Center for Connected Health Policy

The National Telehealth Policy Resource Center

Challenges and Recommendations on Using Telehealth for Directly Observed Therapy in Treating Tuberculosis

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California Health Care Foundation

The Center for Connected Health Policy (CCHP), a project of the Public Health Institute, is a non-profit, non-partisan organization that seeks to advance state and national telehealth policy to promote improvements in health systems and greater health equity. CCHP was created in 2008 with a grant from the California Health Care Foundation. CCHP is the federally designated national telehealth policy resource center, established through a grant from the Human Resources Services Administration under the Office for the Advancement of Telehealth (Grant #G22RH30365).

EXECUTIVE SUMMARY

Tuberculosis (TB) is one of the most widespread infectious diseases in the world, infecting an average of 9 million people annually.[i] Although TB is curable, more than 1 million TB-related deaths occur each year globally.[ii] California reported the largest number of cases in the United States (U.S.), representing 22 percent of the nation's 9,951 cases, and the third highest rate among states.[iii] In March of 2016, the Centers for Disease Control and Prevention (CDC) noted that after over two decades of decline in the United States TB cases have plateaued sparking concerns that we may soon see an increase in cases.[iv]

Treating TB by means of directly observed therapy (DOT) generates high costs, time-intensive travel, and labor burdens on public health departments, yet it is recommended by the CDC as the most effective means of combating TB. One solution to alleviate such strains as well as fight against infectious diseases is to employ telehealth technologies, yet it remains underutilized. With a grant from the California Health Care Foundation (CHCF), the Center for Connected Health Policy (CCHP) examined the potential policy barriers to implementing video technology to deliver electronic DOT (eDOT).

To assess eDOT's current environment, CCHP conducted a literature review of published eDOT studies, examined current policy, procedures, and practices regarding TB management on a state and federal level; conducted key informant interviews with public health officials, an eDOT vendor, and a CDC employee; and administered two surveys: one to attendees at the annual California Tuberculosis Control Association (CTCA) conference in April 2015 and the other disseminated online by the National Tuberculosis Control Association (NTCA) in December 2015.

RESULTS

Common benefits and concerns ran throughout all phases of the CCHP's research. Published literature and studies on eDOT was limited, but showed great promise in medication adherence and patient acceptance due to the flexibility offered by the technology. Encouraging data on potential cost efficiencies were also noted by making better use of staff time and reducing travel. Concerns centered on technology failures. These themes were echoed in the surveys and interviews conducted with additional benefits such as greater protection for staff by lessening exposure and the potential to use the technology to treat other infectious diseases being noted. Other concerns were raised including privacy and security issues, reimbursement and lack of guidelines or materials for effectively building an eDOT program.

These concerns were validated through the research of existing laws, policies and regulations on TB, telehealth and eDOT. A scan of relevant state and federal laws and policies confirmed an absence of the policy in statutes or regulations that pertained to the use of eDOT in combating TB. Existing DOT policies and provisions from the CDC and the US Department of Health and Human Services (HHS) were outdated and did not include technology when discussing DOT procedures. Recently, due to the work in this project and a related pilot conducted by the University of California, San Diego (UCSD) and also funded by CHCF, the California Department of Public Health (CDPH) and the CTCA issued updated

guidelines in 2016 for DOT protocols that recommended the use of live video DOT (LV-DOT) and asynchronous DOT (AV-DOT), one of the first of its kind documents in the country. However, it is only intended as guidance rather than official policy.

No law or regulation to prohibit the use of telehealth in delivering DOT therapy was found under California law whether via LV-DOT or AV-DOT. In-person DOT is reimbursed under the Medi-Cal program as a fee-for-service. However, some Medi-Cal telehealth policies conflict with the opportunity to utilize eDOT and be reimbursed for it, causing some county health departments to hesitate in utilizing the technology.

RECOMMENDATIONS/CONCLUSIONS

Based on the available and present research, telehealth has been shown to be a viable method for delivering DOT to TB patients. However, to address the evident gaps still remaining in this area of public health, CCHP recommends the following:

National & State Level

- Update the CDC Guidelines for DOT to include the use of eDOT.
- Develop guidelines that would address HIPAA, privacy, security, and confidentiality concerns when utilizing eDOT.
- More studies focused on the use of eDOT on other infectious diseases in addition to TB should be conducted.

California Level

- Expand Medi-Cal's list of eligible providers for reimbursement.
- Expand Medi-Cal's list of eligible locations for reimbursement.
- Medi-Cal and other payers should reimburse for eDOT.

Policy must adapt to the advancement of technology. If not, public health departments may very well begin to lag behind modern times and ultimately not be as efficient and resourceful in their services to the public, especially if TB and other infectious diseases continue to rise and pass the departments' level of epidemic controlling capabilities.

[i] Congressional Research Service, "US Response to the Global Threat of Tuberculosis: Basic Facts", Washington, DC, Government Printing Office, June 15, 2012, p. 1.
[ii] Ibid.
[iii] California Department of Public Health, "Report on tuberculosis in California, 2013", Sacramento, CA, August 2014, p. 2.
[iv] Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, "Leveling of Tuberculosis Incidence – United States, 2013-2015". < http://www.cdc.gov/mmwr/volumes/65/wr/mm6511a2.htm> (Accessed July 14, 2016).

INTRODUCTION

Tuberculosis (TB) is one of the most widespread infectious diseases in the world, infecting an average of 9 million people annually.[i] Although TB is curable, more than 1 million TB-related deaths occur each year globally.[ii] California reported the largest number of cases in the United States (U.S.), representing 22 percent of the nation's 9,951 cases, and the third highest rate among states.[iii] In March of 2016, the Centers for Disease Control and Prevention (CDC) noted that after over two decades of decline in the United States TB cases have plateaued, sparking concerns that we may soon see an increase in cases.[iv]

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

While effective in treating TB, DOT is labor intensive and an expensive treatment approach that taxes limited public health resources. Treatment of TB can range from three months for latent infections of TB[vi] to 24 months for multi-drug resistant TB (MDR-TB)[vii] and the cost of treating one patient can range from $2,000 to $250,000 for just the medication.[viii]

Telehealth is the use of technology to provide health services to patients from a distance. In the last few years, there has been an increase in the use of telehealth as a tool to reach rural and underserved communities as well as a more cost-efficient means of delivering heath care. With technological advances combined with budget decreases for public health organizations, conducting DOT remotely with the use of technology (called eDOT) has become a viable option. Telehealth could reduce travel time and costs for both the public health department and the consumer, create more flexibility in scheduling, provide a safer environment for the health care worker by limiting their travel and exposure to TB, and potentially increase the likelihood of adherence due to these benefits. eDOT can be either live/synchronous (LV-DOT) or asynchronous (AV-DOT).

To further explore the potential utilization and expansion of eDOT, the California Health Care Foundation (CHCF) funded two companion studies: one to look at the efficacy of eDOT conducted by the University of California, San Diego (UCSD) and the other to look at potential barriers to employing technology to deliver DOT in treating TB in the state of California. The latter study was conducted by the Center for Connected Health Policy (CCHP).

CCHP assessed the current California policy and reimbursement environment for eDOT and developed recommendations that would assist in fostering the greater utilization of the technology to treat TB and possibly other infectious diseases. CCHP addressed the following in relation to eDOT:

- What are the current policy, procedures and practices related to TB control on a state and federal level?
- What is the level of acceptance of eDOT?
- What other infectious disease treatment plans can use eDOT?
- What are the policy recommendations that would create a more positive environment for the utilization of, and reimbursement for eDOT?

To address these questions, CCHP engaged in a four part process.

- A literature scan of published studies utilizing some form of eDOT to treat an infectious disease including TB.
- A scan of relevant federal and California policies, laws and regulations related to eDOT, telehealth and TB.
- Key informant interviews that included California public health department staff, eDOT purveyors, and a CDC employee.
- Two surveys of public health departments (one California focused, one national).

The above research revealed common findings and themes across all sources regarding the use of eDOT. While enormous potential is seen in using eDOT, existing policies or lack of them make public health departments hesitant to go forward with its utilization.

LITERATURE & POLICY SCANS

The literature and relevant state and federal laws and policies scan revealed limited information. While the published material around the efficacy in using eDOT to treat TB is few, what exists shows great potential. Overall, the studies found both modalities to be feasible approaches to providing DOT as adherence rates were similar and in some cases, better than standard in-person DOT. It was often found in the pilot projects and randomly controlled trials (RCTs) that the virtual visits had a smaller average length of time compared to equivalent in-person visits, including both travel time and face-to-face time. Subjects of studies also frequently reported the technology to be convenient, private, reliable, and flexible. All studies and reviews that included a cost analysis suggested that LV-DOT and AV-DOT are cost-effective alternatives to DOT and offer cost savings regarding patients and health care personnel.

The scan of relevant federal, state and specifically California policy related to the use of eDOT

to treat TB was even scarcer. Existing DOT policies from the CDC did not address the use of technology and had in fact, not been updated since 2003[ix]. Written by the US Department of Health and Human Services (HHS) and the CDC, the "Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws" is endorsed by the National Tuberculosis Controllers Association. The only references to DOT are to delivery in-person.[x]

The research did reveal that California had attempted to provide some guidance on the use of eDOT. In 2011, the California Department of Public Health (CDPH) and the California Tuberculosis Controllers Association (CTCA) did issue joint guidelines on DOT protocols that include suggested guidelines for LV-DOT. Due to the work done for this project and the concurrent one conducted by UCSD, the guidelines have just been recently updated (August 2016) for usage of both LV-DOT and AV-DOT, making it one of, if not the first, such document in the nation.[xi] However, the document is only guidance for public health departments and contains no directives or mandates.

In recent years, however, some public health departments have taken the initiative to run pilots utilizing eDOT. Three states had or are running pilots utilizing eDOT to treat TB: New York, Maryland and Texas. New York State is an intriguing example due to an unusual policy regarding Medicaid and reimbursement for DOT. In 2013, the state of New York made the provision of TB/DOT the responsibility of Medicaid Managed Care.[xii] Among the managed care plan responsibilities are:

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

This differs from California's approach to managed care and DOT, which is discussed in the next section. New York's policies may create a more favorable environment to utilize eDOT as Medicaid managed care plans must pay for DOT, a policy that does not exist in California. While such a policy has interesting potential, it should be noted that no requirement or prohibition to technology to deliver DOT is mentioned.

To read more about CCHP's literature review and scan of relevant federal and California polices, please see CCHP's white paper, "Using Telehealth for Directly Observed Therapy in Treating Tuberculosis."

California TB Policy

In California's Medi-Cal provider manual, TB related services are reimbursable to the County Health Department as a fee-for-service. Medi-Cal managed care plans are not required to cover DOT, unlike New York, and it is instead, billed as a fee-for-service by public health departments. The reimbursement rate for DOT is $19.23 per encounter. Eligible DOT providers are community workers and/or public health nurses employed by county clinics already enrolled or are eligible to enroll as Medi-Cal providers under existing county provider categories.[xiv] The code to bill for a DOT encounter is Healthcare Common Procedure Coding System (HCPCS) code Z0318.

No law or regulation to prohibit the use of telehealth in delivering DOT therapy was found. Additionally, there is no requirement that DOT take place in real time aside from the aforementioned recommended guidelines for DOT protocols issued by CDPH and CTCA. However, certain existing Medi-Cal telehealth policies conflict with the possibility of eDOT being reimbursed.

California Telehealth Policy

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

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

Although AB 415 went into effect on January 1, 2012, DHCS did not issue an updated provider manual until September 2013 when they also held a provider webinar to discuss the changes made. In discussions with DHCS, they noted they continue to work on refining their administrative policy for telehealth, however, information gaps in the provider manual remain. As of this writing, Medi-Cal policy related to fee-for-service reimbursement for telehealth, which is contained in the telehealth section of the Medi-Cal Provider Manual, states:

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

(dermatology, dental, ophthalmology and a small section of optometry services)

No information regarding provider type is listed in the manual despite the clear language in the law that allows for significant expansion in this regard. Additionally, while facility type restrictions have been eliminated, Medi-Cal has noted verbally that only certain locations will be eligible as originating (where the patient is located) sites. While the policy has not been formalized in writing, in discussions with Medi-Cal, the home only will be considered an eligible site if a health care provider is present with the patient. These policy limitations severely impact the potential effectiveness of eDOT. If a health care provider has to be with the patient in order to be reimbursed, there is no need then to use eDOT. Additionally, reimbursement for asynchronous services are provided for a small set of specialties and the typical DOT providers may not be among Medi-Cal's list of eligible telehealth providers.

With a lack of private payer or managed care policy that requires plans to reimburse for DOT, public health departments must go to Medi-Cal fee for service for reimbursement. Yet, they will not be able to be reimbursed if they use telehealth to deliver DOT services due to Medi-Cal's existing telehealth policies.

KEY INFORMANT INTERVIEWS & SURVEYS

The interviews and surveys conducted reaffirm the initial findings in the aforementioned scans in that great potential is seen in utilizing eDOT, but, what remains are outdated, inhibiting or lack of policies and guidance that may make public health departments hesitant to invest resources into the technology.

Key Informant Interviews

Telephone interviews were conducted with eight professionals in six California county health departments. Half of the interviewees were preparing to begin using eDOT while the other four had been using eDOT for several years. Some of the sites had used eDOT with patients who had their own smartphones or used land lines with video technology prior to the start of the UCSD pilot study. Seven of the interviews were with staff participating in the UCSD pilot and one person was in another state who used AV-eDOT. The selection process was based on their role in the organization and the organization (at least one person from each pilot site was interviewed).

The interviewees identified the following benefits of eDOT:

- Flexibility offered in eDOT in scheduling especially if patients were traveling. LV-DOT would still require scheduling a time to view the ingestion of the medication, but AV-DOT allowed the health worker to view the video at any time. AV-DOT also had the added benefit of observation of patients' medication ingestion over weekends and

holidays.

- Patient satisfaction was high.
- eDOT was cost effective.
- Reduction in clinic crowding.
- Potential to improve patient adherence and completion rates.

The challenges the interviews identified when utilizing eDOT were:

- Reimbursement
- Equipment and connectivity issues
- Monitoring side effects

SURVEYS

Two surveys were conducted. The first survey was disseminated at the CTCA annual conference in 2015. The second survey was conducted in collaboration with the National Tuberculosis Control Association (NTCA) and administered online to TB programs in 50 states, 10 big cities and eight US territories and the Pacific Island affiliates (territories). The CTCA survey was completed by 56 participants and the NTCA survey had 120 respondents. CTCA respondents were primarily clinicians with the second largest group being administrators/managers. Most of the respondents worked at a California public health agency. Of the NTCA respondents, half worked at a local TB program, 38 percent at a state TB program, and the remainder at TB programs in big cities and territories. The combined state and local jurisdictions represented 47 states and five US territories and affiliated Pacific islands. The complete results of the CTCA and NTCA surveys are in Appendix A and Appendix B respectively. Because the surveys did not contain identical questions, responses for all questions are not available from both CTCA and NTCA respondents.

