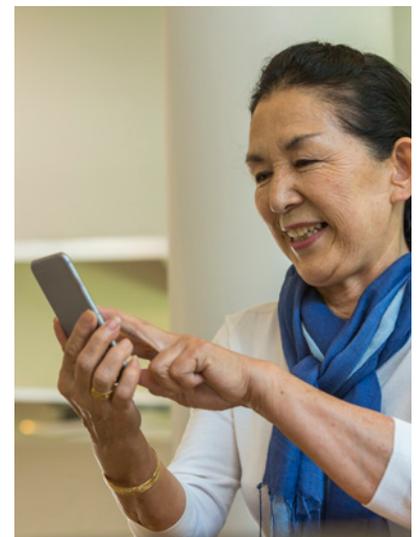
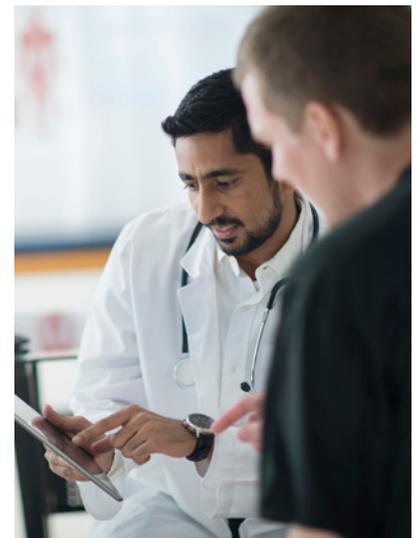


Implementing an Electronic Directly Observed Therapy (eDOT) Program: A Toolkit for Tuberculosis (TB) Programs



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Disclaimer of Medical and Legal Advice: The following toolkit is provided for information only. The information does not represent legal or medical advice. Additionally, this toolkit is not an endorsement for the use of eDOT in the treatment of latent TB infection or TB disease. Further studies are required to evaluate the effectiveness of eDOT.

I. Background

Background

Directly observed therapy (DOT) is the most effective strategy for ensuring that tuberculosis (TB) patients adhere to treatment. DOT means that a health care worker or another designated person watches the TB patient swallow each dose of the prescribed drugs. However, because DOT can be time and resource intensive, some TB programs have expressed an interest in alternative, cost-efficient methods of delivering DOT for both TB disease and latent TB infection (LTBI). Electronic DOT (eDOT) is an alternative method to in-person DOT in which a patient is remotely observed (e.g., over a smartphone) taking his or her TB medication.

Purpose

The purpose of this toolkit is to assist TB programs in developing and implementing a TB eDOT program. There are a wide variety of eDOT programs throughout the United States. These eDOT programs have been designed to meet their respective TB program's patient needs, utilize available resources, and meet management and regulation concerns. Because eDOT programs can be very diverse to accommodate individual TB program needs, this toolkit will provide general information that can be tailored to fit your program needs.

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- ▶ New Jersey Department of Health
- ▶ Public Health Seattle-King County, Washington
- ▶ Snohomish Health District, Washington
- ▶ Tacoma-Pierce County Health Department, Washington
- ▶ Washington State Department of Health

II. Introduction

What is eDOT?

eDOT is the use of electronic technologies to remotely monitor TB patients ingesting their medication, either in real-time or recorded. In addition to eDOT, this type of DOT is sometimes referred to as virtually observed therapy (VOT), mobile DOT (mDOT), remote DOT, video DOT (VDOT), and video-enhanced therapy (VET).

What Technologies Can be Used to Administer eDOT?

There are multiple technologies available to administer eDOT. Some patients will use their own personal device, as long as the technology is compatible with the health department's technology and patient security and privacy are not compromised.

Depending on the resources of the program, the following are some examples of the types of communication devices that can be used:

- ▶ Smartphone
- ▶ Tablet
- ▶ Computer with webcam

With each of these devices, there are a multitude of different software programs that can be used to provide eDOT (please refer to Appendix A for a list of technologies). Additionally, eDOT encounters can either be live or recorded. During a live eDOT visit, the health care worker and the patient schedule a specific day and time to meet virtually, and the health care worker watches the patient take his or her medication in real-time. This allows for the health care worker to ask the patient how he or she is feeling, check the medications before they are taken, ask the patient if he or she is experiencing any side effects, and answer any questions the patient may have. It also allows for the health care worker to continue to build rapport with the patient. In contrast, recorded eDOT is when the health care worker and the patient do not set a specific time to meet, and the patient records himself or herself taking the medications. The patient then saves the recording and sends it to the health department for review. This option may be useful when patient schedules do not align with the health department, and the health care worker is unable to watch the patient live.

