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## VIDEO DIRECTLY OBSERVED THERAPY (VDOT): CHALLENGES AND OPPORTUNITIES TO EXPLORE

Anitha Victoria Noronha<sup>\*1</sup>, Dr. Madhu B.<sup>2</sup>, Dr. Jayaraj B. S.<sup>3</sup>, Dr. Balu P. S.<sup>4</sup> and Dr. Mahesh P. A.<sup>5</sup>

<sup>1</sup>PhD Scholar, JSS AHER.

<sup>2</sup>Associate Professor Department of Community Medicine, JSS Medical College and Assistant Director (Research) JSS AHER.

<sup>3</sup>Professor, TB and Respiratory Medicine, JSS Medical College & Hospital, JSS AHER, Mysuru.

<sup>4</sup>Professor and Head of the Department of Community Medicine, JJM Medical College, Davangere and Chairman, State Task Force for RNTCP, Karnataka.

<sup>5</sup>Professor & HOD, Department of TB and Respiratory Medicine, JSS Medical College & Hospital, JSS AHER,

Mysuru.

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\*Corresponding author: Anitha Victoria Noronha

PhD Scholar, JSS AHER.

## ABSTRACT

In India mobile technology is mushrooming like any other developed countries. Though this is an opportunity for advancement of m Health services, requirement of training for recording and sending videos is a challenge. Video Directly Observed Therapy (VDOT) method allows for video capture to occur at times convenient for the patient and eliminates the need for VDOT to be scheduled around staff availability. Studies shown that VDOT to be costeffective over in-person DOT. The Centers for Disease Control and Prevention and WHO suggestVDOT as a feasible alternative to in-person DOT.

KEYWORDS: Tuberculosis, Adherence, Video Directly Observed Therapy.

#### INTRODUCTION

Tuberculosis (TB) is the world's leading cause of death. According to World Health Organization report 2017, an estimated 10 million new cases of active TB disease occurred worldwide, including 558,000 new cases of multidrug resistant TB, and 1.6 million deaths.The incidence of TB is higher in India than anywhere in the world, with roughly 2.8 million cases reported in 2017, nearly 27% of the global TB burden.<sup>[1]</sup>

WHO South-East Asia (SEA) Region is home to 26% of the world's population with 44% burden of TB incidence. In 2017, an estimated 4.4 million people fell ill with TB and estimated 638 000 died because of the disease which is more than half of global TB deaths. Treatment success for new and relapse TB cases was 75% (for those initiated on treatment in 2016), amongst the lowest in the Regions of the world. It is also estimated that 192 000 Rifampicin-resistant (RR) and multi-drug-resistant TB (MDR-TB) cases accounting for more than 34% of global burden appeared in the Region in 2017, of which less than 52 000 were notified in the same year. Six out of the 30 high TB (and MDR-TB) burden countries are in the SEA Region: Bangladesh, Democratic People's Republic of Korea, India, Indonesia, Myanmar and Thailand.<sup>[2]</sup>

TB is an infectious disease requiring prolonged treatment. Poor treatment adherence can increase the risk of mortality and spread of disease.<sup>[3]</sup> Patients have to stay motivated throughout the treatment period, even when they feel no distress. Failure to complete treatment can lead to relapse and the emergence of multidrug-resistant TB (MDR-TB), resulting in further disease transmission. The World Health Organization (WHO) encourages the of multidimensional adherence interventions, use including staff motivation and supervision, defaulter action, prompts, health education, incentives and reimbursements, contract, peer assistance and emphasizes monitoring through directly observed treatment (DOT).[4]

Completion of therapy is vital not only for the patient but also the community, as public health efforts to mitigate disease spread require treatment success. Presently, mobile phones are an inseparable part of daily activities. Almost all countries have started to use telecommunication especially mobile communication in the health care sector. Mobile phones can help to overcome the barriers such as stigma, privacy loss, and transportation limitations associated with the interventions.<sup>[5]</sup>

India's telecommunication network is the second largest in the world by number of telephone users with 1.1724 billion subscribers as on 31 Dec 2019. According to market research firm techARC, India had 502.2 million smart phone users as of December 2019, which means over 77 percent of Indians are now accessing wireless broadband through smart phones.<sup>[6,7]</sup>

Such a high wireless user base makes the use of mobile phones for health care delivery inevitable. Mobile phone reminders, such as voice calls and short message service (SMS) text messaging, to improve adherence to ATT have shown mixed results.<sup>[8,9]</sup> However, mobile reminders are known to improve clinic attendance.<sup>[10]</sup> Furthermore, mobile health (mHealth) interventions have led to better retention of patients with TB when compared with historical cohorts.<sup>[11]</sup>