The common top concerns NTCA respondents focused on the Health Insurance Portability and Accountability Act (HIPAA)/security issues and equipment failure. CTCA respondents' concerns centered on connectivity and equipment issues as well. While reimbursement was a concern, it seemed less of an issue in the NTCA survey than it did for the CTCA respondents. This may be because on a national level, few programs are reimbursed for in-person DOT or eDOT while in CA in-person DOT services are reimbursed by Medi-Cal but eDOT is not. Therefore, in CA when public health departments switch from in-person DOT to eDOT there is a reduction in the reimbursement for services. NTCA respondents did see similar benefits to eDOT as CTCA did, with medication adherence and treatment completion as good as in-person DOT.

One of the most surprising outcomes from the survey is the amount of experience public health departments have with eDOT. Given the small number of published studies and the minimal

amount of policies found in aforementioned scans, more TB programs have utilized eDOT than anticipated. However, the concerns gathered from the survey indicate what have been limiting factors for wider implementation or in some cases, continuation with using the technology.

Other Applications of eDOT

The CTCA and NTCA surveys both included questions related to other uses of eDOT technology. The responses are in Tables 1 and Figure A respectively.

Table 1

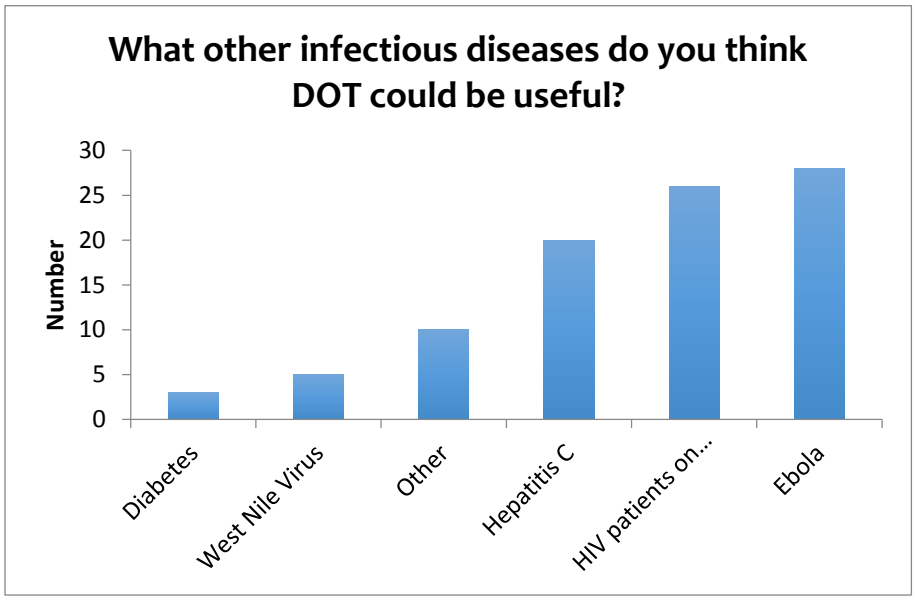
Other Applications of e-DOT, CTCA

Q: In addition to TB, what other infectious diseases or health issues do you think VDOT could be used for to improve disease management?	**Response Percent**	**Response Count**
HIV patients on antiretroviral therapy	73.5%	36
Ebola	38.8%	19
Substance abuse	26.5%	13
Hepatitis B	24.5%	12
Hepatitis C	44.9%	22
Mental health problems	38.8%	19
Other (please specify)		11
answered question		49
skipped question		7

Other (unedited)

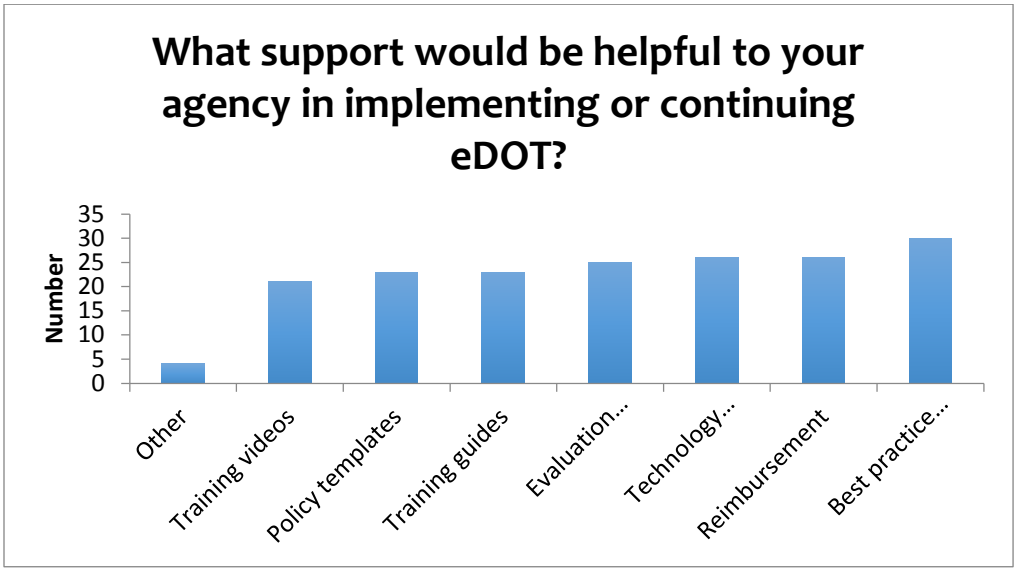
1. Probably any
2. Diabetes management
3. CD
4. Diabetes, malignant hypertension, congestive heart failure, COPD, asthma, any chronic D3
5. Multiple resistance HIV with a history of a lack of adherence to meds.
6. Diabetes management and treatment
7. If cheap and an app for phone could be used for STD treatment (if it isn't a single dose)
8. Due to patient confidentiality issues/patient perceptions I think only some mental health patients in our practice would be interested.
9. N/A
10. Travelers to Ebola affected countries
11. Hep B and Hep C only if on antiviral treatment; measles quarantine

Figure A
Other Uses for eDOT, NTCA



The NTCA survey also contained a question regarding support needed in implementing or continuing eDOT (see Figure B). While reimbursement did score high, it was matched or slightly outscored by technology and best practice guidelines indicating that despite the promise of eDOT, training and education materials are needed..

Figure B



UCSD COMPANION STUDY

Preliminary results from the UCSD companion study that tested the efficacy of eDOT shows great promise. In the UCSD study, a single arm, multi-site study was conducted in five California counties using the asynchronous version of eDOT. Three counties were considered high volume (with at least 50 patients per site) and two counties were predominately rural (target 10 patients per site). Findings from this study matched much of the information gleaned from the aforementioned research conducted in this project.

- Most patients had positive perceptions and preferred eDOT over in-person DOT
- Most patients would recommend eDOT for other TB patients
- It was more convenient and flexible for patients
- The TB Control Programs benefited from reductions in travel and mileage
- It was a more efficient use of staff time

The disadvantages seen in this study were also similar:

- Occasional technical issues with the eDOT software or network connectivity
- There is no reimbursement by Medicaid
- Concerns over monitoring adverse reactions
- Challenges when dealing with older/more severely ill/non-English speaking patients

DISCUSSION & RECOMMENDATIONS

From the foregoing information gathered, several conclusions can be reached:

- While published research on the use of eDOT to treat TB is limited, a number of public health departments in California and across the nation have utilized it, with many seeing positive benefits in medication adherence, cost effectiveness, staff safety, and flexibility for patients.
- While eDOT has shown some benefits, public health departments still see potential barriers to utilization. There are concerns around connectivity and equipment failures, identification of side effects to the medication, privacy and security issues, and reimbursement.
- Public health programs also have identified the lack of best practice guidelines to eDOT as an inhibiting factor to its ubiquitous use.
- The lack of best practice guidelines, published research and reimbursement highlights that there appears to be a lack of policy around eDOT on any level. In CCHP's research, the only specific eDOT related policy or guidance found is the recently updated eDOT CDPH and CTCA joint guidelines that were only updated due to the CHCF funded CCHP and UCSD projects. The CDC lacks any telehealth related policy in their DOT guidelines/materials.

Given the lack of policy directly related to eDOT to treat TB and the small number of published studies, the actual number of programs that public health departments have run as gleaned from the two surveys was surprising. It's not lack of knowledge regarding telehealth that may be impeding the technology to be utilized, but other factors that surround it.

Equally interesting to note were the varied reasons for not having an eDOT program or what is felt as a barrier to having one. Reimbursement and privacy concerns were barriers that CCHP thought would be cited. However, on the national survey, the lack of guidelines also ranked highly as a barrier, showing that while the will to use the technology may be there, the tools to do so may not currently exist.

The foregoing information show that there is enormous potential in utilizing telehealth technologies to deliver DOT to TB patients, and potentially used in treating other infectious diseases. However, a lack of cohesive policies, guidelines and training and lingering concerns continue to impede a more pervasive utilization of the technology. At the moment, there is no existing law or regulation that ***prohibits*** eDOT from being used to treat TB on either the state or federal level. However there is nothing that ***encourages*** it either and the lack of specific policy, such as reimbursement for eDOT, acts as a deterrent in using it. CCHP offers the following series of recommendations to address these gaps:

National & State

Update the CDC Guidelines for DOT to include the use of eDOT.

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

Develop guidelines that would address HIPAA and privacy and security concerns when utilizing eDOT.

Health privacy and protection concerns are also policy issues that should be addressed and were raised in one of the LV-DOT studies as well as in the responses to the surveys.[xv] When utilizing either LV-DOT or AV-DOT, a provider must consider health information privacy. Most file these considerations under HIPAA which protects the privacy of an individual's identifiable health information and sets national standards for security of protected electronic health information. HIPAA does include a set of requirements and issues that health departments will need to address such as whether a live video platform being used can meet HIPAA

requirements or whether business agreements will need to be formed with whatever system or tools are used.

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

1. Privacy – which, beyond identifiable health information, also can be about surveillance and tracking
2. Security – how to keep a system secure
3. Confidentiality – the responsibility of agency or provider administering DOT to keep the patient's information confidential

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

Another complication beyond protected health information is the ability to track an individual's whereabouts. Some eDOT applications may allow for a person to be tracked geographically. These issues may raise questions about an individual's privacy rights. Certain steps may need to be taken by a public health department to address the potential for tracking on any equipment it provides to a TB patient enrolled in an eDOT program.

Programs utilizing the technology will need to be mindful of how they structure their programs in order to meet all requirements regarding privacy and security on both a federal and state level. This is especially true should the technology be utilized for other infectious diseases as some, such as HIV, have specific and sometimes more stringent privacy protections, especially on the state level.

More studies should be conducted on the use of eDOT on TB, but also should be focused on the use of eDOT for other infectious diseases and conditions.

While some studies on using eDOT to treat TB exist, a large, comprehensive study may provide the needed assurance to other public health departments not using or contemplating using the technology. Such a study should be supported by the CDC to ensure any concerns regarding the use of eDOT are addressed. However, more importantly, there should be further research studies on the use of eDOT technology in treating other infectious diseases such as Hepatitis C and HIV. The literature scan showed much less evidence regarding treating other conditions,

though what studies were found indicated potential.

California Specific Issues

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

Medi-Cal should expand the list of eligible providers for reimbursement.

AB 415, the Telehealth Advancement Act of 2011, made all licensed health care providers under Division 2 of the California Business & Professions Code an eligible telehealth provider, though it did not mandate a payer to reimburse all of these providers. Medi-Cal has noted in its policies that it would only reimburse specifically named provider categories delivering services via telehealth. Community health workers, who are listed in the Medi-Cal provider manual as being eligible to perform DOT duties and be reimbursed, are not specifically listed as an eligible provider for telehealth. To reimburse for eDOT in Medi-Cal, the eligible provider list for telehealth would need to be modified accordingly.

Medi-Cal should expand the list of eligible locations for reimbursement.

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

Medi-Cal and other payers should reimburse for eDOT.

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

Medi-Cal will only reimburse for asynchronous services in teledermatology, teleophthalmology, teledentistry, and a narrow set of services for teleoptometry as required explicitly in California law. While DHCS has the administrative capability to expand what types of services it will reimburse if delivered via asynchronous technology, DHCS has not expanded its billing codes to

include other specialties. A change will need to be made, perhaps on a legislative level as was done with teledentistry in 2014, if AV-DOT is to be reimbursed.

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

CONCLUSION

While eDOT shows much promise in addressing what may be a concerning upward trend in TB cases in the United States, use of the technology continues to lag. Coupled with tightened resources for public health departments, should TB cases rise, the country could face a potentially worrisome situation.

As no statutory restriction prohibits the use of telehealth to deliver DOT in California or prevents the reimbursement for it by a public or private payer, much of the needed policy change to standardize the use and allow reimbursement for AV-DOT and LV-DOT may be accomplished through administrative action. One potential pathway for accomplishing this may be through the work of CTCA and the recently released joint guidelines with CDPH on the use of eDOT. This standardization of delivery of DOT using telehealth could ultimately lead to the decision to allow Medi-Cal reimbursement for DOT delivered through virtual means.

The study from CCHP has shown that the will to use virtual technology for DOT is there, but the current policy and reimbursement environment and lack of useful guidelines for public health departments for eDOT use impedes the adaptation. If such policy changes are not made and resources such as guidelines promoting best practices unavailable, public health departments will find themselves lagging behind in adopting available technology that could help them work more efficiently, and more effectively serve the public. Should infectious disease cases like TB continue to rise, public health departments may find themselves dropping further and further behind in being able to adequately respond to control the spread.

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

[ii] Ibid.

[iii] California Department of Public Health, "Report on tuberculosis in California, 2013", Sacramento, CA, August 2014, p. 2.

[iv] Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, "Leveling of Tuberculosis Incidence – United States, 2013-2015". < http://www.cdc.gov/mmwr/volumes/65/wr/mm6511a2.htm> (Accessed July 14, 2016).

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

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

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

[viii] World Health Organization, Tuberculosis webpage, < http://www.who.int/trade/glossary/story092/en/>, (Accessed February 27, 2015).

[ix] Centers for Disease Control and Prevention, "Treatment of Tuberculosis", < http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm> (June 20, 2003).

[x] US Department of Health and Human Services & Centers for Disease Control and Prevention, *Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws*, <http://tbcontrollers.org/docs/TBLawResources/TBLawMenu1014.pdf> (Accessed February 27, 2015).

