



CDPH - CTCA Joint Guidelines

***Guidelines for Electronic Directly
Observed Therapy (eDOT)
Program Protocols
In California***

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1. Abbreviations

ADR	Adverse Drug Reaction
AES	Advanced Encryption Standard
BA	Business Associate
BAA	Business Associate Agreement
CDC	Center for Disease Control and Prevention
CDPH	California Department of Public Health
CTCA	California Tuberculosis Controller's Association
DOT	Directly Observed Therapy
eDOT	Electronic Directly Observed Therapy
EMR	Electronic Medical Record
GPS	Global Positioning Satellite
HIPAA	Health Insurance Portability and Accountability Act of 1996
LVN	Licensed Vocational Nurse
MDR-TB	Multi-Drug Resistant Tuberculosis
PHI	Protected Health Information
PHN	Public Health Nurse
RN	Registered Nurse
RVCT	Report of Verified Case of Tuberculosis
TB	Tuberculosis
TBCB	California Department of Public Health Tuberculosis Control Branch
VDOT	Video Directly Observed Therapy
WHO	World Health Organization
WOT	Wirelessly Observed Therapy
XDR-TB	Extensively Drug Resistant Tuberculosis

2. Administration

2.1 Preface

The following guidelines were developed collaboratively by the California Tuberculosis Controllers Association (CTCA); the California Department of Public Health (CDPH), Center for Infectious Diseases, Tuberculosis Control Branch; the University of California, San Diego School of Medicine; and the Center for Connected Health Policy. These guidelines provide statewide recommendations for tuberculosis (TB) control in California. If these guidelines are altered for local use, then the logo should be removed and adaptation from this source document acknowledged.

These guidelines pertain specifically to statewide uses of Electronic Directly Observed Therapy (eDOT), an approach to remotely monitoring patient adherence to medication during the course of treatment through the use of mobile and electronic technologies.

While eDOT is not intended to replace in-person Directly Observed Therapy (DOT) for all patients undergoing TB treatment, there is growing evidence from epidemiological studies showing that eDOT is an acceptable alternative to in-person DOT for many patients and is associated with comparable or higher adherence. As technologies and systems for eDOT become increasingly comprehensive, TB providers may have the ability to incorporate elements beyond simply documenting adherence, including providing patients with reminders, motivators and expanded means of communicating medication side effects to their providers.

The practice of medicine is an integration of both the science and art of preventing, diagnosing, and treating diseases. Accordingly, it should be recognized that these guidelines cannot guarantee successful outcomes with respect to the treatment of individual patients, and CDPH/CTCA disclaims any responsibility for such outcomes. These guidelines are provided for informational and educational purposes only and do not set a legal standard of medical or other health care. They are intended to assist practitioners in providing effective and safe medical care that is founded on current information, available resources, and patient needs. The practice guidelines and technical standards recognize that safe and effective practices require specific training, skills, and techniques, as described in each document, and are not a substitute for the independent medical judgment, training, and skill of treating or consulting practitioners.

2.2 Background

One-third of the world's population harbors the bacteria that causes TB, 10 percent of whom will develop the disease over their lifetime. TB causes 1.2 million deaths worldwide each year¹. In 2014, a total of 9,412 new TB cases were reported in the United States, an incidence of 3.0 cases per 100,000 population, representing a drop in incidence from 3.4 cases per 100,000 population from just 2011. The progress made in TB control may have plateaued, however, as the decline noted between 2013 and 2014 (2.2%) was the smallest decrease in a decade, a concern given that rates of tuberculosis still far exceed the 2020 target of reducing TB incidence to 1.4 cases per 100,000².

California, Texas, New York, and Florida now account for over 50% of the TB cases nationally despite only containing a third of the nation's population. In California, 2,137 new TB cases were reported in 2015 compared to 2,134 cases in 2014. The decline in California's TB incidence has slowed over the past decade and has now stopped^{3, 4, 5}. Novel interventions, including eDOT, are needed to keep pace with societal expectations and to provide patient-centered strategies to maintain and accelerate declines in TB incidence.

2.2.1 TB Treatment

Strict adherence to TB treatment regimens must be maintained otherwise illness may persist, patients can remain infectious, and selective pressure can result in the emergence of bacteria that are resistant to TB treatment. While standard TB treatment is usually required for six to nine months, multi-drug resistant TB (MDR-TB) treatment currently takes 18-24 months. This length of treatment is indicated because of the necessity to use second and often third line agents. Directly observed therapy is recommended for all TB patients and is required for patients with MDR-TB.

Currently, drug resistant TB has been reported from every country in the world, which includes nearly 500,000 new cases of MDR-TB each year. Many countries have detected cases of extensively drug resistant TB (XDR-TB), defined as TB that is resistant to the two most effective first line antibiotics, plus a fluoroquinolone and at least one injectable antibiotic. Furthermore, some countries have reported cases of TB that are resistant to all currently available anti-TB medications^{6,7,8,9}.

2.2.2 Costs of TB Treatment in the United States

Treating uncomplicated TB for at least six months and drug resistant TB for up to two years places a substantial burden on healthcare systems. Although direct costs vary by drug regimen, non-resistant TB treatment is estimated to cost \$17,000 per patient (outpatient management estimated at \$3,419). Given the longer therapy, more expensive drugs, increased drug reactions, increased hospitalizations and numerous other factors, treatment for MDR- and XDR-TB are significantly higher: although costs vary, it is estimated to cost \$134,000 per case of MDR-TB and \$430,000 for XDR-TB¹⁰.

2.2.3 Directly Observed Therapy (DOT)

Patients cite drug side effects, feeling drugs are unnecessary after symptoms resolve, and treatment fatigue as reasons for poor adherence to treatment. To improve adherence, health departments in the United States use DOT when possible. Through DOT, patients are observed ingesting each medication dose maximizing the likelihood that patients will complete therapy. DOT is typically performed in the patient's home or workplace, but also may be done in a clinic or other mutually agreed upon location. Studies have shown that DOT is effective in achieving adherence to TB treatment and reducing TB mortality, especially when combined with individualized care. While DOT is effective, individual and structural factors make in-person DOT challenging to provide for all patients. For example, DOT is often precluded by transportation and resource limitations. It also requires the patient to be in a specific place at a stated time and does

not easily allow for last minute changes. Vacation days or holidays also can limit DOT. Thus, eDOT offers potentially viable solutions for monitoring treatment in settings already using in person DOT and increasing access to DOT in places where it is performed inconsistently or not at all.

2.2.4 Definition of Electronic Directly Observed Therapy (eDOT)

Electronic Directly Observed Therapy (eDOT) refers to the use of mobile technologies to remotely monitor patient medication adherence during the course of treatment. Different forms of eDOT are available for remote patient monitoring. The choice of eDOT modality will depend upon the TB program's aims and resources, as well as patient characteristics and preferences.

Investigational research is underway on emerging technologies, such as ingestible sensors, that are embedded into medication tablets or placed into capsules. These sensors are detected by a patient-worn external device that wirelessly transfers data to the patient's mobile phone. Termed Wirelessly Observed Therapy (WOT), ingestion data are transmitted securely to a server for a healthcare provider to monitor. WOT is still in trial stages, but one company recently received FDA clearance for WOT as a medication adherence monitoring device.

Facial recognition is another mechanism to assist health care providers and patients monitor therapy. As these technologies evolve, their application may be considered by health departments for eDOT.

Video Directly Observed Therapy (VDOT) utilizes mobile video conferencing or video recording technology to monitor patients taking medications. Two VDOT modalities that are already in use by a number of TB programs in California and elsewhere may be referred to as asynchronous and synchronous VDOT.

eDOT modalities are emerging that can safely and effectively monitor TB treatment while increasing patient autonomy. Unless otherwise stated, this guidance document will focus on VDOT given that it is the eDOT modality at the time of this writing with sufficient evidence of use and formalized development ¹¹. As stressed in these guidelines, although some technologies might not be appropriate for every patient, different eDOT mechanisms have innate strengths that can increase patients' access to care, which should be balanced against the benefits of in-person DOT.

2.2.4.1 Synchronous VDOT

With synchronous VDOT, TB care providers observe patients taking their medications via videophone, smartphone, tablet or computer. Synchronous VDOT is a form of VDOT which allows the patient and provider to see and hear each other in real time. This approach is sometimes referred to as "live streaming" or "video conferencing". Synchronous VDOT can be implemented using fixed phone lines, the Internet or cellular networks.

