HHS Public Access

Author manuscript

Int J Tuberc Lung Dis. Author manuscript; available in PMC 2024 April 01.

Published in final edited form as:

Int J Tuberc Lung Dis. 2023 April 01; 27(4): 298–307. doi:10.5588/ijtld.22.0583.

Challenges associated with electronic and in-person directly observed therapy during a randomized trial

J. M. Mangan[1], **J. Burzynski**[2], **B. Rey deCastro**[1], **M. M. Salerno**[2,3], **C. K. Lam**[1,2], **M. Macaraig**[2], **M. Reaves**[2,3], **S. Kiskadden-Bechtel**[2,3], **S. Bowers**[1,2], **C. Sathi**[2,3], **M. P. Dias**[2,3], **N. D. Goswami**[1], **A. Vernon**[4],

eDOT Study Team

[1]Division of Tuberculosis Elimination, Centers for Disease Control, Atlanta, GA

[2]Bureau of Tuberculosis Control, New York City Department of Health and Mental Hygiene, Queens, NY

[3]Division of Pulmonary, Allergy & Critical Care, Columbia University, New York, NY

[4]Division of Viral Diseases, Centers for Disease Control, Atlanta, GA, USA

SUMMARY

BACKGROUND: Electronic directly observed therapy (eDOT) has been proposed as an alternative to traditional in-person DOT (ipDOT) for monitoring TB treatment adherence. Information about the comparative performance and implementation of eDOT is limited.

METHODS: The frequency of challenges during DOT, challenge type, and effect on medication observation were documented by DOT method during a crossover, noninferiority randomized controlled trial. A logistic mixed-effects model that adjusted for the study design was used to estimate the percentage of successfully observed doses when challenges occurred.

RESULTS: A total of 20,097 medication doses were scheduled for observation with either eDOT (15,405/20,097; 76.7%) or ipDOT (4,692/20,097; 23.3%) for 213 study participants. In total, one or more challenges occurred during 17.3% (2,672/15,405) of eDOT sessions and 15.6% (730/4,692) of ipDOT sessions. Among 4,374 documented challenges, 27.3% (n = 1,192) were characterized as technical, 65.9% (n = 2,881) were patient-related, and 6.9% (n = 301) were program-related. Estimated from the logistic model (n = 6,782 doses, 173 participants), the adjusted percentage of doses successfully observed during problematic sessions was 21.7% (95% CI 11.2–37.8) for eDOT and 4.2% (95% CI 1.1–14.7) for ipDOT.

CONCLUSION: Compared to ipDOT, challenges were encountered in a slightly higher percentage of eDOT sessions but were more often resolved to enable successful dose observation during problematic sessions.

Correspondence to: Joan M Mangan, Centers for Disease Control and Prevention, Division of Tuberculosis Elimination, 1600 Clifton Rd NE, MS US12-4, Atlanta, GA 30329-4018, USA. bpy4@cdc.gov.

Trial Registration: ClinicalTrials.gov Identifier: NCT03266003 (https://clinicaltrials.gov/ct2/show/NCT03266003).

Disclaimer: Opinions expressed herein are those of the authors, and do not necessarily reflect the official view of the U.S. Centers for Disease Control and Prevention nor of the New York City Bureau of Tuberculosis Control.

Conflicts of interest: none declared.

RÉSUMÉ

Une forme électronique de traitement sous observation directe (eDOT) a été proposée comme alternative à la traditionnelle DOT en personne (ipDOT) pour le suivi de l'observance du traitement antituberculeux. Les données relatives aux performances comparatives et à la mise en place de l'eDOT sont limitées.

La fréquence des problèmes rencontrés pendant la DOT, le type de problèmes et l'effet sur l'observation de la prise du traitement ont été documentés en utilisant la stratégie DOT pendant un essai contro^lé randomisé croisé de non-infériorité. Un modèle logistique à effets mixtes ajusté au schéma de l'étude a été utilisé pour estimer le pourcentage de doses dont la prise a été observée avec succès en cas de problèmes.

Au total, 20 097 doses de médicaments ont été programmées pour observation de la prise soit par eDOT (15 405/20 097 ; 76,7%) soit par ipDOT (4 692/20 097 ; 23,3%) pour 213 participants à l'étude. Un ou plusieurs problèmes ont été rencontrés dans 17,3% (2 672/15 405) des sessions eDOT et dans 15,6% (730/4 692) des sessions ipDOT. Parmi les 4 374 problèmes documentés, 27,3% (n = 1 192) ont été qualifiés de techniques, 65,9% (n = 2 881) étaient liés au patient et 6,9% (n= 301) étaient liés au programme. Estimé à partir du modèle logistique (n = 6 782 doses, 173 participants), le pourcentage ajusté de doses dont la prise a été observée avec succès pendant les sessions problématiques était de 21,7% (IC 95% 11,2–37,8) pour l'eDOT et de 4,2% (IC 95% 1,1–14,7) pour l'ipDOT.

Par rapport à l'ipDOT, des problems ont été rencontrés dans un pourcentage légèrement plus élevé de sessions eDOT, mais ils ont été plus souvent résolus afin de permettre une observation réussie de la prise des doses pendant les sessions problématiques.

Keywords

tuberculosis; video-observed therapy; video DOT; vDOT; eDOT; ipDOT; VOT

Directly observed therapy (DOT) is the standard of care for TB treatment.[1,2] DOT objectives include improving treatment adherence and treatment success/cure, monitoring for adverse drug reactions, and providing supportive care to patients.[1] Worldwide, the logistical approaches to implement DOT have varied. Some programs employ staff to conduct DOT on weekdays at patient-selected locations in the community; other programs have patients present daily at health facilities, entrust family members to conduct DOT, or allow patients to self-administer doses with TB program staff observing only selected doses each month.[3,4] These varied approaches have not consistently led to improved cure or treatment completion rates, generating criticism of DOT and the pursuit of alternative methods to facilitate treatment adherence.[3]

