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Video Directly Observed Therapy for TB Treatment in Haitian Correctional Facilities

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2017

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An abstract of
A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University
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Abstract

Video Directly Observed Therapy for TB Treatment in Haitian Correctional Facilities
By Laura K. Dirks

Introduction: Tuberculosis causes significant morbidity and mortality but can be cured through an intensive drug regimen. Providing WHO recommended directly observed therapy has not been possible in settings lacking medical personnel. As a result, many individuals with TB lack adequate therapy. In 2017, 142 individuals incarcerated in Haitian correctional facilities remained at sites unable to provide proper care. We sought a solution for the delivery of observed therapy in low resource prison settings.

Methods: Correctional officer-facilitated VDOT was implemented in four low resource correctional facilities in Haiti. Regimen adherence was tracked using asynchronous VDOT software monitored remotely by medical staff. In the event of VDOT failure, correctional officers delivered in-person therapy. In addition to the primary outcome of adherence, the program was evaluated using the RE-AIM framework.

Results: Median VDOT adherence for 65 individuals enrolled was 81.8%. Median total adherence, including doses delivered by correctional staff, was 99.1%. Adherence varied significantly by site but was not associated with any demographic characteristics. Correctional officers reported high interest in the program and high comfort with its technology.

Conclusion VDOT can provide TB treatment in low resource correctional facilities. It facilitates observed therapy, and enables continuous patient monitoring, and treatment follow-up, which these sites historically lacked. Implementing VDOT for TB treatment could expand treatment in correctional facilities in Haiti and be used in prisons in other low resource areas facing similar challenges.

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Contents

Introduction

Tuberculosis (TB) is a widespread communicable disease caused by the bacterium *M. tuberculosis,* which results in significant morbidity and mortality worldwide. The World Health Organization (WHO) estimates with *M. tuberculosis* infects 1.7 billion people worldwide; however, only 5-10% of those individuals develop into active TB disease in their lifetime(World Health Organization, 2019). Most cases are curable, but treatment of TB is lengthy and intensive. Despite great strides made in the control and treatment of TB, newly evolved strains of multidrug-resistant tuberculosis or MDR TB has added another challenge to completion and further emphasized the importance of adherence to TB medication(Seung, Keshavjee, & Rich, 2015).

In order to address adherence to TB medication, the WHO recommends using directly observed therapy (DOT) to ensure daily medication adherence. While this tool has been proven effective in increasing treatment completion (Karumbi & Garner, 2015), it is also resource-intensive and not feasible in all settings. Recent research introduced video directly observed therapy (VDOT) as a more convenient and less expensive alternative to DOT(Richard S. Garfein, Liu, et al., 2018). VDOT offers observed therapy without the constraints of physical travel by either the observed or the observer. Previous research has proven VDOT to be an effective and acceptable alternative to DOT(R. S. Garfein et al., 2015). Following a superiority trial in 2015, the WHO endorsed the use of VDOT in areas where DOT is not possible(Story et al., 2019). VDOT has been implemented in many contexts, including, to treat MDR TB in London(Story et al., 2019), TB clusters in Puerto Rican care facilities(Olano-Soler et al., 2017) and nursing homes in South Australia(Topp et al., 2019).

TB disproportionately affects vulnerable populations, such as migrant workers, minorities, refugees, and incarcerated populations (Lönnroth et al., 2010). Incarcerated populations are at increased risk for TB due to the environment of correctional facilities in both low and high resources settings. CDC guidelines for the US reflect challenges, recommending protocols for the treatment and prevention of TB in correctional facilities(Centers for Disease Control and Prevention (CDC), 2006). Correctional facilities in low resource settings face even higher pressures, as more crowded and fewer well-ventilated areas in low resource settings facilitate spread.

Haiti has the highest incidence of TB in the Americas. In 2018, the incidence of TB in Haiti was 176 per 100,000 population(World Health Organization, 2019). The 17 correctional facilities in Haiti are at 445% capacity, further facilitating transmission of TB. Most TB cases in the incarcerated population are treated at the National Penitentiary in Haiti's capital, Port-au-Price. While some regional facilities have full-time health staff, others do not. The resource intensiveness of DOT is not maintainable in some facilities. When possible, smaller facilities transfer those with TB to the National Penitentiary, where patients have access to enhanced resources. A study examining TB treatment completion 2016-2018 at the National Penitentiary showed 84.1% treatment completion, leaving prison before treatment completion was the most significant predictor of incomplete care (Kehus et al., 2020).

Security and resource concerns can, at times, make transferring impossible, leading to many individuals with TB stuck at correctional facilities that lack the resources to provide adequate care. In 2017, Health through Walls (HtW), a non-governmental organization focused on improving health in correctional facilities, diagnosed 385 cases of TB in Haiti's correctional population. Nearly 40%, 142 cases, remained in resource-poor facilities. There is not a standard

protocol for these sites; often, it involves giving individuals monthly supplies of medication coupled with periodic visits from caregivers or medical staff. Insufficient TB care not only threatens patient health but also creates a scenario in which TB can spread to others in the facility.

Those with TB leaving correctional facilities face further strain. The high poverty, social struggles, and transience associated with transitioning out of incarceration contribute to poor medication adherence. Despite all of Haiti's correctional facilities utilizing discharge planning, there are high rates of loss to follow-up among this population. For those living with HIV, HtW provides mobile phones for VDOT to improve adherence; however, this program did not exist for those with TB.

Problem statement

TB causes significant morbidity and mortality in Haitian prisons. Some smaller sites lack resources to provide DOT, which is the standard of care. As a result, there is no way to ensure that individuals at these sites are completing TB treatment. Potential transfers to sites with more resources are complicated and not always possible. In the past few years, these challenges have been exacerbated by bouts of civil unrest in Haiti, which blocks roads, making transfers, or periodic visits even more difficult. As a result, in 2017, 142 individuals with TB remained at sites unable to provide sufficient care. Incomplete TB regimens result in poor outcomes for the individual on the regimen. It also creates an environment in which others at the site could become infected with TB, and finally, it has the potential to contribute to the MDR TB epidemic. Currently, there is no solution for the delivery of observed therapy in low resource correctional settings.

Purpose statement

A correctional officer facilitated VDOT program was piloted in select small Haitian correctional facilities without the resources to provide DOT. The program was evaluated for feasibility and efficacy using the RE-AIM framework. The success of correctional officer facilitated VDOT has the potential to close the gap in TB care experienced by low resource correctional facilities.

Research question

Question 1: Is correctional officer facilitated VDOT a feasible way to deliver TB care in Haitian prisons that lack resources to provide DOT.

Objective 1: Assess the feasibility of VDOT to track adherence in low resource Haitian correctional facilities

Objective 2: Assess the acceptability of the program to inform future scale-ups.

Significance statement

Resource strain is a challenge faced by many correctional facilities in Haiti. Correctional officer facilitated VDOT programs have the potential to provide unprecedented TB care at resource-poor facilities. The evaluation of this program can be used to inform future scale-up activities in Haiti. Additionally, these challenges are not unique to Haiti but exist in prison settings around the world. This program has potential applications outside of Haiti in other countries with rural jails and also outside of corrections in other low resource settings. This pilot study will demonstrate the value of VDOT for current and formerly incarcerated individuals in low resource settings.

Definition of terms

Prison Civile / National Penitentiary: Haiti's largest correctional facility located in Haiti's capital Port-au-Prince.

Review of Literature

Tuberculosis

Many challenges contribute to the global prevalence of TB. One factor is the latency of TB infection. Individuals with latent TB infection (LTB) may experience significant gaps in time between contracting the disease and exhibiting symptoms. Others may be asymptomatic their entire lifetime and may never progress to active TB infection. Another challenge of TB care is the long and intensive treatment regimen required for the elimination of infection. Current WHO Guidelines recommend a 4-drug regimen of isoniazid, rifampicin, ethambutol, and pyrazinamide for six months for susceptible TB. Treatment regimens increase in complexity when factoring in drug resistance. Regimens for MDR TB are more involved and can include second-line drugs for an extended length of time(World Health Organization, 2019).

