California Public Health Departments Remotely Treat Tuberculosis: Outcomes & Opportunities

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Abstract

Background and Purpose: Using video-based directly observed therapy (VDOT) to remotely monitor tuberculosis (TB) patients' treatment is now a viable option due to the advancement and expansion of technology. This study determined the utilization levels, benefits, barriers, and outcomes of California public health departments using VDOT to treat TB. **Methods:** Interviews (n=7) with pilot site staff in California and a survey (n=56) were used for data collection. In 2015 the survey was disseminated to attendees of the California Tuberculosis Control Association annual conference. **Results:** Almost 27 percent (n=15) of survey respondents were using VDOT. Reported benefits were high and centered on patient and provider satisfaction, cost savings, and staff safety. The highest concern was reimbursement, specifically that California's Medicaid program, Medi-Cal, reimburses for in-person DOT but not VDOT. **Conclusion:** VDOT is a practical and effective option for providing DOT as it has many benefits with minimal concerns. Reimbursement equal to that of in-person DOT and the continued technological improvements should alleviate the existing hindrances that are currently preventing many health departments from implementing VDOT or expanding their existing program. Satisfaction is high, outcomes are positive, and VDOT is cost effective so efforts should be made to break down the barriers to expansion.

Keywords: Telemedicine, Tuberculosis, Public Health, Directly Observed Therapy, Medication Adherence

Introduction

The steady decline of tuberculosis (TB) cases in California seen over the last 25 years ended in 2015. The number of TB cases and the TB rate were unchanged in 2015 (2,133 cases and a rate of 5.5 per 100,000 population) compared with 2014 (California Department of Public Health, 2016a).

The Centers for Disease Control and Prevention (CDC) recommends the use of directly observed therapy (DOT) as the most effective way of administering medication in treating TB (CDC, 2012). DOT consists of observing patients taking their medication to assure adherence to a course of treatment. Strict adherence to ingesting the medication is necessary, because patients who take their medications inconsistently or stop early are at risk for disease progression and death, transmission of the disease to others, and development of drug-resistant strains of the TB bacteria that are much more difficult and expensive to treat.

While effective in treating TB, DOT is labor intensive and an expensive treatment approach that taxes limited public health resources (Belknap, Weis, Brookens, Au-Yeung, Moon, DiCarlo, & Reves, 2013). Treatment of TB can range from three months for latent infections of TB (CDC, 2014b) to 24 months for multi-drug resistant TB (MDR-TB) (National Institute of Allergy and Infectious Diseases, 2012), and the estimated cost of treating TB patients in California in 2015 is $72 million in direct medical costs alone to treat active TB disease (California Department of Public Health, 2016b). The use of telehealth to administer DOT (Video Directly Observed Therapy [VDOT]) may prove to be an effective way to address the logistical and financial challenges faced by public health departments in using DOT, while still effectively treating TB patients. The Center

for Connected Health Policy (CCHP) and the University of California San Diego (UCSD) conducted a two-year statewide study in California. The study goal was to assess the acceptance and utilization levels, barriers and enabling factors, outcomes, and policy and legal provisions related to VDOT as well as other applications of the technology. Background information about VDOT as well as the study methods and findings are presented in this article.

Background of VDOT

VDOT is a form of telehealth that allows a healthcare worker (HCW) to remotely observe an infected individual taking his or her medications. California law defines telehealth as:

"The mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealth facilitates patient self-management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers." (California Legislative Information, 2012).

Two modes of telehealth delivery may be used for VDOT:

1. Real time (synchronous) VDOT (S-VDOT) allows the HCW to virtually observe the TB patient taking his or her medication using video transmission utilizing a device such as a mobile phone. Observation of the person taking the medication by the HCW occurs at the same time the event is happening.

2. Store-and-forward (asynchronous) VDOT (A-VDOT) consists of the patient digitally recording the ingestion of the medication using technology, such as a mobile phone. The recorded video is transmitted to a secure server where it is stored for viewing by the HCW at a later time. A summary of the features of both modalities is in Table 1.