Digital adherence technologies are a promising alternative to traditional in-person DOT (ipDOT). The use of video-enabled devices to conduct DOT, also known as video-observed therapy (VOT) or electronic-DOT (eDOT), is attractive because eDOT provides dose-by-dose data, retains the ability to visualize medication ingestion, curtails transportation costs, reduces demands on time for patients and program staff, is not affected by travel or inclement weather, and is less intrusive for patients.[5,6] However, there are insufficient

data to assess efficiencies obtained through the expansion of eDOT. Concerns related to network limitations or disruptions, equipment and access costs, and patients' continued engagement have been raised and warrant evaluation (Personal Communication: A Khan's presentation "Implications for policy, practice and future research" on 15 November 2021 at the London School of Hygiene & Tropical Medicine's and the University of Edinburgh's Online Workshop on "Adherence to tuberculosis treatment in the digital era: opportunities, challenges, and future directions").[7]

We evaluated the types and frequency of challenges that arose across four DOT methods and the effect of these challenges on dose observation during a randomized trial whose primary objective was to estimate the difference in the proportion of nonholiday, weekday medication doses observed using eDOT vs. traditional ipDOT.[8]

METHODS

Details regarding study design and participant characteristics have been published previously.[8] Briefly, this crossover randomized controlled trial was conducted in four clinics operated by the New York City (NYC) Department of Health and Mental Hygiene (DOHMH), Bureau of Tuberculosis Control (BTBC), NY, USA. Patients were enrolled from July 2017 to October 2019, and followed until treatment completion or study withdrawal.

In the initial crossover period, participants were randomized to complete 20 medication doses with either ipDOT or eDOT and then switched to the alternative DOT method for 20 subsequent doses; thus, each patient served as their own control. Participants subsequently completed therapy using their preferred DOT method. With ipDOT, participants could choose to meet with health department staff at the TB clinic (CDOT) or a mutually agreed-upon community or 'field' location (FDOT). For eDOT, participants could choose live videoconferencing (LVDOT) using Skype for Business® (Skype, Luxembourg City, Luxembourg), which allowed TB program staff to interact with participants in real time; or recorded (i.e., asynchronous) videos (RVDOT) using the proprietary software SureAdhere® (SureAdhere Mobile Technology, San Diego, CA, USA), which uploaded time-stamped videos to a secure cloud-based server that TB program staff reviewed within one workday.[9,10]

Per BTBC procedures, if a participant was late or missed a DOTappointment, program staff phoned the participant to remind them or to reschedule the appointment. If a technical challenge was identified, assistance was available to patients through BTBC staff and to BTBC staff through the software companies. Consistent with BTBC practices, participants used personal phones or other video-enabled devices (e.g., tablet) to participate in eDOT; participants who did not own or have access to a device were loaned a smartphone by the BTBC at no charge.[11]

To ensure competency with eDOT software applications, we used a standardized teach-back training method[12] to confirm that participants understood and could execute the actions necessary to operate the software for their chosen eDOT method.

Ethics

All participants provided written informed consent in their preferred language. The trial protocol was approved by Institutional Review Boards at the NYC DOHMH, NY, USA, and Columbia University, New York, NY, USA.

Participants who used personal devices were provided a USD10 gift card each month to reimburse data usage costs. Additionally, all participants were provided USD50 for completing the study's enrollment visit and another USD50 if they completed an opinion questionnaire. Per BTBC protocol, patients who traveled to the TB clinic for ipDOT were provided with a two-way public transit voucher (valued at USD5.50) for each visit.

Data collection

All nonholiday, weekday medication doses were considered 'observable' and scheduled in advance for DOT. BTBC staff and study coordinators worked together to supervise DOT sessions. The BTBC defines a successful DOT observation as patients showing and naming each pill and then swallowing them. DOT session outcomes (observed vs. not observed) and any disruptions to the DOT process were recorded in the patients' BTBC records.

Study coordinators used a study form to document the DOT method patients used for each dose, whether medication ingestion was successfully observed or not, and whether any technical-, patient- or program-related challenges occurred. Issues associated with these challenge categories are outlined in Supplementary Data 1: Study Form. The data form's list of challenges (herein referred to as operational challenges) was derived from the BTBC's pilot tests of eDOT.[13] Operational challenges were self-reported by patients and/or documented by the person supervising the DOT session. Multiple challenges could be recorded for a single DOT session. Staff could add notes to provide context. DOT sessions were designated as 'problematic' when operational challenges either delayed, disrupted, or obstructed the dose observation.

If a participant was hospitalized, incarcerated, or if their physician ordered a medication hold or medically approved absence, DOT was suspended. DOT sessions that did not occur due to DOT suspension were tabulated separately from operational challenges.

Analysis

Staff provided notes for 4,310 DOT sessions. These notes were coded for analysis using an iterative process. First, every other note for the first 150 notes was annotated (explanatory comments), and a codebook with an initial set of inductive codes (codes based on the data) was created. These initial codes were then used to code a second random sample of staff notes. During this process, some initial codes were revised, and additional codes added. All staff notes were then coded. Codes assigned to the staff notes were then cross tabulated with existing codes on the study form to remove duplicative coding.

Using SPSS® software v25.0 (IBM Corp, Armonk, NY, USA),[14] we conducted an unadjusted analysis of the frequency of challenges encountered by staff and participants, and whether or not a medication dose was successfully observed when challenges occurred. Data were stratified by challenge type and DOT method.

SAS® software v9.4 (SAS Institute, Cary, NC, USA)[15] was then used to examine the dependence of successfully observing medication ingestion on the incidence of operational challenges and the DOT method used, while adjusting for correlations arising from the study design. This adjusted analysis was implemented with a previously described logistic generalized linear mixed-effects regression model (GLMM),[8,16] where the binary outcome indicated successful observation of ingestion (vs. no observation). Predictors within the GLMM included study design and season (fixed effects); and doses repeatedly observed in the same participant and among participants treated at the same clinic (random effects). Added binary predictors included the occurrence of one or more operational challenges (vs. no challenge) and DOT method (eDOT vs. ipDOT). The interaction term between these binary predictors was included to estimate least-square means and confidence intervals of percentage-doses successfully observed when challenges occurred by DOT method. Participants were included in the adjusted analysis if they completed both crossover periods with sufficient data to represent carryover effects in the GLMM.[8]

RESULTS

Demographic characteristics of participants

We enrolled 216 individuals between July 2017 and October 2019. Three participants were withdrawn before a DOT session outcome was documented in the study database. The median age of the 213* participants included in this evaluation was 42 years (range: 16–86), 65% were male, and a third (n = 64, 30%) needed to borrow a smartphone to participate in eDOT (Table 1).

