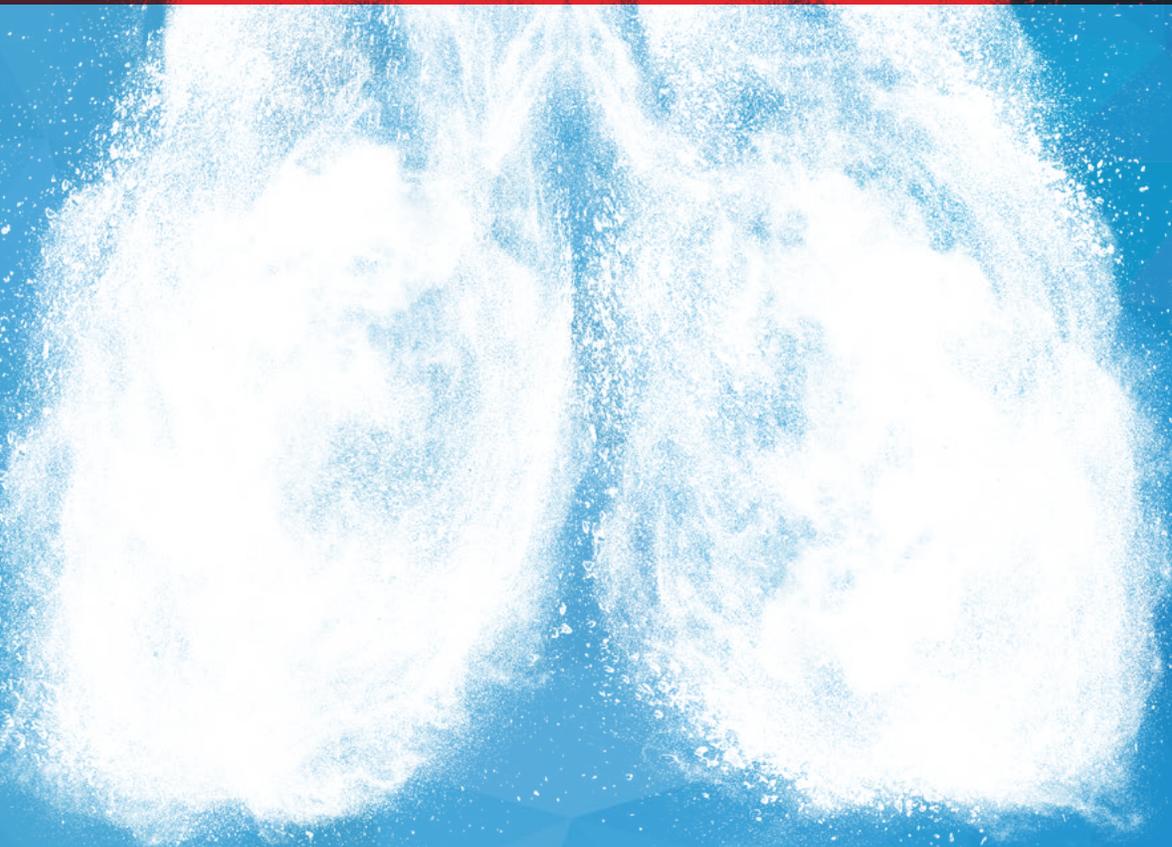


# TUBERCULOSIS

*Video Directly  
Observed Therapy* (VDOT)

IMPLEMENTATION GUIDE



## **HARRIS COUNTY PUBLIC HEALTH**

Disease Control and Clinical  
Prevention Division

## **TUBERCULOSIS ELIMINATION PROGRAM**

2223 West Loop South  
Houston, Texas 77027

[www.hcphtx.org](http://www.hcphtx.org)



Harris County  
**Public Health**  
Building a Healthy Community



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*“Participating in the VDOT program makes it easier to take my medication without waiting for someone to come to the house. It doesn’t interrupt my school and work schedule.”*

*—VDOT Patient*

# Message from the Executive Director

Greetings,

It is my great pleasure to welcome you to Harris County Public Health (HCPH), the county health department for Harris County, Texas. Harris County is the third most populous county in the U.S., one of the fastest growing, and home to Houston, the nation's fourth largest city. We are busy and diverse in every way imaginable. Our agency is made up of over 700 public health professionals who are proud and passionate about the work they do and are dedicated to improving the health and well-being of Harris County. HCPH has an annual budget of \$80 million with a mix of federal, state, and local funding.



## Why Public Health is Involved in Tuberculosis Elimination

Harris County has one of the highest rates of tuberculosis (TB) in the nation based on national and state data (Texas Department of State Health Services, 2015b). TB elimination occurs through public health efforts to educate, provide testing and treatment, and appropriately isolate infected individuals to prevent further transmission. HCPH is dedicated to the mission and works hard to ensure that every Harris County resident can lead a healthy life.

## Technology and the Harris County Video Directly Observed Therapy Initiative

The HCPH TB program uses Directly Observed Therapy (DOT) to treat active TB cases and household contacts with latent infection. Providing DOT is a costly endeavor, routinely requiring outreach workers to drive up to 17,000 miles per month delivering and observing medication doses. HCPH explored an innovative approach to care involving medical devices, secure servers and video technology called Video Direct Observed Therapy (VDOT). After careful research, HCPH partnered with a medical technology provider offering a smartphone based platform for VDOT. As a result, HCPH was able to offer its patients more autonomy, flexibility, and privacy, while reducing the need for costly in-person visits. The following Implementation Guide outlines the approach of HCPH to VDOT.

Sincerely,

A handwritten signature in black ink, which appears to read "Umair A. Shah, MD, MPH". The signature is fluid and cursive.

Umair A. Shah, MD, MPH  
Join me on Twitter: @ushahmd



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**Public Health**  
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## ABOUT HCPH

Harris County Public Health (HCPH) is the county health department for Harris County, Texas, one of the largest and most diverse counties in the United States, providing comprehensive public health services to the community. The HCPH jurisdiction includes approximately 2.2 million people within Harris County's unincorporated areas and over 30 small municipalities (*not including the city of Houston*).

SINCE BEING CHARTERED BY HARRIS COUNTY COMMISSIONERS COURT IN 1942, HCPH has provided leadership in a wide range of public health activities including, but not limited to, public health policy legislation, disaster relief planning and assistance, communicable disease control, veterinary and environmental public health, nutrition and chronic disease prevention, and clinical preventive services.



THE HCPH TUBERCULOSIS ELIMINATION PROGRAM is part of the Disease Control & Medical Epidemiology (DCME) section of the Disease Control and Clinical Prevention (DCCP) division. The DCME section also houses Harris County's Refugee, HIV Prevention, and Epidemiology Programs. The largest division within HCPH, DCCP additionally offers a broad range of population-health and clinical prevention services such as immunizations, family planning, sexually-transmitted diseases (STD) testing and treatment, and dental services and education.

# Tuberculosis-A Shared Global Burden

## TB Achievements & Challenges 2000-2014

### ACHIEVEMENTS



**43 million**  
lives saved  
between 2000 and 2014



**47% drop**  
in TB death rate  
since 1990

### CHALLENGES



**3 million people**  
who fall ill with TB still  
unreached every year



**MDR-TB crisis**  
detection, waiting lists  
for treatment and  
quality of care

Source: World Health Organization. (2015a). WHO End TB Strategy. Tuberculosis (TB). [Factsheet]. Geneva, Switzerland: WHO Global TB Programme. Retrieved from [http://www.who.int/tb/post2015\\_strategy/en/](http://www.who.int/tb/post2015_strategy/en/).

## Tuberculosis is the leading infectious killer in the world.

In 2014, there were 9.6 million active TB cases and 1.5 million deaths (World Health Organization, 2015a). Although improvements have been made, much work remains.

In 2014, the World Health Organization (WHO) launched its “End TB” strategy with the mission of ending TB by the year 2035. The program’s goals are many, including reducing drug resistance, increasing access to new and innovative treatments, and prioritizing programmatic funding (WHO, 2015b).

The WHO global strategy includes providing high quality treatment to all TB patients in a timely manner and ensuring completion of treatment (WHO, 2014).

*To be successful, worldwide participation is necessary. Countries need to support innovative approaches aimed at therapy completion, which will effectively reduce further disease transmission, as well as antibiotic resistance rates.*

# HCPH Commitments to the WHO 2015 Strategy

**EMBRACE INNOVATIVE TREATMENT MODALITIES SUCH AS VIDEO DIRECTLY OBSERVED THERAPY (VDOT) –** Increasing TB treatment completion rates and adherence.

**STANDARDIZE TREATMENT OF LATENT TUBERCULOSIS WITH 3HP IN ALL APPLICABLE PATIENTS –** Reducing the pool of individuals at risk for TB disease.

**FIND TB –** Utilize programmatic savings from innovations to fund Tuberculosis education, testing, and treatment in high-risk Harris County Communities.

*“Pursuing new scientific knowledge and innovations that can dramatically change TB prevention and care.”*

*—World Health Organization, 2015b*

## Five priority actions to address the global MDR-TB crisis



### **PREVENT THE DEVELOPMENT OF DRUG RESISTANCE THROUGH HIGH QUALITY TREATMENT OF DRUG-SUSCEPTIBLE TB**

Prevent MDR-TB as a first priority.



### **EXPAND RAPID TESTING AND DETECTION OF DRUG-RESISTANT TB CASES**

Scale up rapid testing and detection of all MDR-TB cases.



### **PROVIDE IMMEDIATE ACCESS TO EFFECTIVE TREATMENT AND PROPER CARE**

Ensure prompt access to appropriate MDR-TB care, including adequate supplies of quality drugs and scaled-up country capacity to deliver services.



### **PREVENT TRANSMISSION THROUGH INFECTION CONTROL**

Implement appropriate TB infection control measures to minimize the risk of disease transmission. This remains one of the most neglected components of TB prevention and care.



### **INCREASE POLITICAL COMMITMENT WITH FINANCING**

Underpin and sustain the MDR-TB response through high level political commitment, strong leadership across multiple governmental sectors, ever-broadening partnerships, and financing for care and research.