[xi] California Department of Public Health & California Tuberculosis Controllers Association Joint Guidelines, "Guidelines for Electronic Directly Observed Therapy (eDOT) Program Protocols in California," < http://ctca.org/filelibrary/CDPH_CTCA%20eDOT%20Guidelines%20-%20Cleared-%20081116.pdf> (Accessed September 6, 2016).

[xii] New York State Department of Health, Office of Health Insurance Programs, "Guidelines for the Provision of Tuberculosis Directly Observed Therapy", < https://www.health.ny.gov/health_care/medicaid/redesign/docs/tuberculosis_therapy.pdf > (Accessed March 27, 2015).

[xiii] Ibid.

[xiv] California Department of Health Care Services, "Medi-Cal provider manual, TB related services," page 2 (May 2007).

[xv] Wade, V, Karnon, J., Eliott, J., Hiller, J., "Home Videophones Improve Direct Observation in Tuberculosis Treatment: A Mixed Methods Evaluation," *PloS one 7*(11):1-13 e50155 (2012).

[xvi] California Department of Health Care Services, "Medicaid Provider Manual, Telehealth," p. 1. (Dec. 2013)

Appendix A: CTCA Survey Results

Q: Please check the category that best describes your professional role?	Response Percent	Response Count
Clinician (physician, nurse, respiratory therapist)	80.4%	41
Administrator/manager	9.8%	5
Outreach worker	2.0%	1
Researcher	5.9%	3
Educator	2.0%	1
Other (please specify)		9
answered question		51
skipped question		5

Other (unedited)

1. nurse
2. Public health nurse manager-TB case management
3. Communicable disease expert
4. Nurse supervisor for TB clinic
5. Contract worker
6. Contract worker
7. CDC—Public health advisor
8. County TB Controller
9. Epidemiologist

Q: Please check the category that best describes the type of organization that you work for?	Response Percent	Response Count
Public health agency	94.1%	48
Medical clinic or hospital	0.0%	0
Academic institution	3.9%	2
Federal or state payer of health coverage (e.g., Medi-Cal)	0.0%	0
Private health insurance company	2.0%	1
Other (please specify)		7
answered question		51
skipped question		5

Other (unedited)

1. Prison
2. Self-employed
3. County P.H. agency
4. prison
5. non-profit
6. Correctional Health Care Services
7. State

Q: How familiar are you with VDOT?	Response Percent	Response Count
Never heard of it before today	3.6%	2
Heard of it, but never observed it in use	42.9%	24
Observed it in use, but never used it myself	26.8%	15
Used VDOT in practice	26.8%	15
answered question		56
skipped question		0

Q: What type of VDOT have you used?	Response Percent	Response Count
Asynchronous (recorded)	33.3%	5
Synchronous (live videoconference)	40.0%	6
Both asynchronous and synchronous	26.7%	4
answered question		15
skipped question		41

Q: How long have you used VDOT?	Response Percent	Response Count
Less than 3 months	20.0%	3
Between 3 and 6 months	6.7%	1
More than 6 months	73.3%	11
answered question		15
skipped question		41

Q: Based on your experience or perceptions, please indicate your level of concern about asynchronous VDOT regarding each item below by placing an "X" in one column for each row.	No Concern	Minimal Concern	Moderate Concern	Major Concern	Not Sure	Response Count
HIPAA compliance/security	5	17	19	10	2	53
Reimbursement	4	9	25	12	3	53
Staff acceptance	15	22	15	1	0	53
Patient's ability to perform VDOT	5	24	19	5	0	53
Patient's concerns about confidentiality	3	26	17	7	0	53
Medication adherence	8	24	13	7	0	52
Managing side effects	3	18	16	14	1	52

Connectivity problems	1	16	25	9	2	53
Equipment problems	0	18	27	6	2	53
Workload increases	12	33	7	0	1	53
Staff layoffs	19	22	6	3	3	53
Training staff	10	23	19	0	0	52
Training patients	6	23	21	3	0	53
Start-up costs	5	13	23	10	1	52
Legal issues	5	14	24	7	2	52
Lack of data on the efficacy of VDOT	6	33	11	3	0	53
Other (please specify)						11
					answered question	53
					skipped question	3

Other (unedited)

1. County is against any technology because of HIPAA security
2. Assurance that patient also swallows pills (no 'pocketing')
3. Sustaining/expanding program costs.
4. Tool to help determine which patients are best for VDOT
5. Prisons use F2F DOT
6. Legal/confident it's stored on a secure cloud
7. Our county does not have mobile phone access in certain areas, and for patients they often have mobile phone access on a sporadic basis (pay as you go). Also, storage of videos 'on cloud' is likely not acceptable to our board of supervisors. But if secure something like FaceTime may be.
8. Large rural area
9. Physician concerns that could stop progress
10. N/A: We don't use asynchronous VDOT and have no plans to.
11. Consent form has language that indicates pt. log and paper documentation will be destroyed; go no language concerning destruction of videos---concern about violating HIPAA or patient information.

Q: Based on your experience or perceptions, please indicate the level of benefit from asynchronous VDOT for each item below by placing an "X" in one column for each row.	**No Benefit**	**Minimal Benefit**	**Moderate Benefit**	**Major Benefit**	**Not Sure**	**Response Count**
Cost effectiveness	0	3	16	28	5	52
Patient satisfaction	0	3	17	31	1	52
Staff satisfaction	0	3	22	22	5	52
Staff safety	0	6	15	28	2	51
Improved medication adherence	2	7	20	18	4	51

Managing side effects	10	22	7	8	5	52
Other (please specify)						1
					answered question	52
					skipped question	4

Other (unedited)

- Real time (live streaming) accountability of patient adherence

Q: Based on your experience or perceptions, please indicate your level of concern about synchronous VDOT regarding each item below by placing an "X" in one column for each row.	**No Concern**	**Minimal Concern**	**Moderate Concern**	**Major Concern**	**Not Sure**	**Response Count**
HIPAA compliance/security	5	15	20	10	1	51
Reimbursement	6	13	20	10	2	51
Staff acceptance	11	27	10	2	1	51
Patient's ability to perform VDOT	5	28	15	3	0	51
Patient's concerns about confidentiality	3	27	14	7	0	51
Medication adherence	8	30	6	7	0	51
Managing side effects	4	21	16	9	0	50
Connectivity problems	1	13	24	11	1	50
Equipment problems	2	18	21	9	1	51
Workload increases	16	30	4	0	1	51
Staff layoffs	21	16	6	4	4	51
Training staff	9	29	13	0	0	51
Training patients	7	20	22	2	0	51
Start-up costs	4	16	23	6	2	51
Legal issues	3	18	19	7	4	51
Lack of data on the efficacy of VDOT	5	33	8	4	1	51
Other (please specify)						1
					answered question	51
					skipped question	5

Other (unedited)

- Same issues as recorded VDOT (no 'pocketing' pills)

Q: Based on your experience or perceptions, please indicate	**No Benefit**	**Minimal Benefit**	**Moderate Benefit**	**Major Benefit**	**Not Sure**	**Response Count**

the level of benefit from synchronous VDOT for each item below by placing an "X" in one column for each row.						
Cost effectiveness*	**0**	**1**	**14**	**31**	**5**	**51**
Patient satisfaction	0	2	17	30	2	51
Staff satisfaction	0	3	23	22	3	51
Staff safety	0	7	15	26	2	50
Improved medication adherence	1	8	17	20	5	51
Managing side effects	3	18	15	10	5	51
Other (please specify)						1
					answered question	51
					skipped question	5

Other (unedited)

- We have several TB patients who are very busy college students and they love VDOT!

Q: Please rate your interest level in implementing or expanding a VDOT program.	**Response Percent**	**Response Count**
No interest	3.6%	2
Minimal interest	5.5%	3
Moderate interest	21.8%	12
High interest	69.1%	38
	answered question	55
	skipped question	1

Q: If interested in starting or expanding a VDOT program, which type is of most interest to you?	**Response Percent**	**Response Count**
Asynchronous	9.4%	5
Synchronous	18.9%	10
Both asynchronous and synchronous	60.4%	32
Not sure	11.3%	6
	answered question	53
	skipped question	3

Q: In addition to TB, what other infectious diseases or health issues do you think VDOT could be used for to improve disease management?	**Response Percent**	**Response Count**
HIV patients on antiretroviral therapy	73.5%	36
Ebola	38.8%	19

Substance abuse	26.5%	13
Hepatitis B	24.5%	12
Hepatitis C	44.9%	22
Mental health problems	38.8%	19
Other (please specify)		11
answered question		49
skipped question		7

Other (unedited)

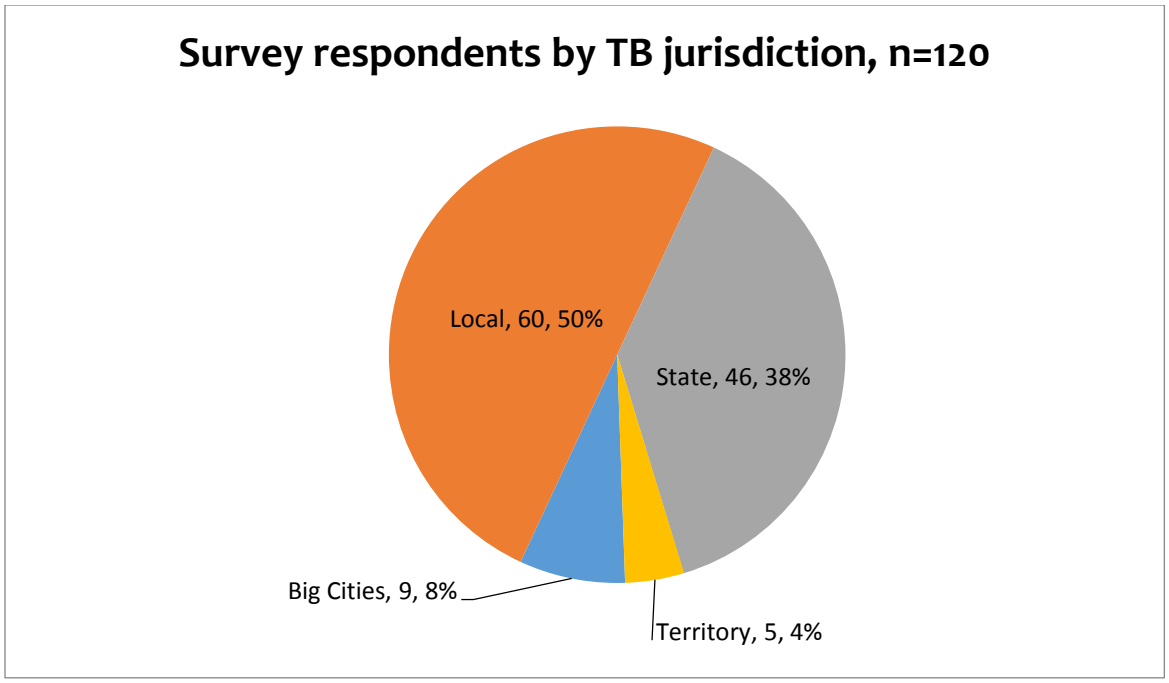
1. Probably any
2. Diabetes management
3. CD
4. Diabetes, malignant hypertension, congestive heart failure, COPD, asthma, any chronic D3
5. Multiple resistance HIV with a history of a lack of adherence to meds.
6. Diabetes management and treatment
7. If cheap and an app for phone could be used for STD treatment (if it isn't a single dose)
8. Due to patient confidentiality issues/patient perceptions I think only some mental health patients in our practice would be interested.
9. N/A
10. Travelers to Ebola affected countries
11. Hep B and Hep C only if on antiviral treatment; measles quarantine

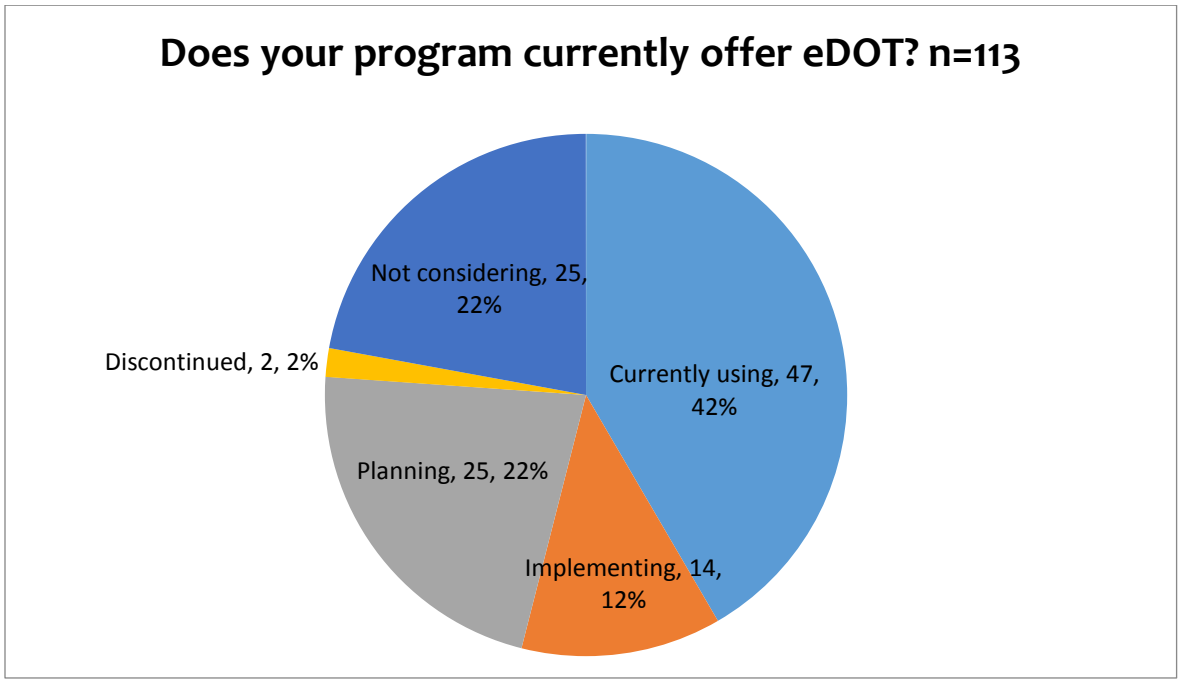
	Asynchronous		**Synchronous**	
	No Concern or Minimal Concern	Moderate or Major Concern	No Concern or Minimal Concern	Moderate or Major Concern
HIPAA compliance/security	43% (n=22)	57% (n=29)	40% (n=20)	60% (n=30)
Reimbursement	26% (n=13)	74% (n=37)	39% (n=19)	61% (n=30)
Staff acceptance	70% (n=37)	30%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

Lack of data on the efficacy of VDOT	74% (n=39)	26% (n=14)	76% (n=38)	24% (n=12)