A study from Lesotho, Africa, indicates that 92% of HIV/TB patients found SMS reminders for medications acceptable.<sup>[12]</sup> However, a randomized controlled trial from Pakistan found that SMS did not significantly improve treatment outcomes compared with a control group.<sup>[13]</sup>

Photovoice, an app that used video recordings from patients cured of TB to promote ATT adherence and outcomes in Pune, India, showed better outcomes in patients exposed to the intervention.<sup>[14]</sup> In addition, mobile video-based directly observed treatment (VDOT), an alternative to conventional in-person DOT, holds promise, given the high mobile phone penetration and wireless users, especially in the Indian context.<sup>[15]</sup>

Table 1: Inclusion and Exclusion Criteria for VDOT.

Currently, video directly observed therapy (VDOT) has been used as a patient-centered alternative to in-person DOT, with pill ingestion monitored remotely via digital video capture. VDOT has been implemented using synchronous technologies.<sup>[16,18]</sup> such as Skype and Face Time as well as asynchronous technologies,<sup>[19,20]</sup> where recorded videos are uploaded and digitally stored for future review. This method allows for video capture to occur at times convenient for the patient and eliminates the need for VDOT to be scheduled around staff availability. Recent work has shown asynchronous VDOT to be feasible, well received by patients and providers, and associated with high rates of treatment adherence.<sup>[21-25]</sup> Further, two economic evaluations in the United States have suggested VDOT to be cost effective over in-person DOT.<sup>[26]</sup> These encouraging findings have led both the US Centers for Disease Control and Prevention and WHO to suggest VDOT as a feasible alternative to in-person DOT.<sup>[28-29]</sup>

#### **Definition of VDOT**

Video directly Observed Therapy is the communication between patient and health caregiver, live or self recorded, is used to follow a physical encounter and to enhance TB medication adherence and treatment completion.<sup>[30-32]</sup> It is a process whereby patients record themselves taking their medication by mobile phone and sending the videos to their TB care provider for observation.<sup>[33]</sup>

#### **Inclusion and Exclusion Criteria for VDOT**

Health care providers must consider the individual circumstances of each case to include the patient for VDOT. The following criteria need to be considered when selecting a patient for VDOT.

Inclusion criteria	Exclusion criteria	
<ul> <li>Patient accepts the TB diagnosis, is motivated, and understands the need for TB treatment.</li> <li>Patient has been on in-person DOT for a minimum of 2 weeks with 100% compliance.</li> <li>Patient is 18 years old or above.</li> <li>Patient can accurately identify each medication.</li> <li>Patient is able to demonstrate how to properly use the equipment and/or application.</li> <li>Patient has reliable internet connection (for internet-based VDOT) or reliable landline connection (for videophone-based VDOT).</li> </ul>	<ul> <li>Patient is considered at risk for poor adherence (e.g., homeless, substance abuse, prior TB treatment, psychiatric illness, memory impairment).</li> <li>Patient speaks a language that VDOT cannot accommodate.</li> </ul>	

#### **Initiation of VDOT**

At the start of TB treatment, all of the following must be completed before initiating VDOT:

## Table 2: Initiation of VDOT.

#### Initiation of VDOT

- Complete at least two weeks of in-person DOT with patient.
- Staff will assess for VDOT inclusion and exclusion criteria for eligibility.
- Staff discuss the option of VDOT with the patient.
- Patient agrees to participate in VDOT and signs a consent form to participate in VDOT that includes:
- > Adherence requirements/expectations for VDOT
- Possible confidentiality concerns
- Steps required by patient for VDOT
- > Patient responsibilities in case of technical failure
- Patient and staff agree on a regularly scheduled time (for live video VDOT) or a regular frequency (for storeand-forward VDOT)
- Staff review the procedure for completion of VDOT (live video or store-and-forward) VDOT Staff Responsibilities VDOT Staff are responsible to follow all agency policies and procedures related to VDOT, including:
- Provide regular (weekly, biweekly or monthly) in-person visits to complete full assessments and to provide medications to the patient
- Document each encounter as scheduled
- > In case of technical failure while utilizing VDOT, complete DOT in person
- > Provide patient with instructions and training on how to use the VDOT application(s)/equipment
- > Provide patient with information about whom to call with questions or in an emergency

#### **Types of VDOT**

Different VDOT mechanisms have its own strengths that can increase patients access to care, which should be balanced against the benefits of in- person DOTS.