Is eDOT Right for Your Program and Your TB Patients?

There are many considerations when deciding to develop and implement an eDOT program. It should first and foremost be used only when it has been determined that patients' health will not be at risk.

Benefits of eDOT

The benefits to having an eDOT program include convenience for patients and staff, in addition to reduced staff travel cost and time. It is important to note that eDOT is not a complete replacement for in-person DOT. *In other words, it doesn't have to be an all or nothing approach; it may work for some patients, but not all, and it may work for some part of treatment, but not all.* Additionally, it is likely that a patient will behave the same whether on eDOT or receiving in-person DOT. If the patient has issues around reliability, honesty, substance abuse, or any other behavior that might interfere with adherence, these behaviors may not change just because he or she switches from an in-person DOT to an eDOT program.

Challenges of eDOT

Monitoring adverse reactions to TB medications is a major concern when using eDOT. Patients at risk for adverse effects should have clinical evaluations at least monthly to identify possible adverse reactions to medications, assess adherence, and determine treatment efficacy. Patients should be instructed to look for symptoms associated with the most common and most serious reactions to the medications they are taking.

Other challenges to using eDOT could be the lost opportunity of building rapport with the patient through in-person visits. Some patients thrive on personal contact and may not be motivated to remain adherent to treatment by eDOT. Building a personal connection with the patient to support treatment completion is vital regardless of the mode of delivering DOT.

Security and Patient Privacy

Security and the protection of a patient's privacy are of paramount importance when using eDOT. There are legal, ethical, and moral issues at stake when patients transmit private health data, either in real-time or recorded. For information about the legal permissibility of eDOT, TB programs may want to refer to The Network for Public Health Law, which conducted an analysis of the legal permissibility of eDOT in several states: www.networkforphl.org/the_network_blog/2015/01/21/538/video_directly_observed_therapy_for_tuberculosis_legal_and_practical_issues.

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides national standards for protecting the privacy of health information. The Privacy Rule regulates how organizations and health care workers use and disclose certain individually identifiable health information. Health departments should be well aware of HIPAA requirements. Because eDOT is a relatively new method of health care delivery, there are aspects of it that may not have been considered when HIPAA was passed. Having both an information technology (IT) representative and a legal representative on your workgroup (see workgroup information below) is crucial in understanding both the state and federal laws that will govern your choice to implement your own eDOT program.

III. Preparing for Implementation

To implement an eDOT program, it can be helpful to follow the steps below:

1. Convene an eDOT workgroup
2. Identify resources and technologies
3. Develop eDOT policies and protocols
4. Train staff

1. Convene an eDOT Workgroup

One of the first steps to starting an eDOT program is to establish an eDOT workgroup with representatives from the health department's IT, clinical, legal, outreach, and training and education staff. Representatives should have decision-making authority to enhance the ability of the workgroup to develop and implement the program. Having representatives from all the departments involved creates a sense of ownership, provides an opportunity to problem solve, and increases the chance for success.

2. Identify Resources and Technologies

While trying to establish an eDOT program, TB programs will need to research available technologies that are compatible with their agency's security needs, as well as allow for the level of privacy needed to secure patient information. Thus, TB programs should work with their IT departments to identify technologies that can both be used on health department equipment, as well as technologies that are HIPAA compliant.

When researching technologies, the following factors may be useful to consider:

- ▶ Is the technology HIPAA compliant?
- ▶ What type of communication device is needed (e.g., can the technology be used on a phone, computer, or tablet?)
- ▶ How much are the initial costs of the software?
- ▶ How much are the annual costs (e.g., licensing)?
- ▶ What are the IT requirements (e.g., bandwidth, data)?
- ▶ How easy is the program to use?