DOT outcomes: effect of operational challenges on dose observation

Unadjusted analysis—As shown in Table 2, a total of 20,097 medication doses were scheduled to be observed with either ipDOT (4,692/20,097; 23.3%), or eDOT (15,405/20,097; 76.7%). Overall, medication ingestion was observed without incident in 82.1% (16,505/20,097) of all DOT sessions, 83.0% (3,894/4,692) of ipDOT sessions and 81.9% (12,611/15,405) of eDOT sessions. CDOT sessions had the highest percentage of medication doses observed without challenges (1,820/2,114; 86.1%) and FDOT the lowest (2,074/2,578; 80.4%). Overall, 16.9% (3,402/20,097) of all DOT sessions were problematic. A higher percentage of eDOT sessions were problematic compared to ipDOT (eDOT: 2,672/15,405; 17.3% vs. ipDOT: 730/4,692; 15.6%).

Challenges were resolved and medication ingestion was subsequently observed during 32.5% (1,105/3,402) of all problematic sessions. Ultimately, dose observation occurred more often during problematic RVDOT (543/1,465; 37.1%) or LVDOT (444/1,207; 36.8%) sessions compared to problematic CDOT (68/259; 26.3%) or FDOT (50/471; 10.6%) sessions.

*A total of 216 participants were randomized into the eDOT Study and 211 participants initiated the crossover period. Among the 5 participants withdrawn prior to the start of the crossover period, two had documented DOT sessions prior to their withdrawal. These two participants were included in the analyses presented in this manuscript.

Adjusted analysis—A total of 173 participants with 6,782 doses had sufficient data for inclusion in the GLMM analysis. Per the GLMM, and adjusting for the study design, when one or more operational challenges occurred, doses were successfully observed in 4.2% (95% CI 1.1–14.7) of problematic ipDOT sessions and 21.7% (95% CI 11.24–37.77) of problematic eDOT sessions.

Technical, patient- and program-related challenges

Among the 3,402 DOT sessions with an operational challenge, staff noted 4,374 specific issues that delayed, disrupted, or obstructed the DOT session. Of these operational challenges, 27.3% (1,192/4,374) were categorized as technical, 65.9% (2,881/4,374) were patient-related, and 6.9% (301/4,374) were categorized as program-related.

As shown in Table 3, technical challenges were exclusively associated with eDOT. Most technical challenges involved a poor internet connection and/or software malfunction (587/1,192; 49.2%). Phone malfunctions (i.e., audio not working) were the second most common challenge (200/1,192; 16.8%), followed by quality control issues (i.e., low light that made it difficult to see a patient) (178/1,192; 14.9%), time spent troubleshooting a phone or software-related problem (157/1,192; 13.2%), and miscellaneous technical challenges (i.e., blurry videos) (70/1,192; 5.9%).

All four DOT methods had patient-related challenges. Nearly a third of DOT sessions characterized as a patient-related challenge involved staff making multiple attempts to contact a patient (781/2,881; 27.1%). Another third of the patient-related challenges varied (860/2,881; 29.9%), and included actions such as patient re-education, addressing reports of medication side effects, and medication refusal; 22.4% (645/2,881) of challenges were scheduling conflicts/impediments, and 7.9% (229/2,881) could be ascribed to ‘forgetfulness’ (e.g., forgot appointment, forgot to carry medicines, etc.). To note, 12.7% (366/2,881) of the patient-related challenges affected eDOT sessions only and involved issues such as not following the protocol for a video DOT session, being unable to remember how to open the eDOT app, or unavailability of a family member or friend who helps manage the phone or phone app.

Among program-related challenges, the top three issues were staff absences (126/301; 41.9%), patient reports of not receiving calls from BTBC staff (32/301; 10.6%), and transportation delays (21/301; 7.0%).

The Figure shows the distribution of the 4,374 technical, patient-related, and program-related challenges by DOT method and whether the challenge was unresolved or successfully resolved to allow a dose observation. It should be noted that RVDOT was largely unaffected by program-related challenges when compared to LVDOT, CDOT and FDOT. Furthermore, when technical challenges arose, the challenge(s) was resolved, and the dose successfully observed more often with RVDOT compared to LVDOT. Table 3 provides a detailed breakdown of dose observation outcomes (observation occurred vs. unobserved) by challenge type.

Problematic DOT sessions by participants

In total, 94.3% (201/213) participants experienced one or more problematic DOT sessions (range 1–91). Among these 201 participants, 73 (34.3%) experienced 1–10% problematic DOT sessions overall, 44 (20.7%) participants had 11–20% problematic sessions, 32 (15.0%) participants had 21–30% problematic sessions, and for 52 (24.4%) participants >30% of their overall DOT sessions were problematic.

Table 4 shows participants who experienced 0–30% or >30% problematic DOT sessions according to patient characteristics. Compared to participants who experienced 0–30% problematic sessions, a higher percentage of participants who experienced >30% problematic sessions were male, U.S.-born, or Hispanic.

DISCUSSION

A variety of operational challenges will inevitably occur and hinder medication adherence monitoring over the course of TB treatment. Using data collected during a randomized controlled trial, we found operational challenges occurred in 1.7% more eDOT sessions than ipDOT sessions. While eDOT was susceptible to an additional category of challenges (technical), successful dose observation ultimately occurred in a higher percentage of problematic eDOT sessions than problematic ipDOT sessions. These data highlight the need for program staff to proactively engage with patients to achieve DOT objectives. Thus, TB programs that are poorly resourced, have weak infrastructure, have inadequate organization, are inflexible to patients' needs and circumstances, or are unable to provide support, education, and technical assistance may not attain significant improvements in medication adherence or treatment outcomes after implementing eDOT.