1. Landline Videophones: Videophone equipment is installed in both the patient's home and at the health department through telephone landlines, allowing secure, reliable real-time conversation and observation. This method requires that the patient has a landline and is present at the landline site at the agreed upon time to take medications during the DOT worker's normal working hours. These systems are reliable, but require landline telephones, which are becoming increasingly less common and, thus, may not accommodate some patients.
2. Internet or Cellular Networks: Various options are available to provide video and audio on desktops, laptops, tablets or mobile phones equipped with a microphone and camera that allow real-time conversations and observation. These systems have the advantage of not depending on wired telephone connections and may be mobile. However, reliable network connectivity and transmission security are important considerations.

2.2.4.2 Asynchronous VDOT

With asynchronous VDOT, patients record themselves taking their medications and care providers subsequently observe the recordings to document that medications were ingested. This can be accomplished using smartphones, tablets or computers that can record videos and securely forward them electronically to the TB program to be viewed at a time chosen by the DOT worker. This approach is also referred to as "store-and-forward" or "recorded" VDOT.

1. Store-and-Forward/Recorded Video. A smartphone or tablet is used by patients to record themselves ingesting each medication dose. The video is then transferred securely to a protected server or Cloud where it can be retrieved immediately or at a later time for viewing by the DOT worker. Similar to synchronous VDOT, asynchronous VDOT requires network connectivity and secure data transmission; however, asynchronous VDOT does not require network connectivity at the time the patient ingests his/her medication.

2.2.5 Evidence Basis of VDOT

Research studies have shown that implementation of VDOT can be feasible, acceptable, and cost-saving. For example, Gassanov, et al¹² and Miraseidi, et al¹³, found synchronous VDOT to be patient-friendly and simple to use. Another study involving synchronous VDOT found a cost-savings of nearly \$2500/patient when videophones were used for the administration of TB medications¹⁴. In a study of asynchronous VDOT, researchers found that over 93% of the expected doses were observed through recorded videos, and that patient satisfaction with this method of DOT was high¹⁵.

2.2.6 Comparison of VDOT to In-Person DOT

Given that different modalities of patient monitoring have unique attributes; one or more approach could be employed by a TB program to provide options for client-centered care. Some of these attributes with relative strengths are listed in Table 1.

Table 1 – Attributes of VDOT Methods and In-Person DOT			
Characteristic	Synchronous VDOT	Asynchronous VDOT	In-person DOT
QUALITY ASSURANCE AND SAFETY			
• Allows repeat viewing of ingestion event		✓✓✓	
• Quality assurance using duplicate observers	✓✓	✓✓✓	✓
• Allows DOT worker to make visual assessment of patient’s health	✓✓	✓	✓✓✓
• Allows DOT worker to actively evaluate for medication side effects	✓✓	✓	✓✓✓
• Ease of verifying correct medications and dosages	✓✓	✓	✓✓✓
• Ability to provide concomitant case management, i.e. contact investigation, social support, teaching	✓✓	✓	✓✓✓
PATIENT CONVENIENCE			
• Allows DOT worker to monitor doses taken on weekends, holidays, and after hours	✓✓	✓✓✓	✓
• Allows patients the opportunity to ask questions before medication administration	✓✓		✓✓✓
• Ability to observe patient during travel	✓✓	✓✓✓	
• Suitable for patients in unstable living circumstances (e.g. homelessness, shelters, drug treatment programs)	✓	✓✓	✓✓✓
PROGRAM TIME AND COSTS			
• Ability to decrease DOT worker travel time and expense	✓✓✓	✓✓✓	✓
• Ability to simplify scheduling logistics for patients	✓✓	✓✓✓	✓
• Program costs currently well-established	✓	✓	✓✓✓
• Decreased initial upfront costs and technology requirement			✓✓
TECHNOLOGY AND FUTURE DIRECTIONS			
• Provides a gateway to future mobile health application use	✓✓	✓✓✓	
• Ability to monitor without reliance on consistent internet or cellular connectivity		✓	✓✓✓

2.3 Funding for eDOT

In California, federal and state funding sources may be available for local health departments to support electronic DOT arrangements. Laws regarding reimbursement in California and other states can be found on the Center for Connected Health Policy website www.cchpca.org .

3. Eligibility

3.1 Considerations for eDOT Use

eDOT may be considered for all patients with TB treatment regimens that call for DOT. A patient-centered approach should be taken by the TB program in determining which DOT modality is the best fit for each individual. It is advised that eDOT patients be selected using policy and procedures established by the TB program. In addition to the recommendations in the CDPH-CTCA Joint Guidelines for DOT¹⁶, the following criteria should be considered when determining whether eDOT is suitable for each patient.

3.1.1 Patient Eligibility Considerations for eDOT

- Patient has successfully completed initial weeks of in-person DOT with close to 100% adherence.
- Patient is experiencing no major side effects and has tolerated a stable medication regimen for at least two to three weeks.
- Patient is willing to accept and follow eDOT procedures.
- Patient is able to accurately identify and swallow his/her own medication independently, or patient has a stable caregiver who can provide consistent assistance.
- Patient can recognize side effects associated with TB treatment and is instructed about what to do if side effects occur.
- Patient speaks a language that can be accommodated by eDOT personnel, or the TB program can coordinate with language interpretation services to provide consistent care for the patient.

3.1.2 Additional Considerations for eDOT

Before concluding that a patient is a candidate for eDOT, consider the following:

- A. Network connectivity at patient's residence which may be relevant for many forms of eDOT.
 - i. Check the cellular/internet coverage in the area where the patient and DOT worker will be using their mobile devices.
 - ii. If connectivity coverage is poor, determine whether the patient can bring their device/phone to another location with satisfactory coverage (e.g., work, school, or hotspot) during the day that medications were taken in order for videos/data to be sent.
- B. Patient literacy.
 - i. Ensure patient is capable of using required equipment without help from a DOT worker before starting the program.

C. Patient disabilities

- i. Ensure patient has no cognitive and/or physical disabilities that could prevent them from using required equipment properly (e.g., diminished hearing or vision, severe arthritis), or has support from a responsible and trained individual.

D. Patient mobility (e.g., binational)

- i. Determine if the patient plans on being out of town, and if so, the frequency, duration and location of travel, and access to cellular or Wi-Fi networks.
- ii. Determine whether the patient is willing and able to handle accommodations for continual connectivity.

E. Patients who are younger than 18 years-old, frail, have comorbid conditions, misuse alcohol or drugs, undergoing TB treatment re-challenge or adjustment due to toxicity/side effects or resistance, or have missed clinic appointments should be assessed individually to determine whether eDOT is a suitable option for them. For example, patients whose lifestyles are not conducive to monitoring them with in-person DOT could demonstrate better adherence using eDOT because this modality is not subject to some of the constraints that exist with in-person DOT. Additionally, patients should be considered on a case-by-case bases when they cannot make their own medical decisions and have an appointed designated power of attorney.

4. Roles and Responsibilities

4.1 TB Staff and Procedures

4.1.1 TB Controller Role

Oversight, direction, and size of TB programs vary by jurisdiction; however, TB controllers should identify DOT modalities available and operational considerations for implementing eDOT as an option for treatment monitoring. TB controllers should also assure policy and procedures are in place for determining how patients will be assessed to determine which mode of treatment monitoring they should receive. When patients are placed on eDOT, the TB controller should be made aware of concerns or problems that occur during treatment in order to participate in decisions regarding changes to the mode of DOT. Regardless of the method chosen for adherence monitoring, TB controllers should participate in continual quality assurance.

4.1.2 Program Supervisor Role

Supervision of TB programs may vary by local jurisdiction; however, it remains important to ensure the safe, appropriate and effective use of eDOT. Program supervision may be performed by TB controllers, program or case managers, clinical or public health nurses (PHN), or other personnel who are equipped to provide oversight and evaluate

effectiveness. TB programs should have procedures in place to monitor equipment (e.g., smartphones, tablets, video phones, and computers) and service plan usage (e.g., phone, text message, and data charges) when these items are provided by the program. Access to protected health information (PHI) should be managed according to local health department standards based on federal and state guidelines. Specific considerations will vary depending on the method of eDOT service (cloud based server, smartphone application, in-house software, etc.). A protocol should also be in place for deleting all patient information at the end of treatment from devices and resetting devices to their factory settings before devices are redistributed to other patients.

