

Connecticut DPH TB Control Program

Electronic DOT (eDOT) Guidelines and Procedures

Background

One of the main goals of a tuberculosis (TB) control program is to ensure the successful completion of treatment of TB cases in order to cure individuals and prevent new cases. An important tool in helping to ensure completion of therapy is the use of in-person directly observed therapy (DOT), a patient-centered approach in which patients are observed swallowing each dose of anti-tuberculosis medication (1). The national Advisory Council for the Elimination of Tuberculosis made DOT the standard of care in 1993, transforming federal policy and influencing the practice and policy at the state and local levels (2). Since then, DOT has remained the recommended method for TB treatment nationally and internationally to decrease rates of treatment failure, relapse, and acquired drug resistance and to limit infectiousness.

DOT is a time-intensive service which includes supervision of medication administration, help with identifying and managing side effects, and comprehensive TB case management provided by local health department (LHD) staff or their designees and the Department of Public Health (DPH). In Connecticut, DOT is the standard of care for all patients with pulmonary, laryngeal, or pleural TB, children age <6 years, persons living with HIV, and non-adherent patients and is recommended for all doses during the course of therapy (3). Pulmonary and laryngeal TB patients and children are prioritized for DOT, especially patients with acid-fast bacilli (AFB) smear positive sputum. Although DOT is also recommended for patients with extrapulmonary TB, particularly if patients are high risk for complications or poor outcomes, use of DOT in these cases is dependent on the LHD resources and other individual patient circumstances. Due to limited resources in LHDs and reduced concerns about infectiousness, extrapulmonary TB patients receive DOT much less frequently, which can lead to loss to follow-up or significant treatment interruptions or complications.

Rationale

The results of a recent internal evaluation of the use of DOT in Connecticut (2014) indicate that while most patients in the state are receiving some form of follow-up and monitoring throughout their treatment, only 14% receive DOT exclusively (i.e. not combined with self-administration.) Although DOT is not the only defining factor in treatment completion, it remains useful as cases become increasingly socially and medically complicated and require additional coordination. However, in addition to being resource-intensive in terms of staff time and transportation costs, traditional in-person DOT can be logistically impractical, restrictive of patient mobility and schedule, and intrusive and undesirable to patients due to privacy and stigma concerns. Remote and electronic technologies might offer opportunities to increase the use of DOT in a time of declining resources. Electronic DOT (eDOT) offers a novel approach for improving medication regimen adherence that is less burdensome to both patients and staff.

Definitions

Electronic DOT (eDOT) is an umbrella term to describe the use of electronic devices (eg. computer, smartphone) with video technology to observe TB patients taking their medications at a remote location from the healthcare worker. Other common terms used include video DOT (VDOT) and video observed therapy (VOT). Recorded eDOT describes the process of recording and sending videos of medication ingestion to be viewed at a later time by the healthcare worker and may offer greater flexibility for both parties while still providing the level of care and maintenance needed for the treatment program. Currently, recorded eDOT in Connecticut is not recommended due to confidentiality concerns.

In-person DOT remains a preferred method for observing TB patients ingest medication, however utilization of eDOT provides another tool in the arsenal of case management options to improve treatment adherence.

Case Studies in eDOT Implementation

Many state and local health departments across the US have begun implementing eDOT protocols and guidelines as part of their case management procedures.

New York City Department of Health and Mental Hygiene

The NYC DOHMH piloted the use of VDOT using Fuze/Fuzebox software in 2013–2014 and found equal or better adherence rates compared to traditional DOT. Among this pilot group, 71% of patients had an adherence rate above 90%. The software package used also offers the capability for immediate physician consult during patient calls. The program was cost effective and proved advantageous during severe weather. Although there were technical problems, the experience was overall positive (4, 5).

California – UCSD

A study of binational patients in Tijuana, Mexico and San Diego, California used mobile phones to record and securely transfer time-stamped videos of medication ingestion. Respectively, 90% and 97% of the expected videos were received by the provider on-schedule from patients in San Diego and Tijuana. The technology was easily adopted and patients required only 3 training sessions on average before being able to perform VDOT independently. Overall, patient satisfaction was high: 89% of patients reported never or rarely having problems recording videos, 92% preferred VDOT over in-person DOT, 81% thought VDOT was more confidential, and 100% said they would recommend VDOT to other TB patients (6).