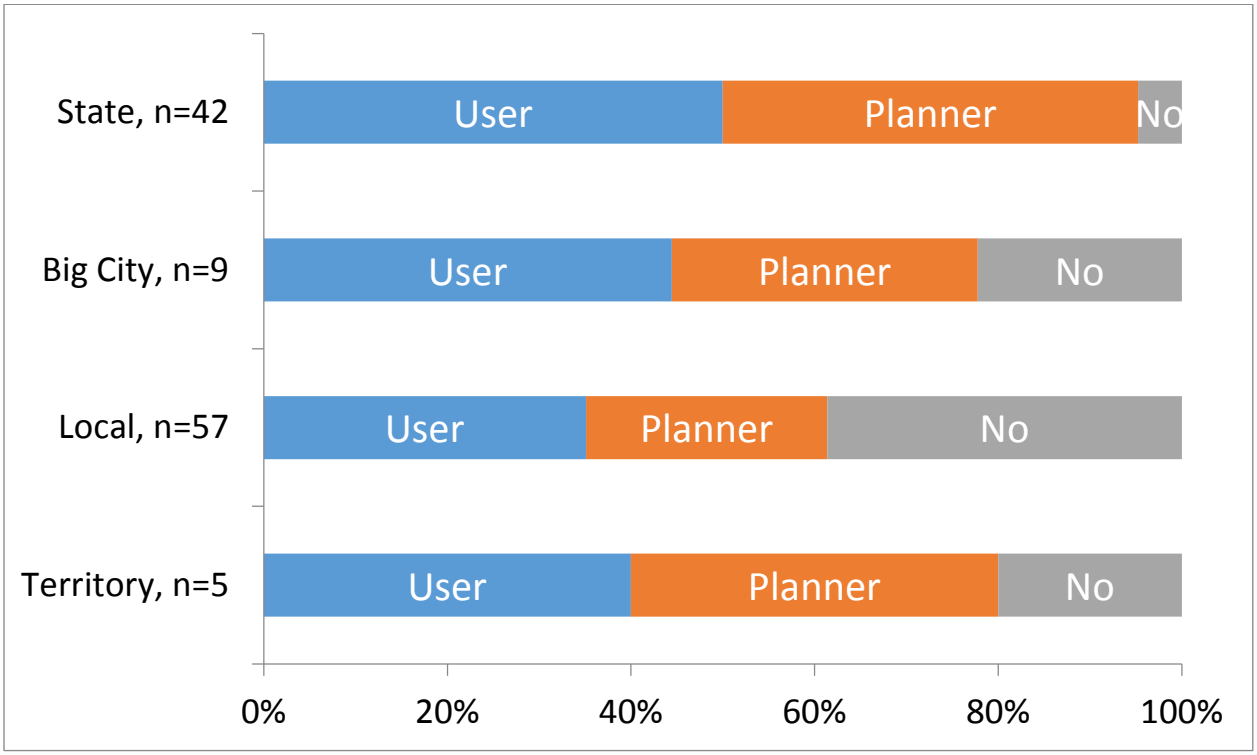
	Asynchronous		**Synchronous**	
	No Benefit or Minimal Benefit	Moderate or Major Benefit	No Concern or Minimal Benefit	Moderate or Major Benefit
Cost effectiveness	6% (n=3)	94% (n=44)	2% (n=1)	98% (n=45)
Patient satisfaction	7% (n=3)	93% (n=38)	4% (n=2)	96% (n=47)
Staff satisfaction	6% (n=3)	94% (n=44)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

Appendix B: NTCA Survey Results

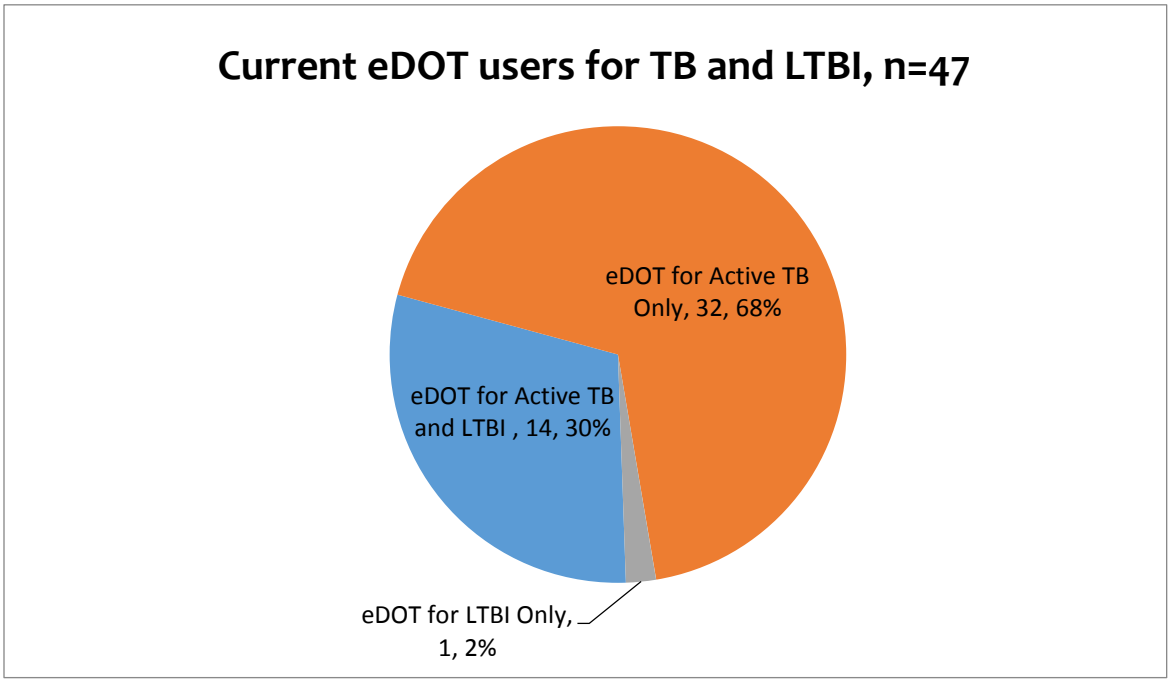

Survey respondents by TB jurisdiction, n=120
Local, 60, 50%
State, 46, 38%
Big Cities, 9, 8%
Territory, 5, 4%

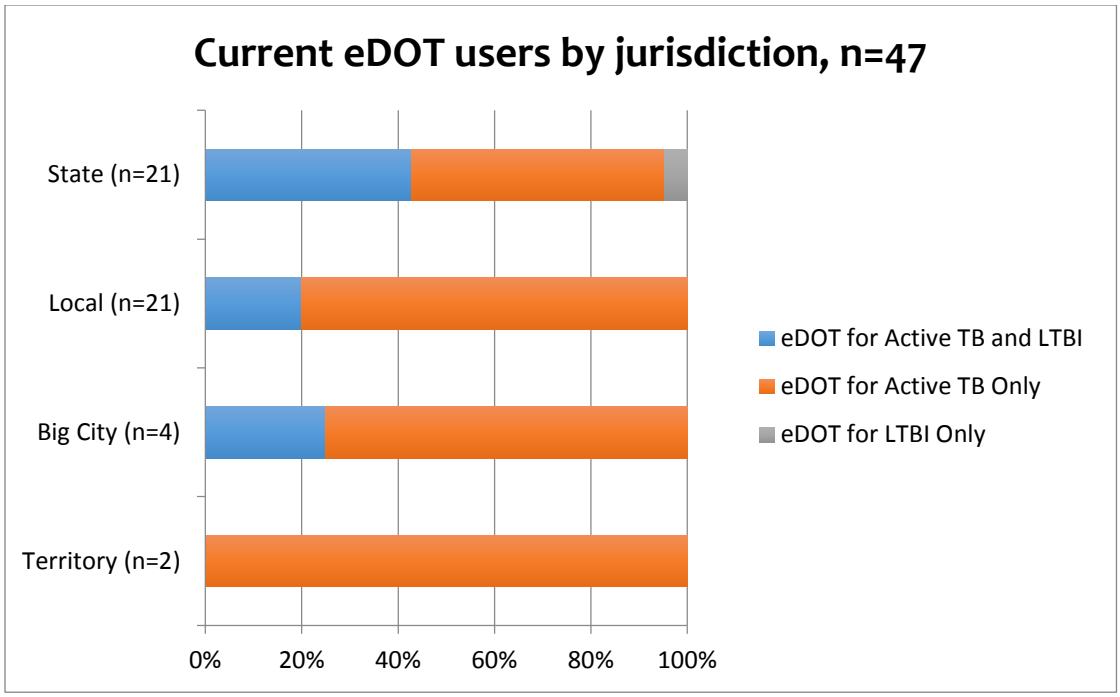

Does your program currently offer eDOT? n=113
Not considering, 25, 22%
Discontinued, 2, 2%
Currently using, 47, 42%
Planning, 25, 22%
Implementing, 14, 12%

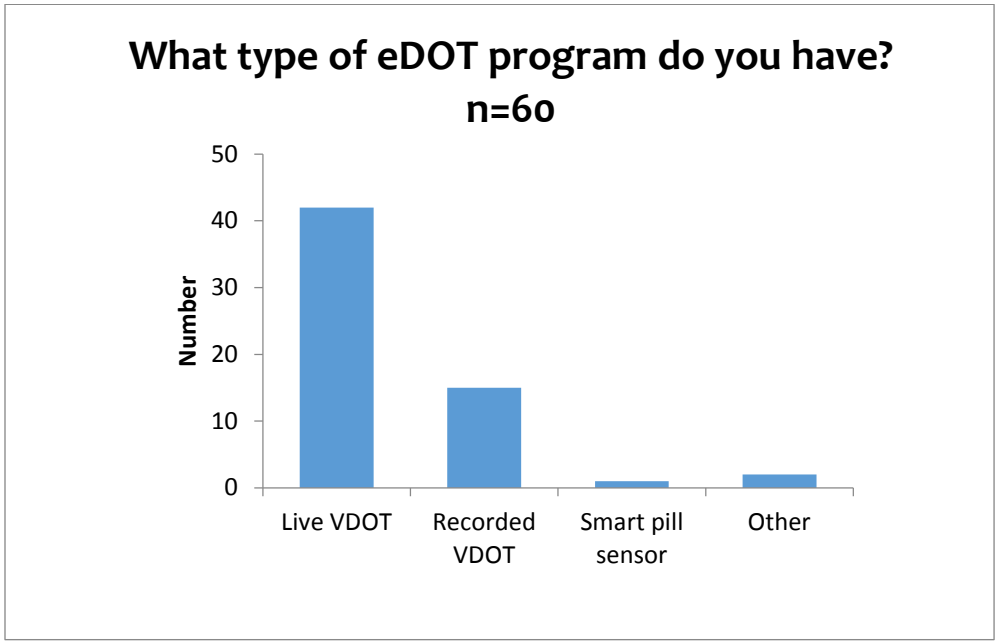
eDOT User, Planner, and Non-User by Jurisdiction. n=113



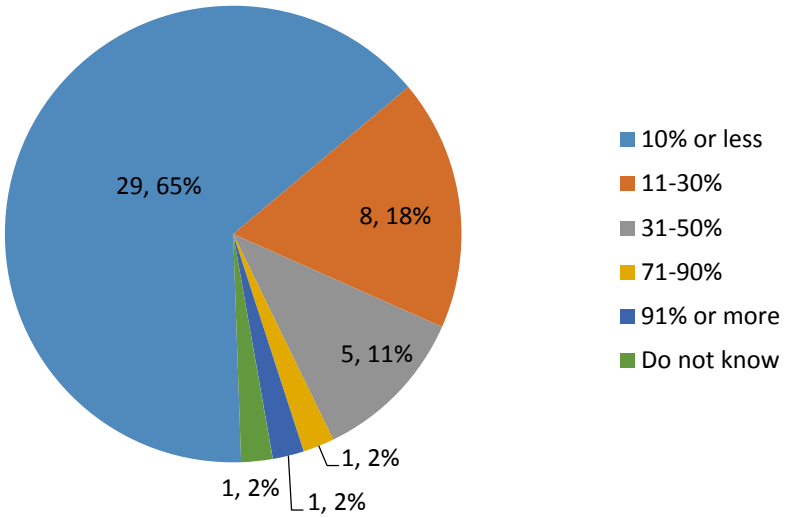
Current eDOT users for TB and LTBI, n=47



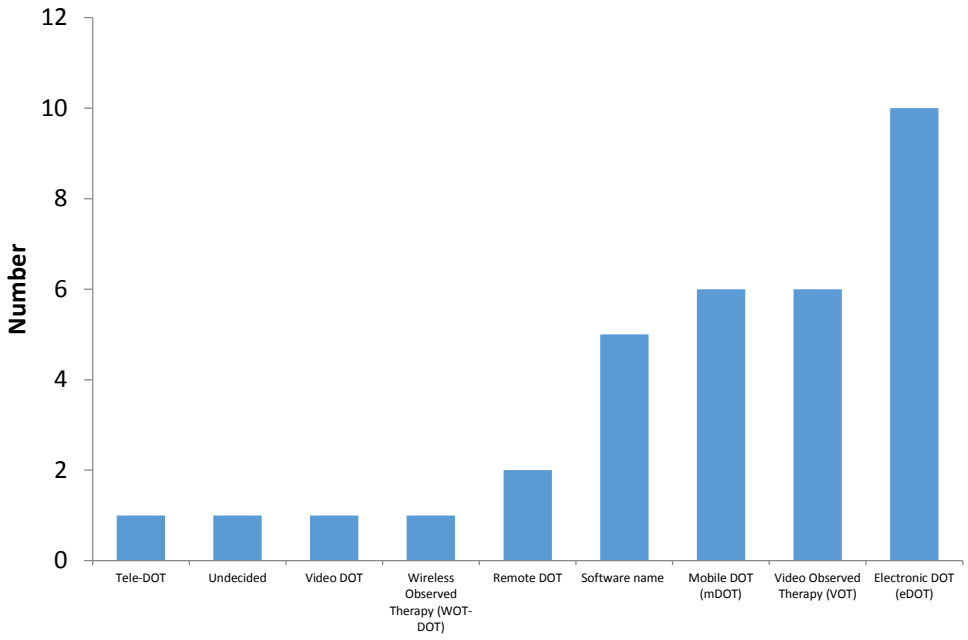

Current eDOT users by jurisdiction, n=47
State (n=21)
Local (n=21)
Big City (n=4)
Territory (n=2)
0%
20%
40%
60%
80%
100%
eDOT for Active TB and LTBI
eDOT for Active TB Only
eDOT for LTBI Only

