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version of the following capstone:**

**Evaluating the Cost-Effectiveness of
Tuberculosis Video Directly Observed Therapy Program
at Harris County Public Health & Environmental Services**

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**Evaluating the Cost-Effectiveness of
Tuberculosis Video Directly Observed Therapy Program
at Harris County Public Health & Environmental Services**

by

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Capstone

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Dedication

I dedicate this work to my family—without their love, support, and encouragement, I wouldn't be standing where I am today in my career and life.

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I'd like to acknowledge my committee chair, Dr. Sapna Kaul, and committee members for their immense support, time, and help throughout this project. I'd also like to give special thanks to Dr. Dana Wiltz-Beckham, the committee member from HCPHES as well as the HCPHES staff for all their help in the program evaluation; I am truly grateful to have had this opportunity to work with such wonderful people who opened their arms and shared with me what TB Elimination Program is all about.

**Evaluating the Cost-Effectiveness of
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Publication No. _____

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The University of Texas Medical Branch, 2016

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Public health professionals are increasingly adopting telehealth to improve the effectiveness of existing services. For example, local health departments in the United States are pilot-testing an alternative approach to Directly Observed Therapy (DOT) among tuberculosis (TB) patients by using video technology. In standard DOT, an individual is required to take medications under the supervision of a healthcare worker in-person. Such a program is in place to increase medication adherence; however, it is labor-intensive, time-consuming, and costly. Alternatively, in the Video Directly Observed Therapy (VDOT), patients record and submit a video clip as evidence of medication adherence through a mobile device, which is then reviewed by the healthcare worker. A few pilot studies have demonstrated the feasibility and effectiveness of VDOT. However, research is limited on the cost-effectiveness of VDOT program.

Within the state of Texas, Harris County has the highest number of TB cases and an incidence rate double that of the United States. Harris County Public Health & Environmental Services (HCPHES) is among the first local health departments to implement VDOT at a large-scale. Our study results provide valuable insight into the cost-effectiveness of VDOT at HCPHES. While the adherence rate of standard DOT was higher than that of VDOT (97% vs. 92%, $p < 0.05$), there was less cost associated with VDOT. The use of VDOT instead of DOT saved \$61,051.70, which was an 83 percent reduction in total cost. Furthermore, VDOT saved 1,832 driving hours (56,902 driving miles) that would have been spent with standard DOT. While this study demonstrates the value of VDOT, we recommend further research in the cost-effectiveness of VDOT using more refined methods.

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List of Abbreviations

App	Application
BCG vaccine	bacilli Calmette-Guérin vaccine
CDC	Centers for Disease Control and Prevention
DOT	Directly Observed Therapy
EMB	Ethambutol
HCPHES	Harris County Public Health & Environmental Services
HIV	Human Immunodeficiency Virus
GSBS	Graduate School of Biomedical Science
IGRA	Interferon-gamma release assay
INH	Isoniazid
PZA	Pyrazinamide
RIF	Rifampin
MDR TB	Multi-drug resistant tuberculosis
<i>M.tb</i>	<i>Mycobacterium tuberculosis</i>
TB	Tuberculosis
TBI	Tuberculosis Infection
TST	Tuberculin skin test
UTMB	University of Texas Medical Branch
VDOT	Video Directly Observed Therapy
XDR TB	Extensively-drug resistant tuberculosis
WHO	World Health Organization

CHAPTER 1: INTRODUCTION

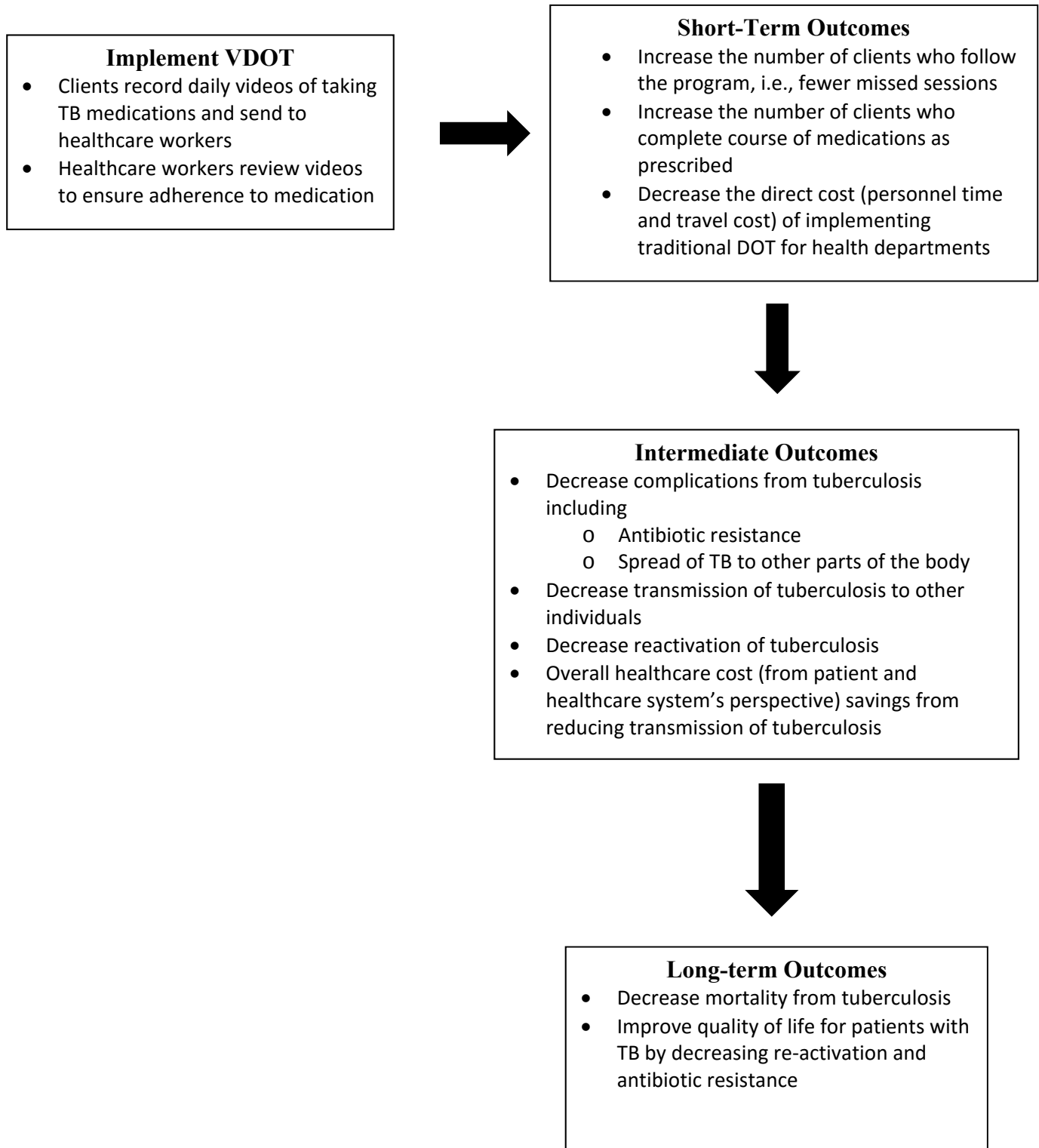
Tuberculosis (TB) is an infectious disease, which spreads person-to-person through airborne transmission of microbes.¹ Due to various factors including the nature of the bacterial agent, the environment and the host immune system, the treatment of tuberculosis is long—at least six to nine months—and requires taking several antibiotics.² The long duration and multiple medications may make it difficult for individuals with TB to adhere to the treatment regimen.^{2,3} This has especially become challenging with the increase in occurrence of multi-drug resistant (MDR) TB and the emergence of extensively-drug resistant (XDR) TB.⁴ Thus, despite local, national, and global efforts, this disease still persists as a public health threat.

One of the key challenges at the population-level includes effectively managing patients' adherence to TB medication.⁴ In the United States as well as internationally, Directly Observed Therapy (DOT) is the recommended form of therapy in order to improve adherence to TB medications.⁵ DOT is an in-person encounter in which a healthcare provider directly watches the patient take the medication.⁶ Traditionally, two methods have been used in which patients will make clinic visits or staff from the health department will travel to patients' homes for DOT.⁶ However, DOT can be costly to implement as it involves direct personnel time and effort.⁵ An alternative approach is to use video technology in DOT.^{5,6} Using video technology in DOT can potentially improve medication adherence and be cost- and time-saving for both the health department and patients including reducing cost associated with vehicle use, time spent driving, and in-person visits.^{5,6}

Initially, the video technology consisted of videophones in which the healthcare provider and patient would teleconference in real-time for TB medication adherence.⁶ While this helped to reduce travel time, it still bounded the healthcare provider and patient to a certain appointment time. To allow flexibility, an asynchronous approach is now being used in which the videos can be recorded and saved by the patient to a secure online interface and the healthcare provider can review the video at their convenience.⁵ This is known as the Video Directly Observed Therapy (VDOT).⁵ Figure 1 describes the potential short and long-term health and other outcomes associated with VDOT that include decreasing transmission of TB, complications of TB, and mortality associated with TB.

Only a few studies have empirically examined the cost-effectiveness of DOT using video technology.^{6,7,8,9} No study has yet evaluated the cost-effectiveness of VDOT in Texas. Harris County Public Health & Environmental Services (HCPHES) piloted VDOT in 2013 and then fully implemented the program in 2014.⁵ The aim of this program evaluation is to assess the cost-effectiveness of VDOT compared to in-person DOT from the perspective of HCPHES.