MDR TB

Multidrug resistance, organisms resistant to isoniazid and rifampin is the greatest threat to TB elimination. Incomplete treatment courses and skipping daily doses both create the opportunity for the organisms to become resistant. Once resistance is developed, MDR TB strains are spread person to person. As a result, individuals with no history of TB treatment may still have resistant strains. In order to address this, drug susceptibility testing can be performed to determine the best treatment options. Susceptibility testing is a lengthy process which requires

high laboratory capacity and thus is not available in many low resource settings. MDRTB treatment required second-line TB drugs, which generally have more side effects and are less effective than first-line drugs. Patients with MDRTB commonly face socioeconomic challenges, including homelessness and unemployment. These challenges, coupled with poor regimen tolerance, contribute to poor adherence. Medication adherence and treatment completion are imperative to prevent the development of resistant strains and to stop the spread of MDR TB(Seung et al., 2015).

TB in corrections

TB prison populations have reported TB rates 100 times higher than the populations outside (World Health Organization WHO). Crowded conditions, delayed diagnosis, lack of proper ventilation, and interruption of care can exacerbate the spread of TB within correctional facilities. These factors, particularly the interruption of care, also contribute to high levels of MDR-TB within the correctional facility population(World Health Organization WHO). Many risk factors for incarceration are also risk factors for TB--the increased risk of infection coupled with sharing a confined space with other individuals also at an increased risk for TB infection. Due to these factors, the CDC developed special recommendations for to control and treat TB in correctional facilities. The recommendations focus on early identification and successful treatment through the entry and periodic screenings. Additionally, suspected cases should be placed in an airborne infection isolation room when possible(Centers for Disease Control and Prevention (CDC), 2006). While effective in an ideal scenario, these measures are limited in low resource settings.

Tuberculosis in Low-Income Correctional Facilities

While there is no literature discussing TB in Haitian prisons, there are multiple studies that examine TB in corrections in other low-income countries. Serval studies have explored TB in corrections in Ethiopia, which is one of the 20 high burden TB countries(World Health Organization, 2019). Ethiopia has higher incarceration at 127/100,00 population(World prison Brief Institute for Crime & Justice Policy Research) vs. Haiti's 83/100,000(World Prison Brief Institute for Crime & Justice Policy Research) and total TB incidence 151/100 000 population which is comparable to Haiti's 176/100,000 population(World Health Organization, 2019).

The first investigation of TB prevalence in Ethiopian prisons was a 2008 study in three prisons in East Ethiopia. It revealed a prevalence of 1913/100 000, seven times higher than the general population. It also examined the associated risk factors of pulmonary TB (PTB) among its populations. Investigators found PTB to be significantly associated with younger age (15-44), urban residence, frequent incarceration, and staying in a cell with a TB patient(Abebe et al., 2011). Another study conducted in Northwest Ethiopian prison settings tested 265 prisoners at three sites and determined a prevalence of 3.4%(Beza, Hunegnaw, & Tiruneh, 2017). Consistent with the previous study in Ethiopia(Abebe et al., 2011), investigators found HIV positivity and sharing cells with TB patients to be significantly associated with TB infection. Marital status was also significantly associated with TB prevalence(Beza et al., 2017).

A 2008 mini review highlighted the challenges of tuberculosis in prisons in low-income settings. Those in prison typically originate form communities with high TB risk, which may contribute to the high incidence in prison compared to general populations. Competing priorities such as safety and control can limit access to health services. As a result, TB care in low resource

correctional facilities requires special attention to ensure the provision of adequate care (Larouzé, Sánchez, & Diuana, 2008)

TB in Haiti

In 2018 the incidence of TB in Haiti was 176 per 100,000 population. Of these, 5.1 per 100,000 were multidrug-resistant/ rifampin-resistant TB (MDR/RR-TB). Moreover, 27 per 100,000 of these infections represented HIV coinfection. The 2018 mortality rate due to TB in Haiti was 9.2/ 100,000 population. An estimated 1000 people died from TB in Haiti in 2018. Out of the 13,713 cases notified in 2018, only 35% received testing with rapid diagnostics at the time of diagnosis, but 92% had known HIV status. Of the 2018 TB cases in Haiti, 90 % were pulmonary TB; 79% of these cases were bacteriologically confirmed(World Health Organization, 2019).

As discussed previously, one challenge in the treatment of TB is the loss to follow up (LTFU). A 2018 analysis of Haiti's national surveillance data from Haiti's National TB Control Program identified multiple factors associated with loss to follow-up among patients on treatment for TB in Haiti. Investigators used logistic regression to analyze surveillance data from 2011-2015 and looked at both treatment outcomes of LTFU and time until LTFU. This study defined LTFU as those who did not start treatment or those whose treatment was interrupted for at least two consecutive months. Results showed an overall LTFU of 9.1%, with the proportion of LTFU increasing by 3.2% from 2011 to 2015. Multivariable analysis revealed significantly higher rates of LTFU for males, those with a history of TB treatment, and HIV coinfection. Facility level factors showed that clinics, non-profit facilities, and facilities in the West Department were associated with significantly higher rates of LTFU(Schnaubelt et al., 2018). While there are likely some differences between the population in Haiti's prisons, it is safe

to assume the patient-level factors identified in this study also influence regimen completion inside the prisons, particularly the association between LTFU and the male sex, as the majority of the prison population in Haiti is male.

In addition to the quantitative analysis, investigators interviewed staff at nine facilities. Staff members identified challenges, including crowded facilities, side effects of medication, lack of understanding of the importance of uninterrupted treatment, and misunderstanding of the source of the illness. They noted a significant barrier to be lack of transportation to facilities, bouts of political instability, or inclement weather making it dangerous to travel(Schnaubelt et al., 2018).

Health in Haitian Prisons

As of October 2019, Haiti prison population totaled 10,905, 75% of which were awaiting trial(World Prison Brief Institute for Crime & Justice Policy Research). There are few publications concerning the health of prisoners in low-income countries and even fewer that specifically explore the health of individuals incarcerated in Haiti.

A 2010 opinion piece published in the Annals of Internal Medicine discussed the inherent challenges of providing health care in Haitian prisons. Authors focused on health care in the Prison Civile in Port-au- Prince. The piece illustrates the overcrowded conditions in the Prison Civile, which was built for 800 but housed up to 4215 individuals. Most individuals slept on the floor or in handmade hammocks as the facility had less than 100 beds. While cooks at prison Civile prepared food twice a day, the food did not provide adequate nutrition resulting in illnesses from vitamin deficiencies and death. Those living at Prison Civile relied on supplemental food brought by visitors. The infrastructure inadequacies carried over to medical care. The authors discussed the lack of essential medicines and diagnostic tools compared to

what is available outside the prison. NGOs working with local corrections, such as HtW, have helped close some of these gaps. The authors conclude by discussing the progress made in the provision of health care such as successful initiation of HIV testing but acknowledge that the delivery of just and adequate health care to all incarcerated individuals in Haiti(May, Joseph, Pape, & Binswanger, 2010).

The Prison Civile (referred to as the National Penitentiary in this publication) was also the site of UNAIDS sponsored HIV peer health education program, the results of which were published in a 2012 field report. UNAIDS partnered with HtW to train 25 persons incarcerated at the national penitentiary as peer health educators who conducted sessions encouraging HIV testing. Additionally, investigators surveyed 400 individuals asking about their experiences with HIV testing. Overall, 51% of men reported interest in testing for HIV; when separated by those who had been part of the peer education sessions, that number increased to 64% a significant increase in interest in testing. In addition to asking about HIV, the 400 individuals answered questions about beliefs regarding TB. 54% of participants expressed interest in getting tested for TB, and 88% of participants believed that individuals should receive testing for TB(Zack, Smith, Andrews, & May, 2013). Despite its focus on HIV, this field report illustrated the perceived importance of TB testing and assumingly the treatment of TB in the Haitian prison population.