4.1.3 Program Staff Role

Careful observation of medication ingestion each time a dose is scheduled is central to the success of a DOT program. The specific personnel responsible for daily viewing and recordkeeping can vary according to the local jurisdiction and community needs, but may include licensed and non-licensed workers (health technicians, LVNs, RNs, etc.). Thus, supervision per the local jurisdiction is important to ensure safety, accuracy and completeness of therapy. Duties of these workers may include:

- A. Documenting whether the medications were ingested as directed using the mechanism provided by the eDOT method and/or TB program procedures.
 - i. For asynchronous VDOT, videos should be reviewed frequently (e.g., daily during the workweek and on the first day back following a weekend or holiday) to document doses ingested and promptly identify patients who require assistance.
- B. Contacting the patient to identify and resolve problems when scheduled medications were not observed/confirmed being ingested.
 - i. For side effects, assessing as per protocol and referring to appropriate clinical/management personnel for resolution.
 - ii. For technical problems, assessing whether patient training or technical support is needed to resolve the problem and implement steps to resolve it.
 - iii. For patient adherence problems, working with patient according to local protocols.
- C. Maintaining patient confidentiality, as per local procedures, with all encounters.
- D. Assisting patient with obtaining and completing laboratory tests, x-rays, transportation, and referrals to needed resources such as additional health care, social services, and housing.
- E. Assessing and reporting symptoms concerning for adverse drug reactions to medication per local protocol appropriate to the chosen eDOT method.
- F. Identifying issues that affect successful eDOT implementation or maintenance and reporting them to supervisors/management for review and resolution.
- G. Reinforcing counseling and educational messages provided by the patient's case manager.
- H. Disbursing DOT incentives and enablers as per local department procedures.

TB programs may consider incentives or enablers throughout the course of treatment. As eDOT often includes the use of additional technologies (e.g., telephones, SMS text messaging, GPS, and internet access), these may in-themselves be seen as an enabler.

For a list of additional incentives/enablers, refer to the CDPH/CTCA Joint Guidelines for DOT¹⁶.

4.1.3.1 Patient Setting

As many eDOT modalities require visualization, patient positioning and lighting should be adjusted to maximize patient comfort, yet produce clear viewing conditions for the DOT worker. The patient should be trained how to videoconference or video record their actions in a manner that allows the DOT worker to unambiguously determine that medications were ingested. For example, patients should ensure that the quality of their image is not obscured by backlighting or glare from windows and room lights. Patients should place their cameras on a secure, stable platform to avoid wobbling and shaking during the videoconferencing session. To the extent possible, cameras should be placed at the same elevation as the patient's eyes with their face clearly visible at all times. The same should apply to the DOT worker in the case of synchronous VDOT. The DOT worker, or designated program staff member, and the patient should also discuss concerns and strategies to maximize privacy. For example, during synchronous VDOT, if other persons are present in either the patient's or the DOT worker's room, both the DOT worker and patient should be made aware and agree to their presence.

4.1.4 Documenting Treatment Observation

Documenting treatment observation should ideally ensure that all members of the TB program team (e.g., case manager/PHN, physician, DOT worker) have the same information for a patient. Each encounter is an opportunity to document relevant information about the patient's treatment progress. Having the documentation available to case managers and providers ensures best practice treatment decisions can be made. The documentation should also promote teamwork between the TB program staff and the patient.

Documentation may vary in each jurisdiction and by method of eDOT, according to the program design, needs, personnel and policies. If the eDOT application/method is capable of capturing and storing DOT elements (e.g., treatment adherence, side effects reported, etc.), these data could be used to complete the jurisdiction's DOT record for each patient. TB programs must decide whether medication adherence will be captured and stored within the eDOT application or on a separate encounter form (See Appendix I – Sample DOT Encounter Form).

4.1.4.1 Measuring Adherence

Adherence means that the patient:

- A. took all medication doses continuously as prescribed; and
- B. executed eDOT procedures which allowed the DOT worker to observe or verify that the medications were ingested.

Observation rate means the number of observed medication doses divided by the number of expected doses during the period of observation.

4.1.4.2 Procedures for Non-adherent Patients

Procedures must be in place that guide the DOT worker when the patient is non-adherent.

Example 1 – the patient records a video, but the DOT worker cannot clearly see the patient swallowing the pills.

Example 2 – no electronic documentation is received by the scheduled time and the patient does not notify the DOT worker regarding a technical problem.

Appropriate monitoring of therapy is vital to accurately document completion of treatment. In the event that TB staff members are not able to clearly document that medications were swallowed, the patient should be contacted immediately. This contact provides an opportunity to troubleshoot possible problems with the technology or treatment and resolve them. In the event of technology problems or unacceptable adherence that cannot be resolved, procedures should be in place to guide the TB program's response, which may vary by local jurisdiction (see Section 4.3).

4.2 Enrollment Procedures

4.2.1 Patient Enrollment

Once eligibility for eDOT is determined, the following procedures should be reviewed with the patient by an authorized TB staff member (e.g., TB supervisor, TB coordinator, PHN, case manager) for continuation of therapy via eDOT.

- A. Present the different eDOT methods that are locally available to the patient (availability may vary by health jurisdiction).
 - i. If patient is interested, continue to next item.
 - ii. If not, assess for concerns about eDOT and answer questions. If patient refuses, maintain patient on in-person DOT.
- B. Assess the patient's literacy.
 - i. If literate, continue to next step.
 - ii. If not, the program should have procedures in place to confirm the patient understands system procedures and/or the consent, if required.
- C. Ensure information is provided in a language that the patient understands.
- D. Review overall procedures with patient, and ensure they are understood.
 - i. Answer any questions the patient has about the procedures.
- E. Review possible risks/discomforts and benefits of using eDOT with patient.
- F. Review confidentiality statement with patient.
- G. Review expectations from the TB program regarding treatment adherence and explain possible reasons for returning the patient back to in-person or another form of DOT.
- H. Coordinate TB medication delivery/pickup with patient to ensure continuous supply (e.g. extended travel or hospitalizations).
- I. Provide instructions to contact case manager/supervisor or provider if patient suspects he/she is having adverse drug reactions/side effects.

- J. Read the elements of a eDOT agreement out loud to the patient and have him/her sign the form, which should include:
 - i. how eDOT will be performed;
 - ii. how confidentiality will be maintained;
 - iii. how to contact their provider directly in the event of adverse drug reactions or side effects;
 - iv. what the patient should do in the event of an emergency (e.g. they must leave the jurisdiction suddenly or become hospitalized) or equipment failure;
 - v. how to maintain and care for equipment (if supplied by health department); and
 - vi. instructions for returning equipment (if supplied by health department) upon cessation of eDOT treatment, either from completion of therapy or reversion to in-person DOT. Note, in the event the patient is able to use their own device/computer/phone, limitations of the health department's role in covering internet/data plan fees should be clearly outlined.
- K. Where required by local TB program policy, have patient sign and date a Consent Form to use eDOT.
 - i. File the signed and dated consent form in the patient's medical record.

4.2.1.1 Patient Consent Form

Where required by local health jurisdiction policy, an informed consent process covering the chosen modality should be conducted with the patient in the language that can be easily understood at the start of eDOT (see Appendix II – Sample Consent Forms). Local, state and federal laws regarding verbal or written consent may impact which procedures to follow. Topics to consider include: the limits to confidentiality in electronic communication; an agreed upon emergency plan, particularly for patients in settings without clinical staff immediately available; process by which patient information will be documented and stored; the potential for technical failure; procedures for coordination of care with other professionals; and conditions under which eDOT services may be terminated and a referral made to in-person treatment.

4.2.2 Handling Equipment and Managing Technical Problems

Use of an eDOT system will require both the TB care providers and the patients to have access to needed equipment and software, which may vary by jurisdiction. Depending upon the eDOT modality selected, patients may personally own or have access to devices that are suitable for the chosen eDOT system. This should be considered on a case-by-case situation depending on local jurisdiction policy. Personal equipment, if used, should meet all standards established by the local jurisdiction. Regardless of whether the equipment is owned by the patient, or provided TB program, the following should be considered before initiating treatment with an eDOT system:

- A. Plan for possible equipment malfunction (e.g., lost, stolen or broken phone, chargers, etc.). In the event the equipment is distributed by the TB program, limitations should be outlined regarding how hardware should be utilized. For patients who use their own equipment, there should also plan for the possibility that patients stop paying for service. A Phone Use Agreement form should be completed and signed by the patient as documentation that they understand the

conditions of the use of the equipment (see Appendix III Sample Phone Use Agreement Form for examples of both phone check out and return).