Figure 1: Short & Long-term Outcomes Using VDOT Program for TB Medication Administration



CHAPTER 2: BACKGROUND

Burden of TB at the Global, National, State, and County Levels

The United States experienced a constant decline in the number of TB cases (i.e. individuals with active TB disease) in the past two decades thanks in part to the contributions of public health and medical efforts. Figure 2 demonstrates this steady decline from a number of TB cases of 26,673 and an incidence of 10.4 cases per 100,000 in 1992 to a number of TB cases of 9,406 and an incidence of 3.0 cases per 100,000 in 2014.¹⁰ This was a 64.7 percent decline during the time period.¹⁰ This has led to the general American perception that TB is a disease from the past and no longer an issue within the United States. However, TB trends are starting to shift. For the first time in over 20 years, the number of TB cases increased to 9,563 in 2015 compared to 9,406 in 2014.¹¹ The incidence of TB leveled off to about 3.0 cases per 100,000 in the past four years.¹¹ This is critical especially during a time when the public health sector continues to experience budget cuts and limited resources.

It is important to note the global trends especially since nations are more so interconnected to and interdependent of each other due to international trade and travel than ever in history. The number of new TB cases worldwide was about 9.6 million in 2014.¹² In addition, TB rivals HIV as the leading cause of death due to infectious disease on the global scale.¹³ About 1.4 million deaths occurred due to TB in 2014 compared to HIV/AIDS at 1.2 million.¹³ About 400,000 of these deaths were among TB cases with HIV-positive status.¹³ Furthermore, World Health Organization (WHO) reports that, “TB is a leading killer of HIV-positive people: in 2015, 1 in 3 HIV deaths was due to TB”.¹²

These are concerning statistics as the United States continues to contribute to global efforts to reduce the burden of tuberculosis. The number of deaths due to TB in the United States is a very different story compared to the global numbers. Nationally, there has been a reduction in TB deaths from 1992 to 2013 by 67 percent.¹⁰ In 2013, some 555 deaths were due to TB in the United States.¹⁴

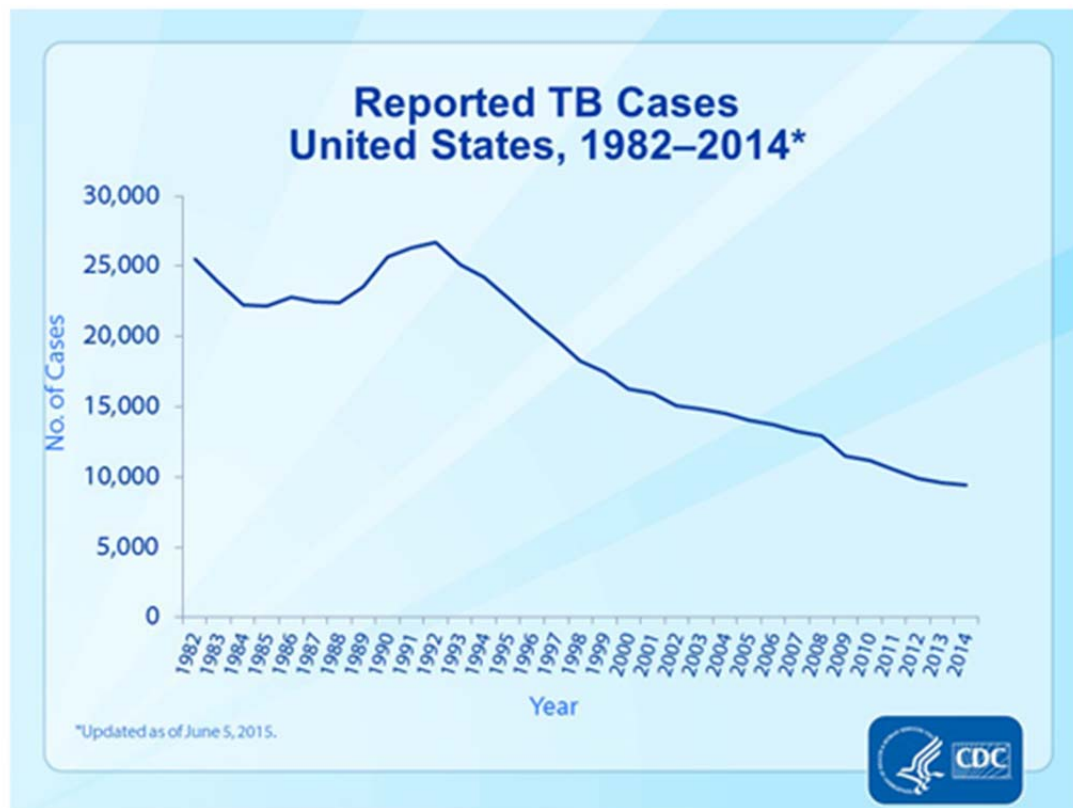


Figure 2: Reported TB Cases in the United States from 1982 to 2014

Source: Centers of Disease Control & Preventive (CDC),
<http://www.cdc.gov/tb/statistics/surv/surv2014/default.htm>

To understand the full scope of the burden of tuberculosis on society, it is also critical to review TB infection (TBI), formerly known as latent TB infection (LTBI). In the United States, close to 13 million individuals have TBI.¹⁵ About one in 10 of these

individuals with TBI who do not seek treatment will develop TB disease during their lifetime.¹⁵ This lifetime risk can increase for individuals who have certain risk factors including HIV, diabetes, and other diseases or medications which lead to immunocompromised state.¹⁶

Figure 3 shows the states with TB incidence above the national average in 2014.¹⁴ Among these states include Texas, California, New York, and Arkansas.¹⁴ Texas had 1,269 TB cases with a 4.7 per 100,000 incidence.⁵ Within the state, Harris County had the highest number of TB cases (320) with an incidence rate of 7.4 per 100,000, which is more than double the United States.⁵ In 2015, the number of TB cases in Texas rose to 1,334, which was a 3.2 percent increase from 2014.¹¹

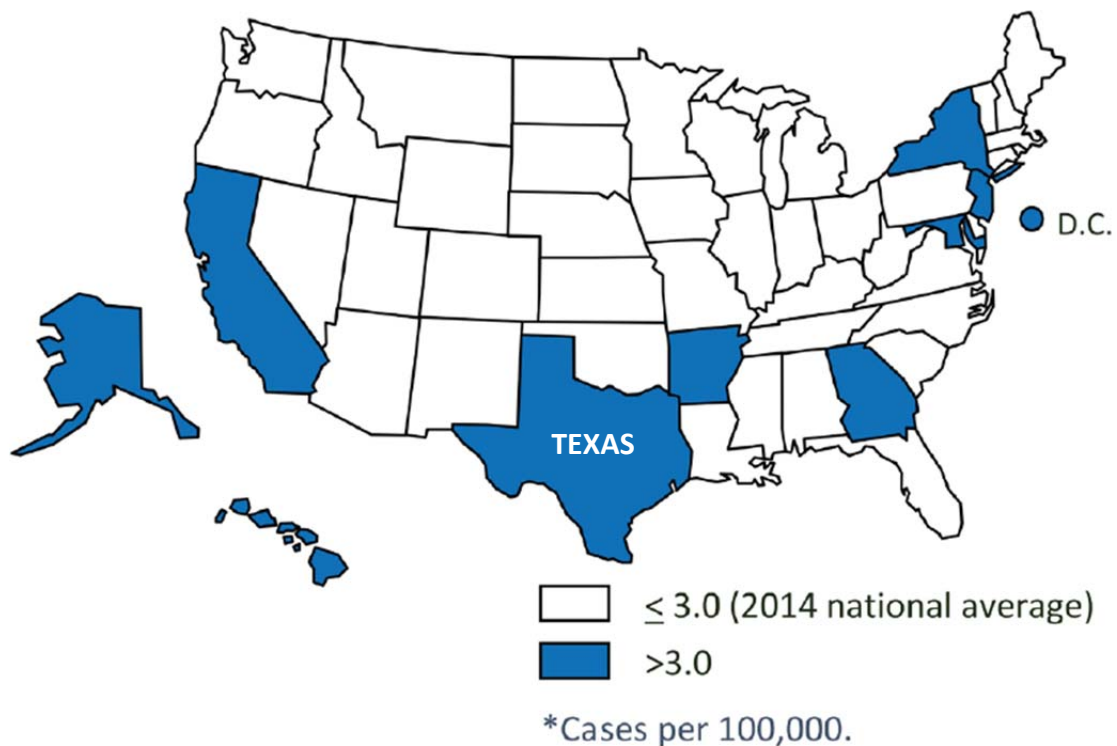


Figure 3: TB Case Rates, United States, 2014

Source: CDC, <http://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm>

Majority of TB cases occurs among adults. In 2014, about 55 percent of the total number of TB cases in the U.S. was made up of individuals with an age of 45 years and above.¹⁰ In comparison, 73 percent of TB cases in Harris County were above the age of 45.⁵ 66 percent of TB cases in Harris County with HCPHES jurisdiction were male.⁵