A recent cross-sectional study published in 2018 sought to characterize the physical and mental health of individuals at three regional prisons in Haiti. Like studies conducted in prisons in other low-income countries, the study revealed poor mental and physical health outcomes for individuals at all three sites. Health outcomes included self-reported health, physical function, and BMI. Results showed a positive association between BMI and length of incarceration. The study also found a negative association between length of incarceration and two health

indicators: physical function and self-reported health. The results also showed that those with an increased number of visitors were significantly less likely to be underweight and significantly more likely to be food secure and had a higher self-reported physical function. Those who had zero visitors were twice as likely to be underweight than those with two or more visitors(LaMonaca, 2018). Consistent with previous publications(May et al., 2010), the authors emphasized the importance of external food sources brought by visitors to supplement the food given to residents of Haitian prisons. Health outcomes also varied by site. Individuals at Prison B reported the fewest visitors, the longest time spent incarcerated, and the worst overall health profile. Those at Prison A, the most urban, were more likely to have visitors and had the best overall health profile. While this could reflect a correlation between rurality and number of visitors is essential to note that the third site Prison C was the most rural of all site; thus rurality is not the only factor(LaMonaca, 2018).

Health through Walls

Correctional health in Haiti is supplemented by Health through Walls (HtW), a USA based non-governmental organization (NGO) that supports local corrections through the implementation of sustainable improvements to the provision of health care. Primary focuses include diagnosing, preventing, and treating infectious diseases with a special interest in HIV cholera and tuberculosis. The organization works in 9 low and middle-income countries in the Caribbean, sub-Saharan Africa, and eastern Europe.(World Health Organization (WHO) Europe, 2019). In 2008 HtW began their work in Haiti by implementing HIV care in the National Penitentiary. The program expanded in 2010 to service Haiti's smaller prisons, where they train local medical and prison staff. HtW leads a program that conducts annual health exams, including TB screening using mobile medical teams(Health through Walls (HtW), 2014). In 2017 HtW identified 385 cases in correctional facilities. Most TB cases in the incarcerated

population are treated at the National Penitentiary in Port-au-Price, so they have access to services and enhanced resources not offered at facilities. This frequently involves transferring patients from other facilities. Security and resource concerns can make transferring impossible, leading to many individuals with TB stuck at correctional facilities that lack the resources to provide DOT. While some regional facilities have full-time health staff, others do not. The resource intensiveness of DOT is not maintainable in some facilities. In 2017 172 cases, nearly 40% of the total cases identified that year, remained in resource-poor facilities. There is not a standard protocol for these sites; often, it involves giving individuals monthly supplies of medication coupled with periodic visits from caregivers or medical staff.

Video Directly Observed Therapy

Due to the length and complexity of TB treatment regimens, adherence can be challenging. Directly observed therapy (DOT) is a widely used method to boost adherence and ensure regimen completion. While useful in bolstering adherence, DOT can be resource-intensive for both patients and providers(Karumbi & Garner, 2015). One solution is to use video directly observed therapy (VDOT), also referred to as video observed therapy (VOT), and electronic directly observed therapy (eDOT). This method uses technology to allow remote monitoring of patient's adherence, eliminating the need for a community health worker to travel and allowing patients freedom while remaining adherent(Olano-Soler et al., 2017). Due to its merits, in 2017, the World Health Organization endorsed the situational use of VDOT in the event DOT is not possible(Story et al., 2019).

A study published in 2001 first illustrated the advantages of VDOT. Six study participants completed part of their TB regimen on standard DOT and the portion using VDOT. They had internet-enabled TV units with a 28K modem installed into their homes to link them

with the health department. During a scheduled call, the patients would take their medication in front of the camera so that the health workers could track adherence. Overall the study reported VDOT adherence was comparable to standard DOT and a cost savings of over $10,000(DeMaio, Schwartz, Cooley, & Tice, 2001).

More recently, VDOT has been successfully used to observe TB treatment in community nursing homes in South Australia(Wade, Karnon, Eliott, & Hiller, 2012) and TB patients in New York City(Chuck et al., 2016). With the evolution of technology, VDOT has also evolved. While previously synchronous VDOT (VDOT over a live feed), there are now programs that facilitate asynchronous VDOT (videos are recorded and viewed later)(Richard S. Garfein & Doshi, 2019).

A 2019 analyst-blinded, randomized controlled superiority trial conducted in England determined VOT to be more effective than DOT. Investigators enrolled 226 randomized by minimization to the DOT and VOT arm and followed them throughout treatment. The primary outcome measured was the successful completion of 80% or more of scheduled treatment observations in the first two months of the trial. Overall, VOT facilitated higher levels of adherence and had a lower drop- out rate. Investigators highlighted VOT success in populations who report social risk factors for non-adherences such as homelessness, incarceration, substance abuse, or mental health problems in the last five years. 70% of individuals with these risk factors VOT met the primary outcome compared to only 45% on DOT. Following the success of this trial, the UK National Health Service has adopted VDOT to treat MDR TB in London(Story et al., 2019).

Asynchronous VDOT for TB adherence has also been applied to low resource settings. A feasibility and acceptability trial compared in-person DOT and VDOT in both San Diego CA,

USA, and Tijuana, Baja California Mexico. Participants initially receiving TB treatment through DOT were enrolled, and their adherence tracked. Investigators conducted follow up interviews with participants to assess the acceptability of VDOT. Mean adherence for the San Diego cohort was 93% and 96% for the Tijuana cohort. Participants overall found the program acceptable. 92% had few technological problems, and 100% would recommend VDOT to others over DOT(R. S. Garfein et al., 2015).

The same group conducted a more recent trial by instituting VDOT in 5 health districts in California. This study used DOT records as a comparison group for adherence.DOT records at each clinic. Researchers reported adherence as a fraction of expected doses (FREDO), which is equal to the number of doses observed using VDOT divided by the number of doses expected. Median FEDO was 93%, with a range of 83.4 – 97.15% compared to 100% for DOT sites. FEDO differed significantly by site and race but was not significantly associated with any other demographic characteristics. VDOT increased with annual income and decreased with marijuana use and perceived difficulty. The multivariable analysis yielded a positive association between FEDO and the duration of VDOT use. Finally, researchers determined VDOT to cost 32% less than DOT (Richard S. Garfein, Liu, et al., 2018).

Field notes published in CDC's Morbidity and Mortality Weekly Report (MMWR) demonstrated VDOT use for TB clusters. In 2011-2012 a Puerto Rican long term care facility identified a cluster of 7 active and 26 latent TB cases. At the time, the Puerto Rico Department of Health faced staffing shortages, which rendered them unable to provide DOT services to the facility, but all latent and active cases were prescribed treatment. In 2016, the same facility had an outbreak of 11 active cases and six latent TB infections. The index case was diagnosed with LTBI during the earlier outbreak. To resolve the latest outbreak, the Puerto Rico Department of

Health used VDOT. All 11 cases completed treatment with >= 80% schedules doses taken(Olano-Soler et al., 2017). This publication illustrated the potential for VDOT to fill gaps in under resources facilities where DOT is not feasible.

A randomized control trial is currently being conducted in Tibet to determine the efficacy of VOT in low and middle-income countries. The protocol published in 2019 shows the study has two sites, one rural, one urban, both with struggling to provide traditional DOT to TB patients in their community. The primary outcome of this study was poor adherence, defined as a patient missing greater than or equal to 20% of doses in a month(Wei et al., 2019). An essential aspect of this trial to note is that the current DOT is failing. TB patients in the two districts reported 38% completion of treatment(Wei et al., 2019). The previous studies had functional DOT systems in place(Chuck et al., 2016; R. S. Garfein et al., 2015; Story et al., 2019; Wade et al., 2012). In this study, both sites had challenges, including a shortage of community health workers, long distances to pick up medication, and weather conditions making travel difficult(Wei et al., 2019). In this case, the advantages of VOT may be more considerable due to the weakness of the DOT system.

RE-AIM

When instituting public health programs, evaluation is crucial. One framework used to evaluate interventions is the RE-AIM model. In 1999 Russ Glasgow, Shawn Boles, and Tom Vogt developed the original RE-AIM framework to address the lack of translation and poor reporting they witnessed in public health research. The model contains five dimensions and allows evaluators to consider these dimensions at individual, community, and facility levels.