- B. Define limitations of equipment use by the patient (e.g., data use, personal telephone use, long distance calls, texting) when the equipment is provided by the TB program. Terms of use for all equipment should similarly be described to the patient and documented in their treatment record.
- C. Establish procedures for ending the use of eDOT, which includes the return of equipment (e.g., phone, charger, phone case), if it was provided by the TB program.

Patients should be provided with the following in writing: instructions on installation and use of equipment; what to do in an emergency; who to call with questions; how to troubleshoot technical problems; patient's responsibilities for damage or loss of equipment (may vary by jurisdiction); and limitations of equipment use/data use parameters if appropriate (see Appendix IV – Sample Patient Recording Procedures Pamphlet).

Prior to allowing patients to use eDOT, the TB program staff should conduct a 'test run' to ensure appropriate function of the equipment and thorough understanding by the patient.

4.2.3 Patient Training for Synchronous VDOT

- A. Patient and DOT worker agree to a regular time for live videoconference calls;
- B. Patient and DOT worker activate video equipment and assure proper functioning;
- C. Patient's position is clearly visible on device display by DOT worker;
- D. DOT worker can confirm patient's identity;
- E. DOT worker talks to patient prior to observing medication ingestion, (e.g., asks how they are feeling, if they experienced medication side effects, if they have encountered problems);
- F. Patient states the name and dosage of each TB medication and holds it in front of the camera long enough for it to come into focus before placing the pill in his/her mouth and swallows it while on camera. Note: patient should be instructed to take pills one at a time to make ingestion easier to confirm. Patients may be provided with a pill placement tool to help them organize their medications before starting to ingestion (see Appendix V – VDOT Medication Layout Tool);
- G. Patient opens mouth after swallowing and shows DOT worker that the pills were swallowed; and
- H. DOT worker and patient confirm the day and time for the next VDOT session.

4.2.4 Patient Training for Asynchronous VDOT

- A. Patient and DOT worker activate video equipment and assure appropriate function and visualization;
- B. Patient clearly identifies him/herself (e.g., states name or unique ID depending upon confidentiality requirements specified by the local jurisdiction);
- C. Patient states whether he/she is having problems with the medicines or reports any new symptoms (e.g., nausea, vomiting, abdominal pain). Note: TB program

protocols should be provided in advance to the patient indicating whether or not the patient should take medications in the event of symptoms;

- D. Patient states the name and dosage of each TB medication and holds it in front of the camera long enough for it to come into focus before placing the pill in his or her mouth and swallows them while on camera. Note: patient should be instructed to take pills one at a time to make ingestion easier to confirm. Patients may be provided with a pill placement tool to help them organize their medications before starting to ingestion (see Appendix V – VDOT Medication Layout Tool);
- E. Patient opens mouth after swallowing and shows DOT worker that the pills were swallowed;
- F. Patient states when the next video will be made and ends session; and
- G. DOT worker communicates with patient regularly (e.g., at least weekly) by phone or in-person to ensure no side effects or concerns exist, and that patient has appropriate quantities of medication on hand. Follow TB program protocol for managing potential medication side effects and notifying the patient's case manager or healthcare provider.

4.3 Terminating eDOT

A patient may be returned to in-person DOT, or switched to another eDOT modality, if their healthcare provider or the TB controller believes that it is in the best interest for assuring adherence. Examples of situations that might compel the DOT worker to suggest reversion to in-person DOT include: eDOT equipment/technology malfunction which is unable to be resolved in a timely manner; patient is non-adherent to eDOT procedures; patient repeatedly misses medication doses; or patient loses or damages the eDOT equipment, or exceeds allowed service usage limits.

As with in-person DOT, the DOT worker should notify the patient's TB case manager (or other person responsible for patient adherence) when doses are missed. Stopping rules should be established in written protocols indicating when the eDOT method is failing and the patient should be returned to in-person DOT or another form of patient monitoring.

Patients can be re-considered for eDOT later in treatment if their circumstances change. These decisions may be left to the discretion of the TB controller.

5. Technology and Data Management

In choosing an eDOT system, factors to be considered include the software application, characteristics of the required device(s), network connectivity options, and data security. The eDOT system and associated devices must also comply with the health department's information technology policies.

5.1 HIPAA Compliance

Efforts to safeguard patient PHI is mandated by the federal Health Insurance Portability and Accountability Act (HIPAA). In eDOT modalities, as in any electronic exchange of health information, only required information that is essential to successfully accomplish

safe and effective care should be included. Proper environments for recording, encryption, safe transfer, appropriate documenting and storage, and processing of health data should comply with HIPAA. Local health departments should consult with their HIPAA compliance officer, Information Technology manager, and/or local legal counsel when assessing whether an eDOT product is HIPAA-compliant in their jurisdiction.

Additional information can be found at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html>

5.2 VDOT Applications

Video conferencing applications must have the appropriate verification, confidentiality, and security features necessary to meet HIPAA requirements. Where practical, health departments may recommend the preferred video conferencing software and/or video and audio hardware to the patient, as well as providing any relevant software and/or hardware configurations to ensure the security of patients' PHI. When choosing a VDOT application, consider whether it runs on Android, iOS, Windows or other device operating systems, and ensure it is suitable for the type(s) of devices that will be used by the patients.

5.3 Equipment Characteristics

Many eDOT devices require front-facing cameras and microphones, which allow the patients to see themselves on the screen while taking their medications. For synchronous VDOT, the device will also need a speaker so the patient can communicate with the DOT worker. The components of the device must be of high quality to ensure the audio is clear and the video resolution is high enough to read the text on a pill bottle or medication tablet. Most smartphones and tablet computers provide these features; laptop and desktop computers may require peripheral devices such as cameras or microphones. Devices used by the patient should be equipped with up-to-date operating systems and antivirus software to ensure data security.

If the patient's device is a smartphone or tablet, it should be equipped with a holster or stand that allows the patient to position the device in an upright orientation to facilitate hands-free operation with the patient's face and hands clearly visible on the device screen. Personal computers should have cameras that can be positioned to provide the same functionality.

5.4 Network Connectivity

Devices used for eDOT may transmit video, audio and other information to the DOT worker via cellular or internet connections. Devices that are capable of using both cellular and internet connections will maximize the likelihood that the patient will consistently be able to communicate with the DOT worker. eDOT services provided through personal computers or mobile devices that use internet-based videoconferencing software programs for synchronous VDOT should provide such services at a bandwidth of 384 Kbps or higher in each of the downlink and uplink directions. Such services should provide a minimum resolution of 640 X 360 at 30 frames per second. Because different

technologies provide different video quality results at the same bandwidth, each end point shall use bandwidth sufficient to achieve at least the minimum quality for appropriate drug adherence monitoring. A connectivity test (e.g., bandwidth test) between the patient and DOT worker should be conducted before formal eDOT sessions occur to troubleshoot possible problems or assess feasibility in a given area.

Since synchronous VDOT systems require a consistent, active connection throughout the patient/provider interaction showing the patient taking his/her medications, network connectivity requirements are more stringent for this method than asynchronous VDOT and other eDOT methods.

5.5 Privacy and Security

Efforts must be taken to make eDOT data transmission secure by using point-to-point encryption that meets the most updated standards. Currently, FIPS 140-2, known as the Federal Information Processing Standard, is the US Government security standard used to accredit encryption standards of software and lists encryption such as AES (Advanced Encryption Standard) as providing acceptable levels of security. Health department IT staff should be familiar with the technologies available regarding computer and mobile device security, and help select eDOT applications that meets these standards.

When the patient and/or DOT worker uses a mobile device, special attention should be paid to ensuring the privacy of information being communicated over such technology. Mobile devices should have security features available and enabled. Although specifics may vary according to local standards, health departments should consider software capable of blocking caller ID; software that prohibits more than one concurrent video session at a time; and a timeout function requiring a passphrase or re-authentication to access the device should be enabled after a period of inactivity (e.g., 15 minutes). Unauthorized persons must not be allowed access to sensitive information stored on the device, and the device must not be used to access sensitive applications or network resources.

eDOT systems should have features to assure patient contact information is restricted. Additionally, electronic equipment should have the capability to remotely disable or wipe a patient's mobile device in the event it is lost or stolen. Applications for performing these functions are available from cellular service providers and third party vendors. Some of these applications also allow users to locate a phone when its GPS function is enabled.