Given that technical challenges accounted for almost a third of all documented challenges, anticipating these challenges may help programs improve eDOT usage. Some technical issues listed in Table 3 could be avoided with appropriate planning and hands-on support. For example, phone memory and limited data plans could be assessed during initial set-up with patients. Many of the technical issues were resolved by troubleshooting over the phone and some patients did not follow the protocol in submitted videos, suggesting that the patient did not fully understand the process.

Table 3 highlights the need for robust communication between patients and staff, and contingency planning when patients use any DOT modality. Data from this evaluation can inform education and training for new program staff and patients.

Limitations

Our report is subject to limitations. First, participants' self-selection of eDOT following the two crossover periods resulted in fewer ipDOT observations. Second, our report is likely a conservative account of the challenges encountered. For example, when staff noted 'one or more attempts to contact a patient' or 'eDOT session repeatedly disconnected,' some singular events may not have been documented. The number of multiple attempts and time spent attempting to resolve challenges were not documented. Furthermore, the impact a DOT session with challenges had on other patients' DOT sessions was not quantified (i.e.,

'patient late more than 15 min' or 'slow internet connection - causing image freezing or buffering') and operational costs were not examined. Finally, there were relatively few individuals from groups prone to poor treatment adherence (e.g., persons with alcohol dependence, or unstable housing) among our participants.[17–19] Further evaluation is needed to characterize patient engagement and efficiencies of digital adherence technologies more fully among persons vulnerable to poor treatment outcomes.

CONCLUSIONS

Although the frequency of operational challenges was observed to be slightly higher during eDOT than ipDOT, we found that when challenges did occur, successful observation of doses took place as much as five time more often with problematic eDOT sessions than problematic ipDOT sessions. This pattern was consistent by subtype of DOT, where challenges were resolved and doses successfully observed for a higher percentage of RVDOT and LVDOT sessions, compared to CDOT and FDOT sessions. Expecting and planning for these operational challenges can ensure persons undergoing TB treatment with eDOT or ipDOT are well supported, which will optimize treatment outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

The authors thank all study participants who took part in this study to the benefit of their fellow patients; the New York City Bureau of Tuberculosis Control Case Management staff, and staff at the Morrisania, Fort Greene, Washington Heights, and Corona Chest Clinics for their collaboration throughout this trial; A Hill, U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA, who consulted on statistical aspects of the data analysis; and R Garfein, University of California - San Diego, San Diego, CA, USA, for his assistance with the design of the study and data collection.

This study was funded by the U.S. Centers for Disease Control and Prevention's Antibiotic Resistance Solutions Initiative. The funding organization participated in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review and approval of the manuscript; and decision to submit the manuscript for publication.

References

1. Nahid P, et al. Official American Thoracic Society/Centers for Disease Control and Prevention/ Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clin Infect Dis 2016;63(7):e147–e195. [PubMed: 27516382]
2. World Health Organization. Treatment of tuberculosis guidelines 4th ed. Geneva, Switzerland: WHO, 2010.
3. Karumbi J, Garner P. Directly observed therapy for treating tuberculosis. Cochrane Database Syst Rev 2015;2015(5): CD003343. [PubMed: 26022367]
4. Alipanah N, et al. Adherence interventions and outcomes of tuberculosis treatment: a systematic review and meta-analysis of trials and observational studies. PLoS Med 2018;15(7): e1002595. [PubMed: 29969463]
5. Garfein RS, et al. Tuberculosis treatment monitoring by video directly observed therapy in 5 health districts, California, USA. Emerg Infect Dis 2018;24(10):1806–1815. [PubMed: 30226154]

6. Division of Tuberculosis Elimination, Centers for Disease Control. Implementing an Electronic Directly Observed Therapy (eDOT) Program: a toolkit for tuberculosis programs Atlanta, GA, USA: CDC, 2017.
7. Subbaraman R, et al. Digital adherence technologies for the management of tuberculosis therapy: mapping the landscape and research priorities. BMJ Glob Health 2018; 3(5): e001018.
8. Burzynski J, et al. In-person versus electronic directly observed therapy (DOT) for tuberculosis treatment adherence: a randomized noninferiority trial. JAMA Netw Open 2022;5(1): e2144210. [PubMed: 35050357]
9. Microsoft Corporation. Skype for Business, Version 16.0.1327. 21062 Redmond, WA, USA: Microsoft, 2016.
10. SureAdhere Mobile Technology. SureAdhere, Version 2.0 San Diego, CA, USA: SureAdhere Mobile Technology, 2018.
11. Burzynski J, et al. Clinical policies and protocols bureau of tuberculosis control 5th ed. New York, NY, USA: New York City Department of Health and Mental Hygiene, 2022.
12. Agency for Healthcare Research and Quality. Use the teach-back method: tool #5 Rockville, MD, USA: AHRQ, 2021.
13. Chuck C, et al. Enhancing management of tuberculosis treatment with video directly observed therapy in New York City. Int J Tuberc Lung Dis 2016;20(5):588–593. [PubMed: 27084810]
14. IBM Corp. IBM SPSS Statistics for Windows, Version 25.0 Armonk, NY, USA: IBM Corp, 2017.
15. SAS Institute Inc. Version 9.4 of the SAS System for Windowse Cary, NC, USA: SAS Institute Inc, 2016.
16. Agresti A Categorical data analysis 3rd ed. Hoboken, NJ, USA: Wiley-Interscience, 2013.
17. Jaggarajamma K, et al. Reasons for non-compliance among patients treated under revised National Tuberculosis Control Programme (RNTCP), Tiruvallur District, South India. Indian J Tuberc 2007;54(3):130–135. [PubMed: 17886701]
18. Lin S, Melendez-Torres GJ. Systematic review of risk factors for nonadherence to TB treatment in immigrant populations. Trans R Soc Trop Med Hyg 2016;110(5):268–280. [PubMed: 27198210]
19. Franke MF, et al. Risk factors and mortality associated with default from multidrug-resistant tuberculosis treatment. Clin Infect Dis 2008;46:1844–1851. [PubMed: 18462099]