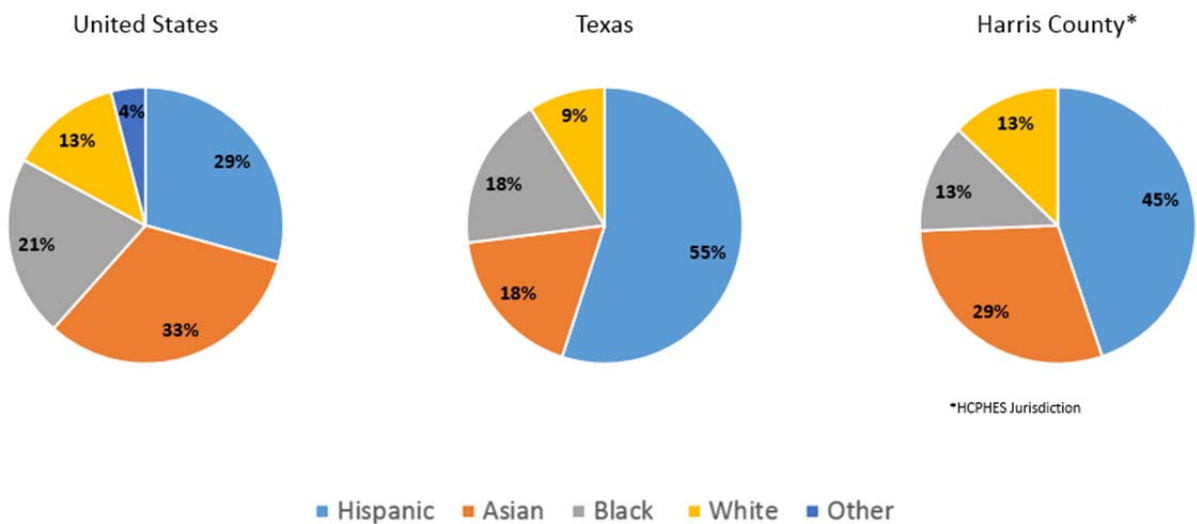


Figure 4: Comparison of TB Cases Reported in United States, Texas, and Harris County by Race/Ethnicity in 2014

Adapted from:

- CDC, <http://www.cdc.gov/tb/statistics/surv/surv2014/default.htm>
- HCPHES, http://www.hcphe.org/UserFiles/Servers/Server_72972/File/Divisions%20and%20Offices/Disease%20Control%20and%20Clinical%20Prevention/TB/Vdot_booklet.pdf

Figure 4 shows pie graphs comparing U.S., state of Texas, and Harris County data on Race/Ethnicity for reported TB cases in 2014.^{5,10} At the national level, Asians constituted the largest group with TB cases (33 percent), while in state of Texas, more than half of the TB cases occurred among Hispanics (55 percent).^{5,10} In Harris County, 45 percent of TB cases (within HCPHES jurisdiction) were Hispanic, 29 percent were Asian, 13 percent African American, and 13 percent Caucasian.⁵

Risk Factors & Vulnerable Populations

Several risk factors are associated with TB including country of origin, certain medical conditions (HIV, diabetes), history of incarceration, history of substance abuse, and homelessness.¹⁰ Figure 5 illustrates the percentages of TB cases for select risk factors in Texas.⁵

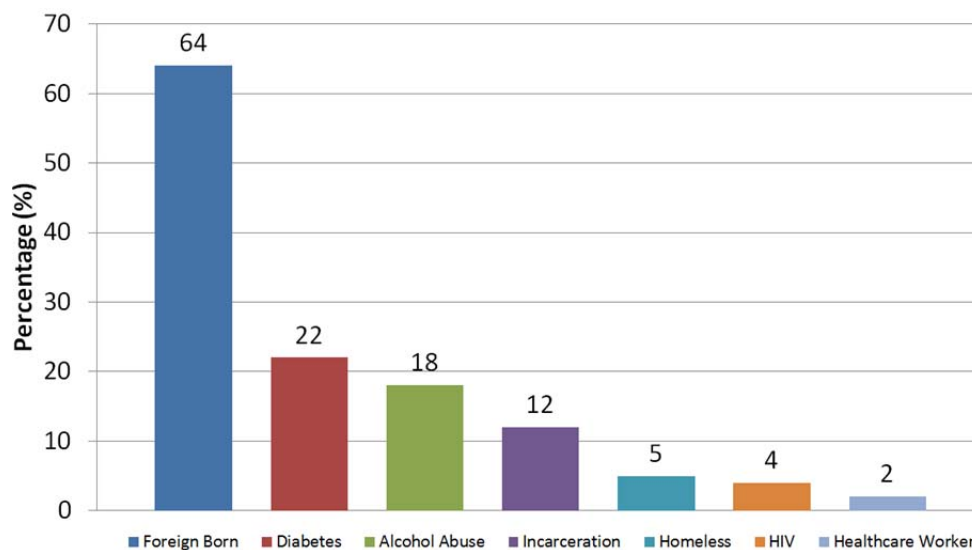


Figure 5: Percentage Distribution of TB Cases among Age 18 and Older with Select Risk Factors in Texas, 2014

Adapted from: HCPHES,

http://www.hcphe.org/UserFiles/Servers/Server_72972/File/Divisions%20and%20Offices/Disease%20Control%20and%20Clinical%20Prevention/TB/Vdot_booklet.pdf

In 2014, close to two-thirds of TB cases reported in Texas as well as United States were among the foreign-born.^{5,10} According to national statistics from CDC, the most common birthplaces for foreign-born individuals with TB disease in 2014 were Mexico (21 percent), Philippines (12 percent), and India (8 percent).¹⁰ Among those who were foreign-born with reported TB disease in 2014, the majority were Asian and Hispanic (46

percent and 34 percent, respectively); 13 percent were Black, 4 percent were White, 2 percent were multi-racial.¹⁰ Of those TB cases who were US-born in 2014, more than a third (37 percent) cases were African American and 30 percent were White.¹⁰

Historically, the HIV/AIDS epidemic in the 1980s contributed towards the drastic increase in the number of TB cases with a peak in the early 1990s.¹⁰ With increased public health efforts, HIV coinfection in persons with reported TB disease has steadily declined since 1993 in the United States.¹⁰ In Harris County (within the jurisdiction of HCPHES), 2.4 percent of reported TB cases in 2014 were co-infected with HIV.⁵

Other risk factors of TB include circumstances in which individuals are in crowded places as in the case of homeless shelters and correctional facilities.¹⁰ In the United States, TB cases reported in the homeless population have remained stable between 5 to 7 percent.¹⁰ A similar trend exists for correctional facilities at around 5 percent of the cases.¹⁰

Another vulnerable population is children. Children with TB infection or disease are indicative of recent TB transmission.¹⁷ In countries where TB is endemic, children are given bacilli Calmette-Guerin (BCG) vaccines prophylactically in order to prevent TB transmission as children can have serious complications from TB including meningitis.¹⁷ BCG vaccine is not recommended in the United States.¹⁷

Management of TB Infection and Disease

Active tuberculosis commonly presents as a pulmonary disease which consists of signs and symptoms including fever, cough, night sweats, and weight loss.²

Complications of TB include extrapulmonary TB and miliary TB.² TB is spread when a person with pulmonary disease exhales droplet nuclei containing *Mycobacterium tuberculosis* (*M.tb*).² These airborne particles can be as small as 5-10 μm in diameter and remain suspended in the environment.² Exposed individuals will inhale these particles, which will reach the respiratory alveoli.² Becoming infected by *M.tb* depends mainly on environmental factors including crowding of people and close contacts.² Figure 6 provides an illustration of TB transmission.

Figure 6: Transmission of TB

Source: CDC, http://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf

TB is spread from person to person through the air. The dots in the air represent droplet nuclei containing tubercle bacilli.

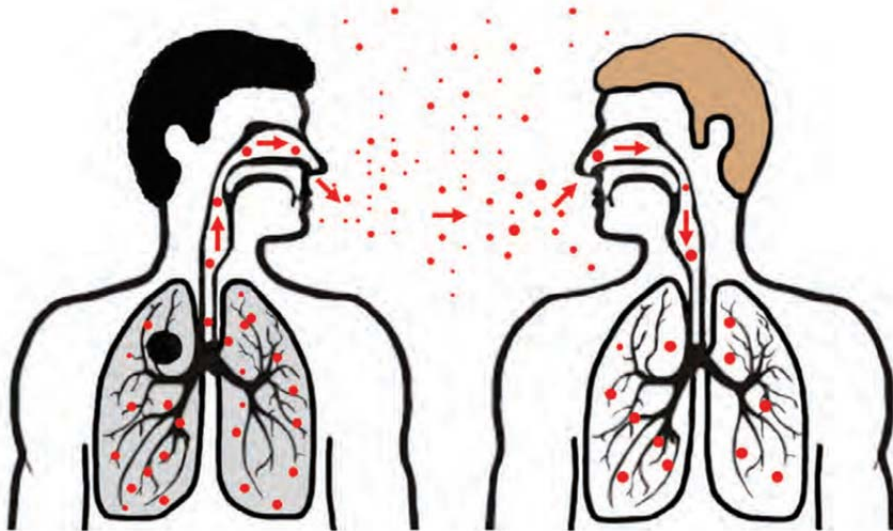


Figure 6 illustrates the transmission of TB.¹⁸ Generally, 90-95 percent of individuals who contract TB infection will be able to mount an immune response, which barricades *M.tb*, but does not destroy the bacteria.¹⁸ In this scenario, the bacteria remains dormant and the individuals will be asymptomatic.¹⁸ Among these individuals with TB infection, healthy adults have a lifetime risk of 10 percent to later develop active TB disease.¹⁸ The lifetime risk can increase depending on individual risk factors as illustrated in Figure 7.¹⁸ Whereas the other 5-10 percent who are infected will develop primary tuberculosis.¹⁸

