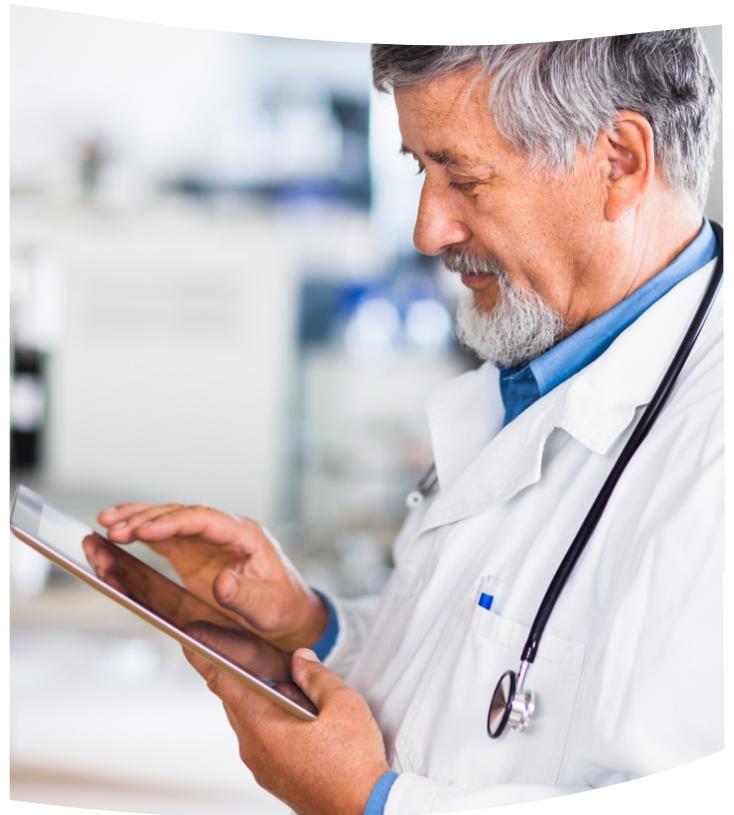


Center for
**Connected
Health Policy**

The National Telehealth Policy Resource Center



**Using Telehealth for Directly Observed Therapy
in Treating Tuberculosis**

April 2015

EXECUTIVE SUMMARY

Tuberculosis (TB) is one of the most widespread infectious diseases in the world, infecting an average of 9 million people annually.ⁱ Although TB is curable, more than 1 million TB-related deaths occur each year globally.ⁱⁱ California reported the largest number of cases in the United States (U.S.), representing 22 percent of the nation's 9,951 cases, and the third highest rate among states.ⁱⁱⁱ

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 tuberculosis.^{iv} DOT consists of observing TB patients taking their TB 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. Treatment of TB can range from three months for latent infections of TB^v to twenty-four months for multi-drug resistant TB (MDR-TB)^{vi} and the cost of treating one patient can range from \$2,000 to \$250,000 for just the medication.^{vii}

The purpose of this paper is to explore the potential use of telehealth as an effective way to address the logistical and financial challenges faced by public health departments in utilizing DOT, while still effectively treating TB patients. Telehealth is the use of technology to deliver care from a distance. Two telehealth modalities, live video DOT (LV-DOT) and asynchronous video DOT (AV-DOT), have demonstrated early promise in several small pilots that it can be effectively utilized to deliver DOT. Telehealth could reduce travel time and costs for both the public health department and the patient, create more flexibility in scheduling, provide a safer environment for the health care worker by limiting their travel and exposure to TB, and quite possibly increase the likelihood of adherence due to these benefits.

Currently, neither the CDC nor the State of California Department of Public Health have any published guidelines or plans for the use of telehealth supported DOT. Aside from the lack of reimbursement for DOT if it is done virtually, public health departments face other challenges in utilizing telehealth to deliver DOT, despite its apparent benefits. These include:

Lack of robust published research regarding the efficacy of using telehealth to deliver DOT.

While there is a growing body of evidence regarding the efficacy of similar forms of telehealth

delivered care, there is limited published research on utilizing telehealth to deliver DOT. However, the findings of these studies are very promising, and have spawned a larger research project that's currently being conducted by researchers at University of California, San Diego (UCSD), who are pioneers in this field. This study is being conducted in five county public health departments in California, and the results of which will be used to inform the State's public policy regarding the payment and use of telehealth supported DOT in the future.

Currently, Medi-Cal administrative policies make it challenging to be reimbursed for telehealth-delivered DOT. Medi-Cal policies restricting reimbursement include lack of approval for the DOT billing code if the service is delivered via telehealth; restrictions on the location of the patient if telehealth is used; and limits on the type of provider who may be reimbursed for services provided via telehealth. Yet, the passage of the *Telehealth Advancement Act of 2011* provides the Department of Health Care Services much greater latitude in redefining these standards if they choose.

Public health departments will need to be mindful of privacy and security issues regarding the use of the technology. With the use of telehealth, public health departments will need to follow protocols that have been discussed and adopted by the California TB Controllers Association (CTCA) to ensure that, among other things, privacy and confidentiality are protected. This could include explicit procedures on how video is viewed and where. Equipment and software that is used may have the capability to track a user's location.

Does the recorded video for AV-DOT become a part of the electronic health record (EHR) for the patient? This is a question that needs to be clarified as potentially this can create issues for public health departments such as interoperability, storage and capabilities of systems to retain the recorded videos, and ownership.

What responsibility does a private health plan have for covering the cost of treatment of TB? Controlling the spread of infectious diseases is a function of public health at both the state and county levels. However, there is some question as to whether the cost of the medications and treatment should be reimbursed if the patient being treated has private health insurance.

Is there potential for using telehealth to manage and treat other infectious diseases and conditions? Similar forms of telehealth as VDOT have been contemplated for managing Hepatitis C, HIV, and even Ebola care. Expanded studies on the use of telehealth for TB adherence and control will directly inform its potential use for these other diseases.

This is the first of two papers in a project examining the use of telehealth to provide DOT to TB

patients. The second paper, to be published later in the year, will focus on specific policy and operational recommendations and actions that encourage the greater utilization of telehealth to provide DOT not only for TB cases, but for other diseases or conditions where DOT is used. Both the California Department of Public Health and CTCA are aware of this project, and the companion UCSD study, and are keenly interested in the results to help shape specific guidelines and policies related to future use of AV and LV-DOT.

ⁱ Congressional Research Service, “US Response to the Global Threat of Tuberculosis: Basic Facts”, Washington, DC, Government Printing Office, June 15, 2012, p. 1.

ⁱⁱ Ibid.

ⁱⁱⁱ California Department of Public Health, “Report on tuberculosis in California, 2013”, Sacramento, CA, August 2014, p. 2.

^{iv} Centers for Disease Control and Prevention. (2012). “Module 9: Patient Adherence to Tuberculosis Treatment Reading Material,” <<http://www.cdc.gov/tb/education/ssmodules/module9/ss9reading2.htm>>, (Accessed March 26, 2015).

^v Centers for Disease Control, Tuberculosis Webpage, < <http://www.cdc.gov/tb/topic/treatment/ltbi.htm>>, (Accessed February 27, 2015).

^{vi} National Institute of Allergy and Infectious Diseases, Tuberculosis webpage, < <http://www.niaid.nih.gov/topics/tuberculosis/understanding/pages/treatment.aspx>> (Accessed February. 27, 2015)

^{vii} World Health Organization, Tuberculosis webpage, < <http://www.who.int/trade/glossary/story092/en/>>, (Accessed February 27, 2015).