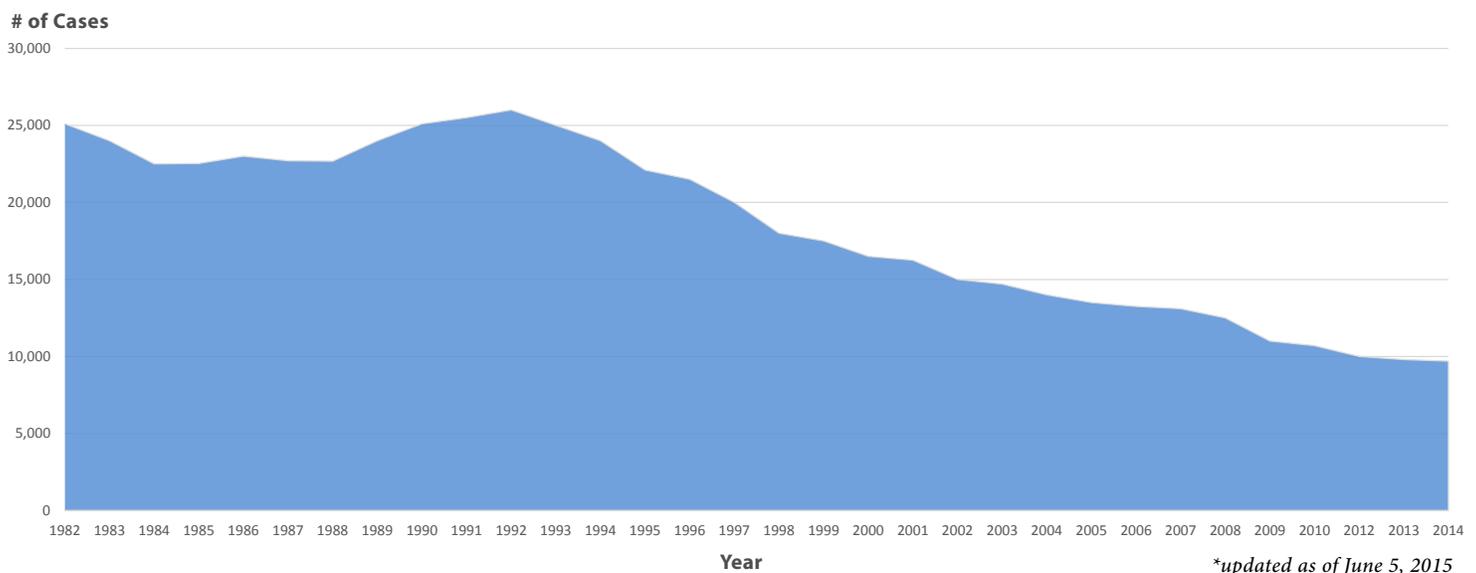
Source: World Health Organization. (2015a). *Multidrug-Resistant Tuberculosis (MDR-TB) (2015 Update)*. Geneva, Switzerland: WHO Global TB Programme. Retrieved from [http://www.who.int/tb/challenges/mdr/mdr\\_tb\\_factsheet.pdf?ua=1&ua=1](http://www.who.int/tb/challenges/mdr/mdr_tb_factsheet.pdf?ua=1&ua=1).

# Tuberculosis in the United States

In 2014, **9,421** cases of tuberculosis were reported in the U.S. (a rate of 2.96 cases per 100,000 people). Fifty-one percent of the cases occurred in four states—California, Texas, New York, and Florida. Although the number of U.S. cases has been declining since 1992, 2014 marked the smallest decline in over a decade (1.5%). Meanwhile, 21 states annually experienced an increase in TB cases (CDC, 2014b).

**Two-thirds of all new U.S. TB cases in 2014 occurred in individuals born abroad – with more than half hailing from Mexico, the Philippines, India, Vietnam, and China. Asians represented the largest ethnic group affected (32% of all cases with a case rate of 17.8 per 100,000 population), followed by persons of Hispanic origin (29%, case rate 5.0 per 100,000 population). African-Americans and Caucasians represent 21% (case rate 5.1 per 100,000 population) and 13% (case rate 0.7 per 100,000 population) of the total, respectively. Among U.S.-born cases, African-Americans made up 37% of TB cases (CDC, 2014a).**

Number of TB Cases United States, 1982-2014\*



Source: Centers for Disease Control and Prevention, Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. (2014a). Tuberculosis in the United States, National Tuberculosis Surveillance System Highlights from 2014 [PowerPoint Slides]. Retrieved from <http://www.cdc.gov/tb/statistics/reports/2014/default.htm>.

## Drug Resistance & Co-infection:

In 2014, approximately 10% of U.S. TB cases were resistant to Isoniazid (INH). Ninety-one cases were primarily multi-drug resistant (MDR), with resistance to both INH and Rifampin. Additionally, there were two cases of XDR TB (resistance to INH, Rifampin, one fluoroquinolone, and one injectable TB agent) (CDC, 2014a).

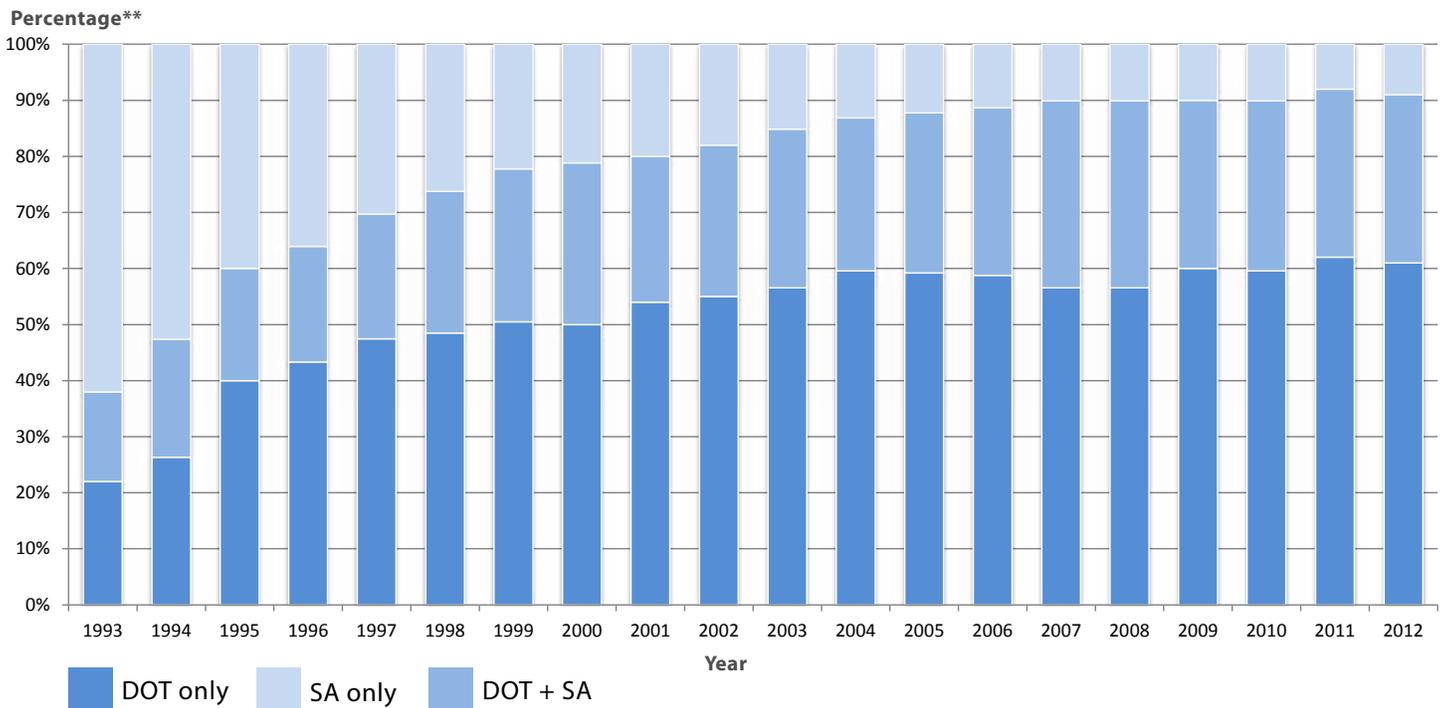
While HIV co-infection rates continue to decline, (approximately 6%), TB continues to be a leading cause of death for HIV-infected individuals globally—responsible for a quarter of all HIV deaths. (CDC, 2014a)



### DOT and Completion Rates:

Directly Observed Therapy (DOT) remains the mainstay of treatment modalities for U.S. TB patients. Of the U.S. TB cases in 2012, approximately 91% received DOT for a portion of their treatment, with 95% of patients completing their TB treatment regimens. Eighty-nine percent of these cases completed treatment within one year (CDC, 2014a).

Mode of Treatment Administration  
in Persons Reported with TB, United States, 1993-2012\*



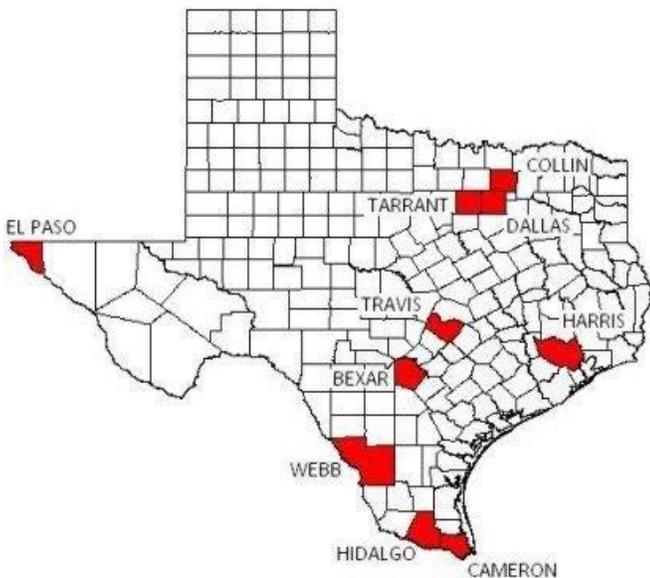
Source: Centers for Disease Control and Prevention, Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. (2014a). Tuberculosis in the United States, National Tuberculosis Surveillance System Highlights from 2014 [PowerPoint Slides]. Retrieved from <http://www.cdc.gov/tb/statistics/reports/2014/default.htm>.

\*updated as of June 5, 2015. Data available through 2012 only.

\*\*Percentage of total cases in persons alive at diagnosis, with an initial regimen of one or more drugs prescribed, and excluding cases with unknown mode of treatment administration. Directly observed therapy (DOT); Self-administered therapy (SA).

# Tuberculosis in Texas and Harris County

Texas Map Showing High TB Incidence Counties

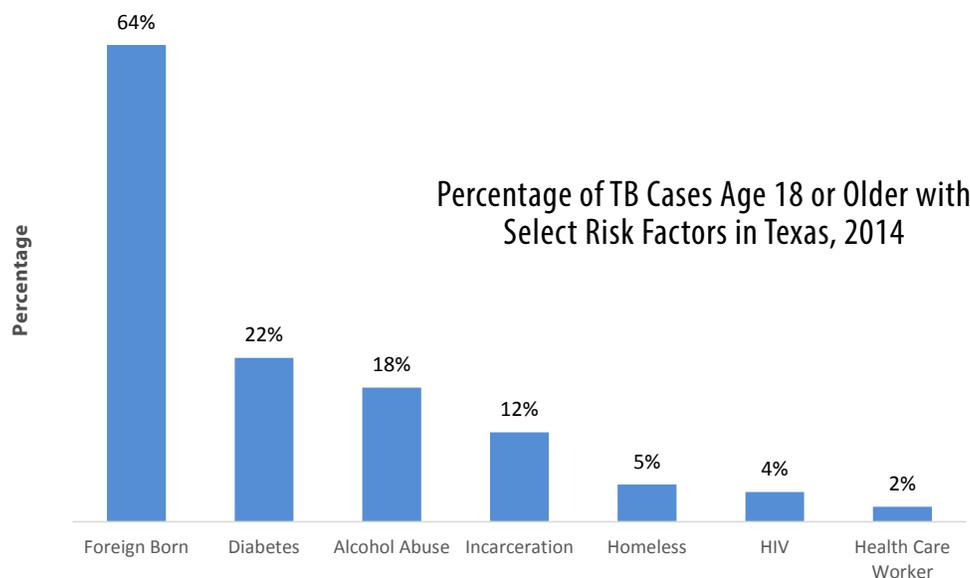


Texas ranked fourth in the nation in TB cases in 2014. The state reported 1,269 cases of TB, with a case rate of 4.7 cases per 100,000 population. The case rate in Texas is over 50% higher than the national rate (CDC, 2014a).