5.6 Data Storage

Cloud services that do not meet HIPAA compliance standards are not recommended for PHI or confidential data. Patients should be informed that using unapproved applications to capture, store or transmit PHI could result in inadvertent disclosure of their data. Health departments may choose to provide guidance to patients on how to best protect their own privacy. Recordings should be encrypted for maximum security. Access to the recordings should only be granted to authorized users. Applications that stream (display only) videos and other data to the DOT worker provide greater security than applications that download this information to the DOT worker's computer or other device.

To communicate expectations for both the patient and the health department, written agreements may be appropriate pertaining to the health department's policy regarding the patient sharing portions of his or her own information.

5.7 Data Management

5.7.1 Minimum Data Requirements

Regardless of the DOT method used, treatment records must be maintained for each patient. The information captured in a treatment record should include: dates of each expected dose; medication type and dosage of each medication expected; dates of treatment initiation and completion/termination; date of each dose observed; medication type and dose observed; doses held; method of DOT (e.g., eDOT, in-person DOT); and self-administered (not observed) doses.

If the chosen eDOT modality does not capture these data elements in a manner that can be extracted for monitoring and reporting purposes, a paper form may be used and kept in the patient's medical record (see Appendix I – Sample DOT Encounter Form). Alternatively, the eDOT application may be used solely to observe the patient taking his/her medication and the adherence data can be captured in a separate electronic medical record or similar database.

Software, devices and network service should be selected to minimize technical problems, but TB programs should also have written procedures for documenting the outcome in the event that a medication dose could not be observed. The DOT worker or designee should immediately contact the patient by any acceptable means once a missed dose is determined. For synchronous VDOT, this would be when the patient fails to join a scheduled videoconference. For asynchronous VDOT, a missed dose would be determined when the DOT worker sees that no video was received within a predetermined number of hours after the patient's scheduled medication time or if a video is received but does not show the patient ingesting his/her medications. Depending on the outcome of the DOT worker's investigation, the disposition of the expected dose (e.g., self-administered, failed, held, etc.) should be recorded in the patient's adherence record.

Immediate follow-up is necessary with patients who fail to connect to a videoconference or send videos to minimize the number of unobserved and failed doses. Since the reason could have to do with technical problems, resolving the problem quickly will allow the DOT worker to resume normal observation. In addition, patients using asynchronous VDOT may have videos stored on their phones that can be used to document ingestion. Unlike in-person DOT, audio or video quality, connection problems, lighting, background noise, or software glitches could make it difficult or impossible for the DOT worker to confidently determine whether the patient swallowed his/her medications. Pre-determined procedures should be established to document these events. For example, when a videoconference loses connection or a recorded video stops prematurely, but part of the dose was observed, the DOT worker may consider that an observed dose with a qualifier (e.g., "partial dose observed") entered into the database or record. Note that the frequency of these exceptional doses should be monitored and used to consider

reversion to in-person DOT. Thus, it is important to rule out technical problems quickly so that the DOT worker can detect and address problems with compliance.

5.7.2 Data Integration and Reporting

eDOT data allows for the possible synchronization in a health department's electronic medical record (EMR). As EMR systems and eDOT technologies evolve, efficiencies of integration should be considered. Further integration of EMRs and TB surveillance reporting systems (e.g., the CDC's Report of Verified Case of Tuberculosis [RVCT]) should also be considered.

eDOT data may also be used for standardized treatment reporting for program evaluation and surveillance. In addition, these data can be used by TB program supervisors to monitor the quality of DOT. For example, tracking the frequency of technical problems could indicate bugs in the eDOT application, or patients who are attempting to avoid taking their medications.

5.7.3 Data storage

For both asynchronous and synchronous VDOT, videos may be recorded and stored. Applications on smartphones, tablets and computers may allow for uploading videos to a TB program's EMR or other database. Depending on the needs and policies of the TB program, videos may be deleted as soon as they are watched, deleted after a fixed period of time (e.g., 30 days, 6 months, etc.), deleted after the patient completes treatment, or stored indefinitely.

Currently, there is no mandate for storing video captured for VDOT. However, TB programs may consider storing videos for a specified time period for quality assurance procedures, training purposes, or legal actions. The cost of keeping long term data, patient approval, and data security should be addressed by health departments considering video storage. Local and state policies should also be considered.

6. Supervision and Quality Assurance

As with in-person DOT, a licensed healthcare professional should provide supervision for eDOT related activities.

A yearly formal performance review should be written into the program protocol, and include:

- chart review;
- regular and ongoing supervision with DOT worker that covers setup of eDOT equipment, patient training, observation of medication ingestion, and documentation of ingestion events; and
- case management/review meetings at least monthly to identify eDOT issues and concerns.

6.0.1 Quality Assurance for Synchronous VDOT

Synchronous VDOT can allow for more than one DOT worker or TB provider to access the same video. While videos are streamed in real-time, the viewing atmosphere can allow more than one viewer. Supervisors or other licensed personnel can be summoned by the DOT worker if concerns exist in real-time. Further, because viewings are pre-scheduled, audits or random check-ins on DOT workers can allow for quality assurance, safe and effective care, and protocol adherence. Policies should be established for regular quality assurance procedures.

6.0.2 Quality Assurance for Asynchronous VDOT

Asynchronous VDOT provides the ability to continually monitor and improve the quality of DOT. Because the medication ingestion event is recorded, the videos can be viewed more than once by more than one TB worker, which allows for record verification, quality control, event monitoring, and consistent supervision. In addition, every event is recorded so post hoc reviews are possible when more quality assurance is required than originally scheduled. Inter-rater reliability can be assessed by having two or more staff members view the same videos and compare their interpretations. Policies should be established for regular quality assurance procedures.

6.0.2.1 Continuous Quality Improvement

Since medication doses observed via synchronous or asynchronous VDOT should be documented on a daily basis, continuous quality improvement is possible. For example, problems in viewing the patient, connectivity issues, setting/atmosphere deficits which compromise the ability to definitively view the medications, and concerns from DOT workers can and should be addressed promptly so that subsequent doses may be properly observed. Responses may include patient re-training, device repair or replacement, software updates, and changing the patient's location to improve network connectivity. eDOT methods should be employed as a tool for improving patient/provider interaction, rather than relying on eDOT to replace continual patient monitoring.

6.0.2.2 Monitoring Adverse Effects of Therapy

eDOT systems, like in-person DOT, should aim to provide care without compromising safety. Identification of medication side effects is key to preventing serious adverse events during treatment. If the patient or the DOT worker has suspicion for a possible drug side effects, videos can be re-reviewed to assess clinical concerns and early warning signs.

Prior to initiating eDOT, patients should be monitored using in-person DOT until the patient's ability to tolerate his/her medications has been established. In the unlikely and undesired event of a true allergy, adverse event, or drug reaction, videos or other electronic data may be audited to explore deficits in monitoring programs in identifying problems beforehand. Lessons learned may prove beneficial towards adapting system changes to ensure safer administration, documentation, and completion of TB therapy.

6.0.2.3 Assurance of Appropriate Supervision

Stored videos or electronic information may be viewed by various personnel in the health department to ensure safe, appropriate and consistent care from all patients being monitored. TB controllers, program and case managers, PHNs, LVNs, and other DOT workers can work together to provide the highest quality care for the patient, while maximizing patient autonomy. If concern exists from any stakeholder—the patient to the TB controller—archived videos or electronic information can be reviewed to assess for deficits. Further, audits can provide insight into a highly successful program, which can showcase high quality care from DOT workers and supervisors alike.

6.0.3 Assessing Patient Satisfaction with the eDOT Experience

eDOT programs should strive to provide not just safe and effective care, but also patient-centered care. This can serve to promote treatment adherence and reporting of problems or concerns with systems, personnel, or technology which may allow for improvement in delivery. TB programs should consider including surveys, especially with the introduction of eDOT modalities to highlight strengths and discover weaknesses. In addition to assessing adherence, side effects, and patient concerns, DOT workers may also ask about overall patient experience. This should be documented for review in aggregate to note deficiencies or areas needing more attention. DOT workers should also note concerns with eDOT programs and provider experiences.