The first dimension is reach, which includes both participation and representativeness of participants. It is an individual-level measure of (participation rate) and the demographic

information of participants compared to the total population; this is to ensure participants are those who need the intervention the most.

The second dimension is effectiveness, which focuses on both the positive and negative outcomes of the program for individuals receiving the intervention(R. E. Glasgow, Vogt, & Boles, 1999). When RE-AIM was first introduced, the second dimension was entitled efficacy, however with the focus on how implementation impacts efficacy, this measure is now more commonly evaluated as effectiveness(Russell E. Glasgow et al., 2019). Effectiveness, evaluated at the individual level, measures the impact of the intervention in addition to side effects and unanticipated consequences. Measures include primary outcomes, behavioral outcomes, and quality of life perspectives, including mental health and participant satisfaction.

Adoption is the third dimension of REAIM and is evaluated at an organization level. It evaluates which settings or facilities participated in the program. It also assesses inherent differences in those who participate and those who do not and examines barriers to future participation. Finally, staff representativeness and participation rates contribute to the measure of adoption.

The fourth dimension is implementation. The primary outcome assesses here is effectiveness in the implementation of the program or fidelity to the program. Individual measures include individual adherence to program protocol. Facility level measures include how well the staff delivers the protocol as intended. This measure also captured adaptations made by program implementors. Other evaluators use implementation to consider is whether the cost of the program is prohibitive compared to the value of the outcome(Gaglio, Shoup, & Glasgow, 2013)

The final RE-AIM dimension is maintenance. Assessment of maintenance occurs at the individual and facility levels. Individually, maintenance is continuing behavior change or lack of relapse usually defined at the six-month mark. At the facility level, it is maintaining program level protocol and investigates the representativeness of those facilities that continue to use the program compared to those who do not. Finally, this measure is used to assess the opportunity for the sustainability of the program (R. E. Glasgow et al., 1999).

Since its conception, over 450 publications have used the RE-AIM framework (Russell E. Glasgow et al., 2019). Multiple studies utilized RE-AIM to address health inequities in low-income settings(Gaglio et al., 2013; Russell E. Glasgow et al., 2013), and to evaluate tuberculosis programs in high burden low-resource settings(Lestari et al., 2019).

Re-AIM has also been used to evaluate tuberculosis screening programs in correctional facilities in South Africa. Investigators successfully applied the RE-AIM framework to correctional facilities in a low resource country to evaluate the success of their current TB screening program and identify areas of improvement(Zishiri et al., 2015).

Methods

Diagnosis of TB

All persons entering prisons in Haiti are screened for TB by symptoms. Individuals who enter the system through the Port-au-Prince prison and report pulmonary symptoms have a digital chest x-ray within days; in provincial prisons, the wait for chest x-ray maybe weeks, until a mobile x-ray is scheduled. A GeneXpert machine for PCR testing of specimens is present at the Port-au-Prison. For this study, a confirmed TB case was one diagnosed through symptom screening, physical examinations, and digital x-rays combined with further evaluation through specimen collection and GeneXpert, microscopy with culture, or both.

The VDOT Intervention

The HtW teams incorporated VDOT via the asynchronous SureAdhere platform, a smartphone/tablet app developed by researchers at the University of California previously used in both feasibility and superiority VDOT trials(R. S. Garfein et al., 2015; Richard S. Garfein & Doshi, 2019; Richard S. Garfein, Lin, et al., 2018; Story et al., 2019). Implementation of VDOT was prison-wide in the selected sites. DOT was not available in these prisons historically or during this study. Prison sites that were selected for VDOT received a video-enabled tablet pre-downloaded with the SureAdhere application. The internet equipped tablets used either Wi-Fi or a cellular data connection. VDOT was facilitated by trained correctional officers who monitored the video taking process as personal communication devices are not allowed inside the prisons. Officers individually escorted each participant to a private location. Patients were logged into the SureAdhere program with their unique PIN, which automatically linked videos to their adherence records. Officers then held the tablet to record the patient taking their doses and escorted them back to their cells.

The SureAdhere program automatically sent the encrypted and time-stamped videos via a secure HIPAA compliant server. In the event that the tablet lost internet connection, videos were stored securely on the device and immediately sent when reconnected. As soon as the videos were uploaded, the program deleted them from the device(R. S. Garfein et al., 2015).

A member of the Health through Walls teams then watched the videos from the Port au Prince offices and marked the dose as adherent or not. HtW staff received training to identify correctly taken doses. Program staff monitored overall adherence at each site and were able to reach out to site staff to inquire about missed doses or challenges. If a VDOT participant was

going to leave prison during treatment, they received a camera-enabled mobile phone with the SureAdhere application to continue their VDOT remotely.

Control Conditions

Control sites consisted of correctional facilities providing the standard of care DOT to its population. At these prisons, adherence was tracked using written ledgers filled out by health care workers. Adherence data were collected from these cards and stored in a secure workbook. In the event that a DOT patient exited the prison while on the treatment, they were given the option to transition to VDOT. If they consented, they were given a cell phone to complete their treatment remotely.

Study Design

This prospective cohort study compared outcomes of TB patients in five provincial prisons where VDOT was implemented with outcomes of patients in three prisons where healthcare worker staffing permitted DOT. The number of anticipated starts in the VDOT prisons equaled the historical number of DOT starts in the control prisons. (See the attached schematic of the study design in the appendix.)

Persons who were at the five intervention and three control prisons were eligible to participate in a survey that had questions on demographics, beliefs about TB, familiarity with cell phone technology, perceived stigma, and depression—all factors that could influence adherence to VDOT treatment in, and after, prison. Individuals eligible to participate in this survey needed to be age 18 years or older, with a confirmed TB diagnosis, and currently incarcerated at a prison site engaged in the project. Those who chose not to participate continued their current treatment with the standard of care. Prospective participants in both arms were read

and given a consent form in Haitian Creole, to prevent any miscommunications due to literacy level. After establishing informed consent, participants that met the eligibility criteria enrolled in the arm of the study corresponding to the facility where they were living.