Additionally, health departments will need to determine what type of communication device to use with the eDOT program, as well as who will supply the device. For example, health departments will need to determine whether patients can use their own devices or whether the health department will provide a device to the patient. If the health department provides one, they should consider having the patient sign a loan agreement form which explains their responsibilities for the general care and security of the device, as well as how the patient may or may not use it for their own personal use (sample patient agreement forms are provided in Appendices B and C). In contrast, if the patient is allowed to use his or her own device, the health department may need to explain to patients that the health department will not cover excess data charges as a result of participation in eDOT, or they may want to provide a small monetary incentive to cover any excess charges.

3. Develop eDOT policies and protocols

Health departments should develop their own policies and protocols on the use of eDOT with their TB patients. The eDOT policy should be written to reflect the health department's philosophy on the use of eDOT. Below is a sample policy statement:

The state will offer electronic directly observed therapy (eDOT) to patients receiving treatment for suspected or confirmed TB disease who meet enrollment criteria. eDOT is an alternative method of ensuring that patients adhere to treatment. Patients may choose in-person DOT, eDOT, or a combination. Continued participation in the eDOT program will depend on adherence and monthly medical follow-up visits.

Below are some samples of patient criteria used by other health departments.

Examples of inclusion criteria

- ▶ Stabilized on treatment for at least 2 weeks and noninfectious
- ▶ Motivated patient (as determined by case manager)
- ▶ Demonstrated adherence to treatment
- ▶ English speaking or ability to effectively communicate with the health care worker
- ▶ Drug-susceptible disease
- ▶ Converted sputum smear and culture to negative
- ▶ No current alcohol or drug use
- ▶ Managing physician accepts the eDOT approach
- ▶ Proficiency in using a smartphone or other technology
- ▶ Able to accurately identify each medication

Examples of exclusion criteria

- ▶ Infectious patients
- ▶ Adherence issues
- ▶ Language barriers
- ▶ Multidrug-resistance
- ▶ Minors without accompanying adult
- ▶ Immunocompromised
- ▶ Patient experiences adverse reactions
- ▶ Patients at risk for hepatic complications while receiving anti-TB medications
- ▶ Patients with disabilities that prevent full participation in eDOT such as hearing or vision disabilities, or physically challenged

Additionally, health departments will need to determine where and when their staff can administer eDOT encounters. For example, will staff only provide eDOT during regular business hours while at the office, or can staff provide eDOT outside of regular business hours? To make this decision, health departments should consider the privacy of patients. During eDOT encounters, staff need to be aware of his or her surroundings. For example, during eDOT encounters, other people should not be able to hear the patient's voice coming through the speaker or see the patient's face on the screen. To help maintain privacy, headphones should be worn and encounters should be done in a place that allows for privacy. Some locations have set up privacy screens to hide the computer monitors from others.

4. Train Staff

Staff should be trained on how to use the technology, as well as how to conduct an eDOT encounter.

The following steps outline the general real-time eDOT process:

- ▶ Prior to each eDOT visit, the health care worker should review the patient information (e.g., chart, medications, notes, appointment date and times).
- ▶ Contact the patient at the specified time (See Appendix D for a sample script for a real-time eDOT encounter).
- ▶ Ask the patient if he/she is having any adverse reactions, address any concerns, and advise the patient to seek medical care if necessary.
- ▶ Ask the patient to verify his/her medications with a verbal and visual pill count.
- ▶ Observe the patient ingest all of the medication.
- ▶ Have the patient confirm verbally that he/she has taken all of the medication and by opening their mouth for a visual inspection.
- ▶ Confirm the next eDOT visit date and time, and any upcoming in-person clinic visits.
- ▶ Remind the patient to call the health care worker if they experience any adverse reactions; ensure the patient knows who and how to contact regarding adverse reactions.

For recorded eDOT the steps are similar to the steps for real-time eDOT, with a few exceptions. The patient records himself or herself and there is no live interaction with the health care worker. The patient logs into a secure system approved by the health department, identifies each pill by name and number of pills being taken, takes the medication, states when the next recording is due, and then sends the recording to the health department. The staff member then views the recording to ensure that the appropriate medication was taken. For recorded eDOT, as with other forms of eDOT, it is important that patients continue to comply with regularly scheduled in-person appointments to assess for any adverse reactions.