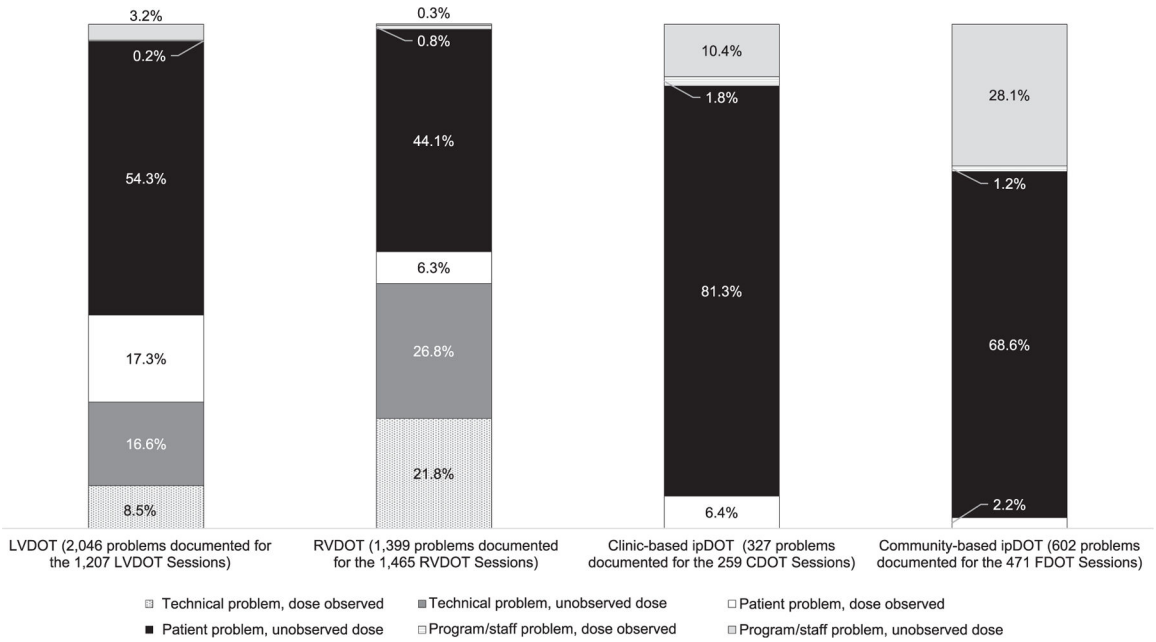

Figure.

Technical, patient-, and program-related problems by DOT method and observation outcome. LVDOT = live video directly observed therapy; RVDOT =recorded video DOT; ipDOT = in-person DOT; CDOT =clinic DOT; FDOT = field DOT.

Table 1

Demographic and clinical characteristics of study participants

Characteristic	(*n* = 213) *n* (%)
Sex	
Male	139 (65.3)
Female	74 (34.7)
Age, years, median [min, max]	42 [16, 86]
Age group, years	
16–20	13 (6.1)
21–30	52 (24.4)
31–40	35 (16.4)
41–50	37 (17.4)
51–60	39 (18.3)
61–70	21 (9.9)
71–80	14 (6.6)
81–90	2 (0.9)
Origin	
US-born	26 (12.2)
Non-US born	185 (86.9)
Unknown/missing	2 (0.9)
Region of birth	
Africa	18 (8.5)
Asia	84 (39.4)
Caribbean	31 (14.6)
Central America	5 (2.3)
Europe	7 (3.3)
North America	38 (17.8)
South America	28 (13.1)
Unknown/missing	2 (0.9)
Race/ethnicity *	
African American/Black, non-Hispanic	41 (19.2)
Asian/Pacific Islander/Hawaiian	80 (37.6)
Hispanic	70 (32.9)
Other/multiple †	13 (6.1)
White, non-Hispanic	9 (4.2)
Employed, in the past 24 months	
Yes	123 (57.7)
No	61 (28.6)
Unknown/missing	29 (13.6)
Loaned a health department smartphone	
No	149 (70.0)

Characteristic	(*n* = 213) *n* (%)
Yes	64 (30.0)
Primary language spoken	
English	54 (25.4)
Spanish	54 (25.4)
Chinese (Cantonese, Fujianese, Mandarin)	24 (11.3)
Other	76 (35.6)
Unknown	5 (2.3)
Educational attainment	
No formal schooling	12 (5.6)
Primary school (Grades 1–5)	9 (4.2)
Middle school (Grades 6–8)	27 (12.7)
Secondary school (Grades 9–12)	82 (38.5)
College+	62 (29.1)
Unknown/refused to answer	21 (9.9)
Diagnosis setting	
Hospital	79 (37.1)
Private practice	4 (1.9)
Local/state health department	100 (46.9)
Other (i.e., correctional facility) or unknown	30 (14.1)
TB disease, pulmonary (yes)	187 (87.8)
Known positive HIV status	8 (3.8)
Homeless within 12 months of diagnosis (yes)	4 (1.9)
History of incarceration, ever (yes)	8 (3.8)
Excess alcohol use, past year (yes)	4 (1.9)
History of substance use (yes)	19 (8.9)

*Participants' race and ethnicity were obtained from clinic records.

†Denotes persons who identified as a combination of two or more fixed race and ethnicity categories.