*“The minimal decline (in U.S. TB case counts) stresses the importance of refining our strategies in surveillance, contact investigations, and screening and treating contacts with latent TB infection...”*

—CDC Annual Report (CDC, 2014b)

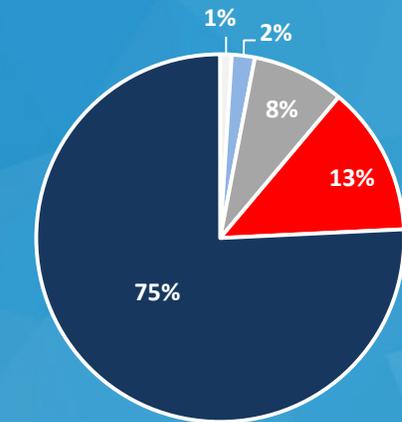
Source: Texas Department of State Health Services. (2014). TB Statistics. [Map]. Retrieved from <http://www.dshs.state.tx.us/idcu/disease/tb/statistics/>.



Source: Texas Department of State Health Services (2014). TB Statistics. [Bar Graph]. Retrieved from <https://www.dshs.state.tx.us/idcu/disease/tb/statistics/>.

As the third most populous county in the nation, TB is a disease of great public health concern for Harris County. In 2014, the case rate of TB disease in Harris County was 7.4 cases per 100,000 population, almost 60% higher than the Texas rate, and more than double that of the U.S. (Texas Department of State Health Services, 2015a). Incidence rates are higher in vulnerable populations such as the homeless, low income, uninsured, refugee and immigrant communities—all of which are found in large numbers in Harris County.

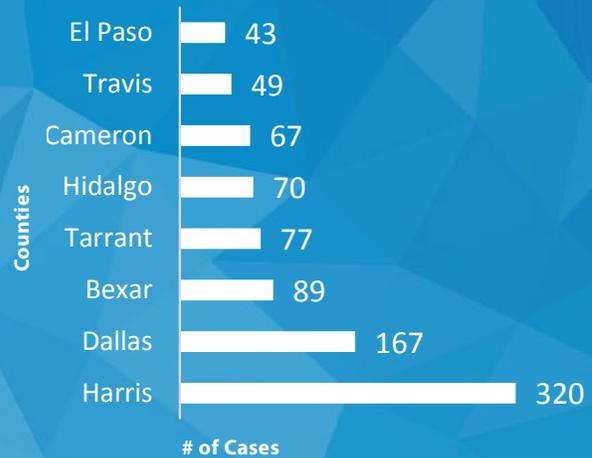
## TB Case Disposition, Harris County\* 2014



\*HCPH Jurisdiction Only

- Lost to Follow-up
- Expired
- Completed Treatment
- Moved
- Still in TX

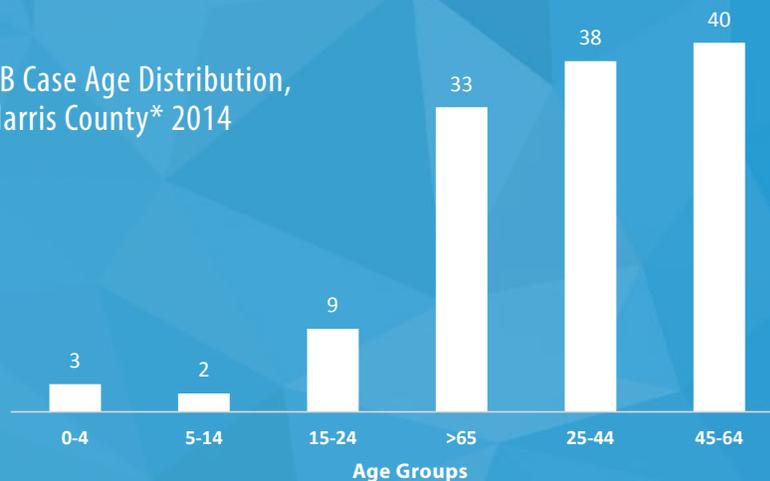
## TB Cases in Selected Counties



Source: Texas Department of State Health Services. (2014). Cases and rates by County. Texas Tuberculosis Data. [Data files]. Retrieved from <http://www.dshs.state.tx.us/idcu/disease/tb/statistics/>.

HARRIS COUNTY PUBLIC HEALTH PROVIDES (HCPH) TB CARE FOR INDIVIDUALS LIVING IN UNINCORPORATED AREAS OF HARRIS COUNTY including 30 small municipalities, not including the city of Houston. In 2014, HCPH treated and provided Directly Observed Therapy (DOT) to 125 patients with active TB, one patient with Multidrug Resistant (MDR) TB and 38 TB suspects ultimately not found to have active disease. Seventy-five percent of these cases completed treatment as of September 2015, while 13% remain in treatment (8% expired, 2% moved, and 1% failed to follow-up). Prophylactic treatment was started on 401 Latent TB Infection (LTBI) patients, with 70% finishing the regimen as of September 2015 (Harris County Public Health, 2015).

## TB Case Age Distribution, Harris County\* 2014



Source: Texas Department of State Health Services. (2015a). Texas Tuberculosis Data. [Data files]. Retrieved from <http://www.dshs.state.tx.us/idcu/disease/tb/statistics/>.

In 2014, almost three-quarters (72%) of HCPH' TB patients were foreign-born, 66% were male, 17% had extra-pulmonary disease, and 2.4% were co-infected with HIV. Many were uninsured, medically indigent, or on Medicaid. Approximately 45% of cases identified as Hispanic, 30% as Asian, 13% Black, and 13% White.

*Almost one-third of patients were between the ages of 44 and 64, and over one-quarter were elderly (>65yrs)*

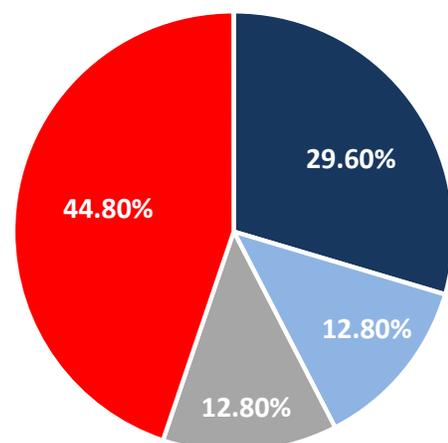
—HCPH, 2014



## Tuberculosis in Texas and Harris County (cont.)

Currently, HCPH TB staff provide DOT and Directly Observed Preventive Therapy (DOPT) to an average of 163 patients, contacts, and suspects each week. The majority of patients provided with prophylactic treatment against active TB disease are in close contact to active TB cases and new immigrants settling in Harris County.

TB Case Ethnicity, Harris County\* 2014



\*As of Sept. 2015, HCPH Jurisdiction Only

■ Asian ■ White ■ Black ■ Hispanic

### Close to two-thirds of Texas TB patients diagnosed in 2014 were foreign-born.

Fifty-five percent (55%) of TB cases occurred in persons of *Hispanic origin*, 18% in *Asians*, 18% *African-American*, and 9% in *Caucasians*. Harris County's statistics showed a similar trend. (Texas Department of State Health Services, 2015b).

# Rationale and Potential Impact

*HCPH expects early adoption and implementation of VDOT will prove to be a beneficial model for other health departments.*

Treatment for active TB disease is lengthy and requires at least six to nine months of antibiotic treatment. Antibiotic resistance and other host factors can extend treatment to more than two years (CDC, 2013). The state of Texas requires that all TB cases and suspected cases be treated with Directly Observed Therapy (DOT)(TB CARE I, 2014). DOT ensures compliance with the long and grueling treatment regimen required for a cure. However, it is quite costly. DOT requires that a health worker travel to a patient's home to observe each medication dose, often occurring multiple times per week. As a result, public health departments located in rural areas or sprawling metropolises, such as Harris County, incur significant costs.



## Patient Burden:

- Time consuming
- Interrupts work schedule
- Lack of privacy
- Limits travel
- Conspicuous reminder - stigma

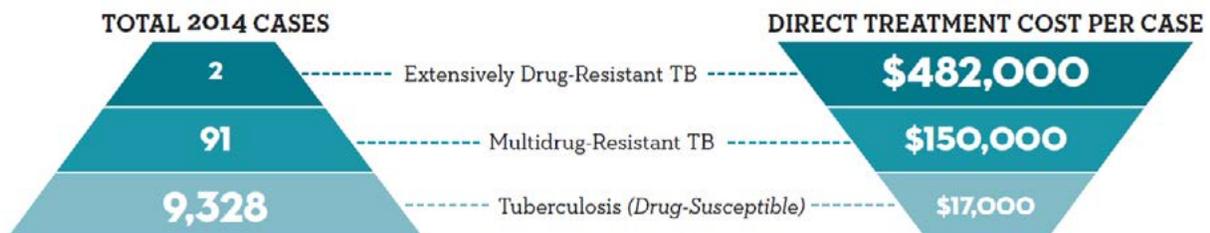
## Health Department Cost:

- Costly mileage and vehicle maintenance
- Outreach worker (ORW) time
- Vehicle accidents and safety concerns



**In 2013, HCPH became aware of the possibility of providing DOT services to TB patients utilizing video technology.** Remote services would require Health Insurance Portability and Accountability Act (HIPAA) compliance and needed to meet other regulatory requirements (Weidennar, Agrawal & Hodge, 2014). However, if successful, video technology could significantly reduce operating

costs and overhead, increase patient privacy and satisfaction, and enhance regimen adherence. Since implementing VDOT for the treatment of active and Latent Tuberculosis Infection (LTBI), HCPH has experienced noticeable reductions in outreach worker costs and travel expenses. Additionally, patients have offered overwhelmingly positive feedback.



Source: Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention . (2014). [Infographic Illustration]. Take on Tuberculosis. Retrieved from <http://www.cdc.gov/tb/publications/infographic/pdf/take-on-tuberculosis-infographic.pdf>.