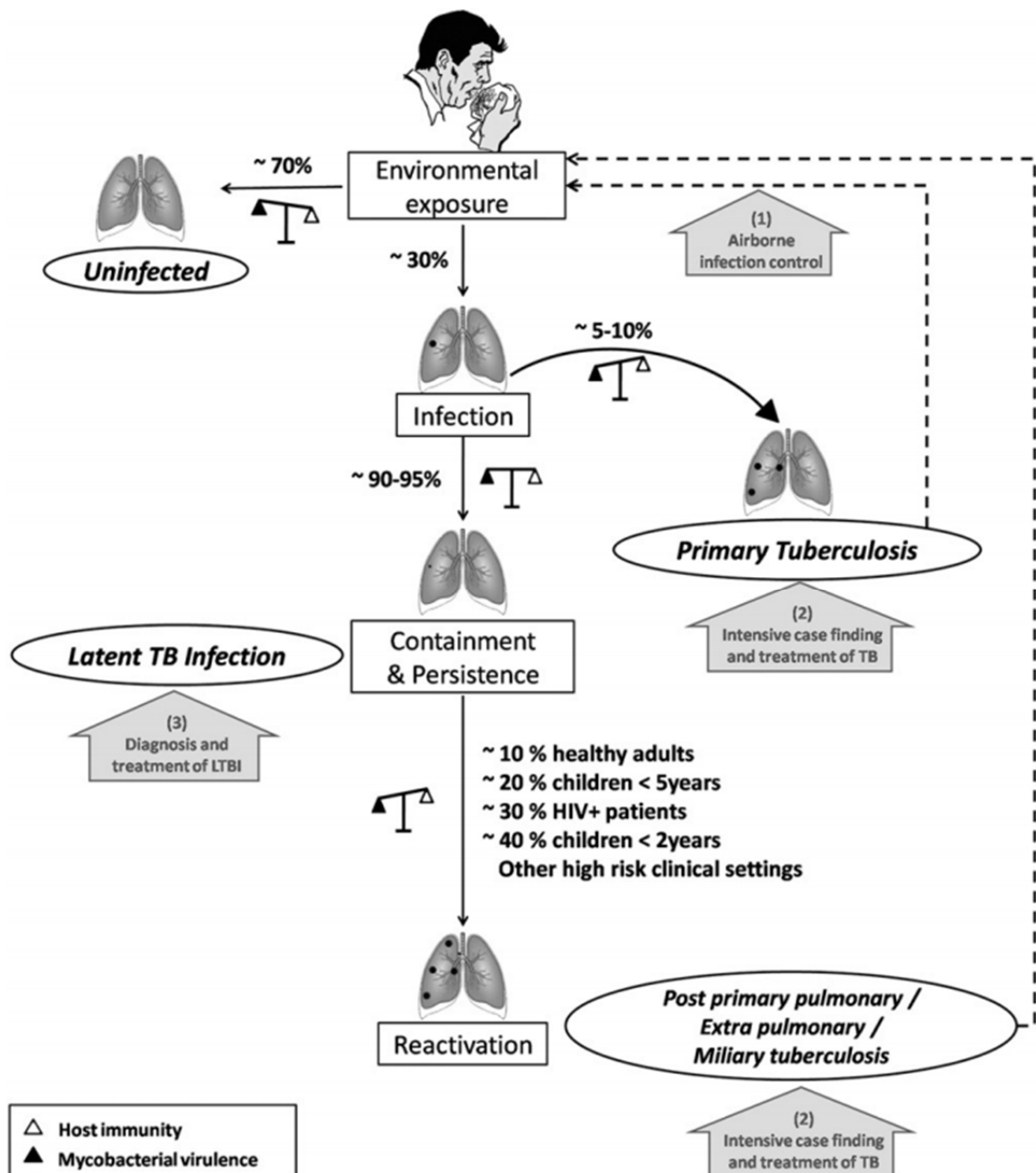


Figure 7: Outcomes Following Exposure to *M.tb* in an Individual: Scope for Interventions in TB Disease Control

Source: Relevance of Latent TB Infection in Areas of High TB Prevalence. *CHEST*. 2012; 142(3): 761-773.

Targeted testing is recommended to detect and treat those individuals who have TB infection to prevent progression of infection to disease.¹⁹ It is also used to detect and treat TB disease.¹⁹ Table 1 shows the list of high-risk groups, who are tested for TBI and TB disease.¹⁹

Table 1: Groups at high risk for TBI and TB Disease

Adapted from: CDC, http://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf

People at High Risk for Becoming Infected with <i>M.tb</i>	People at High Risk for TB Disease after <i>M.tb</i> Infection
• Close contacts of people known or suspected to have TB • People, including children, who have come to the US (within last 5 years) from areas of the world where TB is endemic • Low-income groups with poor access to health care, including homeless people • People who inject illegal drugs • People who live or work in high-risk residential settings (e.g. nursing homes, homeless shelters, or correctional facilities) • Health care workers who serve high-risk patients • High-risk racial or ethnic minority populations, as locally defined • Infants, children, and adolescents exposed to adults in high-risk groups	• People living with HIV • People recently infected with <i>M.tb</i> (within the past 2 years) • People with medical conditions known to increase risk for TB ○ silicosis ○ diabetes ○ severe kidney disease ○ certain types of cancer ○ certain intestinal conditions ○ organ transplant ○ immunosuppressive therapy (chronic use of steroids, tumor necrosis factor-alpha (TNF-alpha) antagonists) ○ low body weight • People who inject illegal drugs • Infants and children younger than 4 years

The two common tests which are used for targeted testing are TB skin test (TST) and Interferon-Gamma Release Assay (IGRA).¹⁹ In TST, purified protein derivative (PPD) from tuberculin is injected into subcutaneous tissue. A healthcare worker will examine the site of the injection about 48 to 72 hours later for induration to determine whether a reaction occurred.¹⁹ The test will be considered positive depending on the size of the skin induration and the patient's risk factors.¹⁹ If the patient has a positive TST without prior history of BCG vaccine, then he or she has TB infection.¹⁹ TST could be falsely positive due to patient having prior history of receiving BCG vaccine.¹⁹

A blood test which has advanced the process of TB diagnosis is IGRA. The benefits of this test include that it is not affected by the BCG vaccine and that the results generally are available within 24 hours.¹⁹ The two type of IGRA tests approved for use in the US are: 1) QuantiFERON TB Gold Test, and 2) T-SPOT TB Test.¹⁹ Table 2 provides a detailed list of factors which are considered when deciphering whether a patient has TBI.²⁰

Table 2: Candidates for the Treatment of TBI

Adapted from: CDC, <http://www.cdc.gov/tb/publications/factsheets/treatment/tbitreatmentoptions.htm>

Groups Who Should be Given High Priority for TBI Treatment	
People who have a positive IGRA result or a TST reaction of 5 or more millimeters	People who have a positive IGRA result or a TST reaction of 10 or more millimeters
• HIV-infected persons • Recent contacts of a TB case • Persons with fibrotic changes on chest radiograph consistent with old TB • Organ transplant recipients • Persons who are immunosuppressed for other reasons (e.g. taking TNF-alpha antagonists)	• Recent immigrants (less than 5 years) from high-prevalent countries • Injection drug users • Residents and employees of high-risk congregate settings (e.g., correctional facilities, nursing homes, homeless shelters, hospitals, and other health care facilities) • Mycobacteriology lab personnel • Children under 4 years of age, or children and adolescents exposed to adults in high-risk categories

Persons with no known risk factors for TB may be considered for treatment of TBI if they have either a positive IGRA results or if their reaction to the TST is 15 mm or larger. However, targeted testing programs should only be conducted among high-risk groups.

IGRA = Interferon-Gamma Release Assays, TST = TB Skin Test

Treatment of TBI usually requires one to two anti-mycobacterial agents. The regimens are listed in Table 3.²⁰ TB infection can be challenging to treat as individuals do not have symptoms and treatment usually requires as long as 9 months of medications.²⁰ The risk also includes side effects of the medications which include liver toxicity.²⁰

Table 3: Treatment Regimens for TB Infection

Adapted from: CDC, <http://www.cdc.gov/tb/publications/factsheets/treatment/lbtreatmentoptions.htm>

Medications	Duration	Interval	Minimum Doses
Isoniazid	9 months	Daily	270
		Twice Weekly	76
Isoniazid	6 months	Daily	180
		Twice Weekly	52
Isoniazid and Rifapentine	3 months	Once Weekly	12
Rifampin	4 months	Daily	120

In individuals for whom TB disease is suspected, further testing is required including chest X-ray and sputum cultures to confirm the diagnosis.²¹ The standard treatment that is available for uncomplicated TB disease is six to nine months in duration.²² The first two months, or the Initiation Phase, generally requires taking 4 different medications and then the last four months, known as the Continuation Phase, requires takings 2 medications.²² Table 4 shows the medications and duration of time needed.²² Several medications are used simultaneously to have increased chance of fighting against *M.tb* and to avoid development of drug resistance.² Treatment regimen can change depending on the clinical scenario (e.g. for individuals with HIV coinfection).²²

Children of 5 years or below, who are identified as close contacts to patients with active TB disease, are treated for potential TBI for at least 8 weeks regardless of TST being negative.¹⁹ Chest x-ray is also performed to rule out TB disease.¹⁹ Once at least 8 weeks have passed, then TST is re-checked.¹⁹ If TST is negative, then treatment is stopped.¹⁹ This treatment is known as “Window Prophylaxis.”¹⁹