#### 1. Synchronous VDOT

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

## 2. Asynchronous VDOT

With asynchronous VDOT, patients record themselves taking their medications and care providers subsequently observe the recordings to document that medications were ingested. This can be accomplished using smart phones, tablets or computers that can record the videos and securely forward them electronically to the TB program to be viewed at a time chosen by the DOT worker. This approach is also be referred to as "store and forward "or "recorded "VDOT.<sup>[32,33]</sup>

#### Table 3: Protocol for VDOT.

Protocol for Synchronous VDOT		Protocol for Asynchronous VDOT	
1. 2. 3. 4. 5. 6. 7.	Staff and patient activate the application at the scheduled time. Staff confirms the identity of the patient. Staff assesses the patient for any adverse medication reactions prior to observing medication ingestion. Patient shows the staff each pill separately and identifies the medication. Patient places the pills in their mouth after identification and drinks at least 4 ounces of fluid following pill ingestion. Patient opens mouth after ingesting pills to show the staff that the pills were swallowed. Staff confirms the time and date for the next VDOT.	Patient activates video application upon frequency (daily, biweekly). Patient identifies themselves and the the camera and remains in the came duration of the video recording. Patient takes each pill separately ar medication. Patient keeps the pills in their mout after identification and drinks at lea (300ml) of fluid following pill inge Patient opens mouth after ingesting the staff that the pills were swallow Patient uses the application to send health department. Staff reviews the store-and-forward complete required documentation i manner. Ensure Patient Confidentiality. <sup>[32,33]</sup>	he day's date to era view for the and identifies the th one-by-one ast one glass estion. by pills to show yred. the video to the d videos and n a timely

## **Current status of VDOT in Asian countries**

The last ten years (2000 -2020) Review of Literature on TB and VDOT in Asian countries was conducted to

know how widely VDOT is in use in Asian countries comparing to other countries like Africa and European countries.

Table 4: Publications on VDOT in Asian countries.

Ref. No	Author, place and year	Number of study subjects	Research design and method	Key observation
[26]	Holzman et al. Dr DY Patel Medical College Hospital, India 2019	25 Tuberculosis patients	i.Single-Arm, Prospective Feasibility Study. ii.Use of Smartphone-Based Video Directly Observed Therapy (vDOT) in Tuberculosis Care	i.Majority of patients initiated on VDOT during the continuation phase (20/25, 80%), with 20% (5/25) beginning during the intensive phase. ii.The median number of weeks on VDOT was 13 with a range of 9 to 23 weeks. iii.A total of 80% (20/25) of patients received daily (7 times per week) therapy, while 20% (5/25) received an intermittent (3 times per week) regimen. iv.No in-person DOT was documented either before or after implementation of VDOT.
[34]	Mary E. Wilson, MD UK 2019	112 VOT participants 114 DOT participants	i)compared TB treatment completion using traditional DOT versus asynchronous VOT ii)VOT participants received smartphones and training to record and send videos of themselves taking medication. iii)Trained observers assessed whether participants had taken doses. Smartphone participants could report adverse events and could call and text	<ul> <li>i)70% of 112 VOT participants</li> <li>completed at least 80% of observations</li> <li>during first 2 months (including among those at increased risk for nonadherence)</li> <li>versus 31% of 114 on DOT.</li> <li>ii)In the full follow-up period, completed observations were significantly higher in the VOT than DOT group (77% vs. 39%, respectively). Positive sputum cultures did not differ significantly between VOT and DOT at 2 months.</li> <li>iii)Adverse events were reported by more VOT-group than DOT-group participants. VOT required less staff time and was cheaper than DOT.</li> </ul>
[35]	Angella Musiimenta. Mbarara Regional Referral Hospital (MRRH) in rural, southwestern Uganda June 2017 and June 2018	35 TB patients	i)A parallel mixed-method study design that utilized semistructured interviews and surveys.	<ul> <li>I)The most frequently reported type of social support was being reminded/ encouraged to take medication—</li> <li>24 (69%) (Table 2). ii)The majority of patients also reported that they were currently not receiving enough social support—21 (60%).</li> <li>iii)Patients preferred SMS notifications that do not instruct how social supporters should help—20 (57.2%), compared to notifications that do offer such guidance.</li> </ul>
[36]	AlSahafi AJ and et.al. Saudi Arabia, January to November 2018	200 DOTS patients	i. A comparative cross- sectional study ii. High non-compliance rate with anti tuberculosis treatment: a need to shift facility-based directly observed therapy short course (DOTS) to community mobile outreach team supervision iii. A questionnaire measuring patient attitudes and understanding of the disease and their treatment modes was completed by patients at the beginning of their treatment, and again	i. Overall default rate among those patients served by our mobile outreach team was only 3%, compared with a 22% default rate among non-mobile team treated patients ( $p = < 0.001$ ). ii. A major change in the attitude and understanding scores of patients was noted in both groups after 3 months. iii. A significant difference was also noted in the mean compliance scores (mobile team served =58.43 and facility-based =55.55, $p < 0.001$ ) after 3 months of treatment.