INTRODUCTION

Tuberculosis (TB) is one of the most widespread infectious diseases in the world, infecting an average of 9 million people annually.^{viii} Although TB is curable, more than 1 million TB-related deaths occur each year globally.^{ix} California reported the largest number of cases in the United States (U.S.), representing 22 percent of the nation's 9,951 cases, and the third highest rate among states.^x In 2012, California reported 2,189 new tuberculosis (TB) cases and an incidence rate of 5.8 cases per 100,000 population, a decrease of 5.6 and 6.5 percent, respectively, compared with 2011.^{xi} Despite this success, large disparities remain. Persons born outside the U.S. and racial and ethnic minorities continue to be disproportionately affected by TB as do the elderly and children.^{xii}

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 tuberculosis.^{xiii} DOT consists of observing TB patients taking their TB 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, costly and an expensive treatment approach that taxes limited public health resources. Treatment of TB can range from three months for latent infections of TB^{xiv} to twenty-four months for multi-drug resistant TB (MDR-TB)^{xv} and the cost of treating one patient can range from \$2,000 to \$250,000 for just the medication.^{xvi}

The use of telehealth to administer DOT may prove to be an effective way to address the logistical and financial challenges faced by public health departments in utilizing DOT, while still effectively treating TB patients. Currently there is no comprehensive plan on either the national level (CDC), or state level (state and local public health departments) to utilize telehealth DOT to treat TB. Small pilots in specific local jurisdictions have taken place, but no comprehensive statewide policy exists covering the use and reimbursement for DOT utilizing telehealth means.

This paper examines the current policy landscape for challenges and opportunities to utilize telehealth in delivering DOT to TB patients in California. Pertinent federal policies and use in other states will be examined as well to determine the potential impact on California policy and practice.

This report is the first of two papers in a project examining the use of telehealth to provide DOT to TB patients. The second paper, to be published later in the year, will focus on specific recommendations and actions that will encourage the greater utilization of telehealth to provide DOT not only for TB cases, but for other diseases or conditions where DOT is used.

HOW CAN TELEHEALTH BE USED FOR DOT?

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.”^{xvii}

Two modes of telehealth delivery may be used for DOT:

1. **Synchronous (real-time) video DOT (LV-DOT)** allows the public health worker to virtually observe the TB patient taking his or her medication through the use of video transmission utilizing a hand-held device such as a mobile phone.
2. **Store-and-forward (asynchronous) video DOT (AV-DOT)** consists of the patient digitally recording the ingestion of the medication via a mobile phone. The recorded video is transmitted to a secure server where it is stored for viewing by the DOT worker or other medical provider at a later time. See Table 1 for a comparison of DOT, LV-DOT and AV-DOT.

TABLE 1: Procedures and Requirements of DOT, LV-DOT, and AV-DOT

	Directly Observed Therapy (DOT)	Video Directly Observed Therapy (LV-DOT)	Asynchronous Video Directly Observed Therapy (AV-DOT)
Procedures	<ul style="list-style-type: none"> Occurs in real-time (synchronous) Health care worker (HCW) must be physically present to observe the patient ingesting medication 	<ul style="list-style-type: none"> Occurs in real-time (synchronous) HCW virtually observes (via live-video) the patient ingesting medication 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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/Wi-Fi connection 	<ul style="list-style-type: none"> Does not require patient and/or HCW to travel (unless physical check-ins are required) Treatment regimen must fit to the patient and HCW's schedules Requires a smartphone and a cellular/Wi-Fi connection 	<ul style="list-style-type: none"> Does not require patient and/or HCW to travel (unless physical check-ins are required) Treatment regimen fits to both patient and HCW's schedule Requires a smartphone and a cellular/Wi-Fi connection

The use of these virtual technologies offers several important benefits over real-time, in-person DOT:

- Eliminates travel time and cost for both the health care worker and the patient (if the patient was required to travel to a clinic or public health office)
- Flexibility of schedules if utilizing AV-DOT as no set appointment time must be kept by both the health care worker and patient
- Increased safety and reduced exposure to TB for the health care worker by not having to travel
- Allows one health care worker to cover more cases due to increased efficiency of time

Potentially, LV-DOT and AV-DOT could have a positive impact on the rate of adherence and ultimately completing the course of medication, which could be as long as 24 months. The use

of telehealth offers a more practical method for certain groups that the CDC regards as the most appropriate for DOT such as the homeless or unstably housed persons, and those who are receiving intermittent therapy. These populations, who may not have a stable location for a DOT worker to visit, can ingest their medication from any location and connect via live video to the health care worker or send their recorded video.

However, there may be potential drawbacks to utilizing telehealth to deliver DOT such as difficulties with the technology/connectivity and being able to observe potential adverse effects of the medication. These challenges may be solved by establishing clear protocols for utilizing telehealth delivered DOT. It will be necessary to examine what has been discovered so far by the existing research and the few pilots that have taken place.

WHAT DOES THE RESEARCH SAY SO FAR?

A scan of materials has revealed few published studies of telehealth-delivered DOT. A comprehensive database and Internet search of the literature was conducted by two researchers independently during November and December of 2014 and January 2015. The purpose of the search was to retrieve peer-reviewed articles and other documents to describe the efficacy of the technology in treatment TB, as well as current legislation policies, procedures and practices, and acceptance levels and barriers to utilization related to LV-DOT and AV-DOT at the federal, state, and county level. To accomplish this goal the search focused on written documents related to clinical outcomes of using LV-DOT or AV-DOT, cost effectiveness and satisfaction levels when using LV-DOT and AV-DOT, policies and laws related to DOT, LV-DOT, and AV-DOT utilization and reimbursement as well as telehealth and privacy laws in a broader context.

The search terms included “telemedicine and directly observed therapy”, “telemedicine and tuberculosis treatment”, “telemedicine and tuberculosis control”, “telehealth and directly observed therapy”, “telehealth and tuberculosis treatment”, “telehealth and tuberculosis control”, “video and directly observed therapy”, “video and tuberculosis treatment”, “LV-DOT” and “video and tuberculosis control”. The criteria for inclusion were that it must be focused on using video to treat TB patients, be an original research study, and be from a reliable source. No restrictions on the year, sample size, or type of document (dissertation, white paper, PowerPoint slides) were included. This broad criterion was due to the technology’s relatively new utilization; therefore an expansive search was needed. Both domestic and international studies were collected. Researchers slated each article for “inclusion” or “exclusion” based on the article meeting the search criteria. Several databases were used, such as PubMed®, Medline®, LexisNexis®, EBSCO, Web of Science, and Summon. For the policy search, federal and state laws and regulations related to TB and telehealth were examined as were CDC and

national, other states and California agencies and organizations’ guidelines and recommended policies.

A listing of the LV-DOT and AV-DOT studies is found in Table 2 and a listing of the non-TB applications of LV-DOT and AV-DOT studies is found in Table 3. Refer to Appendix 1 for more details regarding the descriptions, criteria, outcomes, and notes of the LV-DOT and AV-DOT studies in Table 2. The studies in each table are listed in reverse chronological order by the year the literature was published.

