TB SharePoint Documents Link

B. Live Streaming. VDOT Observer and VDOT User participate in the medication-taking session in real time. This is the method most like traditional DOT. It can result in poor video quality (depending on where the VDOT User is at the time of the session) and demands that both the VDOT User and VDOT Observer be available at a specific time.

Consider this option only if you believe your client requires more emotional support but is still considered a viable VDOT candidate. The live streaming method can facilitate conferencing with a third party, commonly the supervising TB physician. The client can be redirected if the encounter cannot be clearly viewed and allows for questions regarding side effects prior to the medication being taken.

C. Device Options:

- State-owned Device: VDOT is generally facilitated using a state-owned device provided by TBCS to the CHD for the use of the VDOT User. Devices are ordered using the Incentive and Enabler process.
- 2. **Personal or VDOT User Device:** When approved, VDOT Users can opt to use their personal devices for VDOT. The VDOT User will download the Polycom RP® Client, or like-named Polycom application, from their "app store." An account is then created by Central Office Information Technology (CO IT) for VDOT using the same technology. A signed informed "consent" will replace the VDOT consent and must accompany every personal device use.

Division of Disease Control and Health		Procedure
Protection		Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 4 of 12
	IOP 360-02-19	

- **D. Determining Client Eligibility:** Clients on treatment for TB disease or for latent TB infection (LTBI) will be ideally eligible for VDOT if they meet the following criteria.
 - Have completed an initial eight-week phase of treatment or have demonstrated sufficient reliability for medication adherence under traditional DOT for a lesser period.
 - 2. For treatment of LTBI using twice weekly INH or once weekly 3HP, when to request VDOT is at the discretion of the CHD staff. Adherence is defined as having missed no more than one scheduled traditional DOT encounter.
 - 3. Have been assessed as medically stable, herein defined as having:
 - a. No significant side effects to TB treatment.
 - b. Co-morbid disorders that are actively managed and monitored, for example, well-controlled diabetes.
 - 4. Have completed education regarding potential side effects of TB treatment and been given a phone number to call if side effects arise.
 - 5. Have tested connectivity at the location where they will most often be located for VDOT. This can most easily be tested by attempting a cell phone call from that location during multiple traditional DOT visits. Connectivity can be improved by going to a location where Wi-Fi is available.
 - 6. Have demonstrated effective communication with a VDOT Observer over the phone; for example, sharing a common language. Language Line services cannot currently be incorporated into VDOT.
 - a. If there is no VDOT Observer available at the CHD who speaks the client's language, arrangements can be made for another CHD with that language capacity among its staff to 'adopt' the client for VDOT provision only. Also, VDOT methodology for hearing impaired clients can be made available.
 - b. All VDOT consents and scripts have been translated from English into Spanish and Creole. The documents can be found on the TB SharePoint home page at: TB SharePoint Documents Link
 - 7. Have no current substance use problems.
 - 8. Have no unmitigated mental health disorders requiring in-person support for successful TB treatment.
 - 9. Have a safe and secure place to store TB medications away from children as verified by the VDOT Observer, if applicable.
- **E. Exceptions.** Exceptions to **any** of the eligibility criteria above or to use VDOT for clients diagnosed with multi-drug or extremely drug-resistant TB and those with a history of previous TB treatment will be considered by the State TB Medical Director or designee on

Division of Disease Control and Health Protection		Procedure Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 5 of 12
	IOP 360-02-19	

a case-by-case basis. Exceptions are generally granted and are certain to be approved if there is no practical method to provide traditional DOT.

NOTE: Exceptions are most commonly granted for those clients who have not completed two months of standard DOT, to expedite a client's return to work, or school, to travel, or any combination of the three.

F. Building Consensus for VDOT

- CHD TB Program staff members identify a client eligible for participation in VDOT and obtain CHD Administrator/Director approval and local Sys Admin support for discussing VDOT with TBCS.
- CHD calls TBCS to discuss the client's eligibility, to learn more about how VDOT works if needed, and to determine the best type of VDOT for patient and CHD circumstances (Store and Forward, live streaming, state-owned or personal device).
- 3. If considered appropriate for the client, a training and orientation session is planned and contact persons at TBCS and the VCT are identified for software installation, and the appropriate paperwork is initiated.
- 4. CHD decides to use VDOT and participates in training. See VIII. Training.
- Client agrees to VDOT after a thorough review of their responsibilities as explained in the appropriate Consent, appearing as an Appendix to this document and found with all VDOT documents and guidance on the TB SharePoint home page at: <u>TB SharePoint Documents Link</u>