New Jersey Department of Health

In 2011, the New Jersey DOH implemented eDOT using the Tango app on smartphones with 35 participants in 7 counties. Although they experienced some issues with Wifi connectivity, the project resulted in 93% treatment compliance and all clinics felt it was an overall successful experience that reduced field time. Patients were able to receive DOT during Hurricane Sandy, during inclement weather, while on vacation or abroad (7).

Washington State Department of Health

Tacoma-Pierce County Health Department & Snohomish Health District

Using retrospective chart review for 57 patients with TB disease who utilized videophone technology from 2002–2006, these two counties in Washington state found significant cost savings. A total of \$139,546 was saved in staff salaries, benefits and travel costs. The average cost savings per patient was \$2,448 (8).

Clark County Department of Public Health

This local health department in Washington state began using Skype with a total of 12 out of 52 patients for both TB disease and the 12 week INH-RPT regimen for LTBI. The state health department issued guidance however local health jurisdictions were responsible for implementing their own policies. Clark County used both asynchronous (recorded) and livestream eDOT. Despite HIPAA concerns with the video platform, they found their program to be successful and cost-effective. They found no statistically significant difference in the number of missed doses for those who received eDOT (3.8%) compared to those who received in person DOT (2.4%) (9).

References

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eDOT Protocol for Connecticut

Potential candidates for eDOT

- a. Patients diagnosed with suspected or confirmed TB disease for whom in-person DOT is recommended may be given the option of enrolling in eDOT.
- b. Patients receiving 12 weekly doses of INH-RPT by DOT for treatment of LTBI may also be considered for use of eDOT (although the protocols and procedures will differ.)

Enrollment criteria

Patients can be identified at any point in their treatment for enrollment in eDOT and may opt to return to in-person DOT at any time; the local health department might also have a patient return to in-person DOT during the course of treatment. eDOT may be used for short time periods (ie. travel, religious observance) or for the remainder of treatment. All patients should be motivated to complete treatment and must meet the following enrollment criteria:

- a. Demonstrated proficiency in using mobile technology (smartphone, tablet, or computer) after 1–2 training sessions (see below) with state or local health department staff.
- b. Ability to accurately identify medications and self-administer by mouth.
- c. Ability to communicate in English or another language spoken by the assigned eDOT worker (or available via a language translation service).
- d. Access to a location that supports patient confidentiality (i.e. private room or separate area) based on patient needs.
- e. Demonstrated $\geq 80\%$ adherence rate with in-person DOT for at least 2 weeks is recommended but not required; ability to adhere to the regimen should be evaluated by the DOT/eDOT worker prior to starting eDOT.

Exclusion Criteria

Patients with any of the following characteristics should not be enrolled in eDOT:

- a. Patients at risk for hepatic complications
- b. Pediatric patients <18 years old [exception: eDOT may be used to observe parents of infants administer medication or on a case by case basis with adolescents with parental permission.]
- c. Patients with disabilities that preclude full participation in eDOT (ie. vision problems, hearing problems)
- d. Patients at risk for poor adherence (e.g., homeless, substance abuse, prior TB treatment, psychiatric illness, memory impairment)
- e. Eligibility for multi-drug resistant TB patients should be made on a case by case basis.

Discontinuation Criteria

In addition to the above exclusion criteria, patients in the following categories should be discontinued from eDOT and restarted on in-person DOT. Patients may be reassessed for eligibility for eDOT if issues are resolved during the course of treatment.

- a. Patients who experience severe adverse reactions to prescribed medication
- b. Patients who consistently miss eDOT appointments, defined as missing:
 - a) 3–5 days during the initiation phase of treatment for TB disease
 - b) 1–2 weeks during the continuation phase of treatment for TB disease
 - c) 1 dose of INH-RPT treatment of LTBI
- c. Patients who miss monthly medical follow-up visits or in-person meetings with the case manager/TB nurse for medication distribution

Project Management Roles and Responsibilities

Case managers in the TB Control Program will maintain a record of patients started on eDOT in collaboration with local health department staff. As with in-person DOT, they will assist in coordination of care and provide technical assistance as necessary.