***“Preliminary results indicate TB patients can be successfully treated remotely with VDOT, with improved side-effect monitoring. Routine use of VDOT may be a cost-effective and efficient means of reaching TB treatment goals.”***

**—HCPH**



**Since piloting its Video Directly Observed Therapy (VDOT) program in late 2014, HCPH has placed a total of 115 patients on the smartphone technology,** giving them the opportunity to complete their regimens remotely. Feedback has been overwhelmingly positive, prompting plans to increase access to all eligible patients within the program.

*VDOT is an innovative technology leading the way towards eliminating TB. There is improved medication adherence, and patients benefit from greater flexibility and autonomy. Moreover, significant cost savings allow for increased testing and treatment in high-risk communities.*

—HCPH

# Implementation Planning

In 2013, HCPH began exploring the possibility of using remote video technology. During the year-long review, HCPH researched the history of VDOT utilization in other U.S. health departments and interviewed several HIPAA compliant VDOT platform providers. Ultimately, two platforms were selected for pilot testing. (See Appendix B - Sample Technical Requirements for VDOT Platform Selection).

## A Smartphone for Each Enrolled Patient

Realizing that some patients may have limited access to smartphone technology, cellular service providers were interviewed with the goal of obtaining low-cost smartphones and service plans. The VDOT team contracted a smartphone service provider who offered free phones, with an agreement that HCPH would pay monthly service fees only for phones actively in use by patients. Concerns were raised regarding potential patient misuse or loss of borrowed phones. However, the overwhelming majority of patients exhibited the utmost care for their assigned smartphones, and used them solely for the purpose of submitting VDOT videos.

## VDOT Smartphone Requirements

- Ability to enable/block international calls, texts, and roaming
- Hot spot capability
- Ability to monitor monthly voice, data, and text usage
- Ability to block access to inappropriate mobile applications or websites



# Platform Selection



*"VDOT is convenient for me; it allows me to go to work without having to meet someone during my work day; it gives me flexibility to take my pills at different times."*

*—VDOT Patient*

## Training Outreach Workers

Outreach workers (ORW) were trained to operate the VDOT smartphone application including the Client Management System (CMS), the administrative 'back-end' of the application. After each session, surveys were issued to assess ORW comfort-level with application tasks. (See Appendix A - Post-Training Survey).

## VDOT Platform Selection Criteria

HCPH requested proposals from several remote VDOT software providers offering a system designed for use in the remote treatment of TB patients. After extensive evaluation of available options, a platform provider was selected. (See Appendix B - Sample Technical Requirements for VDOT Platform Selection).

### SOFTWARE REQUIREMENTS:

- A customizable turn-key system
- Easy-to-use patient-facing application
- Easy-to-use Client Management System enabling remote video viewing and acceptance
- Security - Health Insurance Portability and Accountability Act and 21 CFR Part 11 compliance, encryption
- Android/IOS system compatibility
- Platform integration into Electronic Medical Record
- Future expansion capability
- Readily available product support
- Company billing infrastructure

## Phase I – Pilot

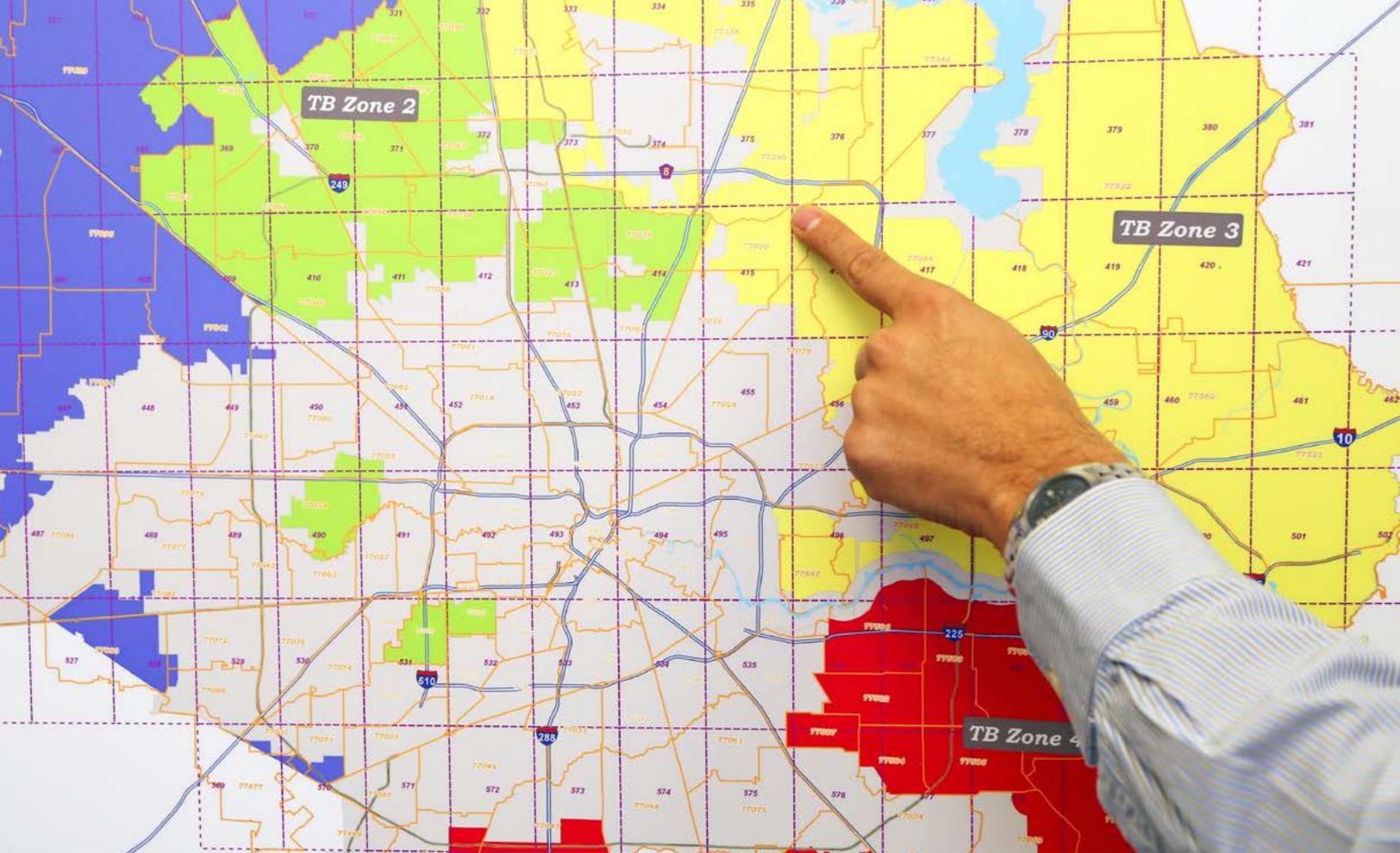
Nurse Case Managers (NCM) enrolled 30 patients into the pilot program based upon pre-determined criteria (See Patient Selection Section). Patients were educated on the use of the technology, signed consent forms for VDOT participation and smartphone use, and were instructed to call the VDOT hotline with questions or concerns. (See Appendix B, VDOT Participation Agreement and Smartphone Agreement).

## Phase II – Full Implementation

Patient selection criteria were modified based upon pilot-phase experiences. A total of 45 additional patients were enrolled into VDOT. Technology platform modifications were made to streamline video-capture, while medication adherence calculations were embedded into the software. Patient feedback was continually evaluated. Towards the end of this phase, the program initiated analysis of the cost-effectiveness and overall utility of VDOT as a treatment modality.

*"VDOT gives me privacy; I'm no longer asked by neighbors why the county car comes to my house and visits me every week."*

*—VDOT Patient*



# Patient Selection

## Criteria for Patient Selection

As part of the selection process, consent was required from patient(s) and/or guardians in order to participate in the VDOT program. Patients at risk of poor adherence (e.g. homeless, history of recent substance abuse, non-compliance, or memory impairment) were not eligible for enrollment.

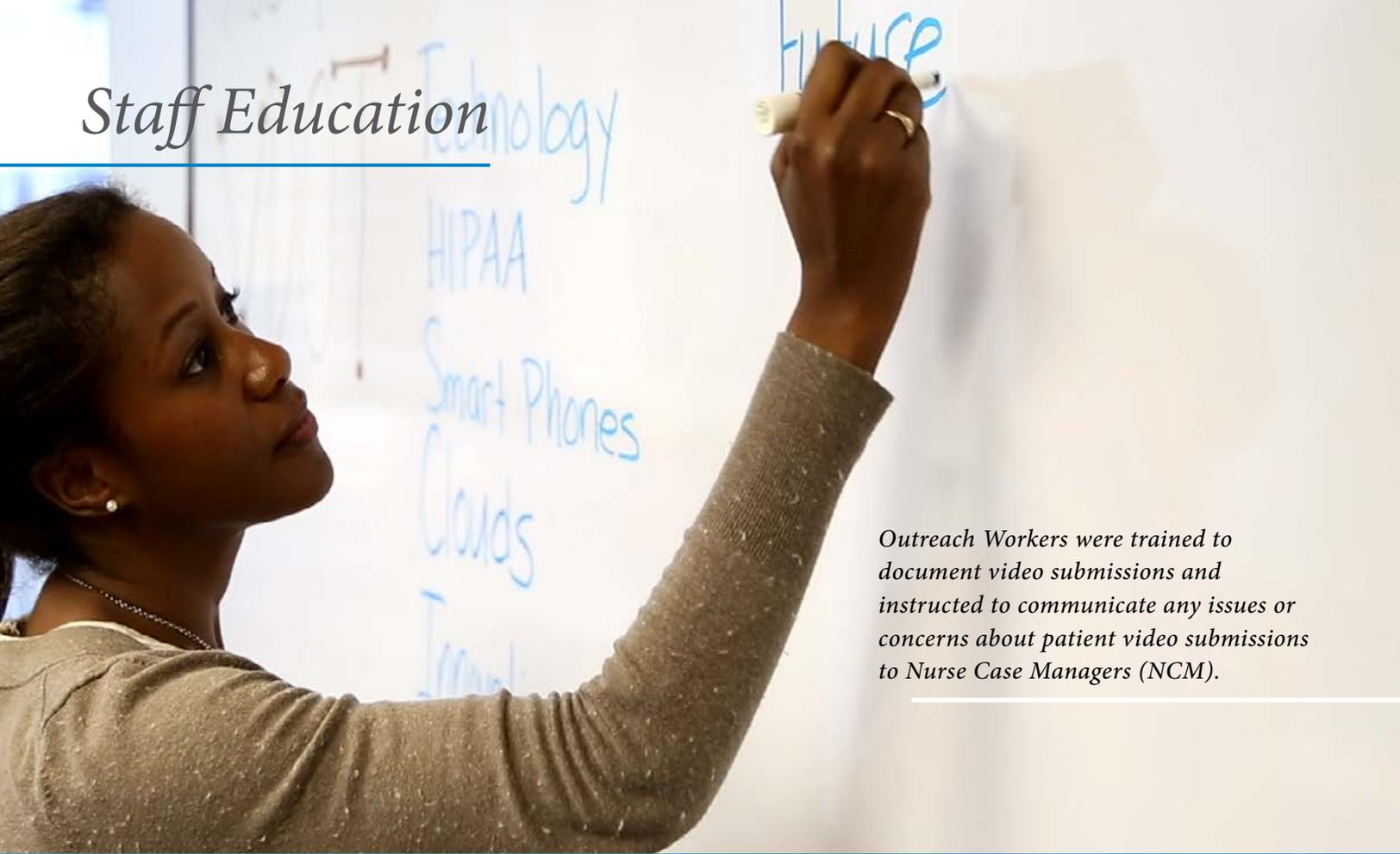
### OTHER CONSIDERATIONS:

- Patient's overall medical condition and stability
- Patient's motivation towards his/her current TB treatment
- Drug-Resistance may pose additional worries about compliance
- Whether or not the patient has achieved sputum conversion
- Patient's ability to open medication packets and identify each medication
- Patient's skill in operating phone technology and VDOT software
- Patient access to an environment conducive to recording and submitting confidential videos
- Patient's ability to securely store up to 30 days of TB medications in the home environment

### REMOVING PATIENTS FROM VDOT:

- Patient non-compliance with signed agreements – abuse of VDOT equipment
- Change in patient's health or mental status
- Patient non-compliance with medical appointments, treatment regimen, or provider recommendations
- Patient request to return to traditional DOT for valid reasons

# Staff Education



*Outreach Workers were trained to document video submissions and instructed to communicate any issues or concerns about patient video submissions to Nurse Case Managers (NCM).*

## TB staff were trained on VDOT application software and implementation protocols:

### STAFF LEARNING OBJECTIVES

- Setting-up a phone for patient use
- Downloading the VDOT software onto the phone
- Reviewing and explaining consent forms with patients
- Ensuring patient ability to consent
- Training patients on taking medications during video recording
- Proper video recording technique
- Successful submission of VDOT videos

### Auxiliary clinical staff were trained on:

- Navigation of Client Management System (CMS, or “back-end” of application)
- Enrolling a patient onto VDOT in the CMS
- Viewing and accepting (or declining) submitted videos
- Calculation of adherence using the CMS
- Troubleshooting problems with patients



# Patient Education

---

Patients selected to participate in the VDOT program are trained by an Outreach Worker on proper use of the smartphone technology and the VDOT software. Outreach Workers schedule two home visits with patients to answer any remaining questions and to assess the patient's ability to perform the operations necessary for successful video creation.

## Initial VDOT Home Visit

- Patient and Nurse Case Manager or Outreach Worker review and ensure understanding of the conditions and responsibilities defined in the VDOT phone and program agreements
- Patient acknowledges that VDOT participation does not alter his/her public health obligation to complete the TB regimen
- Patient signs all applicable agreements. (*see Appendix B*)
- Patient is instructed on what to do in the event of an emergency, drug side effects, or equipment failure.
- The Nurse Case Manager or Outreach Worker demonstrates the proper use of the equipment and software, such as navigation, video submission, side effect review, and proper smartphone positioning.
- Smartphone is activated. First VDOT dose is observed.





*The Nurse Case Manager or Outreach Worker schedules to meet the patient in their home at least once a month, providing the patient with up to a month's supply of medications. This monthly visit allows for discussion of any clinical or technical issues not already addressed.*

## **Second VDOT Home Visit**

During the second home visit, the patient must successfully demonstrate appropriate use of smartphone device and application to the Nurse Case Manager or Outreach Worker without assistance. The patient is given up to a two-week supply of medications, with instructions to call the VDOT hotline with any concerns or questions.

If the patient shows any difficulties during the second visit, a third in-home VDOT visit is offered. Occasionally, the Nurse Case Manager or Outreach Worker may determine a patient is unable to successfully use VDOT without assistance. The patient is subsequently removed from VDOT and placed on traditional DOT. In a successful VDOT arrangement, the patient and Nurse Case Manager or Outreach Worker mutually agree on days and times medications will be taken and recorded.

# VDOT Patient Instructions

## STEP 1:

**Gather all necessary supplies and find a quiet location.**

### SUPPLIES INCLUDE:

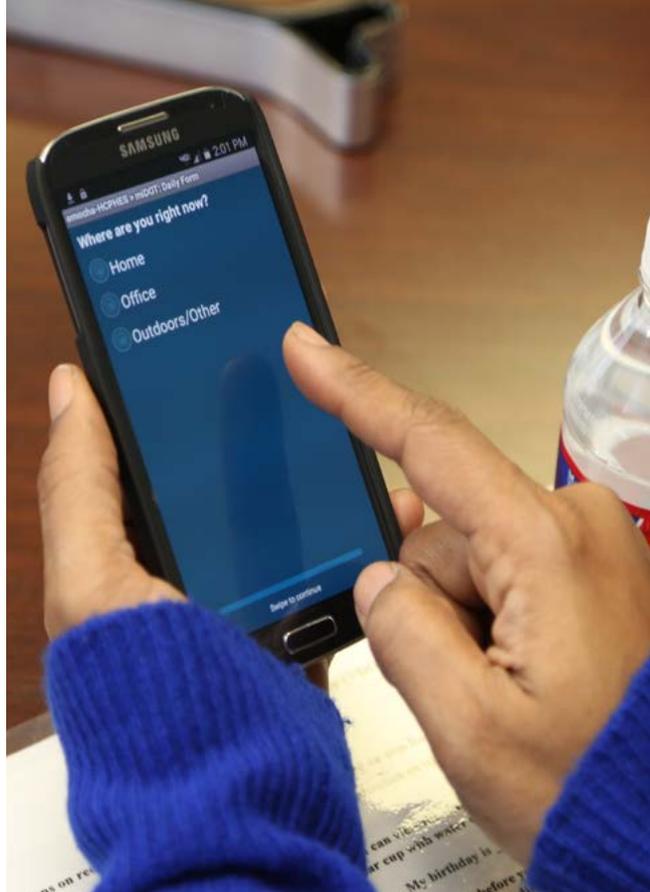
- Smartphone with stand
- A clear glass of water or other clear liquid
- TB medication packet
- TB VDOT Medication Guide Sheet and Cue Card

## STEP 2:

**Start VDOT Software**

### ANSWER QUESTIONS WHEN PROMPTED:

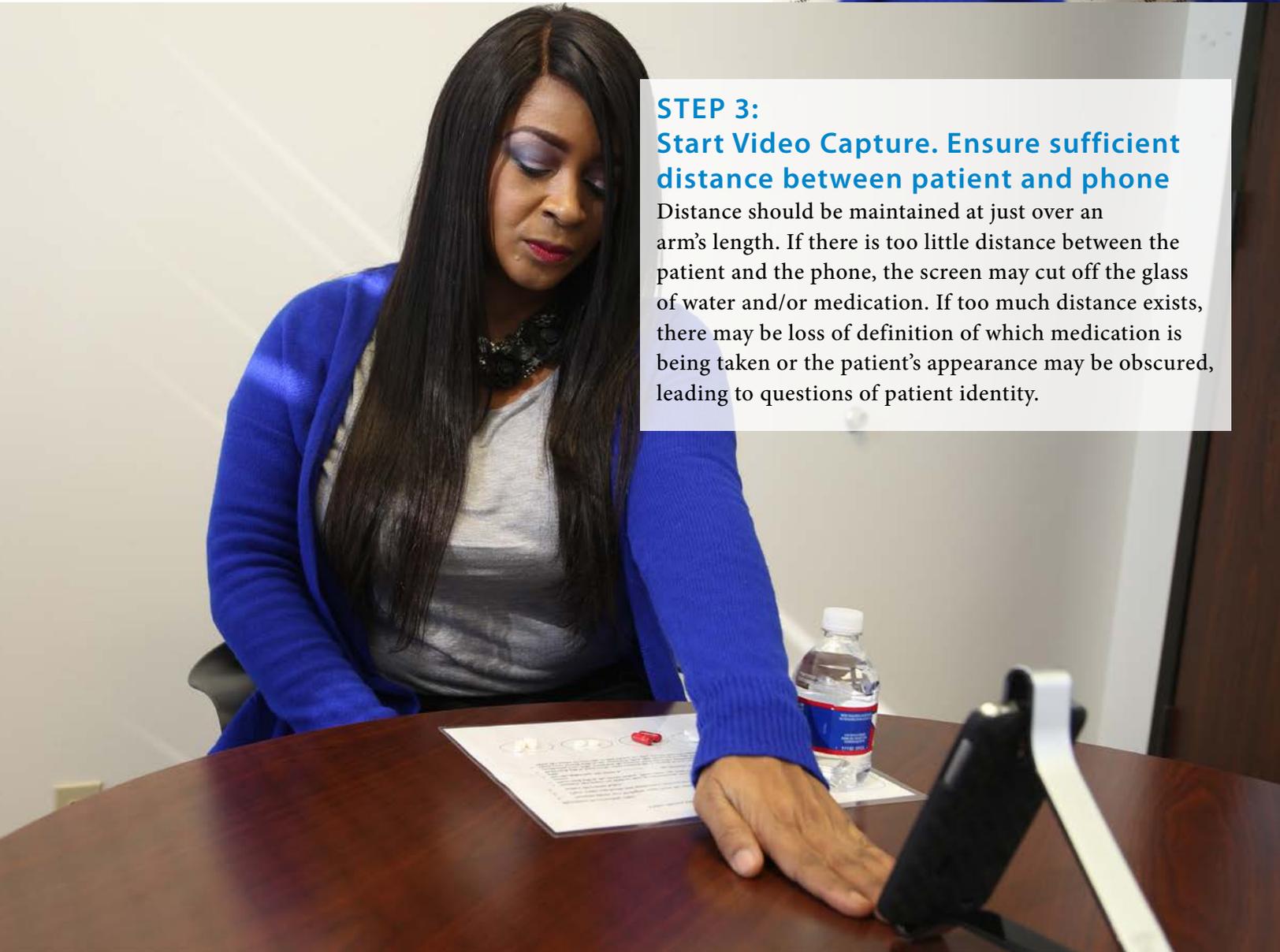
- Setting—home, office, outdoors
- Are you experiencing any of these symptoms?
- If you encounter symptoms, *STOP* and call the Nurse Case Manager



## STEP 3:

**Start Video Capture. Ensure sufficient distance between patient and phone**

Distance should be maintained at just over an arm's length. If there is too little distance between the patient and the phone, the screen may cut off the glass of water and/or medication. If too much distance exists, there may be loss of definition of which medication is being taken or the patient's appearance may be obscured, leading to questions of patient identity.