VI. Operating Procedures: Interaction between Central Office and the CHDs

A. Requesting State-owned Mobile Devices

- CHD TB Program submits an Incentive and Enabler Request Form (Incentform.doc Revised 03/15/2013) and the Exception Waiver Checklist, as furnished and discussed during training, to the TBCS to request a mobile device for VDOT (see IOP 360-1-13, Florida Tuberculosis Control Section Manual, for Incentive and Enabler process).
- 2. Sys Admin or CHD TB designee will use the Cherwell portal to create a DOH IT Service Desk Ticket for VDOT phone programming or may call the CO IT Help Desk to generate the ticket at (850) 922-7599.
- 3. To complete a ticket, the submitter must be able to provide:
 - a. Sys Admin name.
 - b. Names(s) of CHD personnel who will be performing VDOT.

Division of Disease Control and Health		Procedure
Protection		Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 6 of 12
	IOP 360-02-19	Ç

- c. Option requested, device or account only (if personal device is to be used). See B. below.
- d. Whether the Polycom RP® Client has been installed on the CHD VDOT Observer's computer?
- e. Quantity of mobile devices for clients (at one device per client).
- f. CHD address, staff contact, and phone number where the mobile device(s) is to be mailed.
- 4. The VCT configures and tests the mobile device(s). When testing is complete, the ticket is updated and the device(s) is returned to TBCS.
- 5. TBCS ships the mobile device(s) to the address provided on the ticket.
- 6. The VCT updates the ticket upon notification from the Sys Admin when the mobile device(s) is received.

B. VDOT User's Personal Device

- 1. When considering VDOT for a client, CHD Staff may offer the option of personal device use.
- 2. For personal devices, the Cherwell Ticket submitter will advise CO IT that an 'account only' is needed.
- The Submitter will request a date and time most convenient for the client to come to the clinic and schedule that time with CO IT VCT to set up the account and test the device.
- 4. The methodology and use of applications and security options are identical to use of state-owned devices for VDOT.
- 5. A Personal Device Informed Consent is available on the TB SharePoint home page at <u>TB SharePoint Documents Link</u> and must be reviewed with the client and signed.
- 6. Submit the Exception Checklist to TBCS. No Incentive and Enabler Request Form is required when requesting an account for the use of a client's personal device.

C. Using Store and Forward VDOT

1. VDOT User initiates recording and adjusts phone by turning the phone or swiping the screen until they can see their image.

Division of Disease Control and Health Protection		Procedure Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 7 of 12
	IOP 360-02-19	

- 2. VDOT User centers himself or herself to the camera to be clearly visible on the recording.
 - a. There must be no other visual or auditory distractions during recording.
 - b. The surface from which the client is recording must contain only a clear glass of water and the medication.
- 3. VDOT User should follow the VDOT script for the remainder of the session.
 - a. States the date and time of the recording. (Note: Recording is automatically date and time stamped).
 - b. Takes one medication at a time and identifies the medication and number of capsules or pills being taken prior to ingestion.
 - c. Holds each pill or capsule in front of the camera before putting it in their mouth.
 - d. Ingests each pill or capsule and opens mouth after each to confirm that it was swallowed.
- 4. VDOT encounter ends and the recording stopped. It is important the client closes completely out of the Polycom application and powers down the phone after each use to avoid technological problems beginning the next session.
- 5. VDOT Observer reviews the recording the same day or the day after the recording is made at the Polycom media suite link accompanying the email recording alert. Recordings are **usually** viewable within minutes of being made.
- 6. VDOT Observer contacts the VDOT User to correct anything that is contrary to the procedure above.
- 7. If side effects are reported, VDOT Observer seeks the assistance of a licensed medical professional at RN level or above to determine if medications should be temporarily stopped pending evaluation.
- 8. If medication is temporarily stopped due to side effects, the VDOT User must come to the CHD for a medical evaluation before the next scheduled VDOT session.
- 9. If no side effects are reported, the VDOT User is medically evaluated once each month in conjunction with the refill of their prescription.
- 10. Document results of the VDOT session in HMS (See Section VII. Documentation).