TABLE 2: LV-DOT & AV-DOT Studies

AUTHOR, DATE, TITLE, LOCATION	TECHNOLOGY UTILIZED	LV-DOT/STUDY TYPE
<p>Garfein, R., et al. (2014). Tuberculosis Treatment Adherence Monitoring by Video Directly Observed Therapy—LV-DOT: A Binational Pilot Study. <i>The International Journal of Tuberculosis and Lung Disease</i>.^{xviii}</p> <p>Location: United States and Mexico</p>	Smartphone	Asynchronous; Mixed
<p>Wade, V., Karnon, J., Elliott, J., Hiller, J. (2012). Home Videophones Improve Direct Observation in Tuberculosis Treatment: A Mixed Methods Evaluation.^{xix}</p> <p>Location: South Australia</p>	Videophone	Synchronous; Mixed
<p>Hoffman, J., et al. (2010). Mobile Direct Observation Treatment for Tuberculosis Patients.^{xx}</p> <p>Location: Nairobi, Kenya</p>	Smartphone	Asynchronous; Mixed
<p>Krueger, K., et al. (2010). Videophone utilization as an alternative to directly observed therapy for tuberculosis.^{xxi}</p> <p>Location: United States</p>	Videophone	Synchronous; Quantitative (Retrospective)
<p>DeMaio, J., Schwartz, L., Cooley, P., Tice, A. (2001). The Application of Telemedicine Technology to a Directly Observed Therapy Program for Tuberculosis: A Pilot Project.^{xxii}</p> <p>Location: United States</p>	ViaTV units & Videophone	Synchronous; Quantitative

TABLE 3: Non-TB Applications for LV-DOT

AUTHOR, DATE, TITLE, LOCATION	DISEASE; TECHNOLOGY USED	LV-DOT/STUDY TYPE
Nazaraeth, S. et al. (2013). Successful treatment of patients with hepatitis C in rural and remote Western Australia via telehealth. ^{xxiii} Location: Western Australia	Hepatitis C; Not specified (videoconference)	Synchronous; Quantitative
Skrajner, M. et al. (2009). Use of videophone technology to address medication adherence issues in persons with HIV. ^{xxiv} Location: United States	HIV; Videophone	Synchronous; Mixed
Sterling, R. et al. (2004). Treatment of Chronic Hepatitis C Virus in the Virginia Department of Corrections: Can Compliance Overcome Racial Differences to Response? ^{xxv} Location: United States	Hepatitis C; Not specified (videoconference)	Synchronous; Quantitative (Retrospective)

The published studies focused predominantly on the use of LV-DOT. Out of the eight listed studies, four took place in the United States, three took place internationally, and one took place in both the United States and Mexico. Videophones were the main equipment used as the telehealth modality in the randomized controlled trials (RCTs) and pilot projects; review articles, mixed methods evaluations, and a retrospective analysis that reviewed LV-DOT were also examined. Although TB was the main health issue in which LV-DOT and AV-DOT was implemented, other alternative uses of LV-DOT focused on communicable diseases, including hepatitis C (HCV) and human immunodeficiency virus (HIV). Overall, LV-DOT and AV-DOT appeared to be feasible approaches to providing directly observed therapy as adherence rates were similar and in some cases better, than standard in-person DOT. It was often found in the pilot projects and RCTs that the virtual visits had a smaller average length of time compared to equivalent in-person visits, including both travel time and face-to-face time. Subjects of studies also frequently reported the technology to be convenient, private, reliable, and flexible. All studies and reviews that included a cost analysis suggested that LV-DOT and AV-DOT are cost-effective alternatives to DOT and offer cost savings regarding patients and health care personnel.

While there is a lack of extensive LV-DOT and AV-DOT research, what does exist indicates great potential for not only patient adherence and treatment and convenience, but also potential cost savings. Transportation costs as well as personnel time saved on patients' virtual visits

were two of the main cost aspects that were examined in the studies. Although the technology appears promising, studies for both LV-DOT and AV-DOT are rare and sample sizes have typically been small.

Other Relevant Telehealth Research Findings

Although the research related to using telehealth to deliver DOT is limited, there have been numerous studies that show the ability of the technology in both live video and store-and-forward to deliver as good, and in some cases, better care in a cost efficient way to patients. CCHP has created several catalogues that look at published, peer-reviewed studies for remote patient monitoring, mental health, dermatology and one catalogue specifically related to cost savings.^{xxvi}

Many of these telehealth studies' findings reflect the same benefits that the technology potentially offers to DOT, such as decreased travel times, increasing population reach, and providing care in culturally and linguistically sensitive manner. Specific cases include utilizing telehealth to deliver mental health services to underserved Hispanics. A randomized control trial looked at the effectiveness of a psychiatrist providing treatment via videoconferencing compared to treatment as usual via a primary care provider. All participants in the study experienced improvements in depression symptoms suggesting not only the efficacy of the mode of delivery, but that the technology could help close the gap in access for populations with specific cultural and linguistic needs.^{xxvii}

A randomized control trial of heart failure patients receiving home care utilizing remote patient monitoring (RPM) found a reduction in hospital days for patients and facilitation of better ambulatory management, including fewer emergency department visits.^{xxviii}

Utilizing store-and-forward has also proven to be effective and cost efficient in delivering care especially for dermatology and teleophthalmology in diabetic retinopathy. In 2008 a cost-utility analysis of premature infants who received a store-and-forward intervention to identify possible cases of retinopathy of prematurity (ROP) via an ophthalmoscopic examination was conducted. The findings suggested that using the store-and-forward technologies was cost-effective and included other possible benefits such as decreased travel, opportunity cost-savings, and satisfactions levels for ROP identification.^{xxix}

A review conducted by Surendran and Raman (2014) analyzed telehealth practices for diabetic retinopathy (DR) guidelines as well as published studies. The results of the comprehensive review indicated that using store-and-forward for screening is a safe, cost-effective, accurate, and reliable method for detecting DR. Patients from several analyzed studies also reported high satisfaction levels regarding the digital imaging system, perhaps due to the benefits of

increased screening rates, reduction of travel time, increased access to clinical services. The results of the review suggested that using the technology has additional benefits such as decreased examination time and the “availability of nonophthalmologists to screen for DR.”^{xxx}

Another randomized controlled trial was carried out on 9,720 patients in the states in the Pacific Northwest using teledermatological care. When asked to compare their teledermatology exposure to face-to-face care, most (77%) of the surveyed patients were accepting and highly satisfied or satisfied with teledermatology. Their reasons for high satisfaction rates were as follows: “short wait times for initial consultation, a perception that the initial wait time was not too long, a perception that the skin condition was properly treated, and the belief that adequate follow-up was received.”^{xxxi}

Existing Telehealth Platforms for DOT

Pilots that have used LV-DOT have generally used some type of currently existing video platform such as Skype or Face Time. However, in researching this paper, two AV-DOT systems were discovered. The first system was developed by the University of California, San Diego (UCSD), and is called “VDOT”. UCSD has run several pilot projects including one in 2010-2012 in San Diego and Tijuana and pilots in New York City, San Diego and San Francisco in 2012-2015. In these pilots, smartphones were loaned to participants with the software preloaded. The VDOT system sends weekly medication reminders via text message or email depending on the patient’s choice. The VDOT phone application is programmed to send the encrypted, time/date stamped videos to a secure server as soon as the video recorder is stopped. If cellular or Wi-Fi access is unavailable, the video remains in the phone’s memory, hidden to users, until a signal is detected and the video is sent. To protect patient confidentiality, videos are stored on the phone in a manner that cannot be opened on the phone. Once the video is received by the server, an authenticated message is sent back to the phone that causes the video to be deleted. DOT workers monitor videos as they arrive using a password protected website called Case Management System and document each medication dose that is taken. The staff member observes videos each day and receives a daily report listing the identification numbers of participants who did and did not send videos. Patients with missing videos may be contacted by the DOT worker or other staff member to determine whether the medication was taken and troubleshoot potential problems the participant may be having. Clinic staff is informed whenever patients miss a medication dose so they may be contacted according to standard treatment protocols. Programs have varying protocols in checking for adverse effects to the medication beyond having the patient communicating any symptoms.

A new commercial version of UCSD VDOT called SureAdhere was recently licensed from UCSD. While SureAdhere is based on VDOT technology, the software is being modified to work more

appropriately in a commercial environment. SureAdhere representatives intend to provide “production level” engineering and scalability, as well as expanded and enhanced levels of customer training and support. This product is now available for use by health departments nationwide and globally.