Table 1

In-person DOT and VDOT Features

	In-Person Directly Observed Therapy (DOT)	**Synchronous Video Directly Observed Therapy (S-VDOT)**	**Asynchronous Video Directly Observed Therapy (A-VDOT)**
Procedures	Occurs in real-time (synchronous). HCW must be physically present to observe the patient ingesting medication.	Occurs in real-time (synchronous). HCW virtually observes (via live-video) the patient ingesting medication.	Does not occur in real-time (asynchronous). Patient records a video ingesting medication and sends it to HCW to observe at a later time.
Requirements	Requires patient and/or HCW to physically travel. Treatment regimen must fit to the patient and HCW's schedules. Does not require technological equipment nor a cellular/ wireless fidelity (Wi-Fi) connection.	Does not require patient and/or HCW to travel (if periodic physical check-ins are required then travel is significantly reduced). Treatment regimen must fit to the patient and HCW's schedules. Requires technology, such as a smartphone, and a cellular/Wi-Fi connection.	Does not require patient and/or HCW to travel (if periodic physical check-ins are required then travel is significantly reduced). Treatment regimen fits to both patient and HCW's schedule. Allows for monitoring on weekends and when patient is traveling. Requires technology, such as a smartphone, and a cellular/Wi-Fi connection.

HCW=Healthcare worker

Little research exists on VDOT and what does exist uses antiquated technology or telephones. The one article that was located conducted nine focus groups; four with VDOT patients (n=8) and two with providers (n=14) in San Diego, CA and one focus group with patients (n=8) and two with providers (n=33) in Tijuana, B.C., Mexico. The study participants were accepting of the technology and conveyed that they found it to be less burdensome and more confidential when compared to in-person DOT. Culture played a role as the United States patients valued the greater autonomy that VDOT provided and Mexican patients valued improved privacy (Zúñiga, Collins, Muñoz, Moser, Rangel, Cuevas-Mota, Clark, Burgos, & Garfein, 2015).

Terminology

When conducting this study, discussions took place about terminology. There is no term that is used consistently and agreed upon. Terms such as VDOT, Tele-DOT, mDOT, mobile DOT, video-based DOT, remote-DOT, eDOT, and others have been used in the literature and discussions. In this article, the term VDOT is used. VDOT is the name of the technology used in the pilot test sites. This is not a product endorsement for VDOT.

How VDOT Works and was Used in This Study

The VDOT application used in this study was programmed to send the encrypted, time/date stamped video to a secure server immediately after the participant stopped recording him or herself. If the cellular or WiFi connection was unavailable, the video remained in the phone's memory, hidden to users, until a signal was accessed and the video was sent. To protect patient confidentiality, videos were stored on the phone in a manner so that the videos could not be opened on the phone. Once the server received the video, an authenticated message was sent back to the phone that caused the video to be deleted from the phone.

Staff at the public health agency monitored videos as they arrived using a password protected website called the Case Management System. The HCWs observed videos each business day, documented each medication dose that was taken as shown in the video, and received a daily report listing the identification numbers of participants who did and did not send videos.

In this study, UCSD pilot tested VDOT in five urban and rural counties in California with a high incidence of TB. Following treatment schedules prescribed by the patient's care provider, participants (patients with TB) were either loaned a smartphone from UCSD with service or they used their own smartphone. Participants were taught how to use the VDOT recording application and how the medication should be taken and given a brochure containing VDOT instructions as a reference. After training, participants were asked to take the first medication dose using VDOT with the HCW present to ensure they knew how to record their videos. All remaining doses were taken and recorded at a place of the participant's choosing. Participants with missing videos were contacted by the HCW to determine whether the medication was taken and to troubleshoot potential problems the participant may have experienced. Clinic staff were informed whenever participants missed a medication dose so that the clinic staff could proceed with contacting the participant according to the agency's standard treatment protocols.

Methods

Interviews and a survey were used to address to goal of the study. The study was approved by the Public Health Institute Institutional Review Board and the University of California San Diego Institutional Review Board.

Procedures

Interviews were conducted with staff at the pilot sites and a survey was conducted with users and non-users of VDOT at a TB conference in California. Non-users were included in the study to assess the perceptions of non-users, which could be barriers to utilization, and to assess if non-user's perceptions were different than the experiences of users.

Participants
Seven staff at the pilot sites were interviewed. Eight were invited; one did not respond to the request. The inclusion criteria were that the person had to work with VDOT at one of the five pilot sites. The researchers wanted at least one person from each site to participate and for people with different roles to participate. We interviewed three TB Controllers, two Program Managers, one VDOT Coordinator, and one billing specialist. All of the interviewees were females and worked in public health agencies; two worked in rural facilities, and three were pre-implementation interviews.

The survey was completed by 56 participants; one of them was a remote attendee who emailed the completed survey as an attachment. The majority of participants were clinicians (86.3%, n=44) and most were employed at a public health agency (96.1%, n=49).