Local health department staff are responsible for ensuring adherence with treatment and medical visits, assessing treatment response and progress, and documenting each observation encounter and outcome, adverse events, and technical issues with eDOT using the specific eDOT log. They should notify the TB Control Program of any issues during treatment as they would for all patients as well as any issues directly related to the use of eDOT (i.e. technological problems.)

Decisions regarding patient eligibility for eDOT should be made by the local health department in conjunction with the TB Control program case manager and the patient's physician.

Hardware

DPH case managers and LHD staff should use their government assigned workstations or smartphones where possible, but may choose to use personal devices as necessary. In the future, devices could be provided to the patient to be used while enrolled in the eDOT program. The patient would be responsible for reporting any malfunctions or technology-related issues to their local health department and the DPH case manager.

Software

Two platforms are recommended for use as part of the eDOT protocol.

VSee

VSee is a free peer-to-peer video conferencing platform with FIPS 140-2 data encryption to comply with HIPAA. It supports private and group video conferencing (allowing for consultations), screen-sharing with annotation, file-sharing, and instant messaging (standalone and during video chat.) It can be used with any operating system; on computers using the downloadable software and on smartphones and tablets using the app. A webcam and microphone might be needed if the device does not have these built-in functionalities.

FaceTime

FaceTime is a videotelephony and voice over IP software application for supported mobile devices running iOS and Macintosh computers running Mac OS X 10.6.6 onwards equipped with cameras. It supports HIPAA-compliant two-way video conferencing. It is not supported on Windows or android devices. FaceTime is an option only if both the DOT worker and the patient have Apple devices.

There might be other platforms available that could serve the needs of both the patient and staff performing DOT but the compliance of the software would need to be evaluated for ensuring confidentiality (e.g. HIPAA compliance).

Reimbursement

The TB Control Program will reimburse for eDOT visits at the rate for office visits.

Incentive gift cards may be used to purchase data plans and/or phones for patients as needed.

eDOT Procedures

Before

1. All patients who meet the enrollment criteria and agree to participate in eDOT should sign an acknowledgement of the procedures and a statement of responsibility for any devices loaned to them from the TB Control Program or the local health department.
2. Patient Training - The DOT worker/case manager should arrange 1 or 2 initial encounters with the patient to assess the patient's capabilities and determine logistics for appropriate use of the device/equipment. On the first day at the clinic or in the patient's home, the case manager should:
 - a. Explain the eDOT program to ensure clear understanding of his/her rights and responsibilities when receiving eDOT.
 - b. Counsel the patient on the importance of adherence to treatment and keeping appointments as well as inform him/her about discontinuation criteria.
 - c. Download the VSee or FaceTime software or app onto patient's device as necessary.
 - d. Demonstrate the device controls (eg. positioning the camera, changing the volume) and the use of the software.
 - e. Test the equipment while in the home/clinic setting (troubleshoot Wi-Fi connectivity issues).
 - f. Observe the patient performing the first video DOT session while a supervisor or designee calls the patient from the LHD or DPH office.
3. Scheduling - The DOT worker/case manager should arrange a convenient date and time for the eDOT appointments in conjunction with the patient. At the end of each eDOT encounter, the case manager should confirm the subsequent appointment as well as provide reminders for upcoming medical appointments.
4. Patient and DOT worker will collaboratively set standards for communication (e.g. who will initiate video calls) and notification of missed or late appointments (e.g. decide whether a text message will be sent through the video conferencing software or via phone).
5. The patient should have a predetermined supply of medication (e.g. weekly or monthly) available prior to beginning eDOT. The personnel performing eDOT should arrange a set time for the video call with the patient. During the video call the patient should be expected to display the medications onscreen. The health worker should then witness the patient swallowing the medication.