**STEP 4:**  
**Clearly state name and open medication packet & provide a close-up of pills that are to be taken**

Clearly state full name, date of birth, and current date at the beginning of the video. Hold hands in front of the camera to open medicine packet such that the viewer can easily see the pills contained inside the packet. Pills should continue to remain in plain view until swallowed. The names of all medications in the packet should be called out as they are emptied into patient's hands and swallowed.



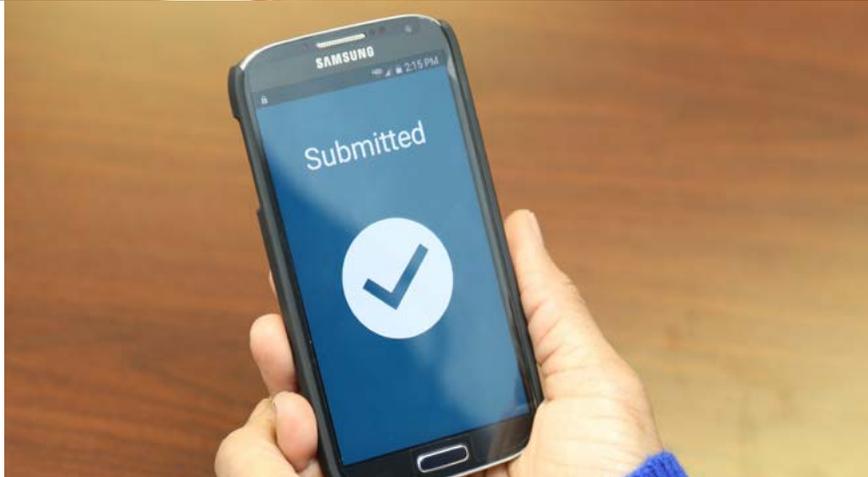
**STEP 5:**  
**Swallow pills in front of camera, then say "Aaaahh"**

With a glass of water in view, swallow all pills in camera view, using the visible glass of water to wash pills down. It is important that the subject is fully visible. Immediately open mouth to show that no pills remain in the oral cavity and say "Aaaahh."



**STEP 6:**  
**Submit video to TB Team for review**

Press button to end recording. Select "Review Video" button to review video, if desired. Select "Submit Video" to transmit video to TB team. A confirmation screen will appear. If submission button is not selected, the video will not upload and there will be no record that the medication has been taken.





# Viewing and Accepting VDOT Videos

Videos uploaded to the secure server are reviewed and accepted by trained TB staff.

## REQUIREMENTS FOR VIDEO ACCEPTANCE:

1. Clear audio and proper lighting
2. Patient identification with full name, birth date, and current date
3. Clear visualization of patient, medication, and glass of water at all times
4. Visualization of all pills being swallowed with verification of no pocketed pills

## REJECTED VIDEOS:

1. Inadequate visualization of patient leading to uncertainty of patient's identity
2. Inadequate visualization of medications
3. Inadequate view of liquid or container used to swallow pills
4. Inability to ascertain whether all pills were swallowed



## EXAMPLES OF UNACCEPTABLE VIDEOS

### PROBLEM:

*Too much space between the camera and the patient makes it difficult to capture video details.*

### PROBLEM:

*The use of an aluminum can makes it difficult to verify if pills were indeed swallowed or spit into the can. A clear container or glass with clear liquid inside is required. Aluminum canned drinks do not allow proper visualization of medication dosing.*

### PROBLEM:

*Too little space between the camera and patient makes it difficult to see medication packet and drink. It is essential the reviewer sees the patient, medication packet, and clear water container at the same time.*



# HIPAA and Data Security

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The Health Insurance Portability and Accountability Act (HIPAA) was established by Congress in 1996 to regulate how healthcare entities may use or disclose a person's Protected Health Information (PHI) (Health Information Privacy, n.d.).

HIPAA establishes national standards for the privacy of individually identifiable health information and includes a wide range of identifiers, including name, birthdate, phone number, various identification numbers, facial images and other data (Health Information Privacy, n.d.).

Successful VDOT implementation including software, interface, network, protocols and procedures – ensures HIPAA compliance. An array of linked administrative, physical, technical and encryption safeguards are utilized to provide data security and protection of patient health information.



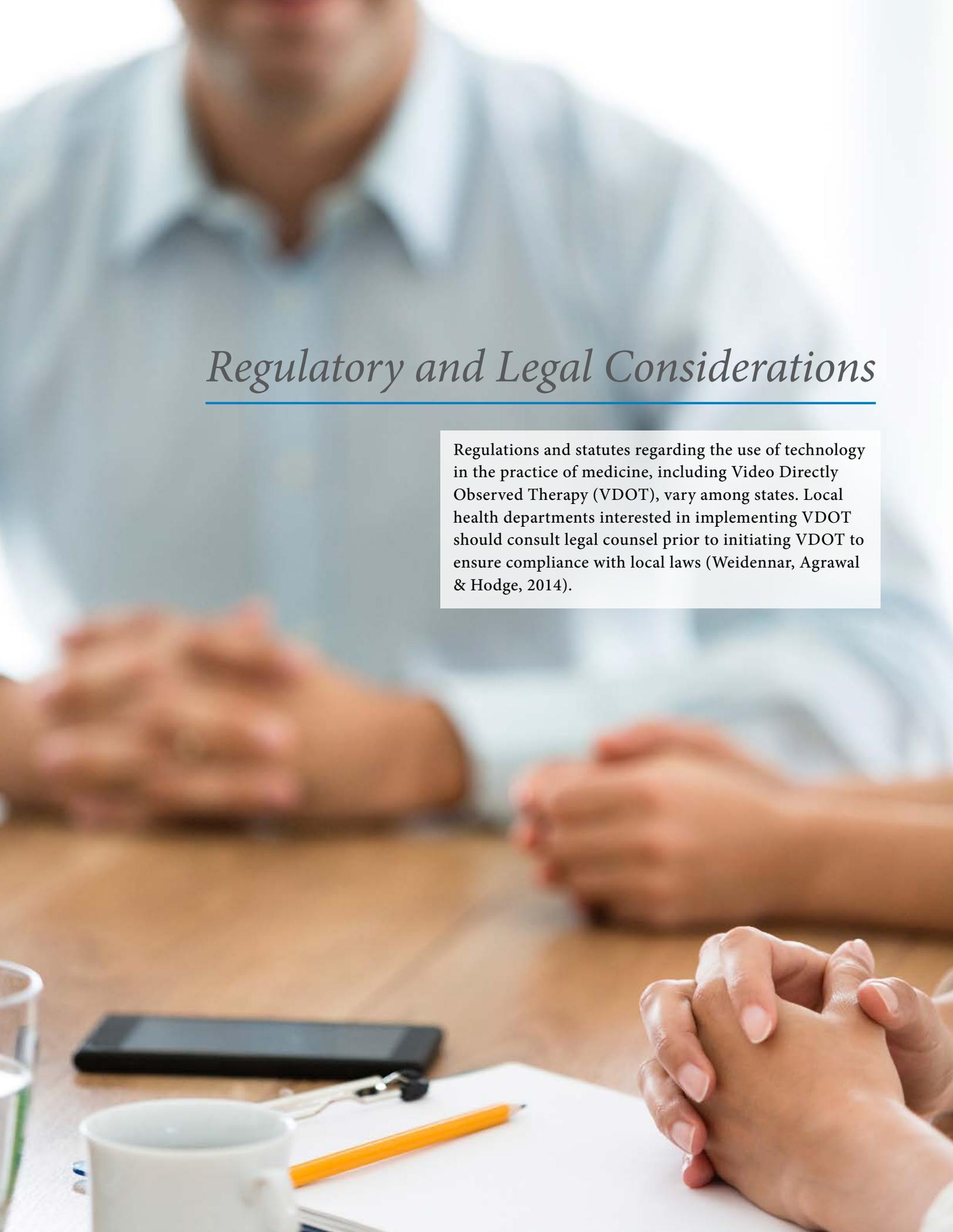
## Why Not a Simple Web-Based Platform?

“The use of web-based platforms, especially those that are proprietary, may make it difficult for healthcare entities to meet some of these obligations. At the very least, I think that use of web-based platforms for patient communication carries higher risk of potentially violating HIPAA rules. And this is becoming increasingly important with all of the heightened HIPAA enforcement activity we have been seeing.”

—TechHealth Perspectives (Ge, Lerman & Quashie, 2012).

*“I live in a close-knit community that is curious when my Outreach Worker comes to visit. VDOT has given me the privacy to take my medicine without any questions from others, and it gives me freedom to move around the city without waiting for her visit.”*

—VDOT Patient



## *Regulatory and Legal Considerations*

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Regulations and statutes regarding the use of technology in the practice of medicine, including Video Directly Observed Therapy (VDOT), vary among states. Local health departments interested in implementing VDOT should consult legal counsel prior to initiating VDOT to ensure compliance with local laws (Weidennar, Agrawal & Hodge, 2014).



## Best Practices

### FACTORS LEADING TO SUCCESS

- DEFINED clear objectives and a timeline
- UTILIZING a process flow map, and Platform Evaluation Survey
- ESTABLISHING a dedicated VDOT Implementation Team
- SEEKING broad stakeholder support and engagement
- MAINTAINING constant communication between parties
- PARTNERING with motivated smartphone and VDOT platform vendors

### WEEKLY MEETINGS TO ASSESS PROGRESS

- DISCUSS problems/troubleshooting
- PROVIDE updates to team members
- REVIEW communication with vendors
- PLAN future enrollment
- MODIFY patient selection/disenrollment criteria as needed

### SUCCESS FACTORS

Accessible multilingual staff, documents, and materials including smartphone device with translation capabilities

- *English*
- *Spanish*
- *Vietnamese*

### VDOT IMPLEMENTATION TEAM

- TB Program and clinical division leadership
- Technical project manager
- Technical lead
- In-house legal counsel
- Finance team
- Clinical and administrative TB staff

### ESTABLISHING A VDOT CHAMPION

- Gains expertise in smartphone and VDOT software use
- Helps enroll new patients
- Trains incoming TB staff
- Provides technical troubleshooting
- Supports VDOT team meetings



## *Lessons Learned*

### **Troubleshooting Smartphone Technology after Patient Complaint or Missed/Unacceptable Videos:**

- **PROBLEM:** Connecting enrolled patients to an Outreach Worker capable of troubleshooting
- **SOLUTION:** Assigned VDOT Champion to address technical troubleshooting until staff is appropriately trained

### **Diversity of Patients Enrolled to the VDOT program:**

- **PROBLEM:** Some elderly and pediatric patients had difficulty using technology
- **SOLUTION:** Upon enrollment, established a responsible and committed family member to ensure proper video technique and smartphone usage. The family member was trained along with the patient on software and smartphone usage. Some patients lacking this support were ultimately removed from VDOT and returned to traditional DOT.