Table 2

Frequencies of DOT observation outcomes

Outcomes of non-holiday, weekday doses scheduled to be observed	All DOT sessions	eDOT			ipDOT		
		All eDOT *n/N* (%)	LVDOT *n/N* (%)	RVDOT *n/N* (%)	All ipDOT *n/N* (%)	CDOT *n/N* (%)	FDOT *n/N* (%)
Medication doses scheduled to be observed via DOT	20,097	15,405/20,097 (76.7)	6,849/15,405 (44.5)	8,556/15,405 (55.5)	4,692/20,097 (23.3)	2,114/4,692 (45.1)	2,578/4,692 (54.9)
DOT observation occurred, no challenges	16,505/20,097 (82.1)	12,611/15,405 (81.9)	5,557/6,849 (81.1)	7,054/8,556 (82.4)	3,894/4,692 (83.0)	1,820/2,114 (86.1)	2,074/2,578 (80.4)
DOT schedule suspended due to hospitalization, medication hold, medically approved absence, or incarceration	190/20,097 (0.9)	122/15,405 (0.8)	85/6,849 (1.2)	37/8,556 (0.4)	68/4,692 (1.4)	35/2,114 (1.7)	33/2,578 (1.3)
Problematic DOT Session: One or more documented challenges	3,402/20,097 (16.9)	2,672/15,405 (17.3)	1,207/6,849 (17.6)	1,465/8,556 (17.1)	730/4,692 (15.6)	259/2,114 (12.3)	471/2,578 (18.3)
More than 1 challenge could be reported for each DOT session (example: buffering video and no audio)	4,374 individual challenges documented for the 3,402 problematic DOT sessions	3,445 individual challenges documented for the 2,672 problematic eDOT sessions	2,046 challenges documented for the 1,207 LVDOT sessions	1,399 challenges documented for the 1,465 RVDOT sessions	929 individual challenges documented for the 730 problematic ipDOT sessions	327 challenges documented for the 259 CDOT sessions	602 challenges documented for the 471 FDOT sessions
Problematic DOT session: challenge resolved and medication ingestion successfully observed	1,105/3,402 (32.5)	987/2,672 (36.9)	444/1,207 (36.8)	543/1,465 (37.1)	118/730 (16.2)	68/259 (26.3)	50/471 (10.6)
Technical challenge resolved, successful observation	479/4,374 (11.0)	479/3,445 (13.9)	174/2,046 (8.5)	305/1,399 (21.8)	Not applicable	Not applicable	Not applicable
Patient-related challenge resolved, successful observation	475/4,374 (10.9)	441/3,445 (12.8)	353/2,046 (17.3)	88/1,399 (6.3)	34/929 (3.7)	21/327 (6.4)	13/602 (2.2)
Program-related challenge resolved, successful observation	29/4,374 (0.7)	16/3,445 (0.5)	5/2,046 (0.2)	11/1,399 (0.8)	13/929 (1.4)	6/327 (1.8)	7/602 (1.2)
Problematic DOT session: Unresolved challenge, no observation	2,297/3,402 (67.5)	1,685/2,672 (63.1)	763/1,207 (63.2)	922/1,465 (62.9)	612/730 (83.8)	191/259 (73.7)	421/471 (89.4)
Unresolved technical challenge, no observation occurred	713/4,374 (16.3)	713/3,445 (20.7)	339/2,046 (16.6)	375/1,399 (26.8)	Not applicable	Not applicable	Not applicable
Unresolved patient-related challenge, no observation occurred	2,406/4,374 (55.0)	1,727/3,445 (50.1)	1,110/2,046 (54.3)	617/1,399 (44.1)	679/929 (73.1)	266/327 (81.3)	413/602 (68.6)
Unresolved program-related challenge, no observation occurred	272/4,374 (6.2)	69/3,445 (2.0)	65/2,046 (3.2)	4/1,399 (0.3)	203/929 (21.9)	34/327 (10.4)	169/602 (28.1)

Table 3

Documented technical, patient, and program challenges by DOT method and observation outcome

	Live-video DOT: sessions with a documented challenge (*n* = 1,207)		Recorded-video DOT: sessions with a documented challenge (*n* = 1,465)		Clinic-based in-person DOT: sessions with a documented challenge (*n* = 259)		Community/field-based in-person DOT: sessions with a documented challenge (*n* = 471)	
	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)
Technical challenges (*n* = 1,192) (27.3% of the 4,374 documented challenges)	174 (33.9)	339 (66.1)	305 (44.9)	374 (55.1)	0	0	0	0
Poor Internet connection/software malfunction (587/1,192, 49.2%)								
Computer or software malfunction (*n* = 389, 32.6%)	18 (10.3)	80 (23.6) *	136 (44.5) *	155 (41.4) *	0	0	0	0
Slow internet connection, causing image freezing or buffering (*n* = 151, 12.7%)	84 (48.3) *	55 (16.2)	10 (3.3)	2 (0.5)	0	0	0	0
Video cut out/lasted only seconds: interrupted medication ingestion (*n* = 47, 3.9%)	2 (1.1)	2 (0.6)	7 (2.3)	36 (9.6)	0	0	0	0
Phone malfunctions (200/1,192, 16.8%)								
Smartphone malfunction: video not working (*n* = 56, 4.7%)	8 (4.6)	40 (11.8)	2 (0.7)	6 (1.6)	0	0	0	0
Phone or voice mail deactivated (*n* = 51, 4.3%)	1 (0.6)	33 (9.7)	0	17 (4.5)	0	0	0	0
Phone needs repair (e.g., camera or screen broken) (*n* = 36, 3.0%)	2 (1.1)	12 (3.5)	3 (1.0)	19 (5.1)	0	0	0	0
Exceeded memory or limited data (*n* = 27, 2.3%)	0	9 (2.7)	0	18 (4.8)	0	0	0	0
Smartphone malfunction - audio not working (*n* = 23, 1.9%)	15 (8.6)	7 (2.1)	0	1 (0.3)	0	0	0	0
Smartphone malfunction: battery not charged (*n* = 7, 0.6%)	1 (0.6)	3 (0.9)	0	3 (0.8)	0	0	0	0
Quality control (178/1,192, 14.9%)								
Low light, poor light: difficulty seeing patient and/or medications (*n* = 92, 7.7%)	22 (12.6)	0	69 (22.6)	1 (0.3)	0	0	0	0
Video submitted after midnight/outside of 24-hour window (*n* = 59, 4.9%)	0	0	59 (19.3)	0	0	0	0	0
A video was submitted no medication ingestion observed (*n* = 27, 2.3%)	0	0	0	27 (7.2)	0	0	0	0