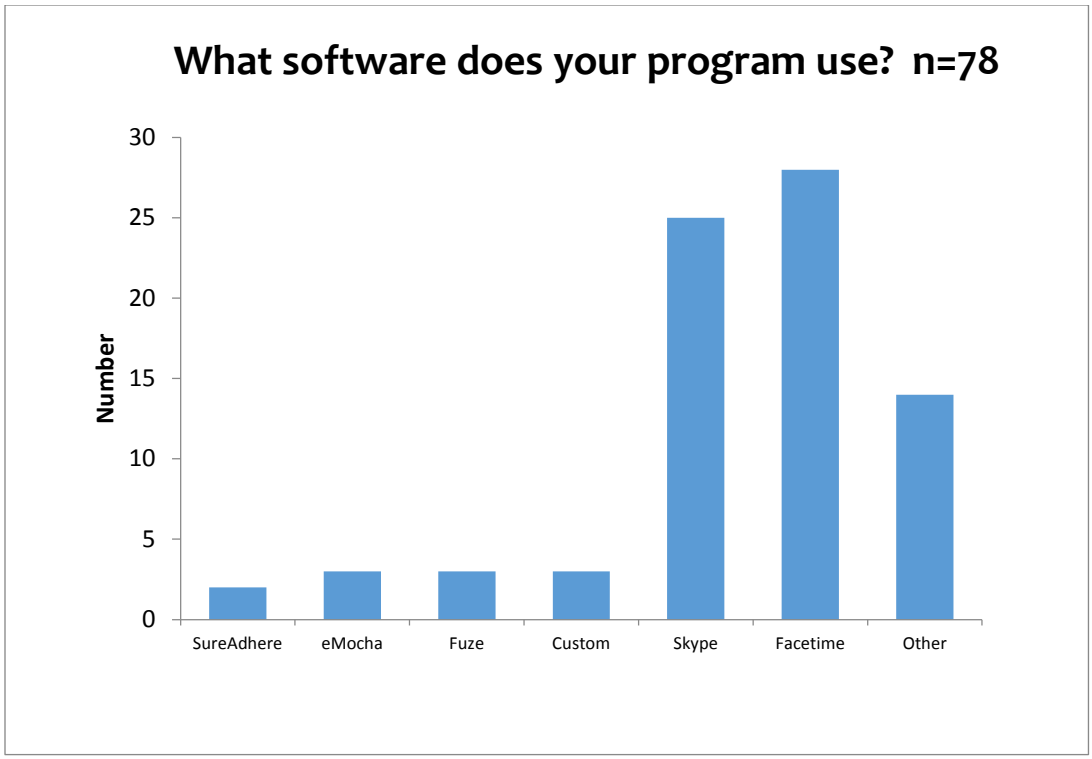

What type of eDOT program do you have?
n=60
Number
50
40
30
20
10
0
Live VDOT
Recorded VDOT
Smart pill sensor
Other

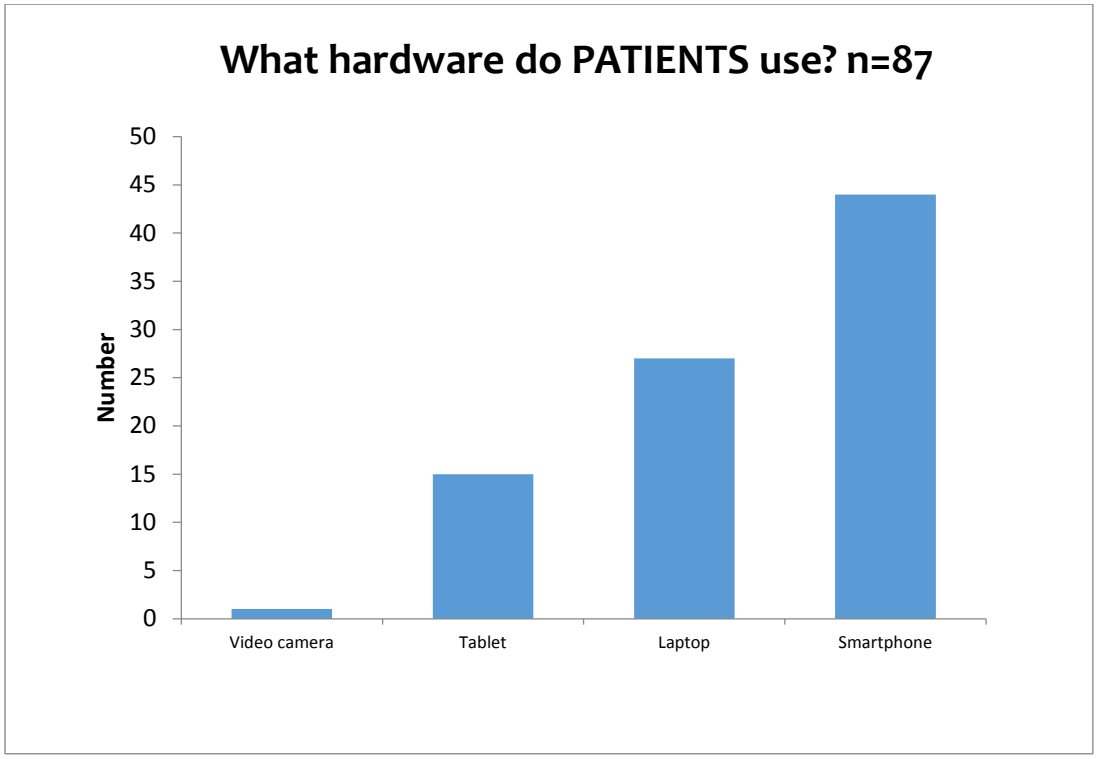
What percentage of your patients are currently on eDOT?, n=45



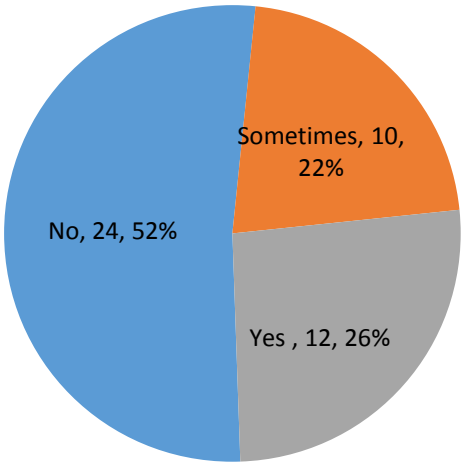
What term for eDOT does your program use? n=41



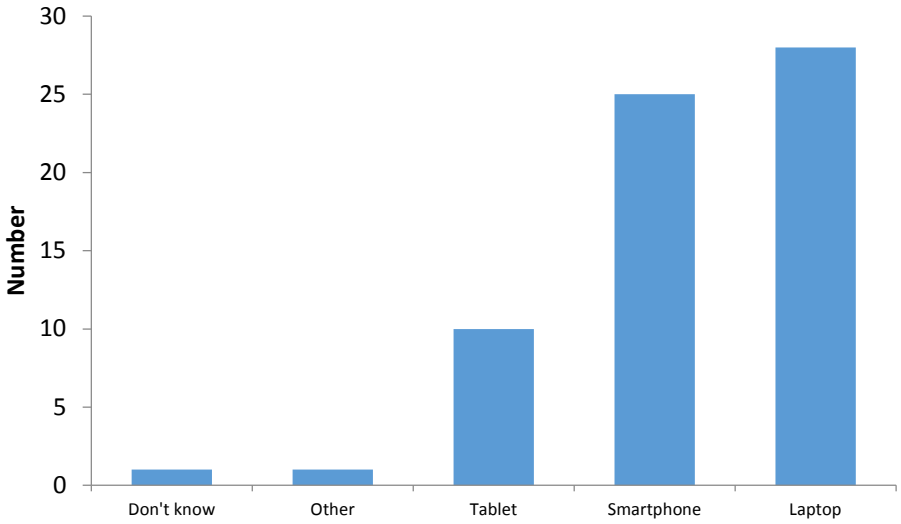

What software does your program use? n=78
Number
30
25
20
15
10
5
0
SureAdhere
eMocha
Fuze
Custom
Skype
Facetime
Other

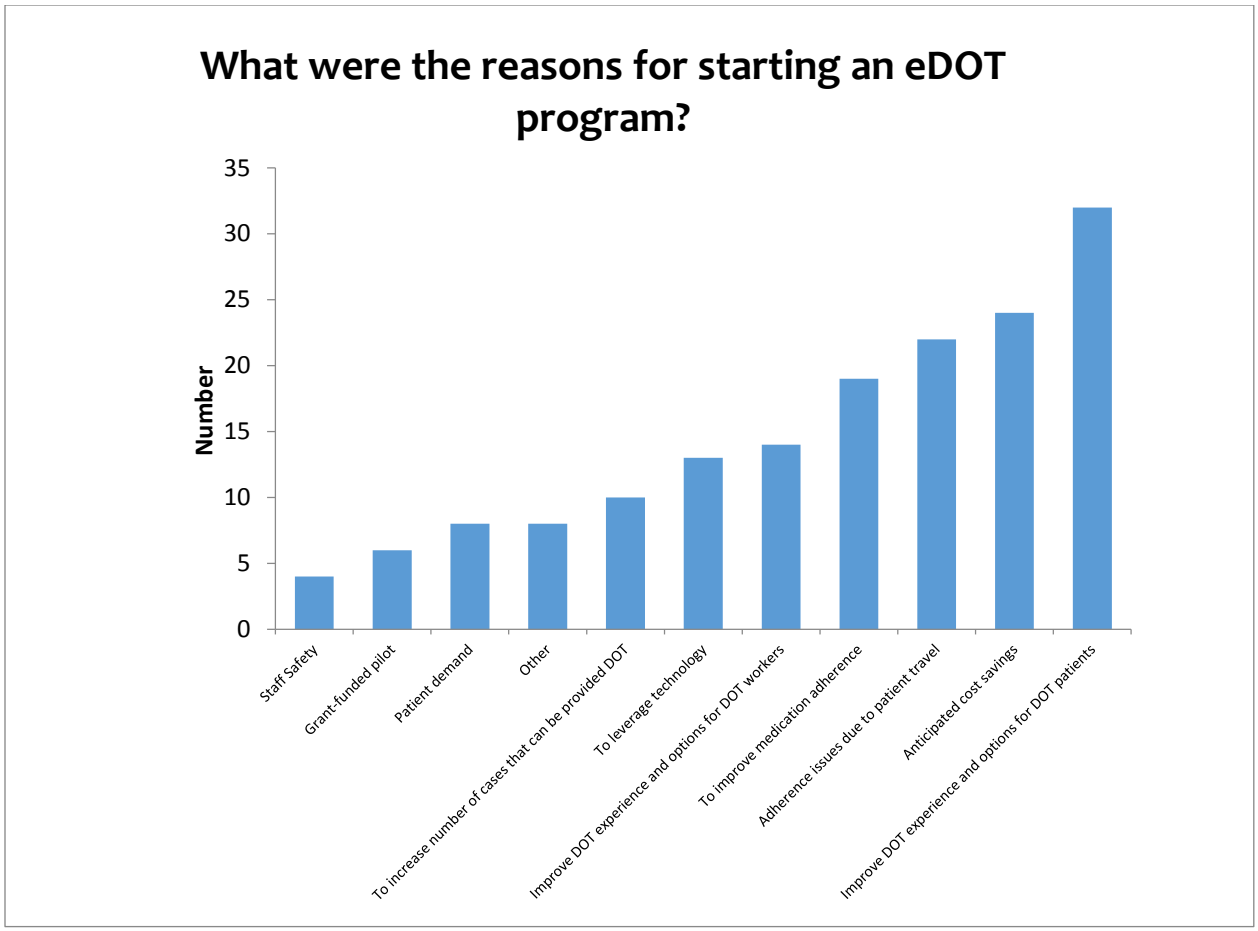

What hardware do PATIENTS use? n=87
Number
50
45
40
35
30
25
20
15
10
5
0
Video camera
Tablet
Laptop
Smartphone

Does your program supply hardware to patients? n=46



What hardware do DOT WORKERS use? n=65





Specify Reasons: Improve for patients (Unedited)

Flexibility for working or student patients
Greater independence and flexibility
Improved timing/access
Increase options to assure DOT done. Extended hours to meet client needs and enabled DOT for
clients who work outside area, are on travel, etc.
Many people work and do not want a nurse coming to their job so eDOT is welcomed
More convenient
More flexibility on when DOT could be completed
More options for patients
Not need to have someone come into thier home every day
Some of our patients have to work and or school and are not available for in person DOT or delivery due to clinic hours e.g. 8:00 to 5:00
This has worked well for patients commuting and/or working non-standard hours
We have college students; it increases the likelihood of compliance and completion.
Weekend DOT
add flexibility for scheduled treatment time
based on work schedule & effects of medications

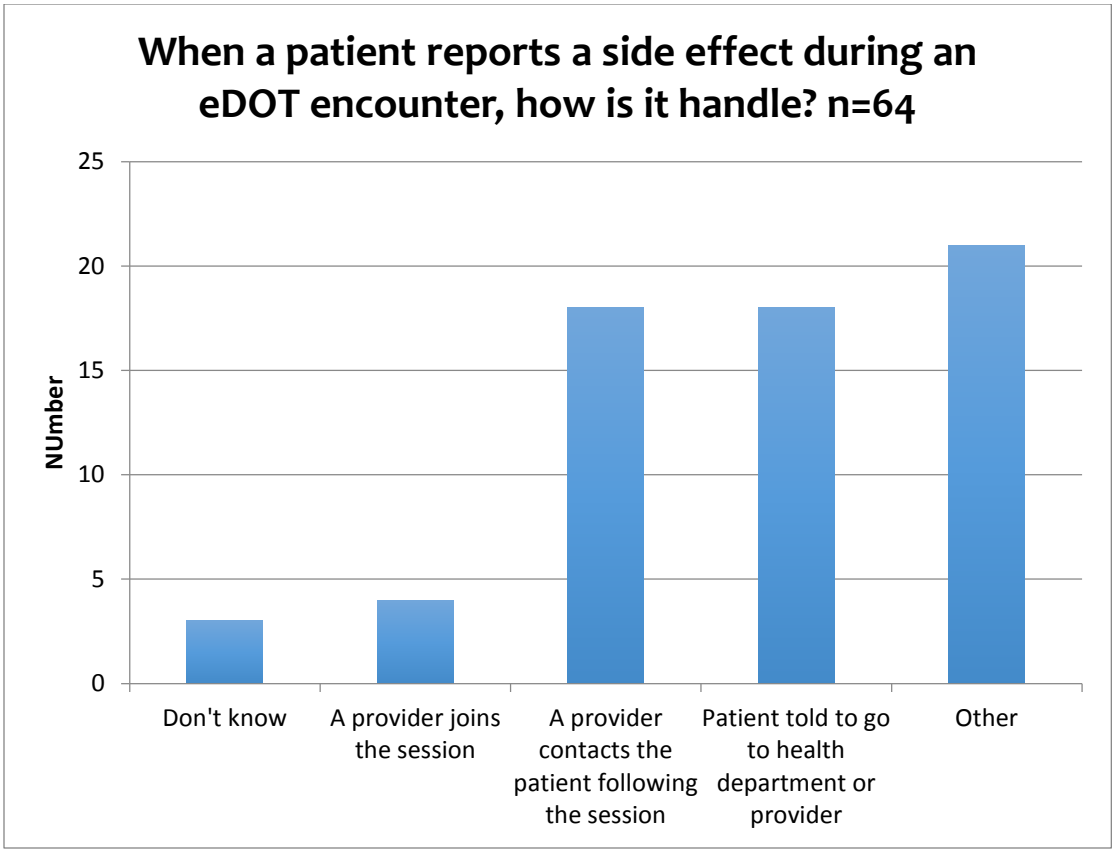
client was a nationwide truck driver; overseas traveler
convenience
good for patients who need early or late DOT
greater flexibility for patients
in rural areas where providers/nurses are rare
increased flexibility and mobility
increased patient convenience, no need to make up doses taken while traveling outside the state
lack of human resources
more convenient and less intrusive
patients not always available to meet in person
patients request
pt that have travel as a requirment for their employement, used as an E/I as well
so patients don't have to come to the PHD for in person DOT
some pts find it difficult to comply w in person DOT due to work or travel
split dosing making it difficult to have DOT coverage
the ability for patients to take treatment outside of business hours
use these avenues for patients when they travel especially over seas