6.1 Personnel Training

In addition to in-person DOT training and experience¹⁶, initial and ongoing training in the use of eDOT provided by properly trained and licensed staff should be documented for all personnel in the program.

6.1.1 Initial Training of Supervisors

Personnel responsible for supervising eDOT programs may vary by jurisdiction; however, supervision remains important for the successful and safe treatment of patients. Supervisors must ensure appropriate treatment regimens, maintain the capacity to successfully troubleshoot problems experienced during treatment, and provide continual quality improvement. Thus, supervisors must be comfortable with any and all software and hardware used by an eDOT program. In the case of a new eDOT program, a supervisor may find it helpful to orient themselves to new systems before enrolling patients. Additionally, training and awareness of required equipment maintenance, inventory systems and management, and information technology changes/updates is advisable. Supervisors should also review privacy compliance, local procedures, and policy per department and jurisdiction. Once comfortable, supervisors should conduct a 'test run' to ensure any major impediments have received attention.

6.1.2 Initial Training of DOT Workers

DOT workers are responsible for the day-to-day video viewing tasks, and serve as the frontline for observing patients ingest their medication doses. DOT workers should be

trained on the use of both the hardware and software selected by the program. Supervisors should work with new trainees to orient them to local system interfaces, including how to access applications/websites/cloud servers to access patient videos (uploaded or streamed). For quality assurance, reviewing documentation and videos should be performed until the supervisor is confident in the independence of the DOT workers. Supervisors should continuously monitor DOT workers to assess for problems encountered, either technological or with patient communication.

Training procedures will vary depending upon the type of hardware and software used. It is important for DOT workers to be comfortable with these systems, or know who to contact when problems arise (i.e., eDOT software/hardware provider, health department's information technology provider, etc.).

Similar to in-person DOT, DOT workers should have at least the minimal training and competencies to assure consistent, safe and effective care. For details regarding the recommended minimal qualifications, consult the CDPH/CTCA Joint Guidelines for DOT¹⁶.

7. Special Circumstances

7.1 Patient Travel while on eDOT

If a patient must travel during TB treatment, eDOT may be the only option to maintain continuous observation. TB staff and patients should have a shared discussion regarding equipment use (see section 4.2.2). Specifics may vary depending upon the device characteristics and the location of travel; however predefined allowances should be discussed (e.g. if the patient is traveling internationally, data-use and cellular coverage, including limitations should be defined). Additionally, backup means of communication should be established in the event of equipment malfunction or connectivity issues.

If the patient and the DOT worker—under the guidance by the TB controller—have identified an appropriate scenario for travel, an agreement documenting the shared discussion about the limitations of data use, the care of medications, the backup agreed upon means of communication, and the plan in the event of suspected medication side effect is advisable. This agreement should be placed in the patient's chart.

Travel may not be appropriate for patients who have recently initiated therapy, or who have had recent changes to their medical regimens, until their risk of side effects has been assessed by a provider.

7.1.1 Asynchronous VDOT while Traveling

Depending upon the software application used, asynchronous VDOT may be considered appropriate for some patients. If the VDOT application allows patients to record videos even when their device lacks a cellular or Internet connection, and each date/time stamped video is stored on the device until connectivity is restored, then this VDOT modality would allow documentation of every medication dose ingested even when

patients travel to regions with no or low connectivity. Patients should be trained in advance of travel to continue recording each medication dose regardless of whether their videos are uploading, because the videos can be retrieved upon their return to document all doses taken. Recognizing medication side effects should be emphasized before travel in the event observation and communication becomes problematic and a predefined plan should be discussed.

7.1.2 Synchronous VDOT while Traveling

Depending upon the software applications used, synchronous VDOT may be a consideration for patients during travel. Specified parameters should be discussed beforehand, with considerations of time zone changes. Backup communication plans should be emphasized in the event connectivity problems arise. Given the high cost of international roaming rates for cellular phones, patients should be trained to connect via the Internet whenever possible.

7.2 eDOT for Pediatric Patients

Under certain circumstances, pediatric patients may be considered for eDOT. In these instances, local, state and federal laws/policies should be followed to assure appropriate informed consent is conducted with the parent or guardian (see section 4.2.1.1). Depending upon the patient, the parent or guardian may need to be involved in the medication administration. In this case, the parent or guardian should follow all procedures outlined for the appropriate eDOT modality (i.e., identifying the date, the patient, the medicine, showing the medicine, having the patient clearly in view of the camera, etc.). As with all TB treatment, if problems arise because of adherence, technologic failure, or medication side effects, the parent or guardian and patient should be contacted, supervisors should be notified and corrective action taken.

7.3 Monitoring Patients with Drug Resistance

Patients with drug resistant TB require longer periods of treatment and may also require administration of injectable medications. Patients with twice daily medication administration may be considered for eDOT for one of the doses allowing for in-person DOT for the other doses. Given its potential to reduce patient burden, TB patients should not be precluded from eDOT based solely on drug resistance; however, TB programs may consider using higher adherence thresholds for reverting patients to in-person DOT and monitoring the status of these patients more closely.

8. Policy and Legal Considerations

8.0.1 Confidentiality

In selecting an eDOT modality, the TB program should ensure compliance with provisions regarding the management of PHI contained in HIPAA. A program should initiate a risk assessment to determine where PHI will be stored and how it will be accessed. Such an assessment would also assist health departments in determining

who may need to sign a Business Associate's Agreement (BAA) to ensure that third parties who are given access to patient PHI are also complying with HIPAA regulations.

8.1 Security and Privacy

8.1.1 Secure lines and end points

When using eDOT, patients will potentially transmit information over unsecured, public Wi-Fi. Therefore, the eDOT modality selected should ensure the transmitted information, such as a recorded video in the case of VDOT, is encrypted to ensure that intercepted files are not viewable.

Both the user and the TB program must ensure precautions are taken to protect PHI. Passwords should be employed at both ends before a device or information can be accessed. If storing PHI on the physical device is unavoidable, the information should be encrypted and/or password protected. If a patient opts to use their own device, the TB program may wish to discuss further safeguards like additional password protection for opening applications pertaining to eDOT.

For VDOT, TB programs should be mindful of the DOT worker's environment when he or she is viewing recorded videos or live transmissions. The DOT worker should ensure that he or she is in a private location where unauthorized persons cannot see or hear the information being received from the patients.

8.1.2 Business Associates

Be aware of who may be potential Business Associates (BA). A BA is a person or entity other than a workforce member (e.g., a member of your office staff) who performs certain functions or activities or services on the behalf of the TB program, when the services involve the access to, or the use or disclosure of, PHI. In the case of eDOT, this may include third party vendors that provide eDOT applications.

8.2 Other Legal Topics

8.2.1 Ethical Considerations

Devices issued by TB program should be limited in what they can be used for beyond what is involved in eDOT. As incentives for patients are sometimes provided for in-person DOT, TB programs may also consider incentives to participate and comply with eDOT. Examples may include data usage, text messaging abilities, domestic calls, or other functions as permitted by the program in the context of loaned devices. Before offering such incentives, TB programs should carefully consider possible negative outcomes such as the phone being used for illicit or illegal activities.

8.2.2 Use of GPS to Locate a Patient

Devices used for eDOT may have locating capabilities, such as a Global Positioning Satellite (GPS) technology on smartphones, which can potentially be used by the TB

program to locate a participant using eDOT. For example, a program might use location data to locate a lost or stolen device. TB programs should establish, and share with patients, clear policies regarding the collection and use of location data.