The second system is produced by emocha Mobile Health Inc. and it is an app called miDOT. Developed together with researchers at Johns Hopkins School of Medicine, miDOT is currently being used by the state of Maryland to track Ebola. Researchers are just in the beginning stages of TB applications of emocha in Baltimore City and Harris County, TX. and as of yet, do not have any data available. With this application, the miDOT is downloaded onto the patient’s smartphone and the patient produces a recording of the ingestion of the required dosage. The video is then uploaded to emocha’s password protected Health Information System where it can be accessed by the health worker for review (or the video is submitted when the app is closed). The video is automatically deleted from the phone after submission. The app allows the patient to enter any symptoms he or she may experience while on the medication regimen, flags the symptoms, and alerts the health worker monitoring the data that a particular patient may have reported issues. The system sends text messages to patients as reminders.

miDOT and the emocha platform can be adapted to address specific needs for different diseases. For example, while DOT for TB may require a video recording, monitoring a patient for potential Ebola infection may not, but there are specific symptoms that a health worker will want to monitor. Baltimore City, Johns Hopkins, and emocha are also planning an application using the miDOT video functionality to support linkage to care and adherence for Hepatitis C patients. While miDOT only utilizes asynchronous video, they are working to develop a live video option to the app.

FEDERAL POLICIES & OTHER STATES ACTIVITIES

Two specific federal laws impact the use of telehealth in delivering DOT. The National Strategy for Combating and Eliminating Tuberculosis, which is found in 42 USCS § 247b-6, allows for the Secretary, acting through the CDC, to make grants “to States, political subdivisions and other public entities for preventive health service programs for the prevention, control and elimination of tuberculosis.”^{xxxii} Grants for research and pilots concerned with TB control also may be made by the Secretary including developing, enhancing and expanding, “information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.” The law also calls for the creation of a Federal Tuberculosis Task Force that among other duties shall “provide to the Secretary and other appropriate

Federal officials advice on research into new tools...” This section of federal law indicates a potential willingness to examine the use of technology in treating and eliminating tuberculosis. With the recent heightened interest in telehealth to deliver clinical health services, federal agencies focused on public health issues such as infectious diseases may also turn to technology for their work and could potentially make grant funding available to explore this avenue.

The Omnibus Budget Reconciliation Act of 1993 provides federal funding via the CDC to State and local health departments for TB diagnosis, case management and contact investigations, surveillance, education, and outreach, but provides limited support for TB treatment or prescription drugs. This program extends Medicaid eligibility to low-income individuals infected by TB who would otherwise not qualify for Medicaid. DOT is listed as an optional service that states may offer but it is not required. The program requires a change in the state plan and California is one of the states that have opted to receive this federal funding. Other states who are receiving this funding are: Arkansas, Maine, South Dakota and Wisconsin. While California is participating in this program and is offering reimbursement for DOT under its Medicaid program, Medi-Cal, the funding is limited and there is no mention requiring the states to use technology in treating TB.

National and CDC Guidelines

According to the CDC’s Self-Study Modules on Tuberculosis, “DOT is the most effective strategy for making sure patients take their medicines.” As a result, health departments commonly consider DOT to be the standard of care for treating TB. However, an examination of national organizations and federal agencies revealed guidelines for in-person delivery of DOT only. Written by the US Department of Health and Human Services (HHS) and the CDC, the “Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws” is endorsed by the National Tuberculosis Controllers Association. The only references to DOT are to delivery in-person.^{xxxiii} These guidelines were published in 2003 when these virtual technologies were not available or widely used, and thus not considered for delivery of DOT. While DOT treatment is acknowledged as an effective means of treating TB, there appears to be a need for expanding these guidelines regarding the use of telehealth virtual technology in delivering DOT.

What Other States Are Doing?

Policies regarding DOT as a means of treatment vary. Some states consider DOT the standard of treatment of TB while others note it as an option. Reimbursement for DOT is made in some states’ Medicaid programs while others are silent. Connecticut and Texas are among the states that cover DOT in their Medicaid programs. Formalized policy around the use of video technology to provide DOT could not be found. However, there are several examples of unique

policies or pilots in other states that bear mentioning.

New York

In 2013-2014, the New York City Department of Health and Mental Hygiene, Bureau of Tuberculosis Control utilized live video in a pilot to treat TB patients with DOT. In a six-month review (September 2013 – March 2014), thirty-seven patients were enrolled in the pilot. Participants were loaned a smartphone with pre-loaded video conferencing software. Twenty-six of the participants had an adherence rate, number of observed ingestions, of 90% or better which was equal or better than in-person DOT and the health care worker's productivity increased from 2-3 daily observations in the field to 25 with LV-DOT.^{xxxiv}

New York State has an unusual policy regarding Medicaid and reimbursement for DOT. In 2013, the state of New York made the provision of TB/DOT the responsibility of Medicaid Managed Care.^{xxxv} Among the managed care plan responsibilities are:

- Managed care plans may not require prior authorization for TB/DOT services if the services are provided under the authority of the Local Health Department.
- Managed care plans may not mandate the location of TB/DOT services or which provider will provide TB/DOT services, however, the local districts/local health departments will work with the plans and try to utilize network providers whenever possible.
- Managed care plans may amend existing provider contracts or enter into new provider contracts for TB/DOT services.
- Managed care enrollees may self-refer to the local public health department for diagnosis and/or treatment of tuberculosis.^{xxxvi}

This differs from California's approach to managed care and DOT which is discussed below. While such a policy has interesting potential, it should be noted that no requirement or prohibition to technology to deliver DOT is mentioned.

Maryland & Texas

As mentioned above, emocha's miDOT has been utilized in both Maryland and Texas for different projects. At this time, the projects are in their nascent stages and no data is available. In speaking with an emocha representative, the use of miDOT in Harris County, TX, has moved beyond the pilot phase and has been incorporated into the county health department's operations for delivering DOT, and an amount of funding has been appropriated for AV-DOT.

CALIFORNIA STATE POLICIES

California TB Policy

Under California's Medi-Cal provider manual, TB related services are reimbursable as a fee-for-service. Medi-Cal managed care plans are not required to cover DOT and it is instead, billed as a fee-for-service. The reimbursement rate for DOT is \$19.23 per encounter. Eligible DOT providers are community workers and/or public health nurses employed by county clinics already enrolled or are eligible to enroll as Medi-Cal providers under existing county provider categories.^{xxxvii} The code to bill for a DOT encounter is Healthcare Common Procedure Coding System (HCPCS) code Z0318.

The California Department of Public Health (CDPH) and the California Tuberculosis Controllers Association (CTCA) issued joint guidelines on DOT protocols that include suggested protocols for LV-DOT. The following elements were suggested when considering the use of LV-DOT:

- Video picture must be sufficiently clear to discern the shape, color and size of the pills
- Ability to visually evaluate the patient's general health in real time
- Patients receiving video DOT must have the capability to use and maintain the equipment
- Patient must be motivated to take their medications
- Trial period of in-person DOT for an initial period before instituting video DOT^{xxxviii}

These guidelines are only suggestions to the county on how to utilize LV-DOT in treating TB patients. They are not directives or mandates on county health departments and they only relate to LV-DOT. No mention was made of utilizing AV-DOT.

No law or regulation to prohibit the use of telehealth in delivering DOT therapy was found. Additionally, there is no requirement that DOT take place in real time aside from the aforementioned recommended guidelines for DOT protocols issued by CDPH and CTCA.

