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eDOT Protocol Requirements

Electronic Directly Observed Therapy (eDOT)

Policy: eDOT is a method to provide directly observed therapy (DOT) that can be used to enhance services provided to tuberculosis (TB) patients in Missouri.

Purpose: The purpose of this protocol is to provide local public health agencies in Missouri guidance on using eDOT to ensure medication adherence of TB patients.

1. eDOT is the use of electronic technologies to remotely monitor TB patients ingesting their medication, either in real-time or via recordings.
2. eDOT provides flexibility for both the provider and patient for DOT because in-person visits are only required once per month. Video sessions can be recorded at any time during the day and eliminate the need to have scheduled appointments for DOT sessions. This may increase medication adherence for some patients.
3. The only in-person visits required for eDOT are for monthly patient monitoring (see [Section 4.03](#)), medication resupply, and follow up visits as needed. For this reason, travel costs for provider and patient are greatly reduced once a patient is enrolled in eDOT.
4. eDOT is a more private way to monitor medication adherence, as the DOT provider will not be observed by others to be routinely visiting the patient.



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EDOT Protocol

Policy: The Missouri TB Elimination Program provides eDOT system access at no charge for all local public health agencies (LPHAs). eDOT is one of many tools for TB case management, and is provided as an option for LPHAs that wish to use it for their TB clients.

Purpose: To provide eDOT protocols for use with Missouri TB Elimination sponsored eDOT resources.

1. Equipment

- a. Equipment used for eDOT may include the patient's personal property, such as a smart phone, at the discretion of the LPHA. If the patient is to use their personal mobile device for eDOT, the patient must agree to pay the cost of data required to transmit videos and text message reminders.
- b. The Missouri TB Elimination Program may provide smartphones for the exclusive purpose of eDOT, if funding is available. LPHAs should request smartphones through Tuberculosis Incentives and Enablers Program processes, as outlined in [Section 4.06](#).
- c. The minimum free memory needed to upload each video for purposes of eDOT through Missouri TB Elimination Program contractor software is 300MB.
- d. Data plans for equipment must be sufficient for full eDOT functionality.

2. Confidentiality Provisions

- a. All eDOT processes and procedures must preserve confidentiality of patient health information.
- b. The Missouri TB Elimination Program eDOT Contractor software is HIPAA compliant and secure.
- c. The Missouri TB Elimination Program eDOT Contractor software does not allow access to videos from the mobile device used for eDOT recordings.

3. Patient Agreement and Consent

- a. The LPHA must obtain signed and dated eDOT Patient Consent Form ([Appendix A](#)) prior to beginning eDOT using the Missouri TB Elimination Program's Contractor software, to be retained in the patient's file.

4. Monthly in Person DOT/Patient Monitoring

- a. At a minimum, the patient must have one in-person DOT session per month. During this visit, staff shall:
 - i. Give the patient one month of medications and observe the patient taking that day's doses
 - ii. Answer patient questions and address concerns
 - iii. Assess patient response to treatment and address adverse effects
 - iv. Conduct monthly patient monitoring ([see Section 4.03](#))



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Patient Eligibility for eDOT

Policy: Patients who elect to participate in eDOT must meet minimum qualifications to ensure standards of care and medication adherence.

Purpose: To establish patient eligibility criteria for eDOT participation.

1. Patient Qualifications

Each patient must be assessed to determine eligibility for eDOT participation. At a minimum, the patient must:

- a. Have drug susceptible TB disease or be on a 3HP regimen for latent TB infection (LTBI) or is a contact to a current active disease case or have LTBI and be approved by the state TB nurse. **A patient with MDR or XDR TB is not eligible for eDOT.**
- b. Be 15 years of age or older (children under 15 years of age must be approved by the state TB Program nurse). For patients younger than 18, a legal guardian must co-sign the consent form and equipment use agreement, if applicable.
- c. Have a positive attitude toward treatment and be motivated toward treatment completion as determined by LPHA DOT staff.
- d. Be at low risk for poor adherence. Factors that influence adherence include, but are not limited to: homelessness, a history of recent substance abuse, previous non-compliance to treatment, and memory impairment.
- e. Have stable housing or other designated eDOT location with a quiet area to minimize distractions during eDOT sessions, a well-lit recording area, and a secure place to store medications.
- f. Be able to communicate in a common language with DOT staff (some exceptions may apply but must be discussed and approved by the state TB Program nurse) **or** have an interpreter available during eDOT sessions. Family members **cannot** be named as interpreters for purposes of medical case management, including eDOT.
- g. Be able to accurately identify medications and prepare them for eDOT sessions.
- h. Be able to communicate if they are having any adverse reactions (ill, sick).
- i. Be able to take all medications in an allotted time frame as determined by the LPHA.
- j. Demonstrate skill in operating eDOT equipment and software (see 3. Patient Training below)

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2. Patient Disqualifications

Some patients may need to be disqualified from eDOT after they begin participation. Disqualifying events include:

- a. Illegal activities taking place in the patient's designated eDOT location as reported to law enforcement or observed on eDOT recordings, including indecent conduct.
- b. The patient loses access to designated eDOT location with no available alternative location.
- c. The patient can no longer accommodate use of eDOT in confidential setting or maintain utility service so that adequate lighting is available for eDOT sessions
- d. The patient misses 1 intermittent or 2 or more daily eDOT session(s) without notifying case manager.
- e. The patient misses monthly in-person DOT appointment.
- f. The patient is no longer able to use eDOT equipment for any reason.
- g. Loss of interpreter, if applicable.
- h. Patient is not adhering to the eDOT protocol, signed patient agreement, confidentiality, HIPPA compliance or no longer has access to required equipment.