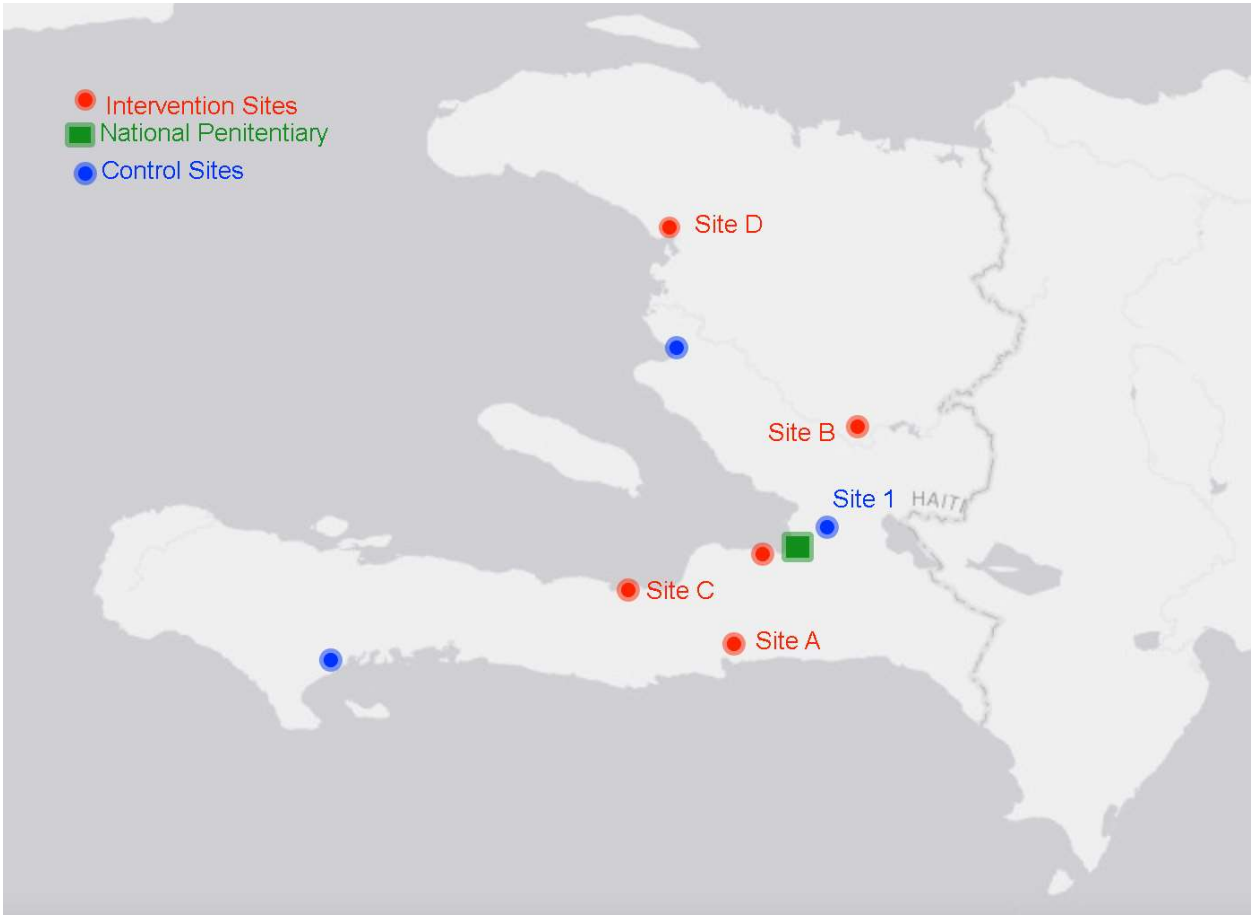

Figure 1: Map of all DOT and VDOT sites.

Correctional Officers

Correctional officers were recruited from each VDOT site to participate in administering the VDOT program. Once recruited, they were given in-person training on software and patient retrieval. Participating correctional officers were compensated for their assistance during the program through a monthly salary bonus.

Evaluation

All four instruments used in this study were adapted from survey instruments used previously to assess the feasibility and acceptability of VDOT using the SureAdhere program (R. S. Garfein et al., 2015). The instruments were translated into Haitian Creole and then back translated into English to ensure accuracy in translation.

Access to continued treatment was not predicated on participation in the survey. After establishing formed consent, 30-45-minute semi-structured interviews were conducted orally in Haitian Creole with participants. Questions on demographics, knowledge about TB, and perception of stigma were collected from participants at both VDOT and DOT sites. Post survey completion, participants were compensated in the form of a hygiene package.

For convenience, DOT interviews occurred at a single visit; eligible participants were all persons at Site 1 who were currently receiving DOT for treatment of TB. Ten participants from the site were interviewed using a DOT survey to collect demographic information and information regarding comfort using technology, perceptions of TB, TB stigma, and mental health information.

A convenience sample of VDOT participants at three sites was interviewed using a baseline survey. VDOT interviews occurred throughout the study. Persons currently receiving VDOT for treatment of TB at the time of a HtW site visit were eligible to participate in the survey. Twenty-four participants from VDOT sites were interviewed using a VDOT baseline instrument similar to the DOT instrument with added items specifically regarding VDOT.

Individuals who previously completed a VDOT baseline interview and had finished treatment using were eligible to participate in a VDOT follow-up survey. These individuals were interviewed based on convenience and occurred during HtW site visits. The instrument collected

data from six individuals at one site concerning final perceptions of VDOT post-treatment completion.

A Correctional officer instrument was developed to acquire facilitator level perceptions and acceptability of VDOT and its use in this program. A brief semi-structured interview was conducted with three correctional officers from 2 VDOT sites. It collected demographic data, perceptions surrounding TB at their facility and perceptions about VDOT. Correctional officers were given $5 (USD) as compensation for their time.

All survey instruments were deidentified and labeled only with a record ID number in order to match adherence with survey responses. All physical copies of study documents were securely stored in a locked cabinet in a locked office; electronic copies were password protected. Data from the instruments were transferred to a REDCap (Research Electronic Data Capture) tool hosted at Emory University(Harris et al., 2019; Harris et al., 2009).

Analysis

Survey data from Redcap and adherence data from SureAdhere were linked using participants SureAdhere record ID number. The combined data was analyzed using R. T-tests were used to determine differences in sociodemographic characteristics for VDOT and DOT sites. Associations between adherence and categorical variables were assessed using a Kruskal Wallis test; binary variables were assessed using Wilcoxon rank sums and continuous variables using a Spearman correlation. Kruskal Wallis was also used to assess adherence variations by site Multivariable analysis was not completed due to insufficient sample size.

RE-AIM: The RE-AIM framework was used to assess various aspects of VDOT implementation

Reach

Reach was evaluated as the total number enrolled in VDOT. It was also used to examine the sociodemographic characteristics of those at VDOT sites. The same information was recorded for DOT sites. According to the RE-AIM, protocol, one goal of evaluating reach is to ensure those participating in the program are those with the greatest need(R. E. Glasgow et al., 1999). As VDOT is implemented only at sites historically unable to provide DOT, this measure will be 100%.

Effectiveness

Despite vast evidence supporting the use of VDOT for both the efficient and effective delivery of TB medication(Richard S. Garfein & Doshi, 2019; Story et al., 2019), there is no previous evidence for its use in correctional facilities; thus, it is essential to evaluate, in practice, the effectiveness of VDOT within the correctional populations. The primary outcome of effectiveness for this program is VDOT adherence.

In order to remain consistent with previous feasibility trials, VDOT adherence rate was defined as the number of medication doses successfully delivered using VDOT divided by the total number of doses expected during their time enrolled(R. S. Garfein et al., 2015; Richard S. Garfein, Liu, et al., 2018). In the event a patient required additional doses added to the end of their regimen due to a missed dose or unknown doses adherence, these additional doses were factored into adherence, and the denominator increased correspondingly (R. S. Garfein et al., 2015). In addition to VDOT adherence, overall adherence was also calculated to assess the ability to continue proving treatment in the event of technology failure. Overall adherence was

defined as the number of medication doses delivered using VDOT or confirmed DOT by correctional officers divided by the total number of doses expected during their time enrolled.

It is also essential to evaluate the impact the program has on enrollees' mental and emotional health. TB stigma and mental health were measured in both VDOT and DOT populations and compared. Stigma was measured using a scale adapted from an existing instrument used to measure TB related stigma in Haitians living in Léogane Commune, Haiti(Coreil, Lauzardo, & Clayton, 2010; Coreil, Mayard, et al., 2010). In the adaptation to correctional populations, a question regarding the disclosure of TB infection to correctional officers was added, and language was adapted to be relevant to the participant's current living situation. The scale consisted of 15 items reflecting five stigma components, internal shame, disease disclosure, external concerns, family reputation, and assumption of other illnesses, see textbox 1. Participants responded to items using a scale of 0-3 where 0 was equal to "not at all" and 3 corresponded to “very much”. Each component's scores were calculated by taking the average value of each other within that component. A t-test of average stigma scores for those enrolled in the VDOT study compared to average scores from DOT participants was performed to investigate if there was a significant difference in TB stigma between the groups.

In addition to stigma, we also evaluated the mental health of participants using a screening instrument for depression validated in Haitian Creole(Rasmussen et al., 2015). The Zanmi Lasante Depression Symptom Inventory (ZLDSI) is a 13-item screening instrument that asks participants how many days they experience specific symptoms of distress in the past two weeks. Responses options are “Not at all” (Di tou), “For a few days” (Pandan ke`k jou), “More than 1 week” (Plis pase yon seme`n), to “Almost daily” (Preske chak jou). Responses to each item are totaled to give each individual an overall score out of 40. Based on the initial study, a

score between 12 and 14 is parsimonious to depression measures in U.S. scales(Rasmussen et al., 2015). This scale has not been validated in the context of correctional facilities nor with TB patients, so we will merely be using the scale as a comparison measure between those enrolled in the VDOT program and those receiving traditional DOT. The final measure of effectiveness is the proportion of negative responses to specific questions related to the use of VDOT. Responses were collected in the VDOT baseline and follow up survey instrument, respectively, questions regarding study concerns and feelings regarding receiving VDOT. (R. S. Garfein et al., 2015).