IV. Implementation

Once all the planning, decision making, and trainings have been completed, the program can begin enrolling patients in eDOT.

The health care worker should discuss the option of eDOT with patients who meet the criteria. The patients who choose to enroll should sign all necessary paperwork. The next step would be to teach the patients how to use the technology (e.g., how to log into the system, and how to record or live stream).

Additionally, health care workers should teach patients the best way to conduct an eDOT visit. For example:

- ▶ The patient should be in a well-lit space.
- ▶ The health care worker must be able to see the patient's face.
- ▶ The patient should have a glass of water nearby to take their pills.
- ▶ The patient should show each pill before taking it; state the name of the medication, shape, size, color, and the number of pills he/she is taking.
- ▶ The health care worker should ask how the patient is feeling to assess adverse reactions, and advise the patient to seek care if necessary.
- ▶ The health care worker should confirm the day and time for the next eDOT visit.

All eDOT encounters (and attempts) should be documented by the health department.

There may be a need to re-assess the patient's ability to participate in eDOT if the patient becomes non-adherent, experiences adverse reactions, communication equipment is lost, or clinical status worsens.

V. Monitoring and Evaluation

When evaluating an eDOT program, staff should look at:

- ▶ **Completion rates**
- ▶ Specifically, TB programs can assess the number of patients who
 - Complete treatment
 - Are lost to follow-up
 - Refuse further treatment
 - Transfer or move
 - Experience treatment failure
 - Die (with death attributable to TB)
- ▶ **Adherence to treatment**
- ▶ **Patient satisfaction with eDOT**
- ▶ To assess patient satisfaction with eDOT, programs can assess
 - Frequency and reasons patients discontinue eDOT
 - Patient perceptions of quality of care and overall satisfaction with eDOT and patient-staff relationships/rapport, and patients' confidence in their ability to adhere to treatment
- ▶ **Cost analysis**
- ▶ To assess the cost of eDOT, programs can look at
 - Staff time and transportation costs for eDOT versus in-person DOT
 - Cost of hardware/equipment
 - Cost of software and licenses

VI. Appendices

Appendix A:
Technology Options for Electronic Directly Observed Therapy (eDOT)

Appendix B:
Patient Electronic Directly Observed Therapy (eDOT) Agreement Form

Appendix C:
Loaner Agreement for Electronic Directly Observed Therapy (eDOT) Device

Appendix D:
**Health Care Provider Script for Electronic Directly Observed Therapy (eDOT)
Real-Time Encounter**

Appendix A: Technology Options for Electronic Directly Observed Therapy (eDOT)

The Centers for Disease Control and Prevention (CDC) has not made any endorsement for the use of electronic directly observed therapy (eDOT) and does not endorse any particular product or application for use in eDOT. These options are provided for review and consideration at the individual TB program level, and should be reviewed with input from local public health staff and local legal counsel. This list is not comprehensive; and due to the rapid change in technology, we recommend that programs conduct further research to ensure they have the most current options available. In addition, CDC has made no assessment on whether these products are compliant with state or federal privacy laws, including HIPAA.

- ▶ AiCure: (<https://www.aicure.com>)
- ▶ Emocha: miDOT (<https://www.emocha.com/solutions/midot>)
- ▶ FaceTime (<https://support.apple.com/en-us/HT204380>)
- ▶ Fuze (www.fuze.com)
- ▶ HipaaBridge (<http://hipaabridge.com>)
- ▶ ooVoo (www.oovoo.com)
- ▶ Skype (www.skype.com/en)
- ▶ SureAdhere (<http://sureadhere.com>)
- ▶ Tango (www.tango.me)

Adapted from the Minnesota Department of Health

Appendix B: Patient Electronic Directly Observed Therapy (eDOT) Agreement Form

Date: ____ / ____ / ____

Patient Name: _____

Provider Name: _____

I, _____, understand that I have been diagnosed with tuberculosis (TB) and have been prescribed medication by a physician to treat this disease. If my disease goes untreated, there may be serious consequences:

- ▶ My illness may last longer or become more severe
- ▶ I may spread TB to others
- ▶ I may develop and spread drug-resistant TB
- ▶ I may die from TB

During my treatment, observation will be performed remotely using electronic directly observed therapy (eDOT). This may be done using a smartphone or a computer. I understand that the equipment provided to me (if any) is property of the Health Department. I agree to return all the equipment to the Health Department at the end of my treatment or upon request. I agree to allow the Health Department staff watch me take my medicines via eDOT at a prearranged time.