3. Patient Training

Each patient that wishes to participate in eDOT must successfully complete training to correctly use eDOT equipment and/or software. Training allows the patient to ask questions and practice eDOT under the supervision of a qualified DOT staff member. Patient training must include the following:

- a. A visit to the patient's residence to record an eDOT session is required.
 - i. During the visit, the patient will receive education about the use of equipment. The patient will also sign the eDOT Patient Consent Form ([Appendix A](#)) and perform the first eDOT session. The patient will complete a practice recording under the supervision of DOT staff. A second recording must be completed while the patient is taking their medications (eDOT), without assistance. After a successful eDOT session is complete and recorded, then notify the state TB Program nurse to approve the session. The patient and DOT staff agree on days and times for eDOT sessions. Some flexibility in eDOT times may be permitted at the discretion of the LPHA, such as allowing evening dose times for patients with family or work obligations during the day.
 - ii. A second visit may be offered if the patient or DOT staff believes it is warranted.
 - iii. Patient should be instructed to **hold the medications** if they experience adverse effects and to seek emergency care if needed. They should notify

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- iv. their medical provider and the LPHA for further direction as soon as possible.
- b. A patient script, or cue card, may be helpful for patients to follow during eDOT sessions. A sample training procedure with patient script is included as [Appendix B](#). Also included with Appendix B is a quick reference tool for the patient, which includes a common symptoms list with emergency contact information on one side and a pill form to help them count out their pills. Both the patient script and quick reference tool can be provided to the patient as laminated forms for use for the duration of treatment.



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DOT Staff Training and Responsibilities

Policy: Local public health agencies (LPHAs) shall provide adequate staff education about eDOT procedures and requirements prior to enrolling patients in eDOT.

Purpose: To ensure standards of care for TB patients enrolled in eDOT.

1. Staff Training/System Access

Because eDOT is a newer strategy to ensure TB patient medication adherence, most DOT staff members will require training on eDOT prior to its implementation.

- a. LPHA staff that will be using the Missouri TB Elimination Program eDOT software must take the following steps to ensure adequate training:
 - i. Review the Missouri TB Elimination Program eDOT Protocol Requirements section of the Missouri Tuberculosis (TB) Case Management Manual.
 - ii. Watched the required eDOT training videos:
<https://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/edot-training.php>
- b. Once LPHA staff have reviewed the required protocols and watched the required eDOT training videos, then send a request for Patient Manager access to the software system by sending an email to: EDOT@health.mo.gov and copy the state TB Program nurse.

2. DOT Staff Responsibilities

- a. For LPHAs using Missouri TB Elimination Program sponsored software, patient dose calendars will be monitored and downloaded by program staff, so TBC-16 forms are not required unless issues are noted.
- b. DOT staff must agree to a plan for in-person assessment if the patient experiences side effects.
- c. If medications are held, the reason(s) must be entered for that dose within the eDOT system.
- d. In the event of equipment failure, DOT staff must complete a home visit for an in-person DOT session within 24 hours.



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Appendix A-eDOT Patient Agreement and Consent Form

- | | |
|---------------------------|-------------------------------|
| Patient's full name _____ | Patient's Date of Birth _____ |
|---------------------------|-------------------------------|
- I understand I have been diagnosed with tuberculosis (TB) and I have agreed to a treatment plan. I have been given the opportunity to ask questions about my diagnosis and treatment plan and all have been answered to my satisfaction. I understand that if I do not finish my treatment plan, there may be serious outcomes:
- My illness may last longer, become more severe, or become more difficult to treat and treatment may last longer.
 - I may spread TB to others.
 - I may die from TB.
- To complete my treatment and protect my family and friends, I will:
- Keep all appointments for medical evaluation and x-rays.
 - Complete my eDOT appointments at the agreed upon time.
 - Keep my monthly in-person appointment with the LPHA staff for monthly assessment. Notify my case manager as soon as possible if I am unable to keep an appointment and reschedule.
- I am aware that the current standard of care for TB disease is for treatment to be observed, called directly observed therapy (DOT). During DOT sessions, doses are observed in person.
- I agree that during my future treatment, electronic directly observed therapy (eDOT) will be performed via a recorded video using my personal smartphone. I have been trained how to use the eDOT application (app) and am able to use it comfortably. (*Initials of staff confirming proficiency*) _____
- I understand that I am responsible for paying for data and text messaging fees that occur as a result of my eDOT sessions. I also understand that I am responsible for ensuring that there are 300 MB of free space to allow video recording and upload for my eDOT sessions.
- I agree to allow the health department worker to watch me take my medicines as if I am at the health department office. I will upload the video by 8:00 AM the following day. Failure to comply with these terms will cancel this eDOT Agreement.
- I understand I must be completely clothed as if I was attending a clinic visit during my eDOT sessions. I must also be in an area appropriate for a meeting/home consultation while recording my eDOT session. There must be good lighting so that my face, hands, and pills can be seen at all times on my eDOT session videos and the area will be free from noise. Failure to comply with these terms will cancel this eDOT Agreement.
- I understand I may switch back to standard, in-person DOT at any time I choose or as recommended.
- I understand that I MUST report any side effects immediately to my case manager and stop treatment until I'm told it's OK to resume taking them. A list of possible side effects to watch for has been provided to me.