California Telehealth Policy

California recently updated its telehealth laws with the passage of AB 415, the Telehealth Advancement Act of 2011. While AB 415 expanded the potential use of telehealth and its reimbursement, many of the changes were subject to the policies of the payer, including Medi-Cal. Payers are given the flexibility to expand their policies for reimbursement of telehealth, but are not mandated to do so. In other words, for a program such as Medi-Cal, the Department of Health Care Services (DHCS) may make changes to policy administratively without a legislative order. Legislated changes made by AB 415 included:

- Expansion of the types of eligible telehealth providers
- Elimination of restrictions on the type of telehealth modality

- Elimination of facility restriction

Although AB 415 went into effect on January 1, 2012, DHCS did not issue an updated provider manual until September 2013 when they also held a provider webinar to discuss the changes made. At that time, the DHCS representative offered its (verbal) clarification of the intent of the new language related to telehealth reimbursement, provider and facility type. This explanation appeared to conflict with the language in the law, which has created some confusion in its implementation. In discussions with DHCS, they note they continue to work on refining their administrative policy for telehealth. However, as of this writing, Medi-Cal policy related to fee-for-service reimbursement for telehealth, which is contained in the telehealth section of the Medi-Cal Provider Manual states:

- Specific service codes that will be reimbursed if the service is provided via telehealth with the addition of a modifier to note what modality was used to deliver the service (GT for live video and GQ for asynchronous/store-and-forward)
- Elimination of facility type restrictions
- Specific list of what will be reimbursed if provided via asynchronous technology (dermatology, dental, ophthalmology and a small section of optometry services)

No information regarding provider type is listed in the manual despite the clear language in the law that allows for significant expansion in this regard.

POTENTIAL OPPORTUNITIES & CHALLENGES

The environmental scan of the policy landscape related to DOT in treating TB has revealed potential challenges and opportunities in utilizing telehealth to deliver DOT in California.

National & State

No Legal Barriers to Utilizing Telehealth

No current legal barriers appear to exist in using telehealth to provide DOT on either the federal level or in California. In fact, there is an indication in federal law of a “willingness” to explore the use of technology for better control over TB. California adjusted its laws in 2011 to provide for greater opportunities to utilize technology in delivering health services. Therefore, statutorily, the environment appears to be favorable.

Lack of Existing Research

As noted above, the published research around LV-DOT and/or AV-DOT is limited. While the findings for these few studies have been very promising, it is likely that many policymakers will

require more robust evidence before adopting more active policy around LV-DOT and/or AV-DOT. There are exceptions. Harris County in Texas has just begun utilizing miDOT to deliver AV-DOT and has dedicated the funds for it. But most health departments still remain either in the pilot phase or are not utilizing technology to deliver DOT. UCSD, with funding from the California Health Care Foundation, is currently utilizing VDOT to conduct a pilot test of AV-DOT in five urban and rural counties in California with a high incidence of TB. CCHP will be conducting interviews with the participating county health departments regarding the challenges and benefits they have seeing using the technology while participating in this project. The data will help in creating a more robust foundation of evidence for the use of telehealth in delivering DOT and help inform future recommendations for improvements in public policy related to VDOT.

Lack of Guidelines for Technology-Delivered DOT

The CDC guidelines for DOT have not been updated in over a decade. When they were first published, the use of telehealth and technology for health service delivery was not as robust or accepted so it is not surprising that there was no mention of technology in those guidelines. However, the delay in updating these guidelines does not acknowledge the potential benefits technology can offer. The CDC guidelines directly influence how state and local public health departments develop their own policies. While the current guidelines may be considered a challenge, the time may be ripe to consider an update that includes uses of LV-DOT and AV-DOT in the treatment and management of TB therapeutic regimens.

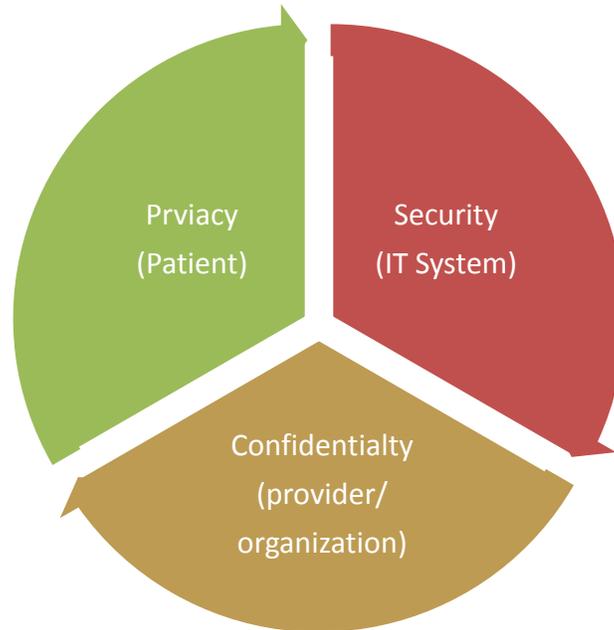
HIPAA: Privacy, Security and Confidentiality

Health privacy and protection concerns are also policy issues that should be addressed and were raised in one of the LV-DOT studies.^{xxxix} When utilizing either LV-DOT or AV-DOT, a provider must consider health information privacy. Most file these considerations under the Health Insurance Portability and Accountability Act (HIPAA) which protects the privacy of an individual's identifiable health information and sets national standards for security of protected electronic health information. HIPAA does include a set of requirements and issues that health departments will need to address such as whether a live video platform being used can meet HIPAA requirements or whether business agreements will need to be formed with whatever system or tools are used.

However, even beyond HIPAA there are privacy and security issues that must be considered when using technology in DOT. The three major areas to consider are:

- Privacy – which beyond identifiable health information can also be about surveillance and tracking

- Security – how to keep a system secure
- Confidentiality – the responsibility of agency or provider administering DOT to keep the patient’s information confidential



These are questions that providers and organizations utilizing the technology will need to ask and then put protocols and systems into place if they do not already exist. There may also be situations in which the unique nature of the technology forces entities to create protocols. For example, in the case of AV-DOT, medical information is stored and transmitted. Proper precautions will need to be taken in the transmission of that information and what information is stored in the device provided to the patient by a public health department. A local department of health may need to consider aspects that are not an issue with in-person DOT such as where the DOT health worker views a video. For example, when viewing a video, the DOT health worker must be in a room where no unauthorized individual is able to see.

Another complication beyond protected health information is the ability to track an individual’s whereabouts. In the UCSD VDOT application, a location stamp is placed on the video that is uploaded to their central information system. That stamp geographically identifies the location of the patient when the video is recorded. Certain steps may be taken by a public health department to safeguard their equipment such as tracking ability on a smart phone. These issues may raise questions about an individual’s privacy rights.

Programs utilizing the technology will need to be mindful of how they structure their programs

in order to meet all requirements regarding privacy and security on both a federal and state level. This is especially true should the technology be utilized for other infectious diseases as some, such as HIV, have specific and sometimes more stringent privacy protections, especially on the state level.

Informed Consent

California and other states have specific laws regarding patient prior informed consent that must be obtained before telehealth can be used. Beyond consent to utilize DOT, patients must also consent to the use of the technology. Additionally, if the system being used can track an individual's location, additional informed consent may need to be acquired.

California Specific Issues

While no statutory prohibition to use telehealth to deliver DOT exists, there are program policies that create challenges to its use.

Provider

AB 415, the Telehealth Advancement Act of 2011, made all licensed health care providers under Division 2 of the California Business & Professions Code an eligible telehealth provider, though it did not mandate a payer to reimburse all of these providers. Medi-Cal has noted in their policies that it would only reimburse specifically named provider categories delivering services via telehealth.

Community health workers, who are listed in the Medi-Cal provider manual as being eligible to perform DOT duties and be reimbursed, are not specifically listed as an eligible provider for telehealth. To reimburse for DOT in Medi-Cal, the eligible provider list for both DOT reimbursement and telehealth would need to be modified accordingly.

Location

AB 415 expanded eligible locations for telehealth services to take place, but it is subject to the policies of the payer. The Medi-Cal provider manual notes the elimination of the location restriction;^{x1} however, during DHCS' September 2013 provider information webinar it was not clear whether the home could be considered an eligible patient site. Specific, written clarification is being sought by DHCS on their policy, but if they do not consider the patient at home without a health care provider present as an eligible originating site, it negates the flexibility and benefits sought in using asynchronous or synchronous DOT. Clarifications and possibly adjustments would be needed in Medi-Cal's policy in order to allow asynchronous and synchronous DOT's full capabilities to be used.

