

Characterizing the Clinical use of a Novel Video-assisted Dosing Protocol With Secure Medication Dispensers to Reduce Barriers to Opioid Treatment

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Objectives: Distance and travel costs to opioid treatment programs (OTPs), especially in rural communities, are barriers to treatment for opioid use disorder. Retention rates at 12 months in our OTP are 55% (range 53%–61%). We piloted a novel treatment platform utilizing a video directly observed therapy (VDOT) smartphone app and a secure medication dispenser to support adherence with take-home doses of methadone or buprenorphine while enabling patients to maintain prosocial activities, reduce time and cost of travel, and increase retention.

Methods: Participants (n = 58) were adults in a Vermont OTP. Inclusion criteria included travel hardship, access to Wi-Fi or cellular

network, and having an iPhone 4S or Android 4.0 or greater. Patients received a dispenser, VDOT app, clinic dispensed medication, counseling, and urine drug testing. Chart reviews assessed VDOT compliance, engagement in prosocial activities, travel costs and time savings, and treatment disposition/retention. Project-associated costs were examined.

Results: Of the 15,831 expected videos, 15,581 (98.4%) were received and only 10 (0.063%) showed signs of medication non-compliance with 1 (0.0064%) showing an overt attempt at diversion. About 93% of participants engaged in prosocial activities, travel time and costs were reduced 86%, median cost saved \$72 weekly, median travel time saved 5.5 hours weekly and 98% of participants were in treatment 12 months later.

Conclusions: VDOT participants using dispensers showed high levels of medication ingestion integrity, had favorable clinical stability, and lower travel time and costs. These findings suggest that using VDOT with dispensers may hold promise as an innovative platform for supporting medication adherence.

Key Words: buprenorphine, dispensers, methadone, opioid use disorder, video

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Contributors: JB conceived of and organized the project, was involved in project oversight and wrote the manuscript. VMB oversaw the MAT-PDOA grant. MH was the case manager for MAT-PDOA grant and managed the database of participants. MaSto was the lead clinic organizer. MaStu was the main clinician in charge of training participants on the dispensers and VDOT and monitoring compliance. DR was the data manager and worked on training materials and as the main contact with Sure Adhere. All authors provided edits and feedback and reviewed and approved the final draft.

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Highlights

- Video directly observed therapy (VDOT) on a smartphone app may support medication ingestion in opioid treatment program (OTP) settings
- Medication ingestion integrity improved with the use of a secure medication dispenser
- Reduction in participant transport costs and travel time were seen with VDOT and dispensers
- An increase in prosocial activities (eg, work, caregiver, homemaker, student) was seen
- Retention in treatment for VDOT participants was higher than typically seen in OTPs

In the United States in 2018, opioid use disorder (OUD) is estimated to affect over 2.2 million people.^{1,2} The current opioid epidemic has impacted rural America particularly hard.³ Many people have limited access to methadone or buprenorphine medications for opioid use disorder (MOUD)—either in office-based opioid treatment programs (OBOT) or

opioid treatment programs (OTPs).⁴ An estimated 30 million US citizens in counties, mostly rural, have no buprenorphine prescriber.⁵ Since most OTPs are in densely populated communities, many rural residents either have no access or must consider the cost of time,⁶ travel,⁷ and distance⁸ when attending. Issues such as vehicle costs/reliability, homelessness, psychiatric or medical conditions, personal preferences,⁹ and clinic hours can be limiting. A 2020 Vancouver, British Columbia study showed that employment emerged as the “only and common predictor” of sub-optimal MOUD retention often due to work schedules.¹⁰ Retention in OTPs can range from 19% to 94% at 3 months¹¹ to an overall 60.7% at 12 months¹² due to dissatisfaction with treatment,¹³ distance, and travel time of over 30 minutes.^{14,15} Tragically, mortality rates rise with treatment dropout.^{13,16–18}

In the US, Federal OTP regulations require daily face-to-face observed dosing of methadone until eligibility is met for “take-homes”; doses ingested unsupervised outside of the OTP. The “8-point criteria” used to determine eligibility include “absence of illicit drug use.”^{19,20} Time-in-treatment restrictions exist for methadone-1 take-home dose for every 90 days in treatment until the 9-month period when up to 6 weekly take-homes can be given.²¹ Entering an OTP, waiting in line to dose, or mistreatment by staff create discomfort and barriers where normally patients have anonymity for other medical conditions.²² Some OTPs dispense buprenorphine with similar restrictions but without time-in-treatment requirements.^{23,24} By accelerating take-homes, patients maintain or gain employment and reduce time and travel to the OTP and extending take-homes sooner can increase retention in OTPs.²⁵ Take-homes are unwitnessed except during a “call-back” when the medication is brought back for inspection. OTP medical directors often face the dilemma of removing take-homes for positive drug screens or failure to complete call-backs knowing that required daily attendance affects employment, family stability, and transportation costs. People who would not have trouble ordinarily coming to OTPs, may under extreme conditions like natural disasters and pandemics, including the stay-at-home orders for COVID-19, benefit from expanded take-homes.