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- I agree not to bring any financial or personal liability claim against the health department or any of their contractors, agents, officials, or employees, connected with the Missouri TB Elimination Program or my local public health agency, for any damages, expenses, or personal harm as a result of the use of eDOT.

Patient Signature: _____ / _____
Date _____

Patient Trainer: _____ / _____
Date _____

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Appendix B-Sample Training Procedure with Patient Script

Patient Training Procedure- eDOT

1. TB staff reviews the list of common side effects with the patient. The patient is instructed that if they have side effects during the course of eDOT, they are to not take the next dose and call the person on their Contact Card immediately. **Patient must be able to vocalize on camera they are “sick or ill” if the medications are making them feel sick or ill.**
2. Patient and TB staff gather the Patient Script, Pill Form, clear glass of clear liquid, and medications. Patient removes the correct dose (correct number of pills) from the medication bottle and places the dose for each drug on the correct Pill Form space.
3. Patient and TB staff activate the eDOT application (app) on phone.
4. Staff ensures clear visualization of patient (upper body and hands must be visible at all times).
5. Patient states their name and holds up picture ID, if available. If they do not have picture ID, staff provides a unique number, such as an RVCT number, to identify the patient on eDOT recording.
6. Patient holds the bottle of TB medication up to the phone’s camera so that the label can be clearly seen. Patients states the drug name and the number of pills they are taking and places them in their hand and shows their hand on camera.
7. Patient places pills in mouth and swallows them while on camera.
8. Patient opens mouth and shows staff that pills have been swallowed.
9. Patient repeats steps 6-8 for each drug until all medications have been swallowed.
10. Patient states the date and time for their next eDOT session and ends the recording in the app.

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Patient Script

Trainers: Use during training sessions to ensure patient can use this script on their own. Patients: Check your Common Side Effects list before beginning each session, and if you have any, do not take your medications and immediately call the person listed on your Contact Card.

1. Turn on the application (app) by tapping the app icon, logging in, and pressing the “Record Video” icon. Your face, hands, and pills should never leave the video.
2. Say: “Hello, this is (say your full name).”
3. Say: “Today I feel ____.” Do not take your medicine if you don’t feel well, feel different than usual or have concerns, and call the person listed on your Contact Card.
4. Show each pill container to the camera so the label can be easily read.
5. Remove the correct number of pills from each container, using your Pill Form as a guide. Place each medication on its Pill Form spot.
6. Put the pills in your hand and hold your hand to the camera so your pills can be seen on the video. Swallow pills one at a time, or all at once. Show your empty hand to the camera after taking your pills.
7. Use a clear liquid in a clear container to help you swallow your pills, like water or a clear juice.
8. When you’re done swallowing your pills, open your mouth so your video will clearly show that you swallowed all your pills.
9. Say: “Thank you. I will record again on __ (day) at __: __ (time) __ (Am/PM). Goodbye.”
10. Stop the recording by pressing the red “Record” button.
11. If you are connected to WiFi, your video will automatically upload. If not, your video will be held in “Pending” status until your device connects with WiFi. Remember that you are required to upload your videos by 8:00 AM the morning after you record them.
12. Enjoy your day!



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Pill Form

Check the list of **Common Side Effects** should you experience side effects on the back of this form **before** starting your medications.

Medication Name

Medication Name

Medication Name

Medication Name

Medication Name

Medication Name

Number of Pills

Number of Pills

DOT Staff: Fold here and laminate after filling in blanks.

Common Side Effects

If you have any of the following symptoms, **DO NOT** take your medications and **DO NOT** record your eDOT session. For emergencies, or for side effects that occur outside normal business hours go to an emergency department for medical care, then call and leave a message at the number below on the Contact Card.

- | | |
|---|--------------------------------|
| Tiredness | Weakness |
| Nausea | Vomiting |
| Loss of appetite | Weight loss |
| Stomach pain | Yellow skin or eyes (jaundice) |
| Diarrhea | Fever |
| Sore muscles | Joint pain |
| Dizziness | Headache |
| Vision changes | Eye pain |
| Itching | Rash |
| Change in color of urine or stool | |
| Tingling or numbness in fingers or toes | |

Local Health Department Contact

Name of Contact Person _____

Phone Number for Contact Person _____

Keep this card for your reference for the duration of your treatment.