Interviews
CCHP worked with the UCSD pilot sites and conducted seven interviews with people at the five sites. The pilot sites were county health departments in San Francisco, Santa Clara, San Joaquin, Imperial, and San Diego. Two of the sites were using VDOT for less than two months while the others had been using it for years. The sample was a convenience sample.

HCWs at the pilot sites were asked to participate in a 30-minute recorded interview. The selection process was based on who could participate (everyone who was asked participated except for one person being non-responsive to the email request) and their role in the organization. One person from each pilot site participated, and they had different roles in the VDOT project. Three people from San Francisco were interviewed. The interviewer guide was developed by CCHP staff and reviewed by the collaborating UCSD research team. Conference calls were held with both organizations until no more changes were needed to the interview guide.

The Principal Investigator of the UCSD study, Dr. Richard Garfein, introduced the CCHP interviewer to the pilot site staff member via email. The interviewer explained the interview to the potential participant. The participants were asked to sign a consent form, which also requested that consent be given for the interview to be recorded. All participants consented to being interviewed and having them be recorded. Two researchers from CCHP participated in the interviews and one took notes.

Survey
The purpose of the survey was to assess the acceptance levels and experiences with VDOT, perceived or experienced benefits and concerns of using VDOT, and to collect ideas for other applications of VDOT. A survey was developed by CCHP in collaboration with UCSD. After conducting an extensive literature review, three researchers at CCHP developed a draft survey. The draft was reviewed and discussed with researchers at UCSD. Several iterations occurred and after no more changes were identified, the survey was reviewed by two people who work in county TB control sites. Final revisions were made after a conference call with the TB professionals at county offices in California. Paper versions of the survey were distributed at the California Tuberculosis Control Association (CTCA) annual meeting held in Sacramento, CA on April 20th and 21st 2015. The survey also was available to remote conference attendees (people could attend all or any part of the conference remotely) who could complete the survey and send it to one of the researchers or complete it online. The survey was distributed to conference attendees at the end of the 45-minute presentation on VDOT. The presentation was given by Dr. Richard Garfein. Attendees were asked to complete the survey and return it to the CCHP exhibit table. When attendees dropped off the completed survey they were entered in a raffle for a free Kindle reader.

Analysis
The recordings from the interviews were transcribed and analyzed using ATLAS.ti version 6. Two people coded the transcripts independently and the codes were compared. No major differences were identified.

The survey data was analyzed using descriptive statistics. Graphs and tables were used in the

analysis. The data for A-VDOT users and S-VDOT users were compared as well as for users and non-users of both A-VDOT and S-VDOT. The former was done to compare the outcomes of the two approaches and the latter analysis was conducted to determine of perceptions of VDOT usage differ from those who have used the technology.

Results

Users and non-users of VDOT were included in the study. All of the interviewees were VDOT users and the survey respondents were professionals working in TB, some of which were pilot study participants but not all.

Interview Results

The interviewees all stated that A-VDOT and S-VDOT each have their pros and cons. For example, S-VDOT has the daily interaction and A-VDOT has the benefit of observation on weekends, holidays, and when the patient is travelling. The best approach is to identify what works for the patient and to have a 'menu' of options and for providers to determine, with the patient, what is the right method for that patient; maybe the method will change at different points in treatment.

In terms of barriers, comments centered primarily around reimbursement and that private insurance does not pay for VDOT (they do not pay for in-person DOT, either). Medi-Cal pays for in-person DOT but not VDOT. This was a major concern as public health departments have reduced reimbursement when using VDOT. Other challenges were equipment and connectivity issues, monitoring side effects, and HCWs initially being concerned about losing their jobs. For the last item, once it was explained that their jobs would not be eliminated the concern was minimized. With regard to connectivity issues, the videos in VDOT are stored in the phone until connectivity occurs. A HCW reported that it is problematic when the person has a lapse in connectivity and when he or she obtains a connection that numerous videos are received by the HCWs simultaneously. Another interviewee shared that rural regions have connectivity problems. On the positive note, interviewees shared their expectation that connectivity will improve in the future. Lost videos are a problem as HCWs do not know if the patient did take his or her medication or not. Another challenge that was mentioned is that some patients miss the human connectivity as relationships between the TB staff and patients often form. Except for reimbursement, participants indicated that all of these issues were not seen as major problems.