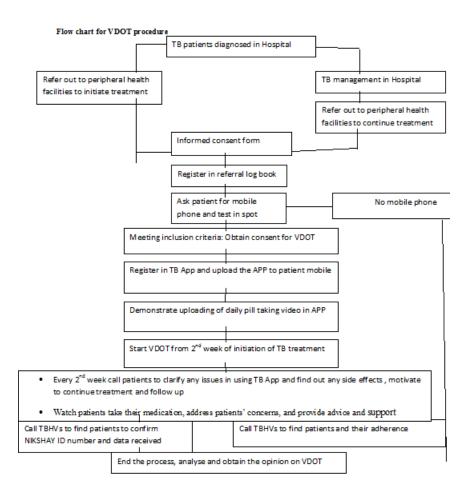
			after 3 months.	
[37]	Subbaraman R, de Mondesert L, Musiimenta A, et al. India 2018	Review article	Review article on digital adherence technologies for the management of tuberculosis therapy: mapping the landscape and research priorities.	i.Digital adherence technologies (DATs) may facilitate more patient-centric approaches for monitoring adherenc. ii.Depending on the specific technology, DATs may help to remind patients to take their medications, facilitate digital observation of pilltaking, and compile dosing histories and triage patients based on their level of adherence, which can facilitate provision of individualised care by TB programmes to patients with varied levels of risk.
[11]	Nguyen TA, Pham MT, Nguyen TL, Nguyen VN, Pham DC and Nguyen BH, Clinics in Hanoi, Vietnam Nov.2016 to Jan 2017	78 patients with bacteriologically confirmed pulmonary tuberculosis.	<ul> <li>i. A prospective cohort study.</li> <li>ii. Consecutive adult patients with bacteriologically confirmed pulmonary TB were invited to enroll in a programme of VDOT.</li> <li>iii. Patients were trained to use a smartphone to record themselves taking treatment for TB.</li> <li>iv. Videos were uploaded to an online server and reviewed daily by study staff for at least two months.</li> <li>v. Adherence was evaluated based upon monthly pill count.</li> </ul>	<ul> <li>i. 27 (71.1%) of patients took all required doses.</li> <li>ii. A median of 88.4% of doses were correctly recorded and uploaded.</li> <li>iii. Participants had rated VDOT interface highly, despite facing same initial technical difficulties.<sup>25</sup></li> </ul>
[38]	Richard S and etal. California, USA 2016-17	174 patients using VDOT and 159 patients using in- person directly ob- served therapy	i)a prospective, multisite, single-arm trial ii)Tuberculosis Treatment Monitoring by Video Directly Observed Therapy in 5 Health Districts, California, USA	<ul> <li>i)Median fraction of expected doses observed (FEDO) among VDOT participants was higher (93.0% [interquartile range (IQR) 83.4%–97.1%]) than among patients receiving DOT (66.4% [IQR 55.1%–89.3%]). ii)Most participants (96%) would recommend VDOT to others; 90% preferred VDOT over DOT.</li> <li>iii)Lower FEDO was independently associated with US or Mexico birth, shorter VDOT duration, finding VDOT difficult, frequently taking medications while away from home, and having video- recording problems (p&lt;0.05).</li> <li>iv) VDOT cost 32% (range 6%–46%) less than DOT.</li> <li>v) VDOT was feasible, acceptable, and achieved high adherence at lower cost than DOT</li> </ul>
[39]	Manalan K,Sivakumaran K, Nayagam M, Villanueva B, Cosgroe C, Dunleavy A England, 2017	11 patients records who have completed treatment with in- house VOT	i)Retrospectve study ii)review of success compared to national centralised VOT services and to develop a robust local standard operating practice.	i) VOT completion rate ranged from 82- 100% with an average of 93% of therapy observed