To complete my treatment and protect my family and friends, I will:

1. Come to the health department clinic to give sputum specimens when requested.
2. Keep all appointments for medical evaluation and x-rays.
3. Participate in eDOT at the agreed upon time with the health care worker. If for any reason I am unable to keep an appointment, I will notify the health department as soon as possible to set up another appointment.

eDOT Day(s): _____ Time: _____

I understand that I may switch back to standard in-person DOT at any time during my treatment.

I have read this agreement and understand the following (initial each box):

- My adherence to this treatment regimen is very important.
- I am responsible for the three tasks mentioned above.
- If I fail to complete these tasks, legal action may be taken to make sure I complete treatment.

Patient Signature: _____ Date: ____ / ____ / ____

Health Department
Representative Signature: _____ Date: ____ / ____ / ____

Adapted from the CDC Self-Study Modules on Tuberculosis, Module 6: Managing Tuberculosis Patients and Improving Adherence

Appendix C: Loaner Agreement for Electronic Directly Observed Therapy (eDOT) Device

Patient Name: _____ Date of Birth: ____ / ____ / ____

Device (Phone/Tablet/Computer) Type: _____ Device Number: _____

Date Device Received: ____ / ____ / ____ Expected Date of Return: ____ / ____ / ____

I agree to the statements below:

- ▶ I received this device to use for my electronic directly observed therapy (eDOT). The device and its accessories are property of the health department; I agree to return all equipment to the health department by the date specified above.
- ▶ If the device or its accessories are lost or damaged, I may be responsible for the cost of repair or replacement.
- ▶ I will take all reasonable steps to keep the device and its accessories safe and working. I will:
 - Not loan the device to others.
 - Protect the device from extreme temperatures.
 - Use the protective case when carried, and take care to not damage the screen.
 - Never leave the device in an unsecured area or visible in a locked or unlocked vehicle.
 - Not share passwords with unapproved persons.
- ▶ I am responsible for using good judgment about acceptable use of the device, and I am responsible for any additional software, apps, or other files loaded onto the device.

Unacceptable use: Unacceptable uses include, but are not limited to:

- ▶ Engaging in illegal or offensive online activity such as sending or receiving abusive, pornographic, sexually explicit, violent, or threatening material.
- ▶ Sending or receiving of material that violates state or federal laws is not allowed. This includes, but is not limited to, confidential information, copyrighted material, online piracy, and threatening material.
- ▶ Introducing harmful code such as viruses, worms, spyware, malware, and adware.

Patient / Legal Representative: _____ Date: ____ / ____ / ____

Health Department

Staff Member Signature: _____ Date: ____ / ____ / ____

Adapted from Clark County Public Health (Washington State)

Appendix D: Health Care Provider Script for Electronic Directly Observed Therapy (eDOT) Real-Time Encounter

1. Staff and patient connect at the scheduled time using the agreed upon technology.
2. "Hello, this is _____ (health care provider)."
3. "Can you please confirm that I am speaking to _____ (patient)?"
4. "Have you had any negative reactions to the TB medicine?"
If yes, follow your health department's protocol to ensure the patient receives medical attention.
If no adverse reactions, then proceed with step #5.
5. "Show me each pill separately and say the name of each medication."
6. "Put each pill in your mouth and drink at least 4 ounces of fluid after you take your pills."
7. "Please open your mouth and show me that the pills were swallowed."
8. "Let's confirm the time and date for the next eDOT appointment (or in-person clinic appointment if upcoming). Your next eDOT appointment is tomorrow at (time). Your next in-person clinic appointment is scheduled for (day) at (time)."
9. "Do you have any other concerns?"
10. "Thank you. I look forward to talking with you tomorrow at (confirmed time of next call). Good-bye."

Adapted from the New Jersey Department of Health