Division of Disease Control and Health		Procedure
Protection		Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 8 of 12
	IOP 360-02-19	

- 11. The script includes the direction, 'When you have finished taking your medication, tell your Observer the date of your next VDOT S/F appointment.' If a VDOT User misses that 'appointment' immediate follow up should be done.
- 12. While a single missed appointment may be deemed acceptable, more than one missed appointment may be considered grounds to retrieve the phone and reinstitute traditional DOT.
 - a. If missed appointments appear to be due to a technical issue, contact your Sys Admin, or the CO IT VCT immediately for a remedy.

D. Using Live Streaming VDOT

- 1. Live streaming encounters begin when the VDOT User and the VDOT Observer each activate the video connection.
- 2. The VDOT User's in-frame position should make the medication-taking activity clearly visible to the VDOT Observer.
- 3. The VDOT Observer begins with questions regarding potential side effects to medications.
- 4. If side effects are reported, the VDOT Observer seeks the assistance of a licensed medical professional at RN level or above to determine if medications should continue to be taken.
- 5. If medication is not taken due to side effects, the VDOT User must come to the CHD for a medical evaluation before the next scheduled VDOT session.
- 6. If no side effects are reported, the VDOT User is medically evaluated once each month in conjunction with the refill of their prescription.
- 7. The VDOT User is asked to take one medication at a time, identify the medication and number of capsules or pills being taken prior to ingestion.
- 8. The VDOT User holds each pill or capsule in front of the camera before putting it in their mouth.
- 9. The VDOT User ingests each pill or capsule and is asked to open their mouth after each to confirm that they were swallowed.
- 10. VDOT Observer confirms the date and time of the next VDOT session with the VDOT User.
- 11. VDOT encounter ends.
- 12. VDOT Observer documents results of the VDOT session in the Health Management System (HMS). See Section VII. Documentation.

Division of Disease Control and Health		Procedure
Protection		Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 9 of 12
	IOP 360-02-19	

- **F. Criteria for Remaining on VDOT.** The VDOT User must meet all the following criteria to remain on VDOT:
 - Do not miss more than one VDOT session or clinical appointment over the course of prescribed treatment. Once the second VDOT session is missed, eligibility to continue to participate in VDOT will be at the discretion of a DOH physician.
 - 2. No unresolved connectivity issues or recurring failure of video connection.
 - 3. No medical or laboratory evidence that disease is worsening.
 - 4. Client has not requested return to traditional DOT.
 - 5. No changes to the configuration of the mobile device.
 - 6. State-owned mobile devices should be kept in a secure location to avoid loss or theft.

G. Retrieving the Mobile Device from the VDOT User

- Devices (state-owned) will be returned to TBCS within one week of the end of VDOT therapy, or when the VDOT User fails to meet any criterion listed in Section VI.E. Criteria for Remaining on VDOT of this IOP.
- 2. The VDOT User will return the state-owned mobile device to the CHD VDOT Observer or NCM.
- 3. If the VDOT User reports that the state-owned device has been lost or stolen, or the NCM suspects such, TBCS will be immediately notified.
- 4. The NCM will request that the state-owned device be returned to the CHD within one week, or as agreed upon with the VDOT User.
- If the state-owned mobile device is not returned within one week of the end of VDOT or by the previously agreed upon date, notify TCBS and CO IT immediately so that the security software can be employed to locate or disable the device remotely.
- 6. Request the VDOT User return the disabled state-owned mobile device.
- 7. All mobile devices (enabled or disabled) returned by a client must be shipped to the TBCS within one week of receipt by the CHD for reconfiguration for the next client. Shipping address is TB Control Section, 4025 Esplanade Way, Suite 105, Tallahassee, FL 32399.
- 8. TBCS notifies VCT when phones are returned so that VDOT accounts can be closed on the VDOT Server.