Specify Reasons: Improve for workers (Unedited)

Dealing with schedule conflicts as well as rural access issues
Decreased resources, down a staff member
Helps when patients are in areas where safety of the workers could be an issue
More flexibility on when DOT could be completed; less driving time; less risk from travel to patients' homes
Prevent long drives for providers
Save DOT workers travel time as many are nurses wearing many different hats
allows the nurse to maintain clinic while being able to do DOT or DOPT
client had erratic schedule, easier to do more
dependent upon situation
efficient for staff
less travel
less travel time meaning more productivity per hour
more convenient
short staffed, no time to drive to do DOT in person

Specify Reasons: Staff Safety (Unedited)

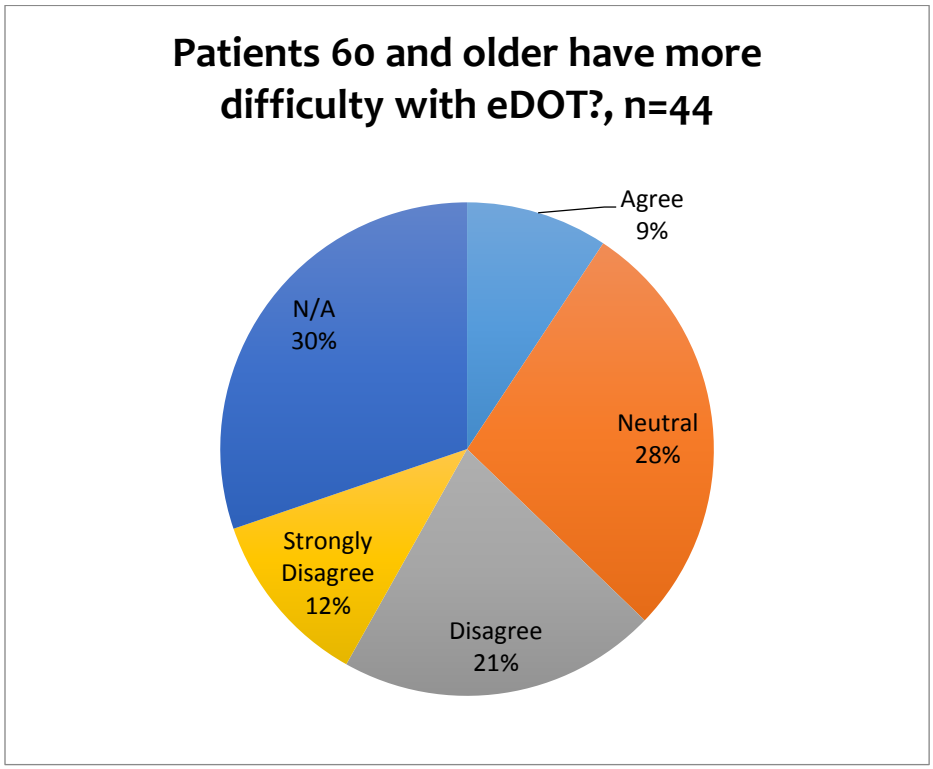
BID doses to patient in a bad neighborhood
Many times have pts that live in an unsafe neighborhood
Reduces risk of injury or accident while traveling or at patients' homes
we have not used for this purpose yet, but would if need perceived



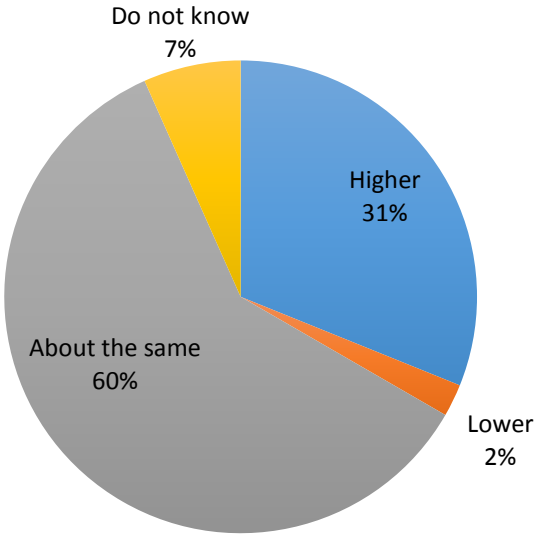
Other (Unedited)

DOT Nurse schedules clinic appt for the patient or refers to ER if it is necessary
Health dept might contact clinician directly
Nurse case manager is contacted and speaks to the patient.
Only MD-Patient vDOT is occuring in PR
PHN makes HV to assess pt
Public Health Nurse doing the DOT will reach out to the patients provider.
RN visits patient if they are unable to go to medical provider for assessment
TB Controller is notified later
The patient is told to return to clinic where a physician will be available and labs obtained.
a nurse is notified if not doing the dot, physician will decide to either give or hold and have them
seen in the clinic the that day or next day
appt is made to see the physician within the week. Advised to come to clinic for labs if necessary.
handled in same manner as when our in-person DOT provider identifies a side-effect. Nurse case
manager is told first and pt assessed either in home or in clinic visit. as needed nurses confer
with clinicians no less frequently than 1/week on all side effects
in person visit done

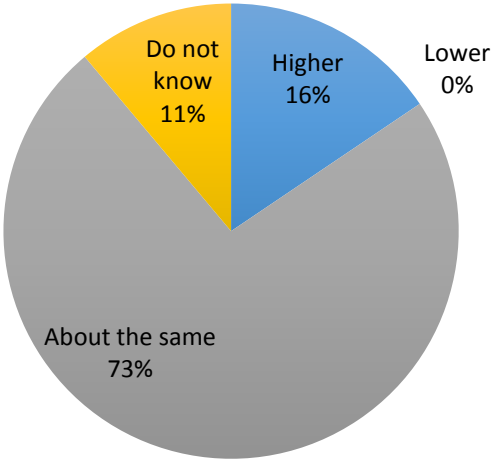
it is documented and reported to physician
n/a
nurse offers patient the option to describe side effect during eDOT encounter or via another means (e.g. telephone call); information is then relayed by the nurse to the treating provider for further assessment
one dose is DOT, the other dose is vDOT so that hasn't been an issue to date
patient comes into clinic for follow-up
patient is told not to take meds or record a video but to call clinic and speak to a nurse
patient maybe referred to local physician or ER
we tell patients not to use edot to report adverse reactions. if they did, their burse would get in touch with them asap

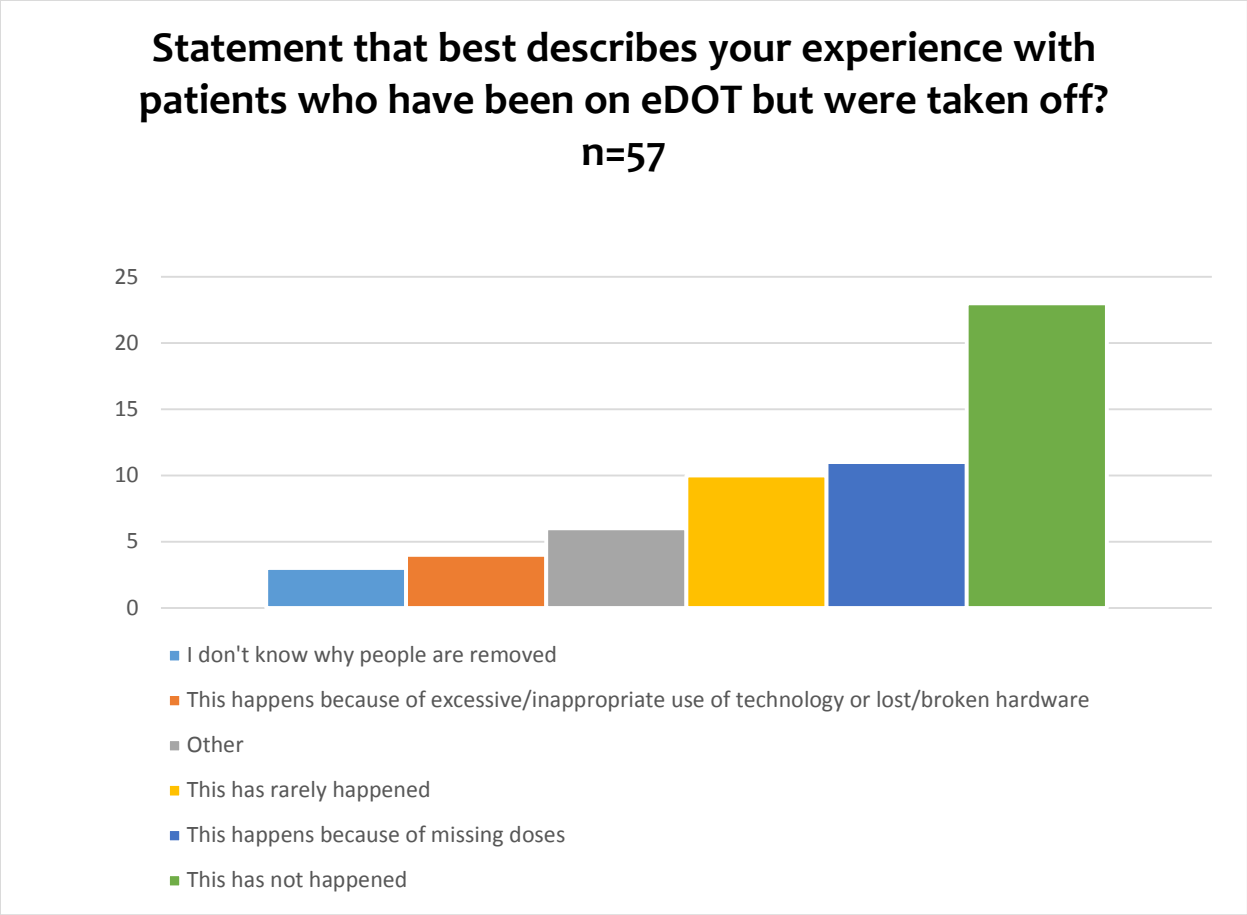


Medication adherence rates are ____ when compared to in-person DOT?, n=45



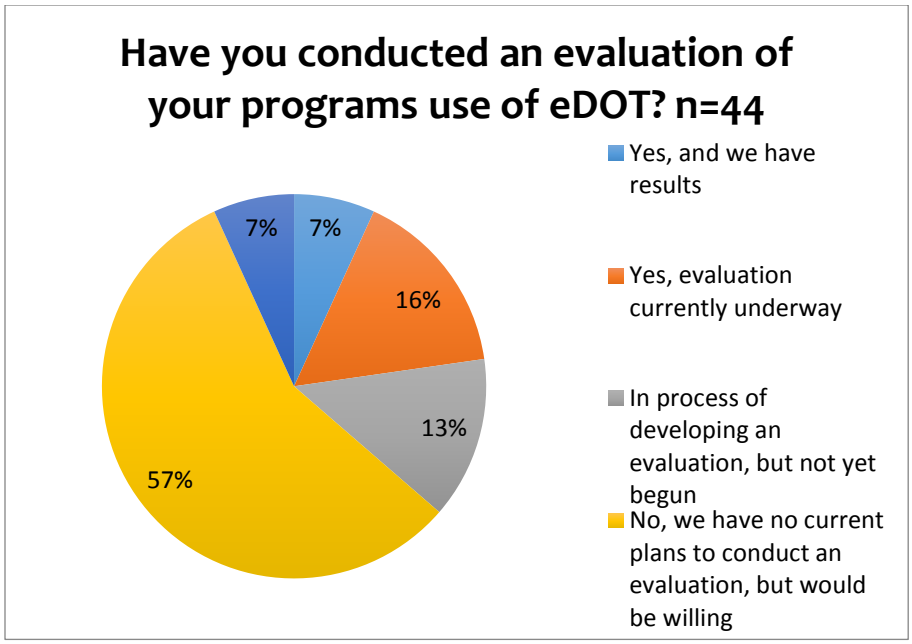
Treatment completion rates are___ when compared to in-person DOT?, n=45