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Appendix Table of Contents

I. Sample DOT Encounter Form

Total doses - previous med sheet

DIRECTLY OBSERVED THERAPY MEDICATION BILLING RECORD

MONTH/YEAR: _____ TOTAL # DOT DOSES TO DATE: Q.D. BIW TIW SAT

Location of DOT: «Location» Date Last Med Fill: _____ DOT Start Date: «DOT_Start_Date»

MEDICATIONS			Mon	Tue	Wed	Thu	Fri		Mon	Tue	Wed	Thu	Fri
AM/PM (circle one)	DATE:												
«Medication1» «Med1_dose»	«No_Pill s1»	«Med1_Fr eq»											
«Medication2» «Med2_dose»	«No_Pill s2»	«Med2_Fr eq»											
«Medication3» «Med3_dose»	«No_Pill s3»	«Med3_Fr eq»											
«Medication4» «Med4_dose»	«No_Pill s4»	«Med4_Fr eq»											
«Medication5» «Med5_dose»	«No_Pill s5»	«Med5_Fr eq»											
«Medication6» «Med6_dose»	«No_Pill s6»	«Med6_Fr eq»											
«Medication7» «Med7_dose»	«No_Pill s7»	«Med7_Fr eq»											
«Other1» «Strength1» «Dose1» «Amount1» «Frequency1»													
«Other2» «Strength2» «Dose2» «Amount2» «Frequency2»													
DOT By - Initials													

Loc: 1-S516, 2-S517, 3-NS12,4-NS14,5-NS13, 6-TBC, 7-S518, 8-Video C-Clinic

S=self administered* F=failed dose* H=held dose* X=special circumstances* (Include comment on S, F, H, X)

POSSIBLE SIDE EFFECTS: (abdominal pain, ↓ appetite, ataxia, bruising, dark urine, diarrhea, dizziness, fever, headache, impaired hearing, impaired vision/color vision, jaundice, joint pain, nausea, numbness, skin rash, tinnitus, vertigo, vomiting, weakness, weight loss)

Ask patient weekly by: Week 1 Week 2

IMMEDIATELY REPORT SIDE EFFECTS AND All S, F, H, X, to NURSE CASE MANAGER. Preferably Monday/Date

DATE	COMMENTS	Initials	Signature/Title
«Date»	«Comments»		

«Justification for 2nd dailyt DOT encount»

Site Of Disease: «Site CodeSite of Disease» Billing Code: «Billing Code»

Insurance: «Insurance»	ID #: «ID»	Issue Date: «Issue_Date1»
Other Insurance: «Other»	ID #: «ID2»	Issue Date: «Issue_Date»

CASE MANAGER: «Case_Manager»

Pt. name: LAST: «Last_Name» FIRST: «First_Name»	D.O.B: «DOB»	CASE #: «Case»
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II. Sample Consent Forms

i. San Diego Health and Human Services Consent English and Spanish



County of San Diego

NICK MACCHIONE, FACHE
DIRECTOR

HEALTH AND HUMAN SERVICES AGENCY
PUBLIC HEALTH SERVICES
TUBERCULOSIS CONTROL BRANCH
3851 ROSECRANS STREET, MAIL STOP P-576
SAN DIEGO, CA 92110-3134
(619) 692-5565 • FAX (619) 692-5650

WILMA J. WOOTEN, M.D., M.P.H.
PUBLIC HEALTH OFFICER

CELL PHONE VIDEO DIRECTLY OBSERVED THERAPY (DOT) CONSENT FORM

Patient Name _____

I am aware that I have been diagnosed with tuberculosis (TB.) It is the standard in San Diego County for TB medications to be observed in order to assure adherence to therapy. The use of cell phone video technology may have certain benefits to me in providing greater flexibility in time of therapy.

I understand that observation of my treatment will be performed using a cell phone video. The cell phone, loaned to me, will be password protected. TB Control staff will have access to my videos and the information in them. I agree to allow TB Control staff to view my videos. I understand that TB Control will do its best to keep the videos private. It is possible that someone who should not have this information may see it. TB Control cannot ensure complete privacy. In order to protect my privacy, the cell phone number will be used instead of my name in the videos. I understand that cell phone transmission will let TB Control know where I took the medications.

It will not be used to locate me personally. I agree to let TB Control staff view the street level location ____ or city level location ____ or I do not agree to let the TB Control staff view any location data sent with my videos _____. In the event that the phone is lost or stolen, the staff will track the phone and erase the data on the phone remotely.

I understand that I may switch back to standard in-home observed therapy at any time during the treatment. I also understand that I may be removed from participation and return to standard in-person DOT if the cell phone is lost or stolen or the TB Program, or my doctor, decides that it is better to continue my TB treatment by in-person DOT.

I understand that the cell phone and all peripherals/cables are not my personal property. I agree to return all the equipment to the San Diego County Health and Human Services Agency within four business days of the end of treatment.

Signature of Patient

Date

Signature of Witness

Date

HHSA: TB-291 (9/14)



County of San Diego

NICK MACCHIONE, FACHE
DIRECTOR

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WILMA J. WOOTEN, M.D., M.P.H.
PUBLIC HEALTH OFFICER

FORMULARIO DE CONSENTIMIENTO PARA VIDEO CELULAR DE TERAPIA DE OBSERVACION DIRECTA (DOT)

Nombre del Paciente _____

Estoy consciente de que he sido diagnosticado(a) con tuberculosis (TB.) En el Condado de San Diego, la observación de la toma de medicamentos es práctica estándar para asegurar el cumplimiento con el tratamiento. El uso de la tecnología de video por teléfono celular puede tener ciertos beneficios para mí al proporcionar una mayor flexibilidad en el horario de tratamiento.

Entiendo que la observación de mi tratamiento se llevará a cabo por medio de un video del teléfono celular. El teléfono celular que se me preste, estará protegido por una contraseña. El personal de Control de Tuberculosis tendrá acceso a mis videos y a la información que contienen. Estoy de acuerdo en que el personal de Control de Tuberculosis pueda vea mis videos. Entiendo que el personal de Control de Tuberculosis hará todo lo posible por mantener los videos confidenciales. Es posible que alguien que no debiera tener acceso a esta información pudiera verlos. El personal de Control de TB no puede garantizar privacidad absoluta. El número de teléfono celular se puede utilizar en lugar de mi nombre en los videos con el fin de proteger mi privacidad. Entiendo que la transmisión del teléfono celular le permitirá al personal de Control de Tuberculosis saber donde tomé los medicamentos. No se utilizará para localizarme personalmente. Acepto permitir al personal de Control de Tuberculosis ver la localización a nivel de la calle ____ o a nivel de ciudad ____, o NO acepto que el personal de Control de Tuberculosis vea los datos de ubicación enviados con mis videos _____. En el caso de que el teléfono se pierda o sea robado, el personal podrá rastrearlo y borrar los datos en forma remota.

Entiendo que puedo regresar al tratamiento observado domiciliario estándar en cualquier momento. Entiendo también que puedo ser retirado(a) de la participación para regresar a DOT estándar en persona si el teléfono se pierde, es robado o si el Programa de TB, o mi médico, decide que es mejor continuar mi tratamiento de tuberculosis por DOT en persona.

Entiendo que el teléfono celular y todos los accesorios/cables no son de mi propiedad personal. Estoy de acuerdo en devolver todo el equipo a la Agencia de Servicios Humanos y de Salud del Condado de San Diego en un plazo de cuatro días hábiles al finalizar el tratamiento.

Firma del Paciente

Fecha

Firma del Testigo

Fecha

HHS: TB-291 (9/14)

ii. San Francisco Department of Public Health Consent

City and County of San
Francisco
Department of Public Health



Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

Edwin M. Lee
Mayor

CELL PHONE VIDEO DIRECTLY OBSERVED THERAPY (DOT) CONSENT FORM

Patient Name _____

I am aware that I have been diagnosed with tuberculosis (TB). It is standard in the City and County of San Francisco for TB medications to be observed in order to assure adherence to therapy. The use of cell phone video technology may have certain benefits to me in providing greater flexibility in time of therapy.

I understand that observation of my treatment will be performed using a cell phone video. TB Control staff will have access to my videos and the information in them. I agree to allow TB Control staff to view my videos. I understand that TB Control will do its best to keep the videos private. Videos will be uploaded to a HIPAA-compliant secure server, and will only be accessed by staff members with a unique username and password. In order to protect my privacy, my patient number will be used instead of my name in the videos.

I understand that I may switch back to standard in-person directly observed therapy (DOT) at any time during the treatment. I also understand that I may be removed from participation and return to standard in-person DOT if the cell phone is lost or stolen, or if the TB Program or my doctor decides that it is better to continue my TB treatment by standard in-person DOT.

I understand that the cell phone and all peripherals/cables are not my personal property. I agree to return all the equipment to the San Francisco General Hospital Tuberculosis Clinic as per program request.