	Live-video DOT: sessions with a documented challenge (*n* = 1,207)		Recorded-video DOT: sessions with a documented challenge (*n* = 1,465)		Clinic-based in-person DOT: sessions with a documented challenge (*n* = 259)		Community/field-based in-person DOT: sessions with a documented challenge (*n* = 471)	
	Observation occurred *n* (%)	**Unobserved *n* (%)**	**Observation occurred *n* (%)**	**Unobserved *n* (%)**	**Observation occurred *n* (%)**	**Unobserved *n* (%)**	**Observation occurred *n* (%)**	**Unobserved *n* (%)**
Troubleshooting activities (157/1,192, 13.2%)								
Clinic visit to fix or troubleshoot eDOT app (*n* = 80, 6.7%)	1 (0.6)	49 (14.4)	3 (1.0)	27 (7.2)	0	0	0	0
Staff helped patient trouble-shoot app over the phone (*n* = 77, 6.5%)	6 (3.4)	34 (10.0)	6 (2.0)	31 (8.3)	0	0	0	0
Miscellaneous: technical (70/1,192, 5.9%) Other technical issue (e.g., blurry video, session repeatedly disconnected, unspecified tech issue) (*n* = 70, 5.9%)	14 (8.0)	15 (4.4)	10 (3.3)	31 (8.3)	0	0	0	0
Patient-related challenges (*n* = 2,881) (65.9% of the 4,374 documented challenges)	353 (24.1)	1,110 (75.9) *	88 (12.5)	617 (87.5) *	21 (7.3)	266 (92.7) *	13 (3.0)	413 (97.0) *
Patient-specific eDOT impairments (366/2,881, 12.7%)								
Patient not able to operate smartphone or software application (e.g., unable to remember how to open the eDOT app) (*n* = 219, 7.6%)	10 (2.8)	83 (7.5)	26 (29.5) *	100 (16.2) *	0	0	0	0
Patient did not follow the protocol for video call (e.g., did not name pills or display pills correctly, etc.) (*n* = 67, 2.3%)	0	0	11 (12.5)	56 (9.1)	0	0	0	0
Lost/stolen phone (*n* = 26, 0.9%)	0	18 (1.6)	0	8 (1.3)	0	0	0	0
Family member/friend who helps patient with phone or phone app not immediately available (*n* = 25, 0.8%)	1 (0.3)	4 (0.4)	0	20 (3.2)	0	0	0	0
Phone bill not paid/no phone service (*n* = 13, 0.5%)	1 (0.3)	12 (1.1)	0	0	0	0	0	0
Patient was out of camera view (*n* = 9, 0.3%)	4 (1.1)	0	3 (3.4)	2 (0.3)	0	0	0	0
Patient did not have phone with them/forgot phone (*n* = 7, 0.2%)	0	4 (0.4)	0	3 (0.5)	0	0	0	0
Forgetfulness (229/2,881, 8.0%)								
Patient forgot appointment (*n* = 143, 5.0%)	4 (1.1)	29 (2.6)	0	28 (4.5)	0	44 (16.5)	1 (7.7)	37 (9.0)
Patient ran out of drugs(s)/patient needs to refill drug(s) (*n* = 47, 1.6%)	2 (0.5)	7 (0.6)	0	27 (4.4)	1 (4.8)	1 (0.4)	0	9 (2.2)

Int J Tuberc Lung Dis. Author manuscript; available in PMC 2024 April 01.

	Live-video DOT: sessions with a documented challenge (*n* = 1,207)		Recorded-video DOT: sessions with a documented challenge (*n* = 1,465)		Clinic-based in-person DOT: sessions with a documented challenge (*n* = 259)		Community/field-based in-person DOT: sessions with a documented challenge (*n* = 471)	
	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)
Patient forgot medication at home or other location (*n* = 39, 1.4%)	1 (0.3)	21 (1.9)	1 (1.1)	3 (0.5)	1 (4.8)	7 (2.6)	1 (7.7)	4 (1.0)
Scheduling conflicts/impediments (645/2,881, 22.4%)								
Patient had conflict with work, school or personal schedule (*n* = 171, 5.9%)	1 (0.3)	67 (6.0)	0	8 (1.3)	0	25 (9.4)	0	70 (16.9)
Patient late by >15 min (*n* = 171, 5.9%)	133 (37.7)*	25 (2.2)	1 (1.1)	0	0	2 (0.8)	0	10 (2.4)
Contact made with patient at scheduled time: patient requested later time for DOT session (*n* = 100, 3.5%)	7 (2.0)	65 (5.9)	0	1 (0.1)	1 (4.8)	26 (9.8)	0	0
DOT appointment rescheduled at patient's request (*n* = 85, 3.0%)	64 (18.1)	16 (1.4)	0	0	1 (4.8)	0	0	4 (1.0)
Patient had a medical appointment with non-TB doc or scheduled for medical procedure (*n* = 58, 2.0%)	0	16 (1.4)	0	0	0	3 (1.1)	0	39 (9.4)
Patient traveled (*n* = 56, 1.9%)	0	4 (0.4)	4 (4.5)	17 (2.8)	0	3 (1.1)	0	28 (6.8)
Patient unable to find a private location (*n* = 4, 0.1%)	1 (0.3)	3 (0.3)	0	0	0	0	0	0
Multiple contact attempts (781/2,881, 27.1%)								
One or more attempts to contact patient were unsuccessful (*n* = 673, 23.4%)	6 (1.7)	388 (34.9)*	0	189 (30.6)*	1 (4.8)	36 (13.5)	0	53 (12.8)
Following one or more attempts, successful contact made with the patient (*n* = 108, 3.7%)	100 (28.3)*	6 (0.5)	0	0	0	0	2 (15.4)	0
Miscellaneous: patient (860/2,881, 29.9%)								
Patient self-administered medications: autonomously or at direction of/with approval from BTBC staff in response to an issue (e.g., staff absence, slow internet connection w/ buffering image: staff directed patient via phone call, etc.) (*n* = 309, 10.7%)	0	207 (18.6)	2 (2.3)	0	0	62 (23.3)*	0	38 (9.2)
Staff noted patient required re-education/ education provided (*n* = 80, 2.8%)	1 (0.3)	12 (1.1)	18 (20.5)*	36 (5.8)	4 (19.0)	6 (2.3)	1 (7.7)	2 (0.5)