Reimbursement

Currently, DOT is reimbursed on a fee-for-service basis with the HCPCS billing code of Z0318. In Medi-Cal fee-for-service, only certain billing codes are recognized as reimbursable if telehealth is used as the mode of delivery. Z0318 is not a recognized code among the codes that are eligible for reimbursement if the service is provided via telehealth. Therefore, DOT will not be currently reimbursed if provided via telehealth unless the Z0318 code becomes eligible for reimbursement if provided via telehealth.

Medi-Cal will only reimburse for asynchronous services in teledermatology, teleophthalmology, a narrow set of services for teleoptometry and most recently for teledentistry, as required explicitly in California law. While DHCS has the administrative capability to expand what types of services it will reimburse if delivered via asynchronous technology, DHCS has not expanded its billing codes to include other specialties. A change will need to be made, perhaps on a legislative level as was done with teledentistry in 2014, if AV-DOT is to be reimbursed.

California managed care health plans are not required to cover DOT services since it is reimbursed on a fee-for-service basis. Managed care plans have either a subcontract or MOU with the local health department (LHD) to ensure they keep the LHD informed of TB cases and provide follow-up with the patient. However, these agreements do not require the managed care plans to provide DOT themselves. LHDs must then bill Medi-Cal fee-for-service for DOT. California could adopt a policy similar to New York's where managed care plans are required to pay for DOT and specifically require the plans to reimburse regardless of whether the DOT was delivered in-person or via telehealth.

DOT and LV-DOT Guidelines

The joint guidelines issued in 2011 by CDPH and CTCA note that technology-enabled DOT should take place in "real time," although no explicit legal or regulatory restriction exists to require it. At the time the guidelines were developed, the asynchronous technology may not have been at the point to effectively provide DOT. Like the CDC guidelines, these joint CDPH and CTCA guidelines can be influential in county health departments utilizing telehealth to deliver DOT. If the technology is capable of effectively providing asynchronous DOT, the guidelines should be updated accordingly.

As no statutory restriction prohibits the use of telehealth to deliver DOT in California or prevents the reimbursement for it by a public or private payer, much of the needed policy change to standardize the use and allow reimbursement for AV-DOT and LV-DOT need to be accomplished through administrative action. The pathway for accomplishing this appears to be through the CTCA, which could develop recommended guidelines for the use of telehealth for

DOT for the formal endorsement from CDPH. This standardization of delivery of DOT using telehealth could ultimately lead to the decision to allow Medi-Cal reimbursement for DOT delivered through virtual means.

Other Considerations

During the environmental scan, certain other issues arose that are worthy of consideration for future research and/or policy recommendations.

Reimbursement by Private Health Plans

Given the public health aspect of tuberculosis control, there is some question as to what extent is a private payer expected to cover treatment costs. Initial discussions with health departments have indicated that private payers regarded TB treatment as a public health issue and thus the responsibility of health departments. Given how expensive the medication alone is, this puts an enormous burden on already strapped public health agencies. The question of whether private insurance plans should be required to pay for medications and treatment is one worth further exploration.

Utilizing Existing Systems

County health departments may be able to utilize existing systems to help implement LV-DOT or AV-DOT programs. For example, the Health Care Interpreter Network (HCIN) may help with a LV-DOT encounter. The HCIN may also be useful in providing interpretation services to participants who speak other languages. As noted above, TB has disproportionately impacted ethnic minorities who may experience language barriers. Additionally, utilizing these systems may help local health departments avoid some of the privacy and security concerns raised earlier if these currently existing systems have already been vetted for security. However, this is only if a county health department is utilizing LV-DOT. AV-DOT may provide more flexibility and savings for both the county health department and patient, but may not work on currently existing systems such as the HCIN.

Electronic Health Records

A question also is raised on whether recorded video from using AV-DOT will need to be a part of the electronic health record (EHR). If so, this could create issues around interoperability between health records, how the records are stored in the EHRs, storage space, and other factors. Additionally, the videos are currently stored in a third party system where they are viewed on that system. How would these videos then be downloaded into an EHR?

Utilizing the technology beyond TB

The case has been made that telehealth technology may be utilized for the treatment and management of other infectious diseases. However, should LV-DOT and/or AV-DOT be utilized for other conditions, there may be other legal, regulatory or policy challenges that are specific to those diseases, such as additional or other privacy laws. These unique facets would need to be examined separately from the TB to ensure no inadvertent violation occurs.

Advances in Treatment

The CDC may recommend a new drug regime in the treatment of some TB cases. This regime could be a 12 week course that includes one dose each week with *no* DOT involved. These changes in treatment may impact county health departments on whether to invest in LV-DOT or AV-DOT. While there are always, hopefully, advancements in treating medical conditions, it will be a while before such treatments become widespread. Additionally, it may prove to be more cost efficient for county health departments to employ LV-DOT and/or AV-DOT in treating TB cases rather than adopting a new regime. At this time and for the foreseeable future, LV-DOT and AV-DOT continue to hold promise to be an effective and cost-efficient treatment for TB and possibly other conditions.

CONCLUSION

While there is currently only a limited set of research studies on LV-DOT and AV-DOT specifically, there is a growing body of evidence of the value of different telehealth modalities in the management of chronic diseases, including asynchronous, store-and-forward modalities. What does exist has demonstrated the promise of these technologies in meeting the goals of the Triple Aim of better health, better outcomes and cost efficiencies. More expansive study is warranted to document the evidence of the relative effectiveness of these approaches, and to formalize the best procedures in utilizing the technology. Further, expanding the body of evidence of the efficacy of LV-DOT and AV-DOT is needed evidence to convince policymakers, including the CDC, to recognize telehealth as a viable, if not better form of delivery of DOT. The results of the current UCSD pilot demonstrations of LV-DOT and AV-DOT in five counties in the State will be summarized in a second paper with specific policy administrative and regulatory recommendations for the advancement of these virtual methods to manage and control the spread of TB and potentially other infectious diseases. These findings and recommendations will be shared with the CTCA, the CDC, and other State TB Control agencies that may be interested.

^{viii} Congressional Research Service, “US Response to the Global Threat of Tuberculosis: Basic Facts”, Washington, DC, Government Printing Office, June 15, 2012, p. 1.

^{ix} Ibid.

^x California Department of Public Health, "Report on tuberculosis in California, 2013", Sacramento, CA, August 2014, p. 2.

^{xi} Ibid., p 2.

^{xii} Ibid.

^{xiii} Centers for Disease Control and Prevention. (2012). "Module 9: Patient Adherence to Tuberculosis Treatment Reading Material," <<http://www.cdc.gov/tb/education/ssmodules/module9/ss9reading2.htm>>, (Accessed March 26, 2015).

^{xiv} Centers for Disease Control, Tuberculosis Webpage, < <http://www.cdc.gov/tb/topic/treatment/ltbi.htm>>, (Accessed February 27, 2015).

^{xv} National Institute of Allergy and Infectious Diseases, Tuberculosis webpage, < <http://www.niaid.nih.gov/topics/tuberculosis/understanding/pages/treatment.aspx>> (Accessed February. 27, 2015)

^{xvi} World Health Organization, Tuberculosis webpage, < <http://www.who.int/trade/glossary/story092/en/>>, (Accessed February 27, 2015).

^{xvii} California Business and Professions Code, Sec. 2290.5.

^{xviii} Garfein, R., Collins, K., Munoz, F. Moser, K., Cerecer-Callu, P., Raab, F., Rios, P., Flick, A., Zuniga, M., Cuevas-Mota, J., Liang, K., Rangel, G., Burgos, J., Rodwell, T., Patrick, K., "Tuberculosis Treatment Adherence Monitoring by Video Directly Observed Therapy—LV-DOT: A Binational Pilot Study." *The International Journal of Tuberculosis and Lung Disease*. (Pending Review) (2015).