### **Connectivity Issues Affecting Video Transmission:**

- **PROBLEM:** Some areas of Harris County experience poor cellular reception resulting in videos not being uploaded to server.
- **SOLUTION:** All enrolled patients living in previously identified poor cellular reception areas (i.e. near airports or other “dead zones”) were placed on high alert by the VDOT team to maintain active communication and ensure adequate cellular reception prior to video submission. The VDOT software provider verified smartphones were downloading software updates. If connectivity issues continued, patients were required to return to traditional DOT.



### Staff Communication Regarding Missing Videos:

- **PROBLEM:** At times, Outreach Workers failed to inform Nurse Case Managers when patients were missing videos or submitted unacceptable videos, leading to inaccurate adherence calculations and misinformed clinical staff.
- **SOLUTION:** VDOT Team established a protocol for notification of missing/unacceptable videos. Outreach Workers who viewed unacceptable videos or noticed missing videos immediately contacted the patient's Nurse Case Manager. Outreach Workers would then contact the patient to discuss the reason for the missed video or inadequate dose, and re-trained patients on correct video recording, if necessary.

### Next Steps:

Moving forward, HCPH expects continued improvements in patient care and program effectiveness using VDOT as a first-line approach. Medication adherence, patient satisfaction, and program resource utilization benefit as this mobile platform gains momentum.

HCPH continues exploring mobile applications in other public health areas such as temperature monitoring in individuals traveling from Ebola-affected countries, Refugee Health follow-up, HIV treatment adherence, as well as other types of infectious disease monitoring.

# References and Additional Resources

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## GLOSSARY

KEY TERM DEFINITION

### 3HP

A 12-dose regimen of weekly rifapentine plus isoniazid (3HP) administered as directly observed preventive treatment for latent tuberculosis infection

### 21CFR Part 11 Compliance

Title 21 of the Code of Federal Regulations Part 11, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records. It requires that computer systems must have a collection of technological and procedural controls to protect data within the system and all records are authentic, incorruptible, and confidential

### Burden of Cost

Referring to productivity lost during treatment of TB and direct treatment cost to include drugs and diagnostics, case management and social work, housing and transportation, hospitalization

### Client Management System

Administrative back-end of the VDOT platform that only the provider sees

### Dead Zone

Geographical area that has no cell phone service

### DOPT

A course of preventive treatment, for tuberculosis infection in which the prescribed course of medication is administered to the person or taken by the person under direct observation by a trained healthcare worker

### DOT

A course of treatment for tuberculosis disease in which the prescribed course of medication is administered to the person or taken by the person under direct observation by a trained healthcare worker

### HIPAA

Acronym for the Health Insurance Portability and Accountability Act that does the following:

- Provides the ability to transfer and continue health insurance coverage for millions of American workers and their families when they change or lose their jobs;
- Reduces health care fraud and abuse;
- Mandates industry-wide standards for health care information on electronic billing and other processes;
- Requires the protection and confidential handling of protected health information

### In-House Legal Counsel

Our in-house legal counsel which consists of a public health lawyer (J.D.)

### Mobile Device

A portable computing device such as a smartphone or tablet computer

### Nurse Case Manager

A registered nurse that is responsible for the patient's education, care, and continuous TB treatment

### Outreach Worker

A staff member that educates patient and provides directly observed therapy

### Secure Server

An Internet server that encrypts information to protect confidentiality

<b>Smartphone</b>	A cellular phone that performs many of the functions of a computer, typically having a touchscreen interface, Internet access, and an operating system capable of running downloaded applications
<b>Stigma</b>	A set of negative and often unfair beliefs that a society or group of people have about tuberculosis
<b>TB Program Leadership</b>	HCPH TB Program Administrative and management staff
<b>TB Staff</b>	All TB program staff, including administrative, clinical, and clerical
<b>Technical Lead</b>	Individual responsible for the underlying technical framework of the project
<b>Technical Project Manager</b>	Individual that is responsible for clearly defining and quantifying each step of the implementation process, as well as establishing concrete deadlines for project milestones and deliverables
<b>Telemedicine</b>	The remote diagnosis and treatment of patients by means of telecommunications technology
<b>VDOT Champion</b>	TB staff member that trains staff and patients, as well as troubleshoots issues
<b>VDOT Hotline</b>	A telephone line dedicated for patients to call and inquire about questions or report concerns
<b>VDOT Team</b>	TB team staff that are directly involved with video directly observed therapy

## ABBREVIATIONS

ACRONYM	MEANING
<b>3HP</b>	A 12-dose regimen of weekly rifapentine plus isoniazid (3HP) administered as directly observed treatment H=isoniazid; 3=3 months; P=rifaPentine
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CMS</b>	Client Management System
<b>DCCP</b>	Division of Disease Control and Clinical Prevention
<b>DOPT</b>	Directly Observed Preventive Therapy
<b>DOT</b>	Directly Observed Therapy
<b>EMR</b>	Electronic Medical Record
<b>HCPH</b>	Harris County Public Health
<b>HIPAA</b>	Health Insurance Portability and Accountability Act
<b>HIV</b>	Human Immunodeficiency Virus
<b>INH</b>	Isoniazid
<b>LTBI</b>	Latent Tuberculosis Infection
<b>MDR TB</b>	Multi-Drug Resistant Tuberculosis
<b>NCM</b>	Nurse Case Manager
<b>PHI</b>	Protected Health Information
<b>TB</b>	Tuberculosis
<b>VDOT</b>	Video Directly Observed Therapy
<b>WHO</b>	World Health Organization
<b>XDR TB</b>	Extensively-Drug Resistant Tuberculosis



# Appendix A





Harris County  
**Public Health**  
Building a Healthy Community



## OUTREACH WORKER VDOT TRAINING

### TOOL KIT:

1. VDOT Cue Card
2. Videography Consent
3. VDOT Participation Consent
4. Phone with charger
5. VDOT Hotline

### TRAINING OBJECTIVES:

1. \_\_\_\_\_ Orientation to VDOT
2. \_\_\_\_\_ Have patient(s) sign the videography and participation consents
3. \_\_\_\_\_ Review VDOT Cue Card with Outreach Worker
4. \_\_\_\_\_ Show VDOT Tutorial video
5. \_\_\_\_\_ Demonstrate VDOT process to Outreach Worker (How to record a good/valid video)
6. \_\_\_\_\_ Outreach Worker returns demonstration to Trainer
7. \_\_\_\_\_ Review practice video and check the criteria for a good video: **Introduction, pill process, video sound, and image.**

#### ***Helpful hints:***

*Place both phone on table at one arm's length*

*Patient needs to be facing light*

*\*Hold the pills for 2 seconds to the camera before ingesting*

8. \_\_\_\_\_ Once your patient agrees to the VDOT call the VDOT Hotline to provide patient information.

Staff signature \_\_\_\_\_

Date \_\_\_\_\_

Trainer signature \_\_\_\_\_

Date \_\_\_\_\_

# VDOT Post-Training Survey

Initials (first/last): (\_\_\_\_/\_\_\_\_) Birthday (mm/dd):(\_\_\_\_/\_\_\_\_)

Position/Job Title: \_\_\_\_\_ Program: \_\_\_\_\_

Please help us learn about the outcomes of today's trainings by completing this survey. Only evaluation staff will see completed surveys, and results will be rolled-up as a group when they are reviewed by staff. Please don't forget to enter the ID information above, but do **not** put your name on the survey. Thank you in advance for your help, and we hope you enjoy the trainings!

Please check the number that best matches your response where 1 = VERY LITTLE and 5 = A LOT

OVERALL,	1	2	3	4	5
How much do you know about VDOT?	<input type="radio"/>				
How confident are you to use VDOT? How much do you know why VDOT can be preferred over traditional VDOT?	<input type="radio"/>				

IN PARTICULAR,  
How would you finish the following sentences in regards to each VDOT item using the scale provided?

	Not well 1	Somewhat well 2	Well 3	Very well 4	Extremely well 5
I can use the VDOT Client Management System	<input type="radio"/>				
I can use the VDOT patient interface	<input type="radio"/>				
I can enroll a patient in VDOT	<input type="radio"/>				
I can view, confirm, or reject a patient video	<input type="radio"/>				
I can verify/unverify documents	<input type="radio"/>				
I can send medication reminders	<input type="radio"/>				
I can use the system admin function	<input type="radio"/>				
I can protect PHI using VDOT	<input type="radio"/>				
I can teach a patient how to use VDOT	<input type="radio"/>				

## BENEFITS AND OBSTACLES,

What are 3 benefits to using VDOT?  
1) \_\_\_\_\_  
2) \_\_\_\_\_  
3) \_\_\_\_\_

What are 3 obstacles to using VDOT?  
1) \_\_\_\_\_  
2) \_\_\_\_\_  
3) \_\_\_\_\_

## LASTLY,

Would you like to give us any feedback about your experience today?

No

Yes: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



# Appendix B



## Video Directly Observed Therapy (VDOT) Patient Participation Agreement

Date:

I, \_\_\_\_\_ (participant name) have been selected by \_\_\_\_\_ (TB Nurse Case Manager) to participate in the Harris County Public Health (HCPH) Tuberculosis (TB) Program Video Directly Observed Therapy (VDOT) Program.

My signature indicates I would like to participate in the VDOT Program and I agree to the following conditions:

1. I agree to actively participate in the VDOT Program. The VDOT Program is an extension of the Directly Observed Therapy (DOT) Program and does not negate orders to implement and carry out measures for a client with suspected or confirmed tuberculosis. Instead of meeting a HCPH TB Employee in person at each visit, I agree to video myself using the assigned cell phone with a proprietary software application taking medications as ordered by my physician and directed by my TB Nurse Case Manager.
2. I have been informed the HCPH VDOT Program software application, interface and network is HIPAA compliant and secure to protect my personal health information.
3. I have been trained and I am able to demonstrate appropriate use of the VDOT application and cell phone equipment to record myself taking medications and to submit the video for the Nurse Case Manager or assigned Outreach Worker to review.
4. If while participating in the VDOT Program, there is equipment failure or apparent software issues and videos can't be recorded or videos can't be submitted, I am required to contact my Nurse Case Manager or Outreach Worker to discuss equipment issues and directions for taking my medication.
5. I am aware if I am not observed taking my medication by video or in-person, doses will not count towards treatment completion.
6. I agree to meet with my Nurse Case Manager or assigned Outreach Worker, no less than once a month to receive medications or participate in a medication pill or package count.
7. If while participating in the VDOT Program, I note a change in my health status, medication side effects, or believe something does not feel right, I will **not** take my medications and I will urgently contact my Nurse Case Manager to discuss my health status. If I experience a life threatening emergency, I will dial 911 for assistance.
8. I have signed the Patient Cell Phone Agreement and will comply with the conditions.
9. If my health status changes or I am unable to comply with VDOT Program conditions list above, I will be required to return to in-person DOT to complete my treatment regimen as ordered.