Textbox 1: Stigma Measures

Internal Perceptions and Emotions
1. Do you think less of yourself? For example, has it reduced your pride or self-respect?
2. Have you ever been made to feel shamed or embarrassed because you have TB?
Disclosure
1. If possible, would you prefer to keep people from knowing that you have TB or have been assigned a cell for people with TB?
2. Have you discussed, or do you plan to discuss with your family that you have TB?
3. Have you discussed, or do you plan to discuss with other people detained here that you have TB?
4. Have you discussed, or do you plan to discuss with guards that you have TB?
External Perceptions
1. Do you think that other persons detained, others in prison or others in your community have less respect for you?
2. Do you think that other persons detained, others in prison or others in your community have less respect for your family?
3. Do you think people are likely to think you have other health problems (even if you don't)?
4. Are you worried that people will assume you have HIV?
External Actions
1. Do you feel others have avoided or might avoid you?
2. Do you think some people refuse to visit your home because of TB even after you have been treated?
3. Have you been asked to stay away from work or social groups?
4. Do you think you might decide on your own to stay away from work or social groups?
Courtesy stigma
1. Do you think contact with you might have any bad effects on others around you, even after you have been treated?

Adoption

We measured adoption through the proportion of facilities participating in VDOT compared to the total number of facilities invited to participate. The representativeness of

facilities was assessed by comparing demographic data of the correctional populations at the VDOT sites to DOT sites. Additionally, adoption was measured through specific questions on a survey instrument for correctional officers and the number of correctional officers who participated in facilitating the program.

Implementation

At the facility-level, implementation was measured using average TB regimen adherence by the facility, and the number of participants who did not finish the protocol. We also evaluated implementation using attitude data collected from correctional officer surveys. Finally, implementation will be used to report challenges with and unintended outcomes. It also includes reported challenges when implementing the VDOT protocol.

A significant advantage of VDOT is that it is cost saving. Because of this, it is also essential to assess the estimated cost of the program. Cost data will be calculated using estimated from HtW factoring in the correctional officer compensation, technology requirements, and staff time to review videos. In this section, we also identified adaptations to the program and facility-level impacts beyond the intended intervention.

Maintenance

Because VOT is a biomedical intervention intended to cure participants of TB disease, we did not evaluate maintenance for all participants at the individual level. The perceived importance of treating TB was reported. For those participants that became formerly incarcerated before completing treatment, we measured the continuation of VOT using a smartphone. At the facility level, we evaluated the sustainability and perceived importance of treating TB for

correctional officers. The sustainability of this program was evaluated by the continued involvement of stakeholders.

Ethical Consideration

Study protocol has been reviewed and approved by the Emory University Institutional Review Board (IRB). Locally, the Haitian National Bioethics Committee also approved the study protocol. Additionally, The National TB Program in Haiti (PNLT) approved the study and voiced support of the protocol in the context of Haitian Prisons. All documents used to collect participant information, including consent forms, were translated into Haitian creole and read aloud to ensure full understanding and informed consent.

Limitations

The number of surveys completed was a direct result of the ability of study staff to reach each site. Due to bouts of civil unrest, there were long periods during which access to sites was limited, and not all VDOT and DOT sites were able to contribute to the evaluation. Evaluators intended to include data gathered from focus groups; however, the sites did not have a space that provided the necessary privacy. Additionally, VDOT implementation in Haiti built on existing TB testing conducted by HtW. Implementation in other low resource countries may be more involved if they lack an existing TB program.

Textbox 2: The RE-AIM Framework

RE-AIM Dimension	Original RE-AIM Definition (R. E. Glasgow et al., 1999)	Unit	Definition in this Study	Outcome	Measurement
Reach	The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program.	Individual	Absolute number and sociodemographic background of VDOT site participants	Total enrolled in VDOT Sociodemographic characteristics of VDOT population	VDOT Adherence Records Surveys
Effectiveness	The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes.	Individual	Regimen adherence and VDOT perceptions and quality of life impacts	Adherence proportions VDOT concerns TB stigma scale scores Depression scores	Adherence records Participant Surveys
Adoption	The absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program.	Facility	The number/proportion of facilities in which the program is implemented. The number of correctional officers who participated	Number of facilities participating in VDOT. Number of correctional officers participating	Adherence records Correctional officer survey
Implementation	At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention. At the individual level, implementation refers to clients' use of the intervention strategies.	Facility	Closeness of protocol implementation to program intention, including adaptations and unintended outcomes. Also includes reported challenges when implementing VDOT Cost of VDOT	Correctional officer perceptions of the program. Adaptations to protocol and unintended outcomes anecdotally Comparisons between sites	Correctional Officer Surveys Reported adaptations and challenges
Maintenance	The extent to which a program/policy becomes institutionalized or part of the routine organizational practices and policies. At the individual level, it has been defined as the long-term effects of a program on outcomes after six or more months after the most recent intervention contact.	Individual/ Facility	Facility level maintenance, including sustainability indicators, and continued stakeholder buy in.	Post-release continuation using VDOT Correctional officer buy in	Adherence data from cell phones Correctional officer surveys

Results

From January 2019 -April 2020, 65 persons received VDOT in prisons; six finished their course after exiting the prison. There was one loss to follow up, one death, and 28 persons were still on treatment when the evaluation period ended. The enrolled population had a mean age of 33 years, range [20 -61] and were 100% male. In comparison, an estimated 50 persons started on DOT. For the intervention group, median total adherence was 99.1%, and median VDOT adherence was 81.8%. DOT sites reported 100% adherence. Twenty-four (37%) participants from three VDOT sites completed baseline surveys, six also completed follow-up surveys. Ten participants from one DOT site completed a baseline survey. Political unrest during the study period prevented evaluation staff from reaching sites and making repeated visits to participants; as a result, survey participation was only offered to a limited number of individuals.

Table 1: TB regimen adherence by site excluding those who used VDOT after leaving prison

	Total	Site A	Site B	Site C	Site D	P-value
Characteristic						
No. Patients	65	13	15	19	16	
VDOT use						
Adherence, Median (SD)	100(11)	97.6 (10)	100 (15.3)	94.5(12.2)	100 (1.2)	<.001*
VDOT Adherence Median (SD)	85.7(21)	63.1 (19.8)	97.8(15.3)	72.7 (24.3)	83.8(14.9)	<.001*
No. participated in baseline survey	24	7	8	9	0	

Reach

Participation in the program was high due to the lack of alternative care. All (67/67) individuals diagnosed with TB at the intervention sites enrolled in VDOT. Of those surveyed, all (24/24) had no concerns regarding participation in the VDOT program. Participants had high knowledge of TB, all identified TB is curable, and most (22/24) correctly identified at least one symptom, and at least one treatment method. The majority of the group (19/24) believe TB is a

'very serious' disease, and (22/24) believe TB is a 'very serious' problem in Haiti. The VDOT population did not differ significantly from the DOT population for any measure other than years of school, 3.3 for VDOT sites, and 6.7 for the DOT site (Table 2).