The benefits shared included flexibility, patient satisfaction, cost effectiveness, and monitoring on the weekends and when the patient travels. One person mentioned that she works in a small clinic and VDOT helps reduce clinic crowding. In a large rural county, there is only one DOT worker who must cover the entire region. With VDOT, there is less travel for the staff, which is cost effective. When patients travel, during holidays and on weekends, in-person DOT cannot be done. A-VDOT allows for patient monitoring during these times. Border-counties found VDOT useful as some patients may go to Mexico for extended periods of time making monitoring and continuity of care impossible.

When asked about eligibility requirements for patients to be able to use VDOT, the common philosophy was that all patients should be considered eligible. Some of the comments that were shared is that if the patient is medically stable, has successfully completed two weeks of in-person DOT, and that the patient is willing and can be trusted then the patient should be considered eligible. Concerns about language translation were shared. One clinic staff person mentioned that they have translation services for phone but not for webcam, therefore non-native English speakers were automatically disqualified from using VDOT. If patients have a disability or mental health issue that prohibits them from being able to use the phone then they should not use VDOT.

Interviewees were asked about other applications of VDOT. The responses included HIV, Hepatitis C, diabetes, individuals on psychiatric medications, people with drug addiction problems, and the elderly who are on multiple medications. One final issue that arose

from the interviews was the inquiry about how long agencies need to store the videos. Are the requirements the same as for other medical records?

Survey Results

Fifty-six people completed the survey. The same questions were asked about S-VDOT and A-VDOT so that the methods could be compared.

To identify the highest and lowest concerns and to make the comparison of A-VDOT and S-VDOT perceived and experienced concerns and benefits, the four options (no concern, minimal concern, moderate concern, and major concern) were collapsed into two categories (no concern or minimal concern; moderate or major concern) and the same process was done for the benefits. The VDOT types were then compared side-by-side (see Tables 2 and 3).

Table 2.

Differences in Perceived or Experienced Concerns Between A-VDOT and S-VDOT

	Asynchronous		**Synchronous**	
	No Concern or Minimal Concern	Moderate or Major Concern	No Concern or Minimal Concern	Moderate or Major Concern
HIPAA compliance/security	43% (n=22)	57% (n=29)	40% (n=20)	60% (n=30)
Reimbursement	26% (n=13)	74% (n=37)	39% (n=19)	61% (n=30)
Staff acceptance	70% (n=37)	30% (n=16)	76% (n=38)	24% (n=12)
Patient's ability to perform VDOT	55% (n=29)	45% (n=24)	65% (n=33)	35% (n=18)
Patient's concerns about confidentiality	55% (n=29)	45% (n=24)	59% (n=30)	41% (n=21)
Medication adherence	62% (n=32)	38%(n=20)	75% (n=38)	25% (n=13)
Managing side effects	41% (n=21)	59% (n=30)	50% (n=25)	50% (n=25)
Connectivity problems	33% (n=17)	67% (n=34)	29% (n=14)	71% (n=35)
Equipment problems	35% (n=18)	65% (n=33)	40% (n=20)	60% (n=30)
Workload increases	87% (n=45)	13% (n=7)	92% (n=46)	8% (n=4)
Staff layoffs	82% (n=41)	18% (n=9)	79% (n=37)	21% (n=10)
Training staff	63% (n=33)	37% (n=19)	75% (n=38)	25% (n=13)
Training patients	55% (n=29)	45%(n=24)	53% (n=27)	47% (n=24)
Start-up costs	35% (n=18)	65% (n=33)	41% (n=20)	59% (n=29)
Legal issues	38% (n=19)	62% (n=31)	45% (n=21)	55% (n=26)
Lack of data on the efficacy of VDOT	74% (n=39)	26% (n=14)	76% (n=38)	24% (n=12)

Discussion

Overall, there is a strong interest in using VDOT and there are numerous benefits, some concerns, and potential other applications.

Utilization

VDOT is used in about 25 percent of TB control county agencies that participated in the survey. Synchronous is used more than asynchronous; about a quarter of users use both modalities. It is recommended that in-person DOT, A-VDOT, and S-VDOT all be available so that the method that best matches the needs to the patient can be used. There is a high interest in using or expanding VDOT use.

Benefits

VDOT eliminates or reduces travel time and costs for both the public health agency and the patient. VDOT also reduces crowding in small clinics. Flexibility is another benefit as when using A-VDOT no set appointment time is needed. A-VDOT allows for observation of medication ingestion during weekends and holidays, when HCWs typically do not work. VDOT allows for observation when a patient is

Table 3.