Table 4: Standard Treatment Regimens for TB Disease

Adapted from: CDC, <http://www.cdc.gov/tb/publications/factsheets/treatment/treatmentthivnegative.htm>

	Preferred Regimen	Alternative Regimen	Alternative Regimen
Initial Phase	Daily INH, RIF, PZA, and EMB* for 56 doses (8 weeks)	Daily INH, RIF, PZA, and EMB* for 14 doses (2 weeks), then twice weekly for 12 doses (6 weeks)	Thrice-weekly INH, RIF, PZA, and EMB* for 24 doses (8 weeks)
Continuation Phase	Daily INH and RIF for 126 doses (18 weeks) or Twice-weekly INH and RIF for 36 doses (18 weeks)	Twice-weekly INH and RIF for 36 doses (18 weeks)	Thrice-weekly INH and RIF for 54 doses (18 weeks)
Total Doses	182 or 92	62	78
Total Duration	26 Weeks (6.5 Months)		

*EMB can be discontinued if drug susceptibility tests demonstrate susceptibility to first-line drug

INH = Isoniazid, RIF = Rifampin, PZA, Pyrazinamide, EMB = Ethambutol

Economic Implications of TB

According to World Health Organization (WHO), the global economic burden of TB is \$12 billion per annum.²³ In 2014, the total direct cost in the United States for the management of TB cases was US \$435 million.²⁴ The average direct cost for managing MDR TB was US \$150,000 per patient, while for XDR TB it was US \$482,000 per patient.²⁴

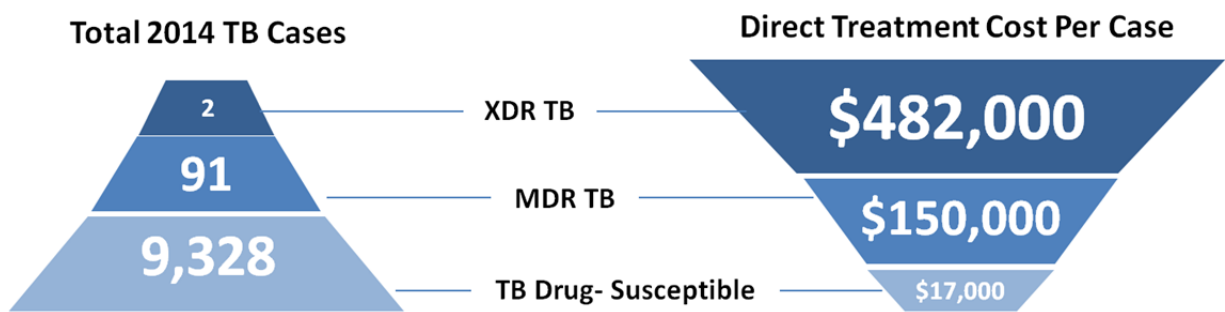


Figure 8: Comparison of the number of TB cases and the average direct treatment cost per case among drug-susceptible TB, MDR TB, and XDR TB in the United States, 2014

Adapted from: CDC, <http://www.cdc.gov/tb/publications/infographic/webresources.htm>

CHAPTER 3: ROLE OF PUBLIC HEALTH DEPARTMENTS IN TB PREVENTION & CONTROL

Roles & Regulations at the State & County Level

According to CDC, “the essential role of the public health sector in TB control is to plan, coordinate, and evaluate TB control and prevention efforts.”¹⁹ Shown in Figure 9 are the key elements that the state and local health departments oversee.¹⁹



Figure 9: Key Roles & Responsibilities of State & Local Health Departments
Adapted from: CDC, http://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf

A vital component in order to oversee these activities is to have partnership with the non-governmental health sector including clinicians, community health centers, academic institutions, medical professional organizations, correctional facilities, and pharmaceutical and biotechnological industries.¹⁹

TB Elimination Program at HCPHES

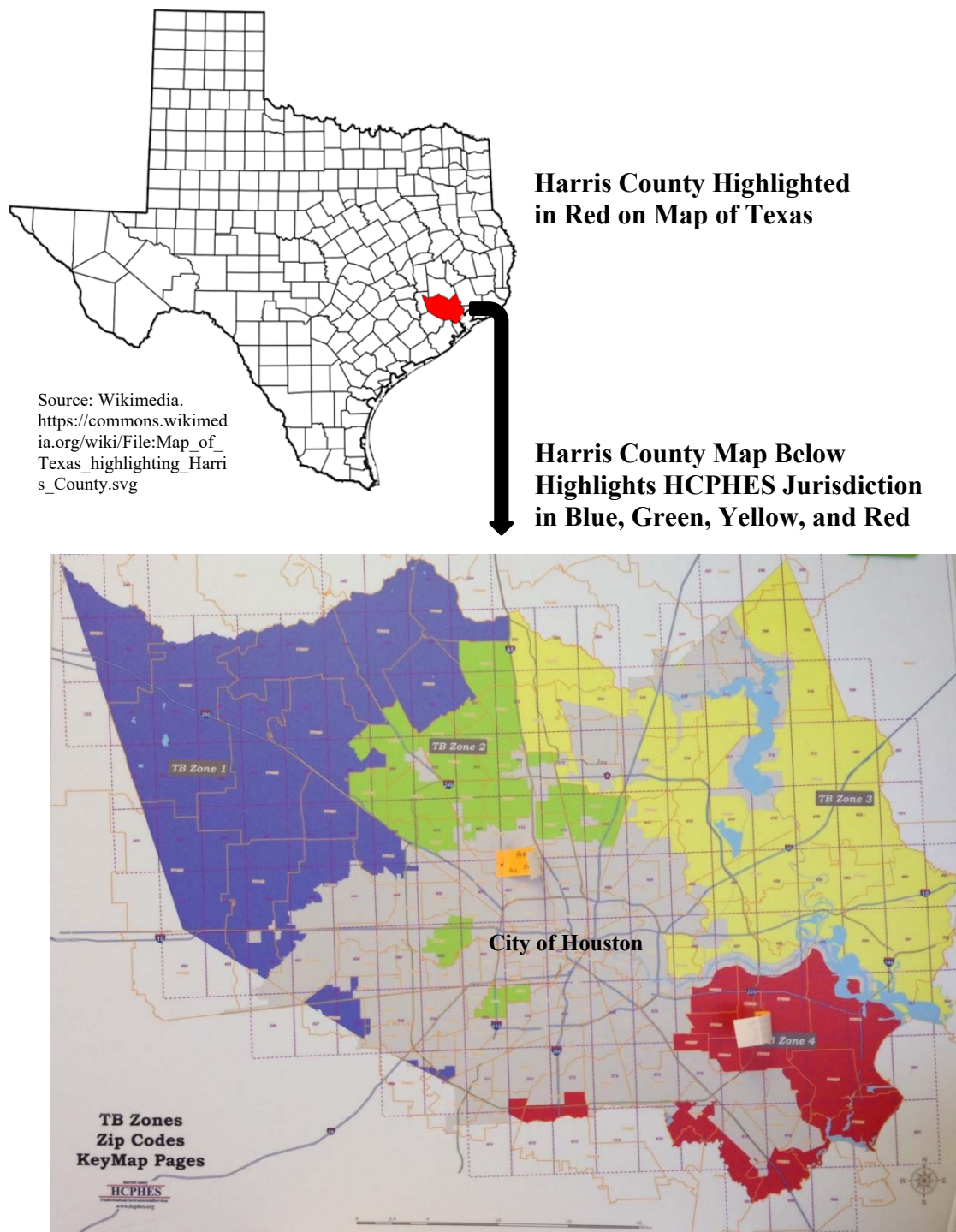
Harris County in Texas—covering a large geographic region—is unique as it consists of a very diverse population and has one of the most densely populated metropolitan cities (Houston).⁵ It is the third most populous county in the United States.⁵

The mission of HCPHES includes “promoting a healthy and safe community as well as preventing illness and injury.”²⁵ HCPHES has several divisions including the Division of Disease Control and Clinical Prevention (DCCP).¹ Within this division is the TB Elimination program, which has essential roles and services for TB control and prevention.¹ These include disease reporting and surveillance services, clinical and case management services, and TB prevention services.¹ Within preventive services are components of contact investigation, outreach and education collaboration, and targeted testing of high-risk groups including homeless shelters and individuals with history of IV drug abuse.¹

Among the many roles and functions for HCPHES is implementing DOT for active TB cases and individuals with TB Infection (TBI).^{1,5} Compared to other local health departments, HCPHES has high volume and individuals living widespread across the large county.⁵ The jurisdiction of this health department includes the entire county, with over 30 municipalities, except the city of Houston—Figure 10 provides maps of

Texas and Harris County with HCPHES jurisdiction.⁵ In 2014, HCPHES provided DOT services to 164 patients with (or suspected) TB disease (1 had MDR TB).⁵ 401 patients with TBI were given prophylactic treatment.⁵

Figure 10: Maps of Texas & Harris County with HCPHES Jurisdiction



CHAPTER 4: USE OF VIDEO TECHNOLOGY FOR TB DOT

Initially, a few local health departments experimented with videophones.^{6,9} This eliminated the need for staff or patients to drive for in-person DOT appointments.^{6,9} However, it still was not flexible as the communication between the staff and patient needed to be in real-time. With the advancement of mobile phones, other health departments started using mobile devices.⁷ VDOT can be used in real-time or asynchronously with mobile devices.⁷ In the asynchronous approach, videos submitted by patients are reviewed by staff at their convenience.⁷ Another benefit is that patients can submit videos during the weekend, which the staff can review during the weekday—as a result, the patient does not need to take additional doses to prove observation (i.e. patients have to take self-administered doses during the weekend, which do not count towards observed treatment since these are not observed). DOT can be time and labor intensive, especially in the jurisdiction of HCPHES, which is densely populated and congested across a large geographic region with high degree of traffic.⁵ Based on this, VDOT would be more convenient and time-saving for both staff and patients.⁵

Figure 11 compares the pros and cons of DOT and VDOT. VDOT has the potential benefits of saving time and cost to both the health departments and patients. As already alluded to, for the health department it can reduce the cost and time associated with driving and vehicle use for home visits. Along with time saving, the benefits to patients include flexibility, privacy, and avoiding lost wages. What is imperative for VDOT is to select those patients who are comfortable with using mobile devices and do not have the risk of poor adherence. The downside to VDOT is when this criteria is not

met, then it will likely not be as effective. This is where DOT has its benefits in that those individuals who are likely to be poorly adherent have a staff member who physically and personally observes these patients to ensure that the medications have been appropriately administered.