Table 2: VDOT vs. DOT survey responses

	Intervention sites VDOT	Control Sites DOT	P-value
Demographic Data			
Participants Surveyed	24	10	
Gender (Percent Male)	100	100	
Average Age	30	30	
Average Years of Schooling	3.04	6.7	0.02
Financial Situation*	3.7	4.5	0.45
Frequency of Visitors**	1.3	1.3	
% First time in Prison	77	78	
Participant experience			
TB Stigma Total	49.7	30.7	0.01
Internal perceptions	63.7	32	0.01
Disclosure	65.7	44.2	0.04
External perceptions	38.2	26.7	0.30
External actions	45.5	30.0	0.18
Courtesy stigma	19.6	10	0.52
Depression Scale	16.3	15.7	0.83
TB knowledge and opinions***	No. (%)		
How serious of a disease is TB?	17/23 (74) 'very serious'	5 (50) 'very serious'	
How serious of a problem is TB in Haiti?	20/22 (91) 'very serious'	8 (80) 'very serious'	
Identified at least 1 correct symptom of TB	20/24 (83)	10 (100)	
Identified TB is transmitted by respiratory droplets	14/24 (58)	4 (40)	
Identified at least one prevention method	16/24 (67)	5 (50)	
Identified anyone can get it	21/24 (88)	10 (100)	
Identified TB can be cured	24/24 (100)	10 (100)	
Identified at least one TB treatment method	23/24 (96)	8 (80)	

*Financial situation was self-reported on a scale from 1-struggling to get by to 10 totally secure
**Frequency of visitors was calculated by assigning values to ranges of self-reported frequencies of visitors and is roughly equal to # of visits per month
***Differing denominators are a result of missing responses

Table 3: VDOT population associations using baseline survey data

Characteristic	Spearman Correlation Coefficient (rho)	P-value
Associations with years of school		
Financial situation	0.01	.96
Total Comfort level 1-10 using phone	0.67	>.001
Make Phone Calls	0.51	.009
Take Pictures	0.67	>.001
Taking videos	0.67	>.001
Sending text	0.41	.04
Using the internet	0.43	.03
Depression	0.45	.03
Stigma	0.61	.01
Associations with Financial situation		
Stigma	0.26	0.31
Depression	0.18	0.37
Technology comfort	-0.14	0.49

Effectiveness

The median total adherence fraction was (TAF) 99.5%, and the median VDOT adherence fraction (VAF) was 71.0%. VDOT adherence was significantly associated with total adherence. Both total adherence and VDOT adherence varied significantly by site (Table 1). In comparison, total adherence from DOT sites is reported as 100%.

The average TB stigma score for VDOT was 49.7, which differed significantly from the average DOT stigma score of 30.7. Sub-grouped stigma scores for internal perceptions (63.7) and disclosure (65.7) were statistically different from DOT (32 and 44.2, respectively). External perceptions, external action, and courtesy stigma were not statistically different. Average depression scale values for VDOT participants (16.3) and DOT participants (15.7) were not significantly different (Table 4). Follow up survey results showed 5/6 participants "did not mind the VDOT process," and one participant felt it made them feel "like I am not trustworthy".

Table 4: Site population data from baseline surveys

	Site A	Site B	Site C
Participants Surveyed	7	8	9
Gender (Percent Male)	100%	100%	100%
Average Age	29.9	29.5	29.3
Average Years of Schooling	2	3.1	3.1
Financial Situation*	3.9	5.8	1.8
Frequency of Visitors**		2	0.3
% First time in Prison	57%	75%	100%
Technology use			
% Phone Owners	85%	75%	78%
% Smart Phones	50%	50%	57%
Total Comfort level 1-10 using phone	31.3	31.6	38.9
Make Phone Calls	6.4	6	7.2
Take Pictures	6.7	7.25	8.2
Taking videos	5.7	7.5	6.7
Sending text messages	4.6	5.5	7
Using the internet	4.3	3.25	6.3
Depression Scale Average total score	16.4	19.25	15.33
TB Stigma scale		51.5	37.0

*Financial situation was self-reported on a scale from 1-struggling to get by to 10 totally secure
**Frequency of visitors was calculated by assigning values to ranges of self-reported frequencies of visitors and is roughly equal to # of visits per month

Adoption

All prisons that were given the opportunity to participate joined the study. Correctional officer recruitment and participation was not a barrier to enrolling any sites. All (3/3) correctional officers surveyed "completely agreed," they would participate in increasing accessibility for treating a disease: Even if they doubted the efficiency in correctional institutions. The group also completely agreed that "My principles are to make treatment accessible for inmates," but two strongly disagreed that it is morally unacceptable to block medical treatment for inmates. Finally, all three correctional officers strongly agree that they feel proud to be increasing the availability of tools to promote adherence to medical treatment.

Implementation

Median total adherence and VDOT adherence varied significantly by site. Sites B had the highest median (SD) total video adherence 100% (15.3) and 97.8% (15.3), respectively, followed by site D 100% (1.2), 83.9% (14.9). Sites A and C reported the lowest median total adherence and video adherence. Median (SD) total and video adherence for site A were 97.6% (10) and 63.1% (19.8). For site C, values were 90.9% (23), and 70.6% (28.3), respectively.

Correctional officers reported three main challenges in implementing VDOT, maintaining a continuous network connection, civil unrest causing complete lockdown or limiting road access, and the tablets having malfunctions, which caused a delay in video uploads or missing videos. During implementation, two sites struggled with tablet malfunctions, which produced an error message when launching the application used for VDOT. These tablets were replaced with upgraded devices that resolved the problem. Other sites reported occasional network and connectivity issues. In the event of network issues, videos were stored on the devices and uploaded once reconnected. One site reported a secondary use for the provided tablet. They are utilizing the tablet camera to create a photo registry of those incarcerated at their site.

The VDOT program, minus the evaluation, costs significantly less than its DOT counterpart. Initial equipment was around $200 per tablet. Monthly costs included data cards Digicel, $10/month, or/and Natcom $8/month and correctional officer compensations. Correctional officers are compensated through a percent increase in their monthly salary, which varies but does not exceed $50 per officer. This compares favorably to adding full-time nurses at the five outlying prisons, which would cost around $6,000.00 annually or an average of $500 monthly per site. Based on monthly estimations, the VDOT first-year program costs were $8,080, compared to $30,000 for full-time nurses.

Table 5: Correctional officer facilitated Adherence associations

Characteristic	No. Patients	Adherence Median (SD)	P-value Kruskal-Wallis	Video Adherence Median (SD)	P-value Kruskal-Wallis
Total	65	99.5 (17.1)		81.8 (23.5)	
Site	65		<.001		<.001
A	13	97.6 (10)		63.1 (19.8)	
B	15	100 (15.3)		97.8(15.3)	
C	23	90.9(23)		70.6 (28.3)	
D	16	100 (1.2)		83.8(14.9)	
Spearman Correlation	No patients	Correlation Coefficient (rho)	P-Value	Correlation Coefficient (rho)	P-Value
Overall adherence and video adherence	65	0.46	<.001	--	--
Age	61	-0.24	0.07	-0.12	0.36
Financial Situation	26	0.05	0.82	0.48	.015
Stigma score	16	0.008	0.98	0.27	0.32
Depression	24	-0.19	0.36	0.37	0.20
Total Comfort level 1-10 using phone	24	-.23	0.28	-.27	0.20
Call	24	-.09	0.66	-.05	0.82
Text	24	-.29	0.18	-.31	0.13
Photo	24	-.03	0.89	-.14	0.51
Video	24	-.04	0.85	-.04	0.87
Internet	24	-.15	0.49	-.32	0.13
Email	23	-.40	0.06	-.47	0.02*
Wilcoxon Rank	No. Patients	Adherence Median (SD)	P-value	Video Adherence Median (SD)	P-value
Education	22		0.45		0.98
Zero years	8	99.2 (3.28)		68.2 (18.5)	
Some school	14	95.8 (28.4)		79.8 (32.7)	
Owned a cell phone	24		.71		0.94
No	5	96.4 (10.3)		63.6 (36.1)	
Yes	19	99.5 (25.3)		70.6 (26.9)	
Owned a smartphone	19		0.41		0.047
No	8	99.7(4.34)		89 (14.4)	
Yes	11	98.9 (31.8)		62.8 (29.7)	
First time incarcerated	23		0.53		0.73
No	6	92.9 (6.52)		77.5 (31.8)	
Yes	17	100(26.8)		68.2 (27.7)	
Cigarette use ever	24		0.98		0.19
No	14	99.7 (20.0)		65.9(27.4)	
Yes	10	99.2 (27.6)		89.4(27.4)	
Marijuana use ever	24		0.60		0.48
No	18	97.7(17.7)		71.7 (28.1)	
Yes	6	99.7(36.4)		62.1(30.7)	

Maintenance

As this was a pilot study, maintenance of the program as a whole was difficult to evaluate. Individually, once participants complete their treatment, they are cured and no longer need the intervention. There were no demographic associations with adherence indicating future enrollments will not have to consider demographics as inclusion or exclusion criteria for adherence success.