During

6. The patient should call the case manager or DOT worker at the agreed upon eDOT appointment time. The patient should set up all medications, beverage, and technological equipment prior to the appointment time to facilitate timely eDOT visits.
7. TB staff should confirm the patient identity and screen for adverse drug reactions and current health status, following the standard medication monitoring procedures.
8. The patient should describe each TB medication (name, number of pills) and display the medications on screen.
9. The patient should use a clear glass and swallow each medication, one at a time, and open his/her mouth after each pill has been swallowed. The case manager should observe the patient swallow the pills and document the outcome of the eDOT encounter. Patients who wish to adapt their pill-swallowing technique (e.g. take all pills at once) may do so in collaboration with the DOT worker.
10. The DOT worker should confirm the day and time for the next eDOT call and provide reminders for any upcoming clinical appointments or laboratory testing. As both parties become more comfortable with the procedure, this process should become easier and more efficient.
11. In case of technical failure, the case manager should arrange an in-person home visit to avoid interruption of the DOT treatment.

After

12. The DOT worker should document the eDOT visit on the appropriate log and will contact the case manager at the TB Control Program regarding any concerns.

Tips for Successful eDOT

For Patients:

1. Use a pillbox, small clear cup, or pill bottle caps to portion out correct doses before the eDOT call. Preparation will make the visits timelier.
2. Set an alarm to remind you of appointments.
3. In order to create a VSee account, you need to sign up with a valid email address. Once you have signed up for the VSee account, the email address simply acts as your username and you do NOT need to be logged into your email in order to use the application. If you do not have an active email account, you can sign up for one for free using one of the following websites:
 - a) Gmail (google) – www.gmail.com
 - b) Yahoo! Mail – www.mail.yahoo.com

For Nurses/Case Managers:

1. These are guidelines that can be adapted to fit your program requirements and the needs of your patients. Supporting documentation (i.e. the eDOT Patient Agreement Form) can also be revised to better serve your needs.
2. If you are able to establish a consistent time for eDOT with the patient, you may wish to add it to the eDOT Patient Agreement Form as part of the informal contract.
3. You can use enrollment in eDOT as an incentive for patients – educate patients at the very start of therapy or at initial privacy complaints regarding eDOT as an option.
4. Consult the TB Control Program for questions or training.

Electronic Directly Observed Therapy (eDOT) Agreement Form (sample)

Client Name: _____
(printed)

Parent/Guardian: _____
(printed)

I am aware that I have been diagnosed with Tuberculosis (TB) and will need a long course of medications. The current standard of care in Connecticut is for doses of TB medications to be observed in order to ensure adherence to treatment. Directly observed therapy (DOT) is generally done in the patient’s home or at the health department. By signing this document, I voluntarily agree to use VSee or Facetime video conference software in place of in-person DOT visits.

I understand that:

- During each eDOT call, _____ (insert name of LHD or DOT worker) will observe me swallowing tuberculosis medications.
- He/She will not save or archive any eDOT session.
- The video conferencing software is secure however I am responsible for the internet privacy settings on downloaded software and on my electronic device.
- I may choose to switch back to standard in-person DOT at any time.
- I must keep all my eDOT appointments and clinic appointments in order to continue eDOT. If I do not keep my appointments satisfactorily, I may be required to return to in-person DOT.

If I have any questions, or need assistance in setting up or performing eDOT, I agree to contact _____ (LHD or DOT worker) at _____ (phone).

By signing below, you acknowledge being counseled on eDOT and understand the above checklist.

Client

Date

LHD Employee

Date

Electronic Directly Observed Therapy (eDOT) Checklist (sample)

The current standard of care in Connecticut is for doses of TB medications to be observed in order to ensure adherence to treatment and monitor for side effects. Directly observed therapy (DOT) is generally done in the patient's home or at the health department. Electronic DOT (eDOT) using video conferencing software can be used in place of in person DOT once a patient is tolerating a stable regimen, understands the process and is willing to follow the protocol set by health department or DOT worker. The following checklist should be reviewed with the patient before starting eDOT.

- Each eDOT visit will take place at a predetermined time each day.
- During each eDOT call, the patient will be observed swallowing tuberculosis medications.
- The patient will be educated on how to show and consume each medication.
- All eDOT sessions will be live and won't be recorded.
- The video conferencing software being used (VSee or Facetime) is considered secure but the patient is responsible for the internet privacy settings on downloaded software and on their electronic device.
- A patient may be switched back to standard in-person DOT at their own request or the health department's request at any time.
- The patient must keep eDOT appointments and clinic appointments in order to continue eDOT.

Client

Date

DOT worker

Date