Signature of Patient

Date

Signature of Staff Member

Date

San Francisco General Hospital • Ward 94
1001 Potrero Avenue, San Francisco, CA 94110
Phone: (415) 206-8524 • Fax: (415) 206-4565 • Web: www.sftbc.org

Updated 7/8/14

iii. Riverside County Synchronous VDOT Consent

**COUNTY OF RIVERSIDE
DEPARTMENT OF PUBLIC HEALTH
DISEASE CONTROL**

Video Directly Observed Therapy
Therapy (DOT) Consent Form

Serial number: _____

I am aware that I have been diagnosed with tuberculosis (TB). I will need a long course of medication for cure. I will be receiving my treatment from Riverside County Department of Public Health Disease Control. Direct observation of medication dosing is normally done in the patient's home or at the treating facility.

During my treatment, observation of dosing will be performed using a computer WebEx link. I understand that a laptop and/or a webcam with software will be placed in my home. I agree to allow the TB nurse watch me take my medicines over the computer at a prearranged time either daily or twice weekly.

I understand that I may request to switch back to standard in-home observed therapy at any time. The use of video technology may have certain benefits to me. It is hoped that Video Directly Observed Therapy will be less intrusive and allow greater flexibility in time of therapy. The use of video technology is not believed to carry any risk for me.

I understand that the laptop and/or webcam are the property of Riverside County Department of Public Health Disease Control. I agree to return all equipment to Disease Control staff, within two business days of the end of my treatment, or upon their request.

I will notify Disease Control at (760) 863-8172 if I have any problems logging on, or if I need to change the scheduled time for Video DOT.

Signature of Patient (Parent/Guardian) _____ Date _____

Signature of Nurse _____ Date _____

Specific Procedure:

1. Turn on computer and go to: <https://countyofriverside.webex.com>
2. Log in by using the password given by your TB Case manager
3. Obtain meeting number to join by calling DOT staff
4. Face webcam
5. Display face and confirm your identity with DOT staff
6. Report any problems with medications
7. Display pills
8. Swallow pills

9/11 East

III. Sample Phone Use Agreement Form

i. **San Francisco Department of Public Health Cell Phone Check Out Form**

City and County of San Francisco
Department of Public Health



Edwin M. Lee
Mayor

Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

VDOT Cell Phone Sign Out Form

I, _____ have been given a _____
(participant Name) (brand)
cell phone on ____ / ____ / ____ for use during my treatment at the San Francisco Department
of Public Health TB Control in the Video Directly Observed Therapy (VDOT) program.

Participant please write your initials besides each statement below to indicate that you understand and agree:

- ___ I am aware that this phone is only to be used to upload videos of myself taking my medication and to make phone calls or text messages directly related to my TB treatment.
- ___ I am aware that I am the only person authorized to use this cell phone.
- ___ I am aware that if I use this phone for unapproved purposes, I may be withdrawn from the VDOT program and return to being watched taking my TB medications in person.
- ___ I am aware that if this phone is lost, stolen, or damaged, I may incur a \$20 fee and also have to return to being watched taking my TB medications in person.
- ___ I am aware that the VDOT phone app, website, and server where videos are stored meet San Francisco Department of Public Health security requirements for patient privacy, but there is always a small risk that my image or voiceprint may become public.
- ___ I am aware that at the end of my participation in the VDOT project I will have to return the phone, charger and holster to the County TB program.
- ___ I am aware that the SF TB Program reserves the right to use certain information about my use of the wireless service, including details of when I use data services and about telephone calls. This information will be used in the event the telephone is lost, stolen, or the SF TB program cannot locate me through the usual channels.

Participant Signature

Date

Staff Member Signature

Date

AND Witness Signature (needed for patient unable to read/or of consenting age)

San Francisco General Hospital • Ward 94
1001 Potrero Avenue, San Francisco, CA 94110
Phone: (415) 206-8524 • Fax: (415) 206-4565 • Web: www.sftbc.org

ii. San Francisco Department of Public Health Cell Phone Return Form

City and County of San Francisco
Department of Public Health



Edwin M. Lee
Mayor

Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

V DOT Cell Phone Return Form

I, _____ have received a;
(Staff Member Name)

Staff member – Please check mark each item returned by participant.

___ _____ (brand) cell phone

___ Cell phone charger

___ Cell phone holster

from _____ on ____ / ____ / ____.
(Participant Name)

Staff Member Signature

Date

Participant Signature

Date

San Francisco General Hospital • Ward 94
1001 Potrero Avenue, San Francisco, CA 94110
Phone: (415) 206-8524 • Fax: (415) 206-4565 • Web: www.sftbc.org

iii. San Francisco Department of Public Health VDOT App Checkout

City and County of San Francisco
Department of Public Health



Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

Edwin M. Lee
Mayor

VDOT Phone App Sign Form

I, _____ am being given access to the
(participant Name)

VDOT phone App on ___ / ___ / ___ for use on my personal phone during my treatment at the San Francisco Department of Public Health TB Control in the Video Directly Observed Therapy (VDOT) program.

Participant please write your initials besides each statement below to indicate that you understand and agree:

___ I am aware that this phone App is only to be used to upload videos of myself taking my medication.

___ I am aware that I am the only person authorized to use this phone App.

___ I am aware that if I use this phone App for unapproved purposes, I may be withdrawn from the VDOT program and return to being watched taking my TB medications in person

___ I am aware that the VDOT phone app, website, and server where videos are stored meet San Francisco Department of Public Health security requirements for patient privacy, but there is always a small risk that my image or voiceprint may become public.

___ I am aware that at the end of my participation in the VDOT program I will have the Staff at TB control Delete the Phone App from my phone.

___ I am aware that the SF TB Program reserves the right to use certain information about my use of the Phone App, This information will be used in the event the SF TB program cannot locate me through the usual channels.

Participant Signature

Date

Staff Member Signature

AND Witness Signature (needed for patient unable to read/or of consenting age)

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IV. Sample Patient Recording Procedures Pamphlet

VDOT System Copyright (2013)
The Regents of the University of California
All rights reserved

Video Cell Phone Direct Observed Therapy (VDOT)

Important Phone Numbers

If you are experiencing problems with your medication, or you are experiencing new or uncomfortable side effects call your TB Case Manager or health care provider immediately. If this a medical emergency, call 9-1-1.


TB Control Department: _____
Name: _____ Phone: _____


TB Case Manager: _____
Name: _____ Phone: _____

Private Doctor: _____
Name: _____

DOT Monitor: _____
Name: _____


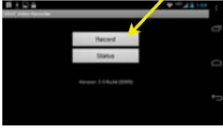
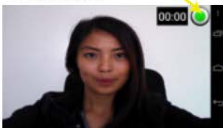

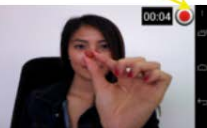
Patient Recording Procedures







University of California, San Diego
School of Medicine
Division of Global Public Health
Phone: 619-767-9602
Email: rgarfein@ucsd.edu


Recording Procedures

- Gather medications, water, and cell phone in well-lit location.
- Turn phone on and set it up horizontally in front of your face on a flat surface.
a. Note: Phone must be horizontal to record videos.
- Press the VDOT icon on the Home Screen.

- In the application, press the "Record" button. Make sure you can see your face clearly on the screen.

- To begin recording, press the **GREEN** button on the top right of the screen.

- Video script: Say your participant ID# and location. Specify the number and type of medication by name, shape, size and/or color.
- Hold first pill in front of camera. Say the name and dosage. Swallow pill.

- Repeat Step 7 until all pills are taken.
- Say when the next dose will be taken.
- To end the recording, press the **RED** button on the top right of the screen.


Video Confirmation

- When recording stops, video is automatically sent to the DOT Monitor.
- A status bar will appear showing the progress of your video upload.

- To check the status of you video, from the home screen press the "Status" button.


Your video uploads will appear as follows:



Teal: In-Progress
Green: Successful

Note: For privacy, you can view the status, but not the video themselves. If you video does not upload successfully, first check that your Wi-Fi is "ON" and if so, take your phone to a new location for better connection.

V. Sample VDOT Medication Layout Tool

Video DOT Medication Layout Tool

Today is _____ (mm/dd/yy)

Place Pills Here:

Name of Pill:

Number:

__ pills

__ pills

__ pills

__ pills

If you are experiencing any of the following side effects, contact your TB care provider at: _____ before taking any medication.

- Abdominal pain/stomach ache

- Dark urine

- Numbness hands/feet

- Decreased appetite

- Diarrhea

- Skin rash/Itching

- Nausea

- Bruising

- Fever

- Vomiting

- Headache

- Dizziness

- Yellow skin

- Change in vision/color vision

- Muscle / joint pain

Version 1.0, Last modified 06/14/2016

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