[40]	Alistair Story and et al England Sept 1, 2014, and Oct 1, 2016,	226 patients aged 16 years with active pulmonary or non-pulmonary tuberculosis 112 to VOT and 114 to DOT.	<ul> <li>i)A multicentre, analyst- blinded, randomised, controlled superiority trial.</li> <li>ii)Smartphone-enabled video-observed versus directly observed treatment for tuberculosis:</li> <li>iii) DOT was delivered according to usual clinical practice.</li> <li>iv) VOT was provided by a centralised service in London (UK).</li> <li>v) Semi-structured interviews were done with 16 patients selected to represent a range of backgrounds and VOT and DOT successes and failures.</li> </ul>	<ul> <li>ii)In the restricted analysis, 78 (77%) of 101 patients on VOT achieved the primary outcome compared with 35 (63%) of 56 on DOT (adjusted OR 2 • 52; 95% CI 1 • 17–5 • 54; p=0 • 017).</li> <li>ii) Stomach pain, nausea, and vomiting were the most common adverse events reported (in 16 [14%] of 112 on VOT and nine [8%] of 114 on DOT).</li> <li>iii) VOT was a more effective approach to observation of tuberculosis treatment than DOT.</li> </ul>
[41]	Sinkou H, Hurevich H, Rusovich V, et al Belarus, Europe 2015	10 patients of mean (range) age 31 (19– 50) years	<ul> <li>i)First Programmatic</li> <li>experience</li> <li>ii) Video-observed</li> <li>treatment for tuberculosis</li> <li>patients in Belarus</li> </ul>	<ul> <li>i)Eight out of 10 patients felt that VOT</li> <li>was easier than daily commuting to take</li> <li>treatment at the tuberculosis dispensary</li> <li>ii) the cost of internet connection was</li> <li>cheaper than tickets for public transport.</li> <li>iii)All patients were prepared to</li> <li>recommend VOT to other patients.</li> <li>iv)Dispensary staff appreciated the</li> <li>improved convenience to patients of VOT</li> <li>when compared with in-person direct</li> <li>observation the high levels of adherence</li> <li>achieved; and the reduced risk of</li> <li>infecting other individuals during travel</li> <li>and clinic attendance.</li> </ul>
[42]	Anindo M, Akkilagunta S, and Chinnakali. India Jan-Mach 2015	Review article	Review article on Video Directly Observed Treatment: How Effective Will it be in Indian Setting?	i.Mobile DOT resulting in better compliance. ii.The advantage for health system is cost effective supervision.

In India mobile technology is mushrooming like any other developed countries. Though this is an opportunity for advancement of m Health services, requirement of training for recording and sending videos is a challenge. Issues of poor cellular network in hard-to-reach areas, data security, back-up, and large data storage requirements in phones need to be addressed.

News in Deccan Chronicle Lifestyle, health and wellbeing on new Smartphone app monitor on daily Tuberculosis therapy reported that VDOT offers an alternative that appears to be as effective as an in person daily visits by health care workers to assure compliance with drug treatment, but also empowers patients to manage their illness without added stress.<sup>[43]</sup>

With the above systematic review findings following flow chart is prepared for use of VDOT to improve the adherence of Tuberculosis patients to drug regimen.



#### Challenges and opportunities to explore

While VDOT shows much promise in addressing what may be a concerning upward trend in TB cases at global level, use of the technology continues to lag. Coupled with tightened resources for health departments, should TB cases rise, the country like India could face a potentially bothersome situation.

Even though VDOT has shown benefits, public and private health departments still see potential barriers to utilization. There are concerns around connectivity and equipment failures, identification of side effects to the medication, privacy and security issues.<sup>[44]</sup>

It is a high time to formulate a policy and practice guidelines at all levels of primary care with available man, money and material resources to practice VDOT in all private and public health care settings. Specifically in India telecommunication companies must join their hand in creating VDOT Apps in local languages; therefore health professionals could use it readily.

#### CONCLUSION

Mobile phone is an easy and cost effective way to communicate and monitor patients. Innovative approaches have been piloted to bridge the gap between caregiver and patient and limit the cost and stress of frequent travel to health centres for DOT. Wider use of VDOT will enable health professionals to watch patients take their medication, address patients' concerns, and provide advice and support. Using VDOT patients will have freedom to take their medications when and where they choose, and it creates a more comprehensive approach to care. Patient can be motivated to adhere to the treatment course and their deaths can be cleared. VOT is likely to be preferable to DOT for many patients across a broad range of settings, providing a more acceptable, effective, and cheaper option for supervision of daily and multiple daily doses than DOT.

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