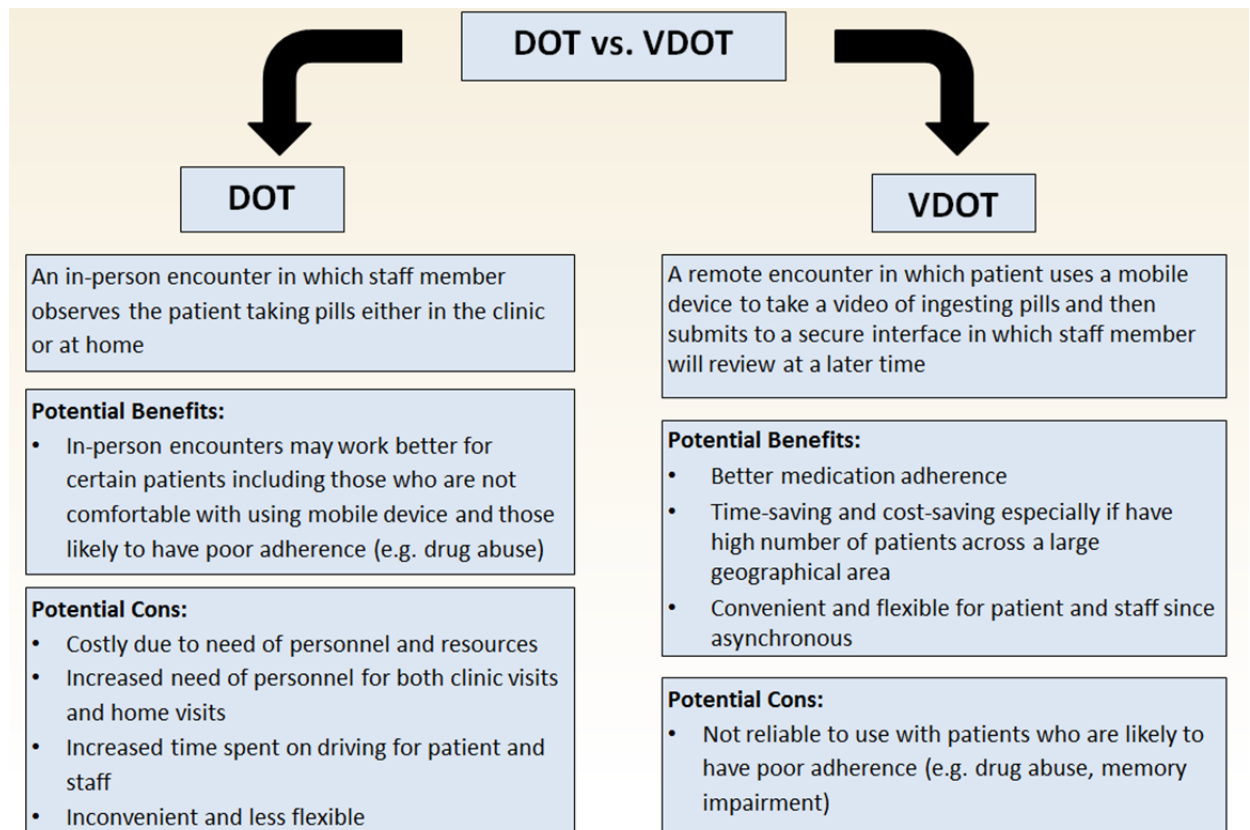


Figure 11: Comparison of DOT with VDOT

Earlier studies have demonstrated that VDOT is effective and feasible. For example, the study in San Diego, California and Tijuana, Mexico analyzed adherence rate of VDOT.⁷ The adherence rates were found to be high in both San Diego (n=43) and Tijuana (n=9) at 93 percent and 96 percent, respectively.⁷ In the study, 94 percent of participants completed a survey in which majority preferred VDOT over DOT and felt it

was more confidential.⁷ In addition to VDOT being feasible and acceptable, the authors further discussed that the asynchronous approach allows for flexibility for both the patient and the healthcare worker.⁷ Similarly, a study found that the Mobile Direct Observed Therapy (MDOT) program was technically feasible and acceptable in a less-developed setting like Kenya among healthcare workers and patients.⁸

A more recent study conducted by the New York City Health Department published in May 2016 assessed the effectiveness of VDOT among 61 patients compared to DOT with 329 patients.²⁶ In this case, VDOT was in real-time and was not an asynchronous approach.²⁶ It showed that VDOT was more effective than DOT by comparing adherence rates: VDOT at 95 percent and DOT at 91 percent.²⁶

Only a few studies have assessed the cost-effectiveness of video technology for DOT. A study conducted by a health department in Washington State compared the adherence rates of standard DOT with videophone DOT among the same six patients, which were 97.5 percent and 95 percent, respectively.²⁷ It also computed that 288 hours were saved in travel time and 8,830 miles saved by using videophone DOT.²⁷

Two health departments in Washington State found that using videophone DOT among 57 patients being treated for TB disease saved a total of US \$139,546 in staff salaries, benefits and travel costs.⁹ The average cost savings per patient was US \$ 2,448.⁹ An Australian study computed the incremental cost-effectiveness ratio (ICER) of videophone (n=58) versus traditional DOT (n=70) as AUD \$1.32.⁶ This study observed that the total costs were comparable between each group; however, the improvement in adherence with videophones made it more beneficial.⁶

With the support of Delivery System Reform Incentive Payment (DSRIP) funding through the Section 1115 Medicaid Waiver, HCPHES piloted VDOT program in 2013 with 30 participants.⁵ During this pilot phase, the program used two software platforms to determine which is better suited.⁵ In late 2014, HCPHES implemented VDOT program with one consistent software platform and mobile phone carrier.⁵



Source: HCPHES

Figure 12: A Collection of Photos Demonstrating How a Patient Records Her Video on the Mobile Device While Taking Her Pills and then Submits the Video to HCPHES for Review

Source: HCPHES,

http://www.hcphe.org/UserFiles/Servers/Server_72972/File/Divisions%20and%20Offices/Disease%20Control%20and%20Clinical%20Prevention/TB/Vdot_booklet.pdf

The current study is aimed at examining the cost and effectiveness of VDOT compared to DOT from the perspective of HCPHES using a sample population in the state of Texas. In addition, being a large-scale VDOT program in the United States—it may serve as an example for other health departments nationally and globally to reference for guidance in implementation and further research.

CHAPTER 5: METHODS

Study Sample

This study consisted of individuals who were enrolled into the VDOT program at HCPHES from October 1, 2014 thru September 30, 2015.⁵ As per the HCPHES protocol, all individuals started with DOT.⁵ DOT consisted of home visits in which a HCPHES staff member drove to a patient's home for the observation. Individuals with TB infection were on DOT for minimum of 2 weeks and then were eligible for VDOT. For those individual with active TB disease, they were eligible for VDOT enrollment once their sputum cultures were negative (which generally occurred in about 2 months). From these individuals, HCPHES invited those who met an established eligibility criteria (refer Table 5) to participate in the VDOT program.⁵ For example, individuals who were homeless, had history of substance abuse, experienced side effects of hepatic dysfunction, who had received prior TB treatment, or had history of memory impairment were excluded from VDOT program.⁵ A total of 47 individuals participated in VDOT.

When reviewing treatment status, 83 percent of the enrolled individuals (n=39) completed their treatment with VDOT. Six of the patients were switched back to DOT due to non-compliance while on VDOT. The remaining patients were either transferred to a different city or county health department jurisdiction or refused treatment for TBI. The study was approved by UTMB's Institutional Review Board (IRB).