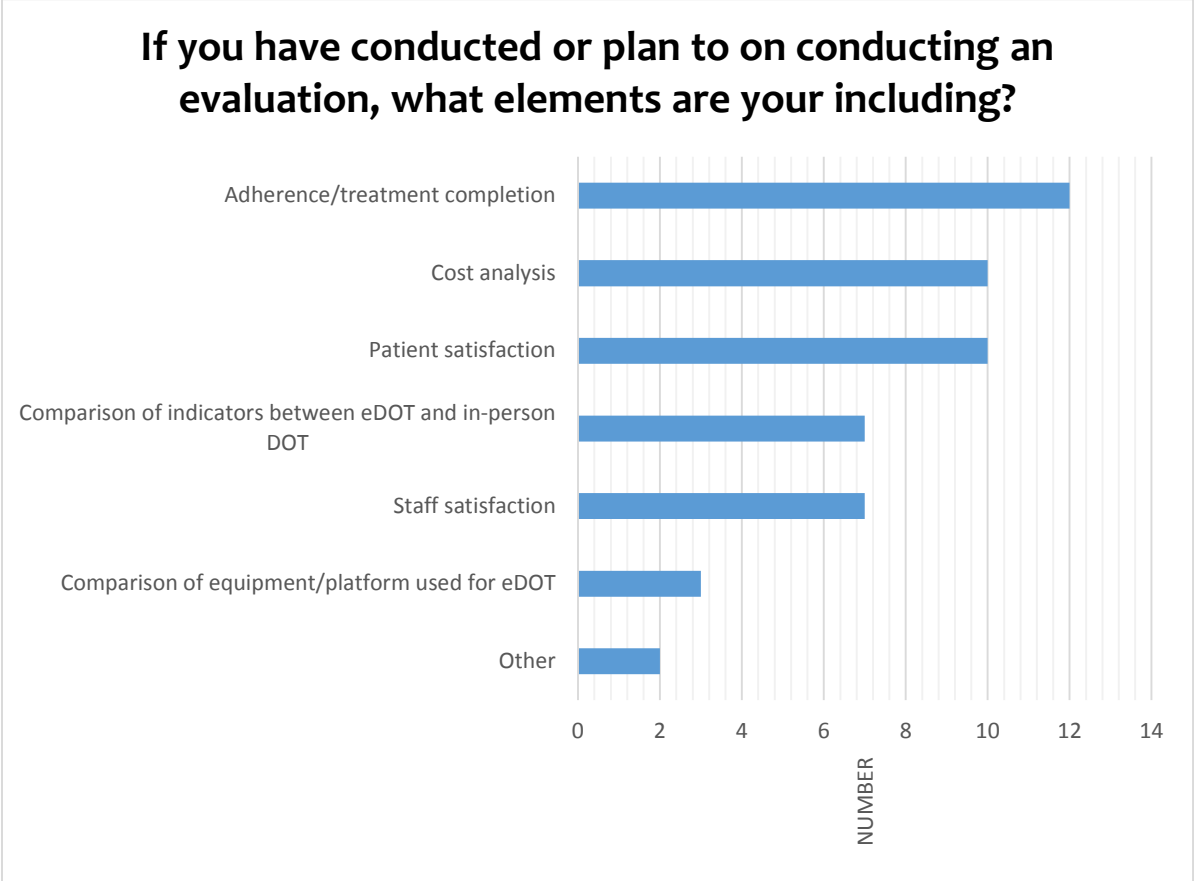


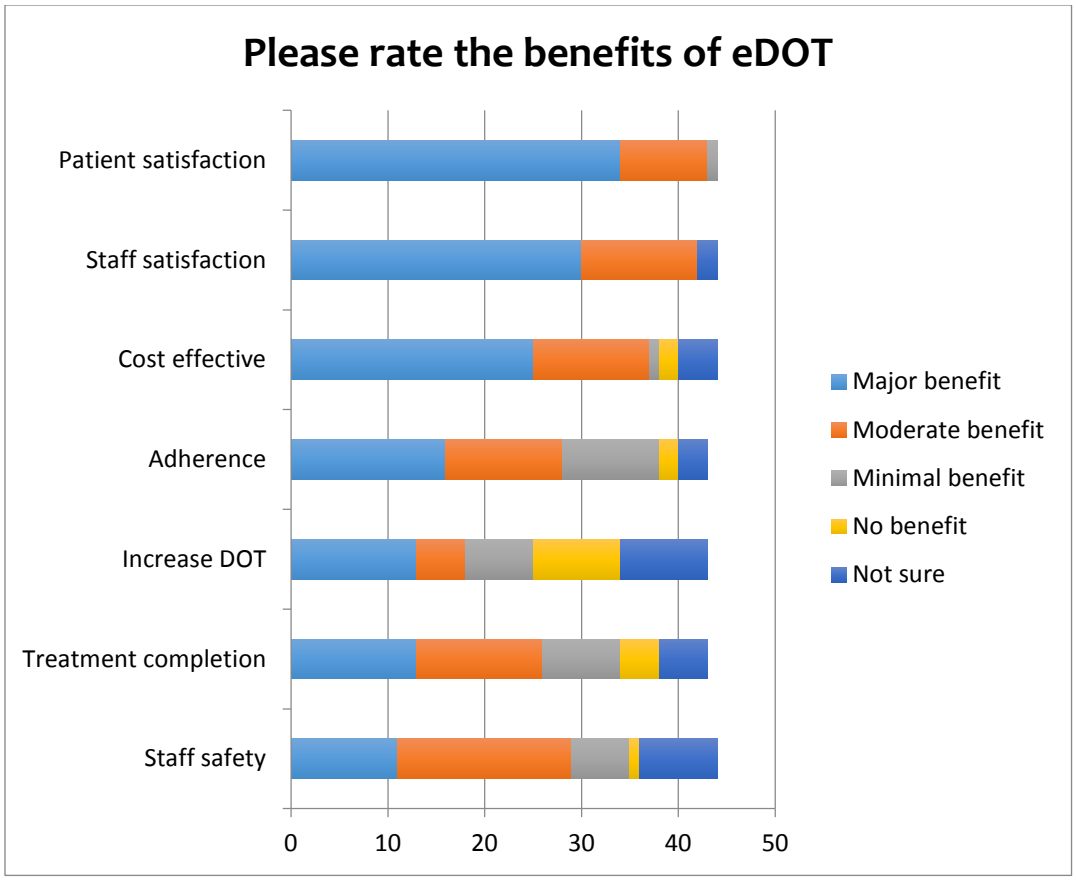


Other (Unedited)

additon of injection to the patient's treatment regimen
alos can happen when pt relapses with drugs/ETOH
changing circumstances (return from travel etc)
taken off eDOT because they moved
technology glitches that made edot frustrating for patient and dot worker
we have just the one case we are doing vDOT to date


Have you conducted an evaluation of your programs use of eDOT? n=44
7%
7%
16%
13%
57%
Yes, and we have results
Yes, evaluation currently underway
In process of developing an evaluation, but not yet begun
No, we have no current plans to conduct an evaluation, but would be willing


If you have conducted or plan to on conducting an evaluation, what elements are your including?
Adherence/treatment completion
Cost analysis
Patient satisfaction
Comparison of indicators between eDOT and in-person DOT
Staff satisfaction
Comparison of equipment/platform used for eDOT
Other
0
2
4
6
8
10
12
14
NUMBER


Please rate the benefits of eDOT
Patient satisfaction
Staff satisfaction
Cost effective
Adherence
Increase DOT
Treatment completion
Staff safety
0
10
20
30
40
50
Major benefit
Moderate benefit
Minimal benefit
No benefit
Not sure

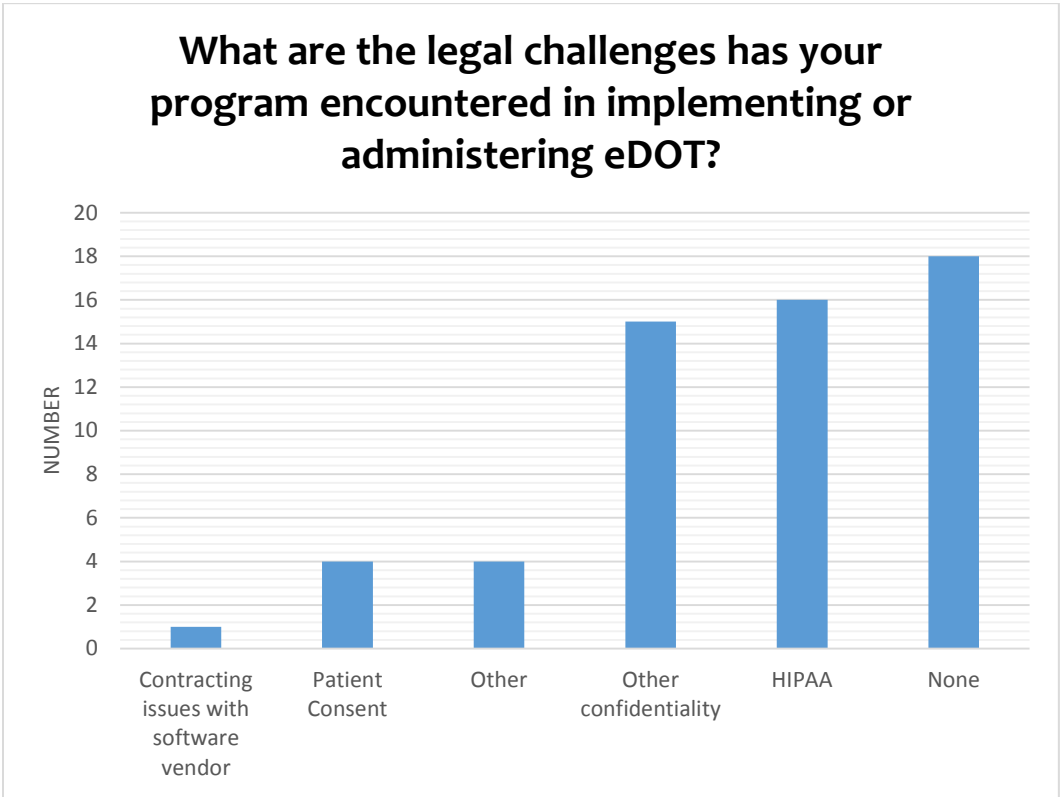

What are the legal challenges has your program encountered in implementing or administering eDOT?
NUMBER
20
18
16
14
12
10
8
6
4
2
0
Contracting issues with software vendor
Patient Consent
Other
Other confidentiality
HIPAA
None

Table 1 Programs Technical Challenges

What technical challenges has your PROGRAM encountered in implementing or administering eDOT? (Unedited)	
Too early to know	2
Software update issues	6
Old/out-dated computers	7
None	7
Inadequate IT support	8
Problems with smartphone/tablet operating systems (e.g., IOS, android)	8
Program's IT policies prevent use of preferred software	11
Lost/cut connections during sessions	12
Other	12
Quality of Internet	22

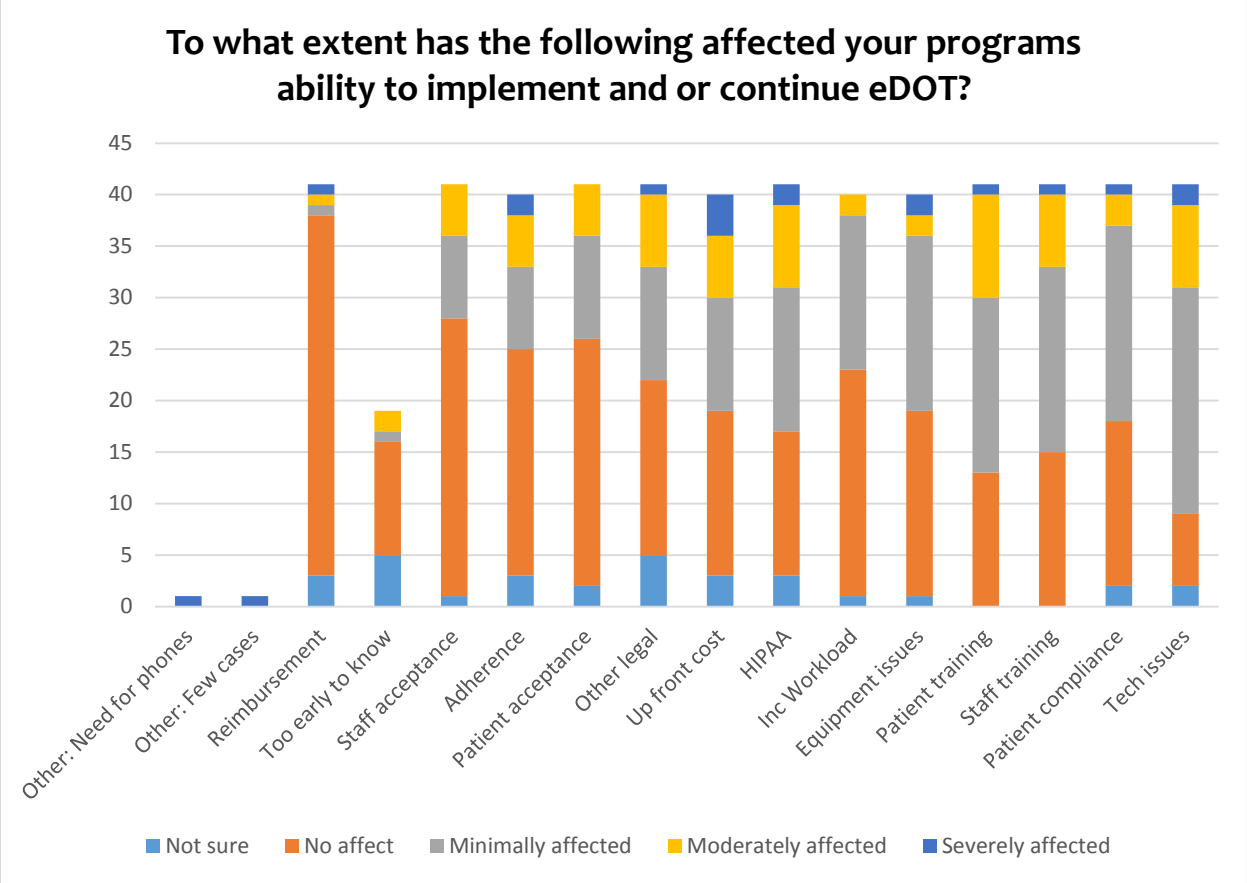
Other (Unedited)
Too early to know
Software update issues
Old/out-dated computers
None
Inadequate IT support
Problems with smartphone/tablet operating systems (e.g., IOS, android)
Program's IT policies prevent use of preferred software
Lost/cut connections during sessions
Other
Quality of Internet