	Live-video DOT: sessions with a documented challenge (*n* = 1,207)		Recorded-video DOT: sessions with a documented challenge (*n* = 1,465)		Clinic-based in-person DOT: sessions with a documented challenge (*n* = 259)		Community/field-based in-person DOT: sessions with a documented challenge (*n* = 471)	
	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)	Observation occurred *n* (%)	Unobserved *n* (%)
Patient reported medication side effects/ health concern/feeling ill (*n* = 31, 1.2%)	6 (1.7)	2 (0.2)	4 (4.5)	1 (0.1)	7 (33.3) *	3 (1.1)	5 (38.5) *	3 (0.7)
Patient did not ingest meds: wanted to go eat and then take medication (*n* = 16, 0.6%)	0	3 (0.3)	0	1 (0.1)	0	12 (4.5)	0	0
Patient: other challenge (e.g., patient hung up on staff or would not open door, patient on intermittent therapy and mistakenly took meds on wrong day, communications lost with patient, etc.) (*n* = 424, 14.7%)	11 (3.1)	118 (10.6)	18 (20.5)	117 (19.0)	5 (23.8)	36 (13.5)	3 (23.1)	116 (28.1) *
Program challenges (*n* = 301) (6.9% of the 4,374 documented challenges)	5 (7.1) *	65 (92.9) *	11 (73.3) *	4 (26.7) *	6 (15.0) *	34 (85.0) *	7 (4.0) *	169 (96.0) *
Staff unscheduled absence/illness (*n* = 126, 41.9%)	1 (20.0)	19 (29.2) *	4 (36.4)	1 (25.0)	0	6 (17.6)	0	95 (56.2) *
Patient reported no communications with BTBC staff/calls not being received (*n* = 32, 10.6%)	0	30 (46.1) *	0	0	2 (33.3)	0	0	0
Transportation/commuting interruptions or delays (*n* = 21, 7.0%)	2 (40.0)	0	1 (9.1)	0	0	1 (2.9)	0	17 (10.1)
Inclement weather caused safety concerns for travel (*n* = 12, 4.0%)	0	0	0	0	0	4 (11.8)	0	8 (4.7)
Planned clinic closure (e.g., painting, etc.) (*n* = 11, 3.6%)	0	0	0	0	0	5 (14.7)	0	6 (3.6)
Staff needed to respond to an emergency with another patient (*n* = 1, 0.3%)	0	1 (1.5)	0	0	0	0	0	0
Staff/program: other challenge (logistics to implement a change in DOT method, communication challenges, etc.) (*n* = 98, 32.6%)	2 (40.0)	15 (23.1)	6 (54.5) *	3 (75.0)	4 (66.7)	18 (52.9) *	7 (100)	43 (25.4)

* Statistically significant.

DOT = directly observed therapy; eDOT =electronic dot; BTBC = Bureau of Tuberculosis Control.

Table 4

Percentage distribution of participants who experienced less than or more than 30% problematic DOT sessions (n = 213)

Demographic		0–30% of all DOT sessions had one or more operational challenges (n = 161) n (%)	>30% of All DOT sessions had one or more operational challenges (n = 52) n (%)
Age, years	<20	8 (5.0)	5 (9.6)
	21–40	66 (41.0)	21 (40.4)
	41–60	59 (36.6)	17 (32.7)
	>60	28 (17.4)	9 (17.3)
Sex	Male	99 (61.5)	40 (76.9) *
	Female	62 (38.5)	12 (23.1)
Birthplace	U.S. born	15 (9.3)	11 (21.2) *
	Non-U.S. born/unknown	146 (90.7)	41 (78.8)
Race	Non-Hispanic White	7 (4.3)	2 (3.8)
	Non-Hispanic Black	35 (21.7)	6 (11.5)
	Hispanic	46 (28.6)	24 (46.2) *
	Asian	64 (39.8)	16 (30.8)
	Other/multiple	9 (5.6)	4 (7.7)
Employed within the past 24 months	No/unknown	69 (42.9)	21 (40.4)
	Yes	92 (57.1)	31 (59.6)
Access to video device	No	43 (26.7)	21 (40.4) †
	Yes	118 (73.3)	31 (59.6)
Primary language spoken	English	38 (23.6)	16 (30.8)
	Spanish	38 (23.6)	16 (30.8)
	Chinese (Cantonese, Fujianese, Mandarin)	22 (13.7)	2 (3.8)
	French, Creole, Pidgin, French-based other	15 (9.3)	1 (1.9)
	Other/unknown	48 (29.8)	17 (32.7)
Educational attainment	No formal schooling	11 (6.8)	1 (1.9)
	Primary school (Grades 1–5)	5 (3.1)	4 (7.7)
	Middle school (Grades 6–8)	18 (11.2)	9 (17.3)

Int J Tuberc Lung Dis. Author manuscript; available in PMC 2024 April 01.

Demographic		0–30% of all DOT sessions had one or more operational challenges (*n* = 161) *n* (%)	>30% of All DOT sessions had one or more operational challenges (*n* = 52) *n* (%)
	Secondary school (Grades 9–12)	62 (38.5)	20 (38.5)
	College+	50 (31.1)	12 (23.1)
	Unknown/refused to answer	15 (9.3)	6 (11.5)
TB disease, pulmonary	No	19 (11.8)	6 (11.5)
	Yes	142 (88.2)	46 (88.5)
HIV status	Negative	145 (90.1)	46 (88.5)
	Positive	5 (3.1)	3 (5.8)
	Refused/unknown	11 (6.8)	3 (5.8)
Homeless, within past 12 months	No/unknown	159 (98.8)	50 (96.2)
	Yes	2 (1.2)	2 (3.8)
History of incarceration, ever	No/unknown	156 (96.9)	49 (94.2)
	Yes	5 (3.1)	3 (5.8)
Excess alcohol use in past year	No/unknown	158 (98.1)	51 (98.1)
	Yes	3 (1.9)	1 (1.9)
History of substance use, ever	No/unknown	146 (90.7)	48 (92.3)
	Yes	15 (9.3)	4 (7.7)

*Results of the Pearson χ^2 measure indicate that participants who were 1) male ($P = 0.042$), 2) U.S. Born ($P = 0.003$), or 3) Hispanic ($P = 0.019$) were more likely than their respective counterparts to have greater than 30% problematic DOT sessions.

†*P* value for persons who did not have access to a video-enabled phone prior to study enrollment = 0.061.

DOT = directly observed therapy.