Division of Disease Control and Health		Procedure
Protection		Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 10 of 12
	IOP 360-02-19	C

- **VII. Documentation.** Provision of VDOT must be documented in HMS for every instance, for example, daily, bi-weekly, thrice weekly or weekly, that the service is provided.
 - **A.** The VDOT session date to be documented should be the day it occurs (with live streaming) or the day it was recorded (with Store and Forward).
 - **B.** CHD staff properly document services by recording a program component and service code that represents each activity. The appropriate service code (4802-VDOT NURSE or 4804 VDOT PARA-PROFESSIONAL) should be entered into the Service Description field in the Record Services screen in HMS.
 - C. In addition, the VDOT User's medication tracking log must be updated each time VDOT is provided. The tracking type should be indicated as DOT and an optional comment may be documented indicating that DOT was accomplished through mobile technology.
- **VIII. Training:** No VDOT services, software, or state-owned mobile devices are released to CHD staff who have not been trained in the use and provision of VDOT.
 - **A.** VDOT training is provided to counties upon request for VDOT services.
 - **B.** VDOT training is a virtual, face-to-face session, led by VCT and TBCS staff to cover all procedures herein, and including a period for questions and answers.
 - **C.** All staff who may be involved in providing VDOT services are expected to be trained, including the county Sys Admin or designee.
 - **D**. VCT and TBCS staff provide refresher training upon request.
 - **E. All** VDOT documents, videos, and self-help guides are available on the TB SharePoint home page at TB SharePoint Documents Link

NOTE: Documents are formatted in Word so that additional individualization can be made as needed.

IX. Supportive Data and References:

- **A.** *Monitoring Therapy Adherence of Tuberculosis Patients by using Video-Enabled Electronic Devices*, https://wwwnc.cdc.gov/eid/article/22/3/15-1620_article#r8.
- B. The California Health Care Foundation, Challenges and Recommendations on Using Telehealth for Directly Observed Therapy in Treating Tuberculosis, http://www.cchpca.org/sites/default.aspx, © 2016 Public Health Institute Center for Connected Health Policy.
- C. Enhancing management of tuberculosis treatment with video directly observed therapy in New York City, International Journal of Tuberculosis and Lung Disease. 2016 May;20(5):588-93. doi: 10.5588/ijtld.15.0738. Chuck C¹, Robinson E¹, Macaraig M¹, Alexander M¹, Burzynski J¹.

Division of Disease Control and Health Protection		Procedure Video Directly Observed Therapy
Bureau of Communicable Disease		(VDOT)
Tuberculosis Control Section		Page 11 of 12
	IOP 360-02-19	

- **D**. Feasibility of tuberculosis treatment monitoring by video directly observed therapy: a binational pilot study, http://www.ingentaconnect.com/content/iuatld/ijtld/2015/00000019/0000009/art00011.
- X. History. Updates IOP 360-2-17 last reviewed May 1, 2017.
- XI. Signature and Effective Date

Opinion Displayers DVAA DED DisplayOV/DNA			
Carina Blackmore, DVM, PhD, Dipl ACVPM			
Director, Division of Disease Control	Date		
and Health Protection			

MESH DCHP DCCD TB "CHD Guidebook" VDOT "mobile device" "polycom mobileiron" "live streaming" "eligible clients" criteria exceptions procedures "request device" "preparing VDOT" "criteria for remaining on VDOT" "retrieving documentation"

Division of Disease Control and Health Protection Bureau of Communicable Disease **Tuberculosis Control Section**

IOP 360-02-19

Procedure Video Directly Observed Therapy (VDOT) Page 12 of 12



XII. APPENDIX 1	
-----------------	--

Participant Agreement for Video Directly Observed Therapy (VDOT)			
PATIENT NAME:			
	TB Case ID #:		
PATIENT ADDRESS:			
I have been offered the opportunity to continue my connection. I have been informed that VDOT must privacy. I understand that the health department m directly observed therapy (DOT) if any of the follow • My disease gets worse as determined by the lambda management of the vide to the lambda lam	t be done in a private setting to ensure my hay discontinue VDOT and resume traditional ving things happen: he doctor or lab results; ntment;		
I have been informed that if at any time I decide VI request that it be discontinued, and I can resume t			
I understand that the health department owns any VDOT, and it may be used for this purpose only. I received it, no more than one week after the end with the health department. I will notify my Nurse phone is lost, stolen or if it breaks. I acknowled this participant agreement and authorize the health department.	agree to return the equipment in the condition of VDOT, or as requested or agreed upon a Case Manager immediately if my VDOT dge that I have been provided a copy of		
Patient Signature	Date		
Staff Signature	Date		

I received the following items as indicated below (initial and date all that apply). The appropriate operation of the equipment has been explained to me.

Device	Patient Initials	Staff Initials	Date
Smartphone			
Tablet			
Charger			
Other (specify):			

DH8000-DCHP-02/2015