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^{xx} Hoffman, J., Cunningham, J., Suleh, A., Sundsmo, A., Dekker, D., Vago, F., Munly, K., Kageha Igonya, E., Hunt-Glassman, J., "Mobile Direct Observation Treatment for Tuberculosis Patients," *American Journal of Preventative Medicine* 39(1):78-80 (2010).

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^{xxvi} Center for Connected Health Policy, Reports and Policy Briefs, <<http://cchpca.org/reports-and-policy-briefs>> (Accessed March 27, 2015).

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- ^{xxxiii} US Department of Health and Human Services & Centers for Disease Control and Prevention, *Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws*, <<http://tbcontrollers.org/docs/TBLawResources/TBLawMenu1014.pdf>> (Accessed February 27, 2015).
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- ^{xxxvii} California Department of Health Care Services, “Medi-Cal provider manual, TB related services,” page 2 (May 2007).
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- ^{xl} California Department of Health Care Services, “Medicaid Provider Manual, Telehealth,” p. 1. (Dec. 2013)

APPENDIX 1

Garfein, R., Collins, K., Munoz, F., Moser, K., Cerecer-Callu, P., Raab, F., Rios, P., Flick, A., Zuniga, M., Cuevas-Mota, J., Liang, K., Rangel, G., Burgos, J., Rodwell, T., Patrick, K. (2014). Tuberculosis Treatment Adherence Monitoring by Video Directly Observed Therapy—LV-DOT: A Binational Pilot Study (n=52)			
STUDY DESCRIPTION	STUDY CRITERIA	OUTCOMES	NOTES
<p>In 2010 to 2012, researchers at the University of California San Diego (UCSD) conducted a pilot study funded by the U.S. National Institutes of Health to evaluate the feasibility and acceptability of a LV-DOT. The pilot study was conducted in San Diego, CA and Tijuana, Mexico to represent high and low resource settings. Participants used a smartphone and recorded videos of themselves taking each dose of TB medication. Videos were uploaded to a secure website and then DOT workers reviewed the videos and documented whether the complete dose was ingested. Over 95 percent of expected medication doses were observed using LV-DOT. Follow-up interviews were completed by 50 (94%) participants.</p>	<ul style="list-style-type: none"> • Ability to speak English or Spanish; • age ≥18 years; • ≥1 month of treatment remaining; and • Willing and able to provide informed consent. • Must not be a patient with confirmed or suspected drug resistant-TB or patient with physical conditions preventing the use of a cell phone (i.e., severe arthritis, diminished vision) • Must have their providers determine that they were tolerating their medications (minimum of 2 weeks) during the time in which patients received traditional in-person DOT 	<ul style="list-style-type: none"> • Adherence in San Diego (93%) and Tijuana (96%) was similar • 92% of LV-DOT users reported never/rarely having problems recording videos • 92% of LV-DOT users preferred LV-DOT over in-person DOT • 84% of LV-DOT users thought LV-DOT was more confidential • 100% said they would recommend LV-DOT to others 	<p>Some videos were lost due to technical problems with the newly developed application. Since we could not confirm whether those doses were actually ingested, we treated lost videos as missing doses in calculating adherence rates. As mobile technology plays an increasingly important role in healthcare, LV-DOT has potential to expand the coverage of TB treatment monitoring to more patients worldwide. This also could reduce the burden on both patients and providers, resulting in higher treatment completion rates, fewer new cases of TB, and prevention of acquired drug resistant TB.</p>

Wade, V., Karnon, J., Elliott, J., Hiller, J. (2012). **Home Videophones Improve Direct Observation in Tuberculosis Treatment: A Mixed Methods Evaluation. (n=128, videophone=58, in-person DOT=70)**

STUDY DESCRIPTION	STUDY CRITERIA	OUTCOMES	NOTES
<p>Conducted in a community nursing service, this retrospective cohort study compared the effectiveness of telehealth to in-person DOT for TB patients. Cost-effectiveness, adherence, and patient and provider levels of acceptability, usability, and sustainability were evaluated. Interviews were conducted to assess levels of acceptability, usability, and sustainability; they were recorded, transcribed, and analyzed using NVivo software. Interviews with 19 staff and 11 current patients were conducted and analyzed. Patients were called daily by a provider on the patient's desktop videophone at a mutually agreed upon time. Records from the beginning of 2003 to early November 2010 were reviewed. The in-person DOT recipients either received DOT in the clinic or the community.</p>	<ul style="list-style-type: none"> • Treated at the Royal Adelaide Hospital Chest Clinic • Had recorded a diagnosis of TB between January 1, 2003 and November 15, 2010 • No data was missing in the patient's chart • Must not be receiving intramuscular or intravenous treatment • Be clinical staff or manger associated with LV-DOT at the hospital and consent to the interview (interviews only) • Be a patient receiving DOT via videophone for at least a month and consent to the interview (interviews only) 	<ul style="list-style-type: none"> • Non-adherence days for videophone was 5.3 as compared to in-person DOT of 6.4 days • Per episode, the costs of LV-DOT (\$2654) were higher than in-person DOT (\$2589) [note: in-person DOT is not done on weekends where LV-DOT does include weekend monitoring] • In about 25 of the 30 interviews, increased convenience and flexibility with LV-DOT was mentioned • Most interviewees felt that the videophone increased patient's privacy; two patients reported feeling an intrusion in the home • Patients interviewed reported that the technology was easy to use • There were frequent and substantial technical difficulties that caused frustration for patients and staff 	<p>If the technology improves, this method of DOT could be expanded to the developing world. The full benefit of this type of service would be seen by having a 24/7 call center.</p>

Hoffman, J., Cunningham, J., Suleh, A., Sundsmo, A., Dekker, D., Vago, F., Munly, K., Kageha Igonya, E., Hunt-Glassman, J. (2010). **Mobile Direct Observation Treatment for Tuberculosis Patients. (n=13)**

STUDY DESCRIPTION	STUDY CRITERIA	OUTCOMES	NOTES
<p>This pilot study was designed to assess the use of remote mobile direct observation treatment (MDOT) for TB patients. Three health care professionals and 13 patients participated in the study. Treatment supporters (a relative or friend) , using a mobile phone, took the videos of the patients taking their medications, and patients then submitted the videos to the health care professionals for review. Videos were sent using a mobile messaging service to a secure central database where it was automatically date and time stamped. Patients were asked to reviewed educational and motivational text messages and videos. Patient surveys were conducted at three time periods: at intake and 15 and 30 days after starting MDOT. Data collection took place in 2008 and was analyzed in 2009.</p>	<p>Not stated in the publication.</p>	<ul style="list-style-type: none"> • 12 of the 13 patients completed the program; the one patient who dropped out was tracked to being in a local jail • Survey respondents (n=11) reported a 4 to 5 (with 5=very positive) range in terms of satisfaction and comfort with the methodology • all survey respondents agreed that MDOT was a viable option • 8 of the 11 survey respondents indicated a preference for MDOT over in-person DOT • The nurses and clinical officers all ranked MDOT as very positive once technical difficulties were overcome • It was estimated that 25% of videos were not received due to technical issues during the first week • Patients indicated that they felt someone cared for them, that they felt more optimism for being cured, and that they valued the reminders to take their medication • Nurses reported that MDOT allows for a higher level of care and timely proactive intervention; also reported that they appreciated the professional development opportunities 	<p>MDOT is a feasible method of treating TB patients. Future research should focus on the cost effectiveness of MDOT, medication adherence, and other diseases that MDOT can be used to improve treatment compliance.</p>

Krueger, K., Ruby, D., Cooley, P., Montoya, B., Exarchos, A., Djojonegoro, BM., Field, K. (2010). **Videophone utilization as an alternative to directly observed therapy for tuberculosis. (n=57)**