Of those given a cell smartphone to continue VDOT after exiting correctional facilities, two admitted to selling their phones due to financial strain, and one individual lost their phone. Many reported network issues and other technical difficulties. Six individuals who maintained possession of their phones were included in this evaluation. Four individuals exiting site C completed treatment, and two individuals exiting the National Penitentiary were still using VDOT at the time of the evaluation. The median total adherence for this group was 57.6%, and median video adherence was 47.3%. Medians for the National Penitentiary, 68.9% total adherence, and 52.5% video adherence were higher than those leaving site C, 53.5%, and 39% total and video adherences, respectively. Despite low recorded adherence, all 4 participants from site C completed treatment.

Discussion

This study evaluated VDOT is a potential alternative for TB care in Haitian correctional facilities lacking the capacity to provide DOT. During the study period, 71 individuals received TB treatment at their current location; prior to this intervention, some of these individuals would have been transferred to another facility, but a significant number would have remained at the site without proper care.

There are additional benefits to preventing transfer. Previous literature has shown the importance of supplemental food brought by family members in Haitian correctional facilities. The frequency of visits is strongly associated with improved health outcomes. (LaMonaca, 2018; May et al., 2010). Transferring of those with TB has the potential to reduce or eliminate visitors, resulting in poor health outcomes. Furthermore, these sites lack separate areas for those with TB; once diagnosed, they return to the general population while awaiting transfer. As a result, the untreated individual has the potential to spread TB.

The median VDOT adherence fraction, 81%, was lower than previous studies conducted in higher resource settings(R. S. Garfein et al., 2015). Variability in adherence for this study was expected due to the unique context in which VDOT was delivered. However, when factoring in doses marked as DOT by correctional officers, total adherence increased to a median of 99.5%, illustrating the intervention's ability to continue to provide care in the event of VDOT failure. It is important to note that before this program, adherence was not tracked in any capacity at the intervention sites. Furthermore, if those who finished regimens outside the prison environment are excluded, the median total and video adherence increase to 100% and 85.7%, respectively. These values represent adherence for pure correctional officer facilitated VDOT.

Correctional officer facilitated VDOT not only helps directed observed therapy but also allows health care staff to monitor regimen progress remotely. Before this program, TB patients at intervention sites were periodically visited by caregivers or medical staff. VDOT allows adherence to be tracked daily by remote health care staff.

Long term maintenance of the VDOT program will depend on correctional officer buy in. Of those surveyed, all correctional officers showed a high interest in increasing treatment accessibility and participating in the program regardless of personal beliefs in its efficacy. They

are also proud to participate in the program. These factors are essential for the success of the program and indicate correctional officer investment beyond monetary compensation.

A primary factor associated with adherence was site. Due to the prison environment, it is logical that location has a more considerable influence on adherence than the characteristics of each individual. Site A and C had the lowest median video adherence 63.1 and 70.6%, respectively. During the evaluation, both sites had issues with their first tablets, which were eventually replaced. In Haiti, two companies provide network access with inconsistent coverage throughout the country; as a result, the tablets provided required dual sim cards. Correctional staff at these two sites had to switch cards depending on which network was providing the strongest signal at the time. These network issues caused delays in video uploads.

Despite the low video adherence, Site A had a median total adherence of 97.6 %, where site C remained lower at 90.9 %. Study staff reported that during some instances of severe civil unrest, all individuals remained in their cells and were not allowed to leave for VDOT. Over the study period, sites experienced technology, and civil unrest challenges unequally. It is more likely that site variation in adherence was a result of these challenges rather than variations in how the protocol was implemented.

Even with these challenges, the success of the program during the study period illustrated the resilience of VDOT during times of civil unrest. Sporadically since December 2019, civil unrest in Haiti prevented staff from reaching prison sites limiting transfers. It is difficult to estimate the full benefits of VDOT during this time, but it is reasonable to assume it facilitated the superior provision of care. Additionally, correctional officers reported they are using the provided video-enabled tablets to create photo registries of incarcerated individuals at their site. Create use of the tablets illustrates comfort with technology and buy-in from correctional

officers. It also introduces the potential benefits of having web-enabled tablets at each prison site outside of TB treatment.

The VDOT population reports significantly higher TB stigma than the DOT population. Specifically, the internal perceptions and emotions and disclosure measures significantly differed between the groups. Previous literature reports that in Haiti, TB stigma is primarily related to economic issues and is associated with poverty. These cultural beliefs likely influence internal perceptions and emotions which participants were exposed to long before entering the jails. The VDOT population was significantly less educated than the DOT population averaging three years compared to 6.7 years of schooling at the control sites, it is likely that individuals of lower socioeconomic status feel higher levels of internal stigma due to TB's historical association with poverty. Disclosure, which is a measure of willingness to discuss TB diagnosis, is highly related to internal perceptions(Coreil, Mayard, et al., 2010). Furthermore, external actions and external perceptions which did not differ significantly by intervention type are more representative of current environment. Further analysis showed a strong correlation between stigma scores and years of education among the VDOT population. The variance in stigma scores is likely the result of underlying socioeconomic differences in the population VDOT serves rather than a result of participating the VDOT program.

Smartphone VDOT for those exiting correctional facilities was less successful than correctional officer facilitated VDOT. Recorded video and overall adherence were low for both those leaving VDOT sites and those leaving the national penitentiary. Those transitioning out of a correctional facility face many social and economic changes that can influence adherence. The selling of phones indicates that the population may need further financial incentives to continue VDOT successfully. Despite these challenges, and low adherence, those who continued using

smartphone VDOT did complete treatment. Perhaps more important than tracking adherence, the VDOT program provides continued contact with health care staff facilitating treatment follow up. Previous loss to follow-up analysis for TB patients in Haiti reported males suffered higher rates of loss to follow up and identified lack of transportation to facilities, inclement weather, and political instability as barriers to follow-up(Schnaubelt et al., 2018). Smartphone VDOT solves all of these challenges.

Recommendations

Civil unrest during the evaluation period created a unique environment to test the effectiveness of VDOT. Despite the program's success, an evaluation during more peaceful times could better illustrate the application of VDOT in low resource prisons. Alternatively, a VDOT program could be implemented in a country that experiences less civil unrest. Health through Walls works in 8 other low to middle-income countries worldwide(World Health Organization (WHO) Europe, 2019). Many of the correctional facilities are unable to provide DOT for TB care. Other correctional programs have expressed interest in implementing VDOT, and because HtW is already involved in health care in these facilities, they are the ideal next sites for this program.

While the depression scale was validated in the Haitian population is has not been validated in the prison population. Some questions regarding loss of appetite or ability to fall asleep may not correctly assess depression in prisons. Still, the average scores are in the range of depression, indicate this is an area that warrants further investigation in Haitian correctional populations with and without TB.

The TB sigma scale used in this study severed only as an evaluation measurement. However, the results indicate there is a high level of stigma in both VOT and DOT population.

Previous studies have examined stigma in Haitian Americans, and Haitian immigrants but has been used less in Haiti and not at all in Haitian prisoners. Further research must be conducted by sampling from more DOT and VDOT sites to determine how stigma affects TB treatment in this population.

Smartphone VDOT is a promising method to deliver TB care for those transitioning out of prison. Those included in this evaluation have low adherence but were still able to complete treatment and maintain contact with health staff. Further investigation should be completed with this population to determine how best to support patients during their transition, including factors associated with both adherence and treatment completion.

Finally, a complete evaluation of the VDOT program would benefit significantly from qualitative data. Although focus groups were not feasible in prison settings, one-on-one interviews are possible. Unstructured or semi-structured interviews would give greater insight into the participant experience and shed light on issues such as stigma, which would inform future scale-ups at additional rural Haitian prisons.

Conclusions

VDOT facilitated by correctional officers can provide TB treatment in low resource correctional facilities and extend the reach of HtW's TB program into rural prison settings. Not only does it facilitate observed therapy, but it also enables continuous patient monitoring and follow-up on treatment that historically was extremely challenging for these prison sites. Implementing VDOT for TB therapy could expand treatment in correctional facilities in Haiti and be used in prisons in other low resource areas facing similar challenges.

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