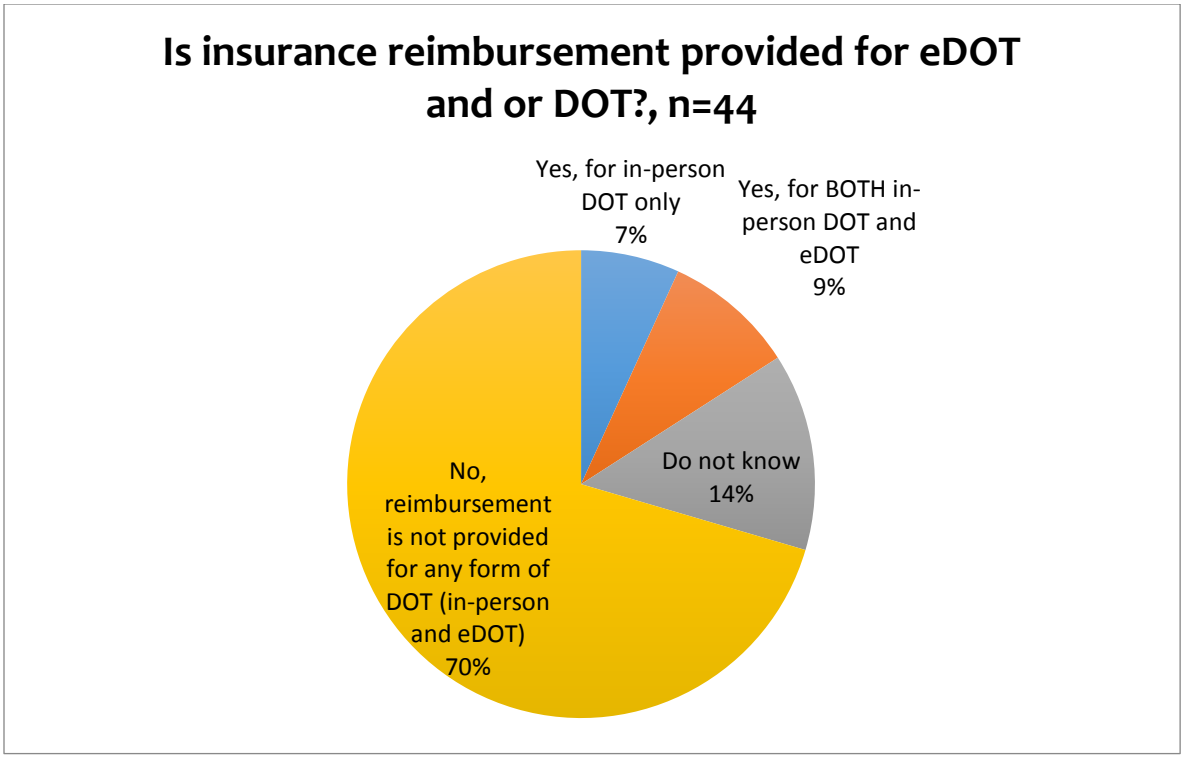
What technical challenges has your PATIENT encountered in implementing or administering eDOT?	
Incompatability between eDOT platform and patient equipment	3
Patients exceeding limits on data plans	3
Software update issues	7
Old/out-dated computers	7

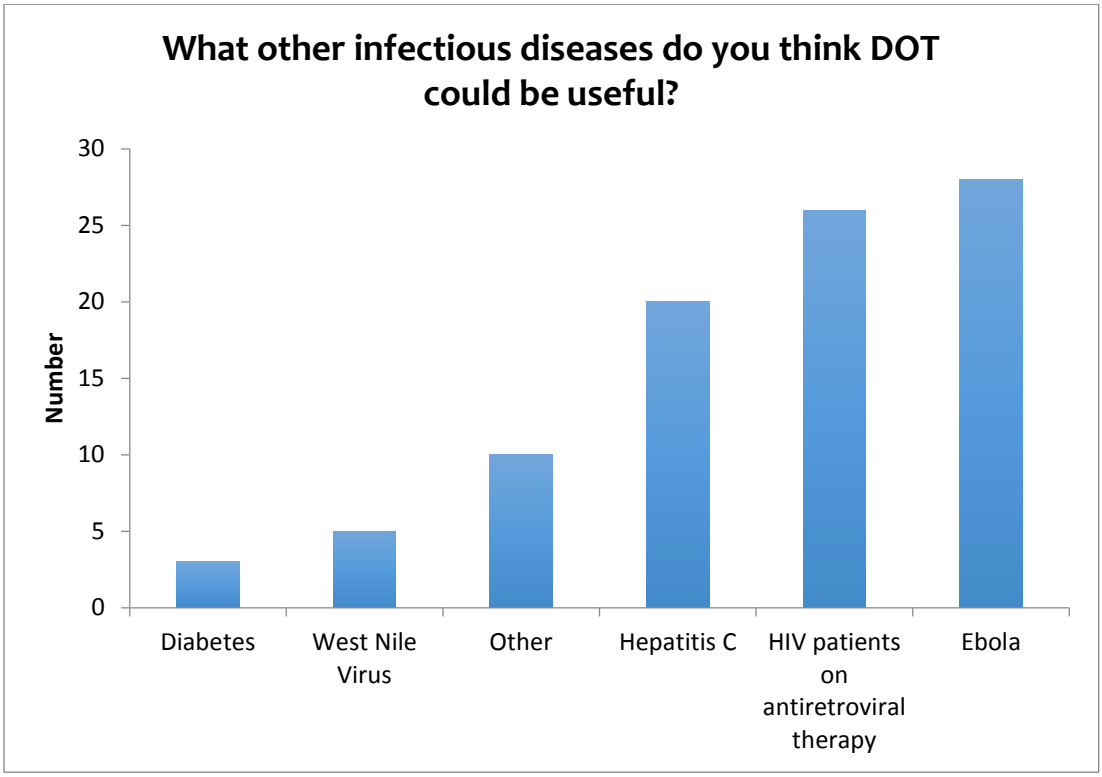
Hardware connectivity	7
Problems with smartphone/tablet operating systems (e.g., IOS, android)	9
Lost/cut connections during eDOT sessions	11
Patients inability to use the technology (lack of training/familiarity/knowledge)	13
Quality of internet	25

Other (Unedited)

Don't have a phone or computer
MD-PT complete a practice session prior to vDOT beginning
Only 1 patient has done eDOT
client could not get internet at one site while out of country
only minor issues early depending on smartphone model, but all issues solved promptly





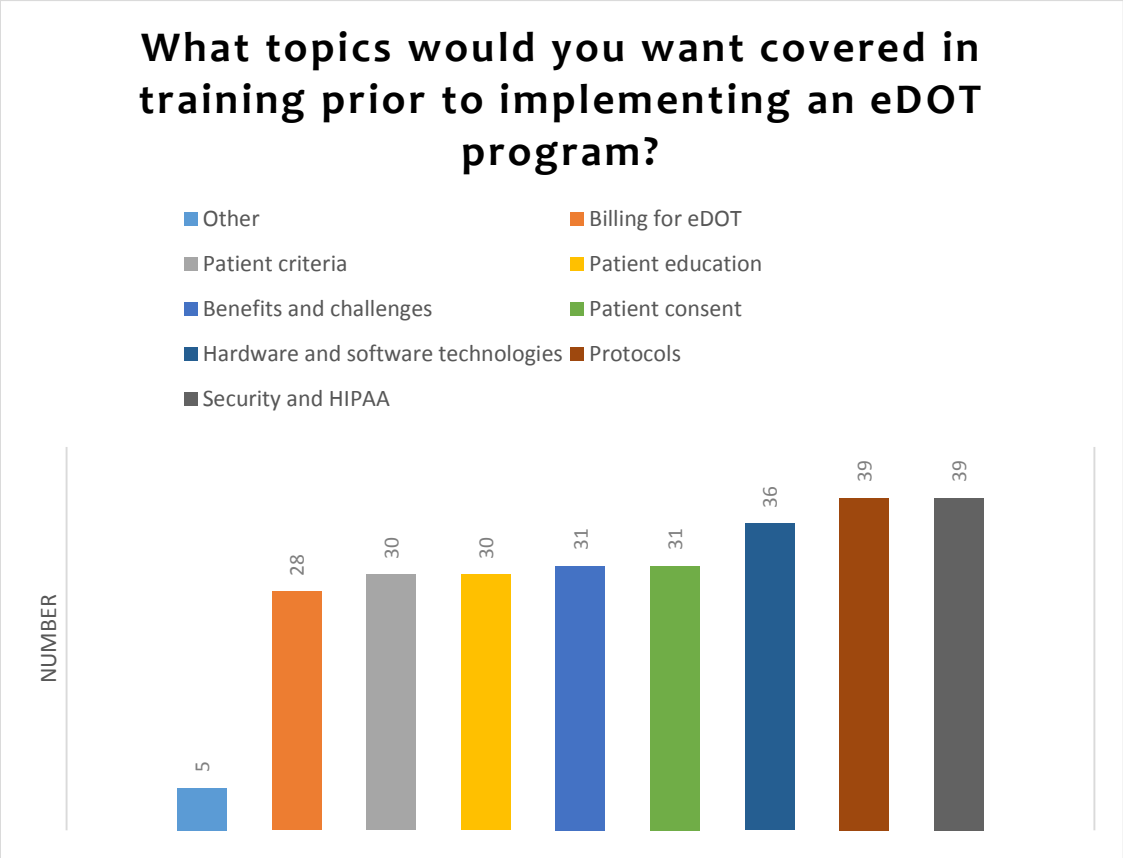


Others (Unedited)

Rabies post-exposure prophylaxis

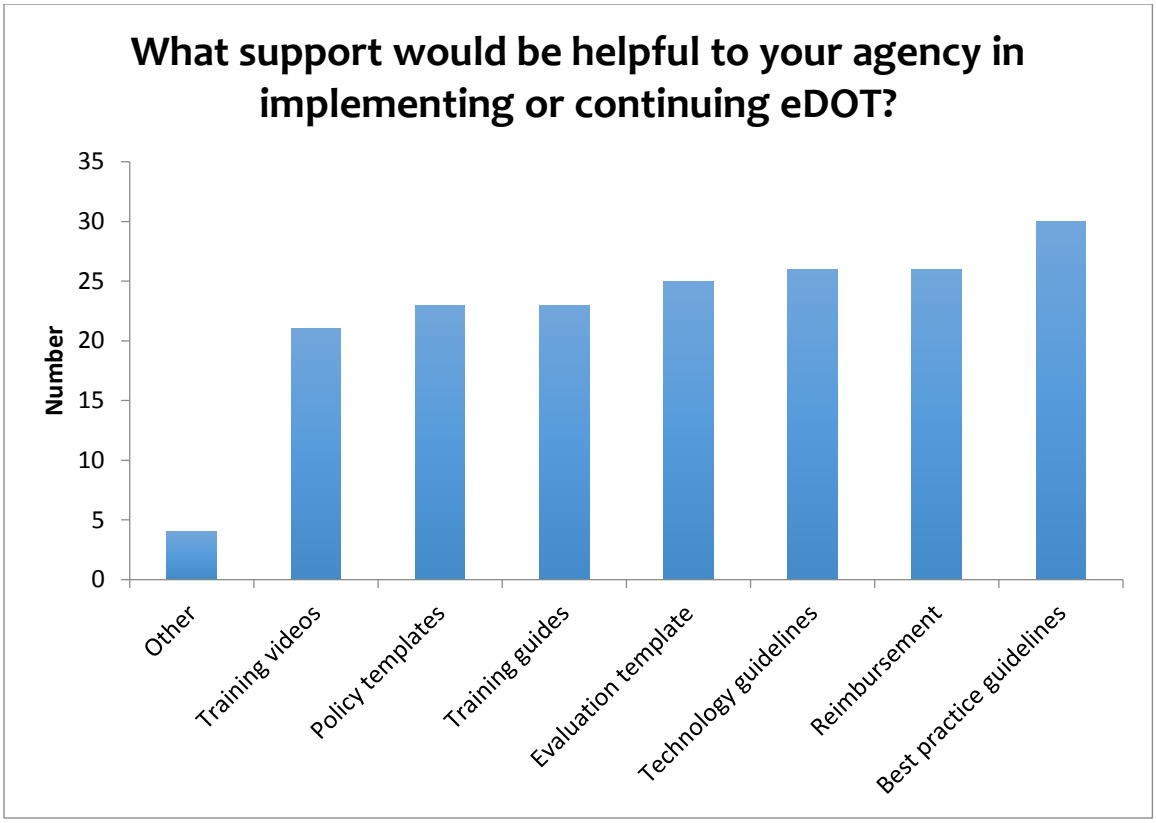
STD Rx for persons allergic to penicillin

Treating comorbidities, e.g. diabetes, that affects TB treatment outcome
any disease where adherence and monitoring is vital
monitoring isolation for things such as measles and mumps or discussing pertussis with families.
non-infectious mental health Rx
not sure, our is based on pt and RN
Management of hypertention
Other disease exposures that require follow-up (eg, measles)
other drug resistant conditions



Other (Unedited)

Funding (eg grants) for start-up
What to do if DOT doesn't happen.
documentation, quality assurance/case review, monitoring and reporting of medication side effects, observer and patient responsibilities, legal frame work; public vs HIPAA
i-phone use contract
we are writing a best practice edot document already in California



Other (Unedited)

Pushing for insurance coverage
any information would be welcome
iPhones and data plans
patient information in multi-languages

List materials you developed for your eDOT program (Unedited)

eDOT Protocol; patient and staff educational material, patient survey questionnaire
CA is developing one already. Topics covered are fairly comprehensive
In process of developing policies and protocols, we were using study policies and protocols.
Patien consent
video DOT protocol
Written procedure for VDOT
Staff Guidelines, Policy/Protocols Lync Guidelines Patient Consent Form Evaluation Tool
Policies/Protocols
protocols
We just verbally explain to patients how it is done. We take the phone to their home and then demonstrate how to do it by having them call into the office.
Protocols for videophones. They are outdated.
Policy
Signed agreement for appropriate use of the i-phone for e-DOT and that the phone will be returned upon the therapy being completed or stopped.
Protocol, sample patient agreement forms, DOT logs

Policies, protocols, consents, selection criteria

We have many forms as well as our protocol

Patient criteria list Patient consent form including acknowledgment that Face Time is not secure.

VDOT protocol and inclusion criteria VDOT patient consent form How to download Skype Medication delivery tracking tool

Policies, protocols and consents for inclusion criteria, procedure and patient equipment liability general policy/guidance in program manual requirement for Local Health Depts to develop protocol for review prior to initiating eDOT

Internal Operating Procedure (IOP) IT educational materials for local IT administrators, medical providers & patients

Policy in-process Draft policy completed

New Jersey Department of Health Tuberculosis Control Program Guidelines for the Use of Direct Observed Therapy (DOT) by Video Remote Access (Facetime, Personal computer, etc.)

Protocol for VDOT for TB and that protocol to was altered for ebola monitoring.

standard operating procedure, criteria for inclusion, etc. policies developed and approved by state TB Expert panel.

Protocol and Consent form

Additional Comments (Unedited)

I would like to disclose that I am the inventor of miDOT, now licensed to eMocha.

Our use of eDOT is on an as needed basis we still use in person DOT primarily

Our agency implemented it out of sheer necessity.

Not much at this time. It saves time and resources that are very limited in our jurisdiction

We have several of our local health departments using it and it has been generally well-received. It will be most useful in getting more patients (esp extra-pulmonary pts) on DOT.

Given these difficult time we have to think outside box to make it work. You have to trust the pt wants to get better and give them a chance

Needs to be developed as a way of expanding persons on DOT not replacing in person DOT which remains the gold standard in most settings. Simple, standardardized procedures that still are compatible with HIPAA and public health confidentiality requirement

FaceTime works great. If in a meeting or unable to accept, patient sends time stamped video.

Only higher SES patients have been able to use this technology in PR.