STUDY DESCRIPTION	STUDY CRITERIA	OUTCOMES	NOTES
<p>A retrospective chart review and data analysis was conducted on patients from 2002 to 2006. The patients had active TB in two Washington state counties, Pierce County (n=41) and Snohomish County (n=16). Videophone technology was utilized for LV-DOT to compare to standard, in-home DOT. The focus of the study was to assess the cost-effectiveness of LV-DOT.</p>	<ul style="list-style-type: none"> • “Mutual trust and reliability • Completion of at least 2 weeks of treatment by directly observed therapy with an adherence rate of 90% • Special needs requiring client to take medication at a set time • Stable place of residence • Availability of land-based telephone line • Ability to demonstrate effective use of equipment during training period • Ability to maintain effective communication via the videophone • Lack of problems with drug intolerance that require home visits • Ability to complete videophone with directly observed therapy visit within 15 minutes” (pg. 780). 	<ul style="list-style-type: none"> • Medication administration could not be assessed 4.4% of the time • Average length of the call was 5.3 minutes • Average savings in miles driven per patient was 1818 miles • Approximately 2994 hours of staff time in travel and 103,632 in miles driven were saved • Patients averaged US \$2,448 (per patient) in cost savings • In total, US \$139,546 was saved using LV-DOT over the five years 	<p>LV-DOT is a cost-effective alternative to in-home DOT.</p>

DeMaio, J., Schwartz, L., Cooley, P., Tice, A. (2001). The Application of Telemedicine Technology to a Directly Observed Therapy Program for Tuberculosis: A Pilot Project. (n=6)

STUDY DESCRIPTION	STUDY CRITERIA	OUTCOMES	NOTES
<p>A pilot project conducted in Washington and funded by the Tacoma-Pierce County Health Department compared the adherence rate on standard DOT compared to live LV-DOT; as well as mileage saved, and personnel time saved for each patient when using LV-DOT. Although the sample size was small, there were a total of 246 in-person DOT or standard DOT (SDOT) visits and 304 LV-DOT visits spanning two years (1998-2000).</p>	<ul style="list-style-type: none"> • Active TB case • Reside in Tacoma-Pierce County • Successful completion of in-person DOT for four weeks with a >90% adherence rate • Patient must have a touch-tone phone and television • Patient must not have a history of injection drug use 	<ul style="list-style-type: none"> • Cost • SDOT took an average time of one hour per visit, LV-DOT took an average of three minutes per visit • Use of SDOT instead of LV-DOT would have required an addition 288 hours of personnel time; LV-DOT required a total time of 20 hours • 8,830 miles were avoided using LV-DOT (average round trip was 30.6 miles) • \$2870 of travel expenses and \$7933 patients' personal expenses were saved, which offset the equipment costs of \$1000 • Adherence • Patient adherence on SDOT was 97.5 percent, LV-DOT was 95 percent (adherence would have been 98 percent if it was not for the nine technical problems) • Patient Satisfaction Levels (assessed via a survey) • LV-DOT received an overall average satisfaction rate of 9.2 (on a scale of 1 to 10 with 1 being very unsatisfied and 10 being very satisfied) (n=5) • All patients reported that LV-DOT was less intrusive than SDOT 	<p>Technological difficulties that occurred in this study may be eliminated with improved technology.</p> <p>LV-DOT is the most appropriate for patients who have demonstrated good adherence; it should not be used for patients who are trying to avoid therapy, are in unstable social situations (homeless, substance users), and/or have language barriers.</p>

GLOSSARY

The Telehealth Advancement Act (AB 415) became California law on January 1, 2012. AB 415 updated legal definitions of telehealth, streamlined medical approval processes for telehealth-delivered services, and broadened the types of allowed telehealth-delivered services.

Asynchronous (see also Store and Forward) technologies allow for the electronic transmission of medical information, such as digital images, documents, and pre-recorded videos.

Asynchronous transmissions typically do not occur in real time, and take place primarily among medical professionals, to aid in diagnoses and medical consults, when live video or face-to-face patient contact is not necessary.

Asynchronous Video-based directly observed therapy (AV-DOT) is recording an infected patient taking his or her medication on video which is then transmitted through a secure system to allow a public health worker to observe that individual taking his or her medication at a later time.

California Department of Health Care Services (DHCS) assists low-income and disabled Californians through various programs as well as medical, dental, mental health, and substance abuse services and long-term care. DHCS oversees California's Medicaid program, Medi-Cal.

California Department of Public Health (CDPH) focuses on advancing the health and well-being of those living in California through various programs, services, and educational information and publications.

California Tuberculosis Controllers Association (CTCA) consists of health professionals dedicated to eliminating the threat of tuberculosis from California through tuberculosis prevention and treatment.

Case management system is a password protected website in which DOT workers monitor videos and document each medication dose that is taken.

Center for Connected Health Policy (CCHP) is a nonprofit, nonpartisan organization working to maximize telehealth's ability to improve health outcomes, care delivery, and cost effectiveness. It is the national telehealth policy resource center.

Center for Disease Control and Prevention (CDC) is a federal agency under the Department of Health and Human Services and is the leading national public health institute of the United States.

Directly observed therapy (DOT) consists of observing TB patients taking their TB medication to

assure adherence to a course of treatment.

Health and Human Services (HHS) is a cabinet-level health department of the United States federal government.

Healthcare Common Procedure Coding Schedule (HCPCS) is a series of procedure codes founded on the Current Procedural Terminology (CPT) of the American Medical Association. CPT is a type of medical code set.

The Health Insurance Portability and Accountability Act (HIPAA) is a set of national standards, which includes security and privacy of health data for electronic health care transactions, and national identifiers for providers, health insurance plans and employers.

Hepatitis C (HCV) is an infectious disease in which the hepatitis C virus attacks the liver and leads to inflammation.

Human Immunodeficiency virus (HIV) is a type of virus that causes acquired immunodeficiency syndrome (AIDS), which causes the immune system to weaken and increases the chance of developing an opportunistic infections or cancers to thrive.

Live Video Conferencing (see also Synchronous) refers to the use of two-way interactive audio-video technology to connect users, in real time.

Medicaid is a program that provides medical coverage for people with lower incomes, older people, people with disabilities, and some families and children. Medicaid provides medical coverage and long-term medical care to low-income residents. It is jointly funded by the federal government and individual states, and is administered by the states.

Medi-Cal is California's Medicaid program which provides health care services for low-income individuals including families with children, seniors, persons with disabilities, foster care, pregnant women, and low income people with specific diseases such as tuberculosis, breast cancer or HIV/AIDS.

Medicare is health insurance for people age 65 or older, people under 65 with certain disabilities, and people of all ages with End-Stage Renal Disease. (ESRD is permanent kidney failure requiring dialysis or a kidney transplant.)

Randomized Controlled Trials (RCT) are types of scientific experiments that randomly assign the study participants to one or the other of the different treatments under examination.

Store and Forward (see also Asynchronous) technologies allow for the electronic transmission of medical information, such as digital images, documents, and pre-recorded videos.

Asynchronous transmissions typically do not occur in real time, and take place primarily among medical professionals, to aid in diagnoses and medical consults, when live video or face-to-face patient contact is not necessary.

Synchronous (see also Live Video Conferencing) refers to the use of two-way interactive audio-video technology to connect users, in real time, for any type of medical service.

Telehealth is a collection of means or methods for enhancing health care, public health, and health education delivery and support using telecommunications technologies.

The Triple Aim focuses simultaneously on three goals for optimizing health system performance: improve the health of the defined population; enhance the patient care experience (including quality, access and reliability); and reduce, or at least control, the per capita cost of care.

Tuberculosis (TB) is a deadly airborne infectious disease that is spread in the air when an infected person coughs, sneezes, or talks and someone close by breathes in the bacteria.

University of California at San Diego (UCSD) is a public research university located in the La Jolla area of San Diego, California.

Video-based directly observed therapy (LV-DOT) allows a public health worker to observe an infected individual taking his or her medication over video in real-time.