Differences in Perceived or Experienced Benefits between A-VDOT and S-VDOT

	Asynchronous		**Synchronous**	
	No Benefit or Minimal Benefit	Moderate or Major Benefit	No Concern or Minimal Benefit	Moderate or Major Benefit
Cost effectiveness	6% (n=3)	94% (n=44)	2% (n=1)	98% (n=45)
Patient satisfaction	7% (n=3)	93% (n=38)	4% (n=2)	96% (n=47)
Staff satisfaction	6% (n=3)	94% (n=44)	6% (n=3)	94% (n=45)
Staff safety	12% (n=6)	88% (n=43)	15% (n=7)	85% (n=41)
Improved medication adherence	19% (n=9)	81% (n=38)	20% (n=9)	80% (n=37)
Managing side effects	68% (n=32)	32% (n=15)	46% (n=21)	54% (n=25)

travelling or when he/she lives in more than one state or country. There is increased safety and reduced exposure to TB for the HCW as the worker does not need to travel, be in unsafe areas, and be in direct contact with the patients.

Concerns

In California, Medi-Cal reimburses for in-person DOT is reimbursed but not VDOT. Managing side effects is a concern. It was reported that side effects are more easily managed using S-VDOT than A-VDOT. If a patient on A-VDOT is having side effects, switching the person to S-VDOT is recommended. Connectivity problems, especially in rural areas, and start-up costs are problematic.

Other Uses of VDOT

For other applications of VDOT, HIV patients on antiretroviral therapy, Hepatitis C and many other applications were identified. Psychiatric illnesses, such as bipolar disorder, may be easier to manage with VDOT, as these patients often stop taking their medications when they are feeling better.

Even with its potential, VDOT is not appropriate for all patients. Patients with disabilities or language barriers, for example, may not be good candidates for VDOT. The situation should drive what modality is used. That is why when using VDOT, having both A-VDOT and S-VDOT available for patients is recommended. This allows the HCW and patient to select the best modality for the circumstances.

When benefits and concerns of users and non-users were compared by percentage of responses (data not shown), concerns generally declined and the benefits were greater than expected for all categories. There are two areas of concern that increased (patient's concern about confidentiality, medication adherence, but the increased was minimal (2 percent or less). This indicates that VDOT users experienced fewer concerns and greater benefits than non-users. This implies that perceived barriers to using VDOT are lower than user's experiences and the benefits are greater than anticipated.

While VDOT has been shown to have a positive impact on TB treatment, there are unique challenges to using VDOT in place of in-person DOT, such as difficulties with the equipment/connectivity and reimbursement differences. These challenges may be solved by establishing clear protocols for utilizing VDOT, technological improvements, and reimbursement policy changes. While these challenges do exist, the benefits appear to outweigh these noted challenges.

The expansion in utilization of VDOT is recommended. To successfully achieve this outcome, the following activities are needed:

- changes in policies so that VDOT is a reimbursable service,

- research that compares the VDOT technologies and identifies the key features of the technologies that address the identified concerns including the cultural barriers to utilization (e.g., translation services),
- educate TB providers about VDOT to reduce the gap between perceived and actual benefits and problems related to using VDOT,
- explore the option of a having a central hub where VDOT videos are reviewed and monitored, and
- perform research on using this technology with other health problems, such as HIV.

A limitation of this study is that the number of interviewees was small (n=7) and all were female. Another limitation was the small convenience sample used in the survey. It is possible that counties with low incident rates were not included as they did not see attendance at the CTCA conference as a priority due to the low number of cases. Therefore, low-incident counties may not be represented in the survey results. Because the survey respondents were CTCA attendees, the findings cannot be generalized.

Conclusion

This study shows that there is a high interest in VDOT and that after people use VDOT their concerns diminish and the benefits are higher than anticipated. If VDOT becomes a reimbursable service and as the technology improves, the barriers to utilization will decrease and the full benefits can be achieved.

VDOT has been shown to be a viable method for delivery DOT to TB patients. Overall, users of VDOT have reported numerous benefits that have a positive impact on the staff, patients, and the public health department. There is a high interest in using this modality and policy changes related to reimbursement are needed before widespread utilization can occur. There are other health issues where VDOT can be applied that are worthy of exploration. With the improvements in technology and decreased funding, VDOT is a viable solution to providing DOT to TB patients.

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