Table 5: Inclusion Criteria for Enrollment into VDOT

Source: HCPHES, VDOT Policy

The eligibility criteria constructed by HCPHES for VDOT program is as follows:

- Must be an adult at least 18 years of age and be able to consent (for children must have an adult guardian who will consent on their behalf)
- Patient has pan-sensitive TB disease
- Patient has converted to sputum smear and culture negative in initial phase of treatment
- Patient is motivated, understands the need for TB treatment and accepts the TB diagnosis
- Patient is able to open appropriate TB medication packets and can accurately identify each medication
- Patient is able to demonstrate how to properly use the equipment, communicate with Nurse Case Manager or designee and take TB medications at the appropriate scheduled time
- Patient lives in an environment where the equipment can be charged and is able to make and transmit required confidential video or calls
- Patient must not be considered at risk for poor adherence (e.g. homeless, substance abuse, prior TB treatment, psychiatric illness, or memory impairment)

Intervention

HCPHES provided a mobile device equipped with a video application (app) to all individuals enrolled in the VDOT program.⁵ Individuals were given 30 day supply of medications at a time.⁵ Whenever a patient needed to take his/her medication, he/she recorded and submitted the video to a secure online interface via mobile app.⁵ Staff at HCPHES retrieved and reviewed the video at their convenience on weekdays only.⁵ Patients were expected to be on VDOT for about 4-9 months, depending on diagnosis and prescribed treatment regimen. Since this was the first year for full-implementation, some patients were enrolled into VDOT during the treatment phase (e.g. 7 months from starting treatment). Table 6 provides the expected number of DOT and VDOT observations for

common TB disease and TBI treatment regimens based on HCPHES rules and regulations.

Table 6: Expected Number of DOT and VDOT Observations for Common TB Treatment Regimens

Source: HCPHES Policies

Diagnosis	TB Disease	TB Infection
Treatment Duration with Frequency of Dosing	Daily medication doses for two months, then three times weekly for 4 months	Twice a week for nine months
Minimum Duration of DOT Observations	First 2 months (until sputum cultures are negative)	First 2 weeks
Number of DOT Observations	44	4
	Patient is enrolled into VDOT Program	Patient is enrolled into VDOT Program
Number of VDOT Observations	32	72

Parameters and Data

HCPHES provided the data including various demographic and clinical variables for all patients (i.e. age, sex, race and ethnicity, insurance status based on initial visit, type of disease [active TB disease or TBI], duration of treatment with frequency of dosing, number of DOT observations, and number of VDOT observations) as well as cost parameters. The parameters for the average time spent on DOT observations, time spent on VDOT observations, and staff salary were self-reported by staff involved in VDOT. The average roundtrip trip distance traveled and roundtrip time driven were computed by HCPHES using Google maps for each of the 47 subjects in order to compute cost of vehicle use and time spent during driving by staff.

VDOT Observations

Since all the 47 patients were required to start with DOT, each patient has both VDOT and DOT observations. We first determined the expected number of observations and months patients would have been on VDOT by reviewing their diagnosis, treatment duration and total number of actual observations. We also computed the actual average number of months on VDOT.

Adherence Rates

Adherence rate was used to measure the effectiveness of the VDOT program. The calculations used for adherence rates were as follows:

$$\text{Adherence rate of VDOT Observations} = \frac{\text{Successfully Completed VDOT Observations}}{\text{Total Scheduled VDOT Observations}}$$

$$\text{Adherence rate of DOT Observations} = \frac{\text{Successfully Completed DOT Observations}}{\text{Total Scheduled DOT Observations}}$$

We used the chi-square test to determine the statistical significance of the difference between VDOT and DOT adherence rates.

Cost of VDOT Observations

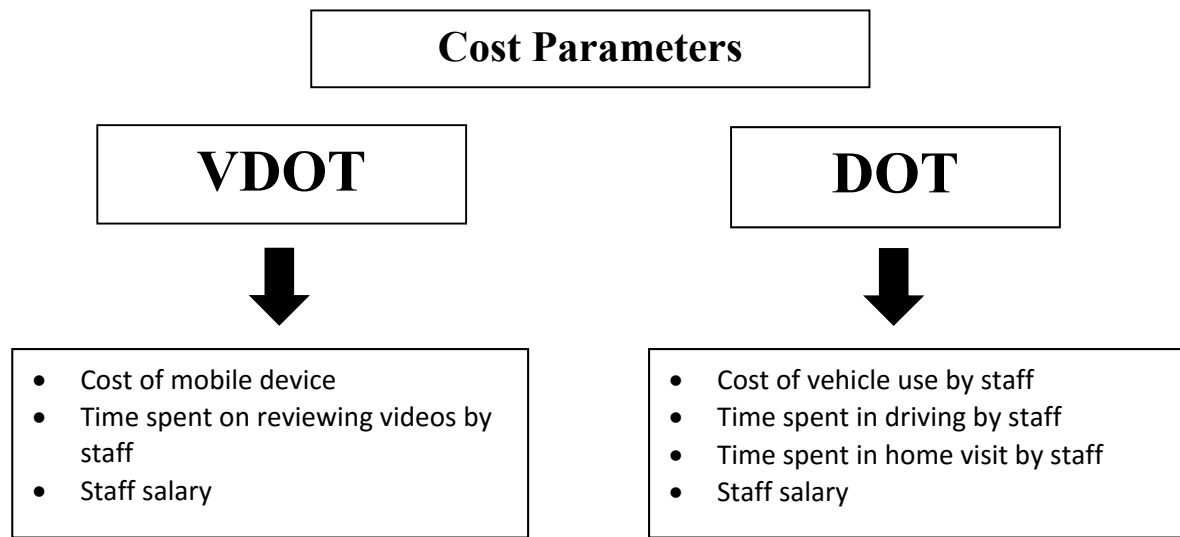
We calculated the cost of VDOT observations using data on all 47 patients. The parameters used for cost included the cost of mobile devices, the time spent by staff reviewing videos, and staff salary.

Costs Averted by VDOT Program

We then analyzed the costs averted due to VDOT usage. This was conducted by first imputing the costs for the VDOT observations as if they had been DOT observations (i.e. counterfactual costs). The expenses for DOT included cost of vehicle use, time spent on driving by staff, and time spent by staff during home visits. Once the cost associated with counterfactual DOT observations was computed, the difference was taken between this and the actual cost of VDOT observations. Figure 13 shows the basic framework to determine the cost of VDOT and DOT observations. Based on these parameters, we also calculated the time saved by staff and mileage saved with VDOT.

For practical reasons and time constraints, certain costs and benefits were not included in the evaluation. For example, overhead costs such as office space, computers, and mobile app fee were excluded. Certain direct costs like those associated with self-administered medications, time spent on follow-up clinic visits, time spent on following up patients for missed DOT and VDOT observations, time spent on technical issues with mobile devices, and time spent on vehicle issues were not included. Since this analysis focused on the perspective of health department, benefits to patients of using VDOT such as aversion of lost wages and convenience had to be disregarded.

Figure 13: Parameters included in Cost for VDOT and DOT



CHAPTER 6: RESULTS

Table 7 shows the baseline characteristics of the 47 patients enrolled in the VDOT program. In this sample, the age distribution is skewed towards the younger ages with about two thirds of the individuals being 39 years old or less. Close to two-thirds of the individuals were male. In terms of race and ethnicity, 43 percent were Hispanic, 30 percent were Asian and 23 percent were Black. More than half of the individuals were categorized as low-income uninsured while 30 percent had Medicaid insurance. About 57 percent of the individuals had active TB disease, while 42 percent were treated for TB infection or window prophylaxis.

VDOT Observations

Patients were expected to be on VDOT for an average of 6.5 months with an expected number of 3,995 VDOT observations. The actual average was less than expected at 4.5 months because some patients were enrolled into VDOT much later in their treatment. The actual number of VDOT and DOT observations among the 47 patients was 2,303 and 2,879, respectively.

Adherence Rate

The adherence rate of VDOT observations was 92 percent (2,216/2,303). In comparison, the adherence rate of DOT observations was 97 percent (2,799/2,879). The difference between the adherence rates for the two types of observations was statistically significant ($p < 0.05$). This is shown in Table 8.

Table 7: Baseline Characteristics of Patients Enrolled in VDOT Program

Characteristics	Patients Enrolled in VDOT Program (n=47)
Age	
Less than 15 years	16 (0.34)
15-39 years	16 (0.34)
40 years and greater	15 (0.32)
Sex	
Male	31 (0.66)
Female	16 (0.34)
Race and Ethnicity	
Hispanic	20 (0.43)
Non-Hispanic Asian	14 (0.30)
Non-Hispanic Black	11 (0.23)
Other	2 (0.04)
Insurance Status	
Low-Income Uninsured	27 (0.57)
Medicaid	14 (0.30)
Other	6 (0.13)
Diagnosis	
TB Case (Active TB Disease)	27 (0.57)
TB Infection (TBI) & Window Prophylaxis	20 (0.43)

Table 8: Adherence Rates of VDOT & DOT Observations among 47 Patients

Type of Observation	Total Scheduled Observations	Successfully Completed Observations	Missed Observations	Adherence Rate*
VDOT	2,303	2,126	177	92%
DOT	2,879	2,799	80	97%

*The difference between the two rates is statistically significant ($p < 0.05$)

Cost of VDOT Observations

The parameters used to calculate the cost of VDOT observations are listed in Table 9. The average time spent to review a video session by staff was 5 minutes (\$1.34 of salary). The average monthly fee for a mobile device was \$45.00. Based on these parameters, the cost of all VDOT observations (i.e., 2,303) among the 47 patients was \$12,723.70.

Table 9: Parameters of Cost for VDOT Observation

<u>Time Spent by Staff</u>	<u>Average Time (Minutes)</u>	<u>Average Staff Salary for Time Spent</u>
Time Spent to Review a Video Session by Staff	5	\$1.34
<u>Mobile Device Fee</u>		<u>Average Monthly Fee</u>
Monthly Fee for One Mobile Device	-	\$45.00

Cost Averted

In order to determine the cost averted by VDOT, first the counterfactual cost of DOT was calculated. The parameters of cost for DOT observation (i.e., 2,879) are listed in Table 10. Among the 47 patients, the average time spent for a visit by staff was 20 minutes which was calculated to be \$5.37 based on average hourly staff salary. The average time spent driving by staff for one home visit was 52 minutes (staff salary of \$13.97). The average cost of vehicle use based on average roundtrip distance of 28 miles was \$15.68.