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
HCPH Staff Signature/Witness

\_\_\_\_\_  
Date



## Video Directly Observed Therapy (VDOT) Phone Agreement

Date: \_\_\_\_\_

I, \_\_\_\_\_ (participant name) have been provided a \_\_\_\_\_ (brand) cellular phone on \_\_\_\_/\_\_\_\_/\_\_\_\_ (date) for use during my enrollment in the Harris County Public Health (HCPH) Tuberculosis (TB) Program Video Directly Observed Therapy (VDOT) Program.

My signature indicates I agree to the following conditions:

1. I am aware that this phone is only to be used to upload videos of myself taking my medications and to make phone calls or text messages directly related to my TB treatment.
2. I am aware that I am the only person authorized to use this mobile phone.
3. I will take appropriate care of the assigned cell phone and peripheral equipment while enrolled in the VDOT Program.
4. If in the event the phone is lost, stolen or is broken, I will contact the HCPH VDOT Hotline @ **XXX-XXX-XXXX**. If the cell phone is lost or stolen, I will file a police report within 3 business days and promptly provide the police case report number to the HCPH VDOT Hotline.
5. Federal (HIPAA) and state privacy laws govern HCPH and other parties use and disclosure of protected health information. I am aware that information about my use of the wireless service, including details of when I use data services or place calls and to what number may be shared for administrative purposes only with emocha® Mobile Health Inc. or Harris County Public Health. Personal identifiable information or content may only be disclosed in compliance with HIPAA and applicable federal and state laws.
6. I am aware if I use the cell phone for unapproved purposes, I may be withdrawn from the VDOT program and return to in-person Directly Observed Therapy to complete the treatment regimen.
7. I am aware if the cell phone is lost or stolen, I will return to in-person Directly Observed Therapy to complete treatment regimen.
8. I am aware in the event I can no longer participate in the HCPH VDOT Program (e.g. move, change in health status) or I have completed my treatment regimen, I will promptly return the cell phone and peripheral equipment to my Nurse Case Manager or Outreach Worker.
9. I understand the cell phone and peripheral equipment is the property of Harris County. Misuse, abuse or loss of county property may result in a penalty or fine and or may be prosecutable under law.

Cell Phone Number: \_\_\_\_\_ IMEI Number: \_\_\_\_\_

\_\_\_\_\_  
Participant Signature

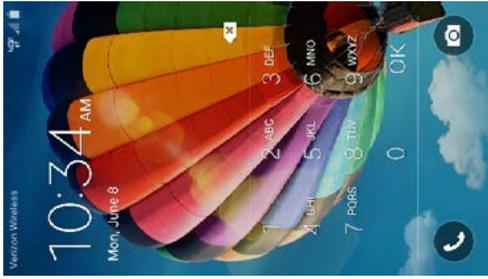
\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
HCPH Staff Signature

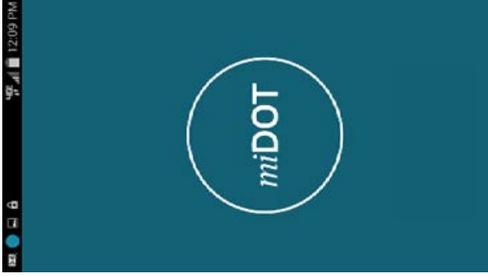
\_\_\_\_\_  
Date



**Step 1:**  
Enter Code  
XXXXX  
Press OK



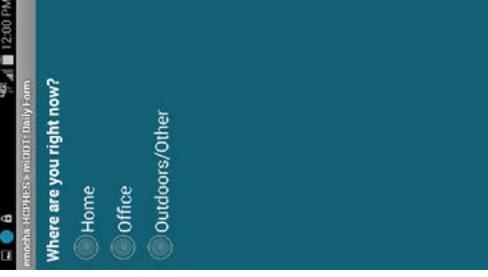
**Step 2:** Press miDOT app



**Step 3:** Press miDOT circle



**Step 4:** Verify today's date;  
Swipe screen to left



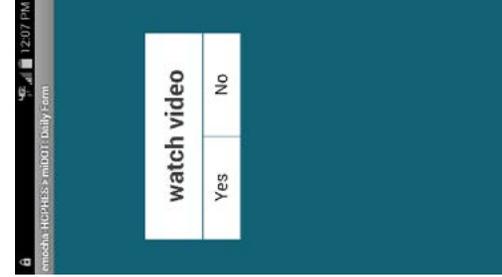
**Step 5:** Choose location;  
Swipe screen to left



**Step 6:** Answer questions  
if no symptoms, press none  
& swipe screen to left



**Step 6:** Press red button  
to record video



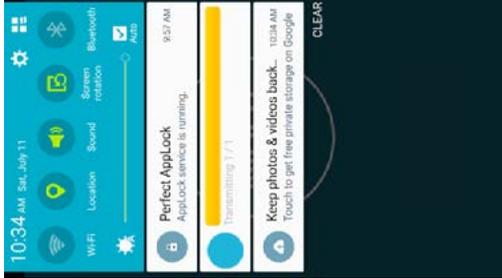
**Step 7:** Answer question;  
Press no to proceed to next  
screen



**Step 8:** Press submit



**Step 9:** Press check sign  
to complete submission of  
video



**Transmitting video**



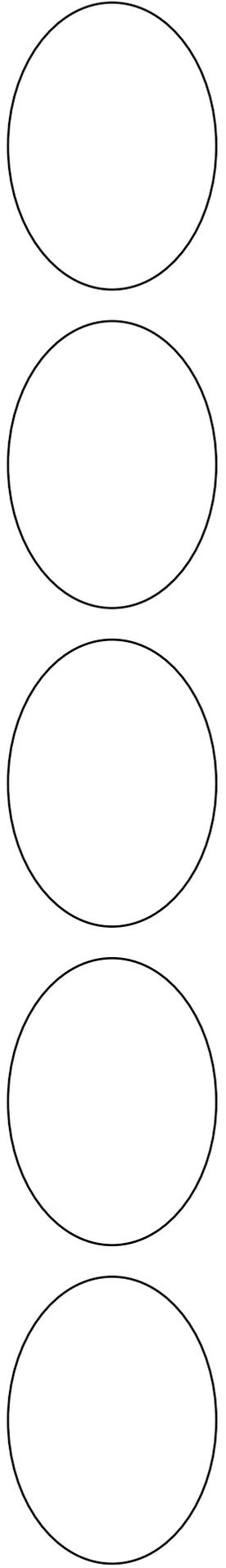
**Submission completed**

**Directions on recording video**

- 1. Position phone at a 90 degree angle from the table and an arm length away from your body.**
- 2. Place water cup/bottle and medication sheet (w/medication on it) in front of the camera.**
- 3. Follow directions below.**
  - **Position this paper on table so that the camera can view the sheet of paper.**
  - **Place each pill in the circles below. Place clear cup with water on square in upper right hand corner of this sheet of paper.**



- **Say the following: My name is \_\_\_\_\_. My birthday is \_\_\_\_\_. Today is \_\_\_\_\_.**  
**I am taking “#” of pills.**
- **Hold each pill in front of the video camera for 4 seconds before you swallow your pills. Drink your water after swallowing your pills. Complete the process until all of the medication is taken.**
- **Open your mouth wide to the camera to show that there are no pills left in your mouth or between your mouth cheeks. Show the inside of your cup so that viewer of video can see that it is empty and does not contain any pills.**





### Video Directly Observed Therapy (VDOT) Instructions

1. Find a quiet place. Avoid background noise, such as TV and radio. Close the door.
2. Have a clear glass or bottle of water ready.
3. Have proper lighting area and try to face bright light, avoid shadowing, and back light.
4. Have medication package and pill sheet available. Open medication package. Sort pills by name on pill sheet.
5. Slowly say your name “My Name is…… (First and Last name). My date of birth is month/day/year……Today is……(month/day/year)
6. Have you had any health problems/concerns today or since your last dose of medication?
  - If NO state: NO PROBLEMS
  - If YES explain the PROBLEMS you are experiencing
7. State YES or NO to following symptoms
  - Nausea/Vomiting
  - Skin Rash
  - Loss of Appetite
  - Abdominal Pain/Diarrhea
  - Fatigue/Weakness
  - Sores in Mouth
  - Jaundice (Yellow Skin/Eyes)
  - Joint Pain/Swelling
8. IF ARE EXPERIENCING PROBLEMS OR STATED YES TO ANY OF THE SYMPTOMS ABOVE-----STOP!!!!!! NOTIFY YOUR NURSE OR LOCAL HEALTHCARE PROVIDER IMMEDIATELY BEFORE CONTINUING YOUR MEDICATION.
9. Show pills to camera for 2 seconds and state name of medications and quantity. Place pill into mouth, take sip of water, swallow pill, and say AHHHHHH!!!!!! (ALWAYS have medications visible in camera)
10. When you are finished taking your pills, tap the red circle button to stop recording video. The blue screen will automatically appear with the “Watch Video” button in the center.
11. Make sure the video image and sound are clear, and that it shows you taking your medications without the pills leaving the frame once you’ve shown them. After you review the video, the blue screen will automatically re-appear with the “Watch Video” button in the center. If you are satisfied with the video, swipe left and the “Submit” button will appear.

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Participant Name (Print)

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Date

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Participant Signature

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Date

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HCPH Staff Signature/Witness

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Date

## Sample Technical Requirements for VDOT Platform Selection

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### **Security**

- Platform demonstrates HIPAA and 21 CFR Part 11 compliance
- Vendor demonstrates understanding of the implications of HIPAA relative to encryption of transmitted videos, electronic storage of Protected Health Information (PHI), etc.
- Platform provides a secure clinician-facing interface via web browser, authenticated by user id log-in

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### **Features & Functions**

- Technology Readiness Level (TRL) of at least 7 (system prototype demonstrated in an operational environment)
- Maturity of the system to be able to support immediate deployment in the field, including operation by patients
- Supports a minimum of 200 patients and 10 clinicians simultaneously
- Compatible with both Android operating systems and iOS
- Smartphone application can be downloaded to patients' private smartphones for use
- Application asks patients about symptoms and side effects prior to allowing medication dose
- Platform has the ability to categorize, analyze and report symptoms and drug side effects to TB staff
- Platform allows TB program staff to remotely view, accept and/or reject patient VDOT videos via web
- Platform provides the capability for automated medication dose reminders to be sent to patients
- System integrates with existing Electronic Medical Record (EMR) systems using XML medical data format
- Architecture of the system supports future expansion of capabilities within VDOT
- Platform has the ability (or the potential) to be used for other public health needs

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### **Support**

- Vendor is able to customize the VDOT application on an Indefinite Delivery/Indefinite Quantity (IDIQ) basis
- Vendor maintains reliable customer support for both clinicians and patients including, but not limited to, Help Desk support





## *Acknowledgments*

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### **HCPH VDOT Implementation Team:**

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### **Executive VDOT Champions – The HCPH Leadership Team**

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**Les Becker, MBA, Deputy Director**  
**Dr. Brian Arenare, MD, MBA, MPH, Disease Control & Clinical Prevention Division Director**  
**Marva Gay, JD, Assistant County Attorney, VDOT Legal Counsel**