Table 10: Parameters of Cost for DOT Observation

<u>Time Spent by Staff</u>	<u>Average Time (Minutes)</u>	<u>Staff Salary for Time Spent</u>
Time Spent in a Home Visit by Staff	20	\$5.37
Time Spent in Driving by Staff for a Home Visit	52	\$13.97
<u>Cost of Vehicle Use</u>	<u>Average Distance (Miles)</u>	<u>Total Cost for Miles Driven*</u>
Roundtrip Distance Traveled by Staff for a Home Visit	28	\$15.68

*Based on cost of vehicle use per mile determined by Internal Revenue Service (IRS) in 2014

Source: <https://www.irs.gov/2014-standard-mileage-rates-for-business-medical-and-moving-announced>

Based on these parameters, the cost of the observations would have been \$73,775.40. Therefore, the cost averted by VDOT was \$61,051.70. This was an 83 percent reduction in the cost by using VDOT.

Table 11: Costs Averted by VDOT Program

	<u>Cost of VDOT</u>	<u>Counterfactual Cost of DOT</u>	<u>Cost Averted by VDOT</u>	<u>Relative Percent Change in Cost</u>
For All Patients, (n=47)	\$12,723.70	\$73,775.40	-\$61,051.70	-83%

Time Saved & Mileage Saved

The time spent by staff on the 2,303 VDOT observations was 192 hours. If these observations were DOT then the time spent would have been 2,600 hours. Thus, VDOT saved a total of 2,408 hours or over 100 days. 1,832 travel time hours were saved and

576 hours saved on time that would have been spent in home visits. The total mileage saved by VDOT was 56,902 miles.

Table 12: Time & Mileage Saved with VDOT Program for 47 Patients

Total Time Saved	2,408 hours
Time Saved on Driving	1,832 hours
Time Saved on Home Visits	576 hours
Total Mileage Saved	56,902 miles

CHAPTER 7: DISCUSSION

Incorporating video technology to patient care comes at a time in which the nation is experiencing a transformation in the healthcare system. Whereas once delivery of care was driven by volume, the shift is now towards improving value and quality of care. The VDOT program has the potential to achieve the Triple Aim of improving population health, reducing cost, and improving experience of care.²⁸ Using DOT, an individual with TB disease, or even an asymptomatic patient with TBI, has to schedule his/her day-to-day routine based on the need to be observed taking TB medications by someone, which is especially challenging with conflicting commitments like work, school, and family life and giving up privacy. VDOT addresses these potential barriers by making it more convenient and private for patients to use a mobile device rather than having to adjust their schedules and even in some cases miss work or school for these home visits. These benefits for patients may potentially improve the effectiveness of VDOT by increased adherence rate over time. With VDOT, overall population health may improve by reducing further TB transmission within the community and complications from TB—including MDR TB and XDR TB—with reduced overall costs.

Effectiveness

The effectiveness of VDOT program in this study was comparable to other prior studies.^{7,26,27} Though each study used different technology—only the binational study in San Diego and Tijuana utilized the asynchronous VDOT program like that of

HCPHES.^{7,26,27} Table 13 compares the adherence rate of the VDOT program at HCPHES with other studies, which used video technology.^{7,26,27}

Table 13: Comparison of VDOT Effectiveness among Studies

Sources: Garfein RS, *Int J Tuberc Lung Dis.* 2015; 19(9): 1057-1064.

Chuck C. *Int J Tuberc Lung Dis.* 2016; 20(5): 588-593.

DeMaio J. *Clinical Infectious Disease.* 2001; 33: 2082-4.

Location of Health Department	Type of Video Technology	Adherence Rate	<u>Successful Observations</u> Total Observations	Sample Size
HCPHES	Asynchronous VDOT	92%	2,216/2,303	47
San Diego, CA	Asynchronous VDOT	93%	N/A	43
Tijuana, Mexico	Asynchronous VDOT	96%	N/A	9
New York City	Real-time VDOT	95%	3,292/3,455	61
Tacoma-Pierce County, Washington State	Real-time Videophone	95%	288/304	6

In our study, the adherence rate of VDOT observations was five percentage points lower than DOT observations; this difference was statistically significant. This could be due to various factors including that a select number of patients who were non-compliant on VDOT and had to be switched to DOT. In addition, this was a new program at the time and could be going through adjustments in terms of overcoming the learning curve of using mobile devices and the mobile app among staff and patients as well as coping with technical issues, which come with using a new app. For instance, a certain number

of VDOT observations were classified as missed events, even though the patients submitted the videos, but during staff review the videos emerged as a blank screen. This technical issue was subsequently resolved, but did result in missed VDOT observations. It was not recorded at the time as to how many VDOT observations experienced such issues. In our study, 17 percent of the individuals did not complete treatment with VDOT. Some individuals were transferred to different city and county jurisdictions for completion of treatment, and 6 individuals were switched back to DOT for having difficulties using the mobile device, forgetting to submit video sessions, and refusing treatment for TBI. In the binational study conducted in San Diego and Tijuana, 13 percent of its participants returned to DOT.⁷ The authors of that study made a crucial point that there were specific circumstances in which individuals may not be able to use VDOT and that VDOT should be a complement of DOT rather than replacement.⁷ This current study again highlights that VDOT is complementary to in-person DOT, but it does make a vital and very significant contribution of its own. It further illustrates the need for appropriate selection of patients who are likely to be adherent in general to avoid having to switch these individuals back to in-person DOT.

Cost

As evident in our study, VDOT has the potential of cutting costs in a very significant way, which is especially beneficial for the health department as it constantly has to struggle with budget restrictions. The major cost of DOT at HCPHES is the travel time and personnel needed for home visits. This study demonstrates that the total cost of treatment reduces by \$61,051.70 or by 83 percent if we replace DOT by VDOT. Though

the caveat is that these numbers do not take into consideration all factors including staff benefits, overhead costs such as mobile app fee, and some direct costs such as time spent on technical issues on the mobile devices and app or vehicle issues. In addition, due to lack of data at individual case level, certain parameters such as roundtrip travel time, time spent with the patient during home visit, and time spent reviewing videos were based on indirect estimates and staff reported averages.

We also were not able to observe the full savings potential of VDOT as some patients were enrolled in the program much later into their treatment. We expected patients to be on VDOT for an average of 6.5 months, but they were actually on it for an average 4.5 months. We see this with the number of VDOT observations as well—the expected number was 3,995 while actual number was 2,303.

While this study does show that the VDOT program can avert costs, save time and mileage, it is important to retain the quality and safety of observed visits. For example, HCPHES has within its eligibility criteria that those with TB disease must have pan-sensitive TB and can only be considered for VDOT until sputum cultures have converted to negative, which generally takes about 2 months. This helps to ensure safety and quality of care by patients receiving appropriate length of antibiotics and those who have more complicated TB should be monitored more closely.

Lessons Learned

The study has shown that costs can be averted in a significant way with the application of VDOT. It has also shown that due to the requirements of TB treatment, the technology used for VDOT will remain as a complement to in-person management. The

key to further savings is to efficiently and effectively utilize the mix of human effort with technology. Due to the retrospective nature of the study, the parameters are rough estimates at best. As already mentioned, the time spent measurements were proxy for the actual times. Thus, the time spent driving could be an underestimation as travel time and traffic is unpredictable in the Houston and Harris County area. Certain parameters were not included in this study due to practical and time constraints including time spent on technical issues with mobile device/app, time spent on vehicle issues, and mobile app fee.

Another limitation to this study was that the analysis was in the perspective of the health department and did not take into consideration factors related to the patient. Thus, it did not take into consideration the time spent by patients on observations or the potential lost wages. This study is generalizable to health departments with similar characterizations as HCPHES. It is especially applicable for those which have a large burden of TB within its jurisdiction. Another point to consider is that the study sample may not be generalizable to other populations with TB disease and TB infection.

Future Direction

The current study provides insight that the first year of full implementation of the VDOT program at HCPHES potentially saved cost, travel time and mileage for HCPHES staff. While the difference in adherence rates of VDOT and DOT was statistically significant; the adherence rate of VDOT was comparable to other adherence rates from prior studies. Also, the difference in these adherence rates is potentially explained by inclusion of some patients in VDOT who may not have been the best candidates for VDOT. The analysis of cost and effectiveness reveals encouraging results for HCPHES

as they continue to implement the program. It also highlights the potential benefits of using VDOT so that other health departments can consider implementing it, especially if their jurisdiction has a large burden of TB disease and infection.

The next step for HCPHES to consider is to perform a formal cost-effectiveness analysis, which compares two groups—1) those on VDOT and 2) those on DOT. The more robust design is a prospective cohort study or a randomized trial which follows these two groups simultaneously over a period of time.

Further research is needed to determine whether VDOT is cost-effective compared to DOT. Currently, studies in United Kingdom and Moldova are undergoing randomized controlled trials assessing the efficacy and cost-effectiveness of TB VDOT compared to DOT.^{29,30} The technology which is used for VDOT can also be considered for other medical and public health applications, for example, for other disease processes which may require DOT.

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Vita

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