Despite Vermont’s robust treatment network, the Hub and Spoke,²⁶ residents struggle to attend treatment regularly²⁷ due to weather, vehicle, work, or home issues. Reliance on Vermont Medicaid for transportation to OTPs is significant; \$954,000 was spent in 2012. Vermont’s largest OTP, located in the Burlington area, serves a catchment area of four rural counties. Retention in treatment is challenging, particularly for rural patients at greatest distance from the OTP. From 2014 to 2017, 3- and 12- month retention rates averaged 65% (range 46%–80%) and 55% (range 53%–61%), respectively, with the barriers listed above as reasons for discontinuing treatment.

In this pilot project, we explored the potential utility of a novel video-assisted dosing protocol utilizing a smartphone app that allowed for Video Directly Observed Therapy (VDOT) combined with take-home doses of methadone or buprenorphine tablets in secure medication dispensers. This was inspired by successes in using locked dispensers in three studies^{28–32}; however, medication ingestion was not

witnessed. VDOT shows promise in tuberculosis treatment by reducing cost and increasing compliance rates^{32–34} and is now recommended globally for tuberculosis.³⁵ There is little published data on VDOT for opioid treatment³⁶ and there are no reports of combining a dispenser with VDOT for MOUD. Our primary objective was to assess VDOT recording compliance by tracking all received and missed videos to ensure medication ingestion. Secondary objectives were to assess reduction in time and transportation costs for patients getting to the OTP, if prosocial activities could be enhanced, and compare VDOT treatment retention to treatment as usual through a chart review.

METHODS AND MATERIALS

Participant Characteristics

The project was open to all OTP patients and participants were recruited between December 2016 and June 2018 through clinic signage, word-of-mouth, or clinical referral. The general OTP population on intake is 52% female, median age 34 years (range 20–70), 60% employed, 87% use opioids by injection, 93% use heroin, and 93% use more than opioids (stimulants, benzodiazepines, or alcohol). Typical daily census is 980 patients. Inclusion criteria were having (1) a smartphone iOS or Android version 4.0 or greater, (2) clinic access challenges (distance from clinic, hours of employment, homelessness, cost/mode of transportation, or psychological/medical factors such as social anxiety disorder, post-traumatic stress disorder, wheelchair-bound) (3) a stable dose of buprenorphine from 2 to 24 mg or methadone less than 151 mg for at least 2 weeks with negative illicit drug screens. Few people lacked the requisite smartphone to participate. Participation requests were completed by clinical staff and reviewed by the Medical Director. Each participant signed an Informed Consent form. Federal and Vermont regulatory exemptions were sought for methadone if the time-in-treatment requirements were not met for take-homes. Approval was sought and deemed not necessary by the Vermont Agency of Human Services Institutional Review Board. It was considered exempt.

Medication Dispensers

This project used 2 medication pill dispensers that were easy to use, tamper resistant, durable, portable, and manufactured by Addoz in Finland.³⁷ Neither held liquid or films. Both dispensers had 28-cell cassettes. The smaller dispenser’s cells could hold up to 5 buprenorphine tablets (24 mg or less) or low-dose methadone tablets (<51 mg). The larger dispenser’s cells held up to fifteen 10 mg methadone tablets (<151 mg). This unit was modified to prevent destruction by placing it in a round, hardened steel case with a modified dispensing spout and double locks to make it exceedingly difficult to reach in and extract extra methadone pills. Dispensers were filled and securely stored in our OTP dispensary; each timer was set to dispense one dose (or 2 if split dose) per day. Any tampering with the smaller dispenser generated a blinking surface light that remained on until returned to the OTP. Seven day’s supply of medication was chosen for ease and timeliness of filling by dispensary nurses.

Video Directly Observed Therapy

We used a commercially available VDOT app (SureAdhere)³⁸ to remotely monitor participants ingesting each dose of medication asynchronously. OTP staff trained participants to use the app and record a video showing medication ingestion. Video recording entailed holding the portable medication dispenser, upending it to dispense the dose, placing pills on a flat surface, putting the phone over pills to show the markings then stating name, dose, and date. After medication ingestion, participants would drink water, lift the tongue and speak their name while recording. At no time could any of the medication or any body part above the torso be out of the frame; otherwise staff would contact VDOT participants to review the procedure.

After video recording completion, the VDOT app automatically encrypted the video with a date and time stamp and transmitted it by cellular or Wi-Fi network to a secure HIPAA-compliant server for storage. The app prevented participants from viewing, editing, manipulating, or deleting videos. OTP staff members could view submitted videos through a password-protected website, observe whether correct and complete dose ingestion occurred, and document observations. The VDOT website dashboard allowed OTP staff to enter information about each dose (eg, taken or not), comments about video quality (eg, lighting, positioning, and technique), and statements made in their videos. If videos were not received, the counselors were notified in a daily report and would contact the VDOT participants to determine the reason, which was almost always a technology issue with uploads. These were not medication reminders. The VDOT app was provided at no cost to the VDOT participants. In areas with poor cellular coverage, the videos could be uploaded from a community Wi-Fi “hot spot” for viewing at a later time by staff.

Interventions

Our usual OTP programming standards were provided to VDOT participants. This included counseling 1 to 4 times a month, based on treatment plan goals, and both urine drug screens (opioids, cocaine, amphetamines, benzodiazepines) and alcohol breathalyzers, 1 to 3 times monthly. Positive results did not result in loss of the dispensers. Standard OTP program callback procedures were followed. VDOT participants were allowed to use the dispensers and VDOT for as long as they found them useful with a targeted goal of 12 months. Videos were received until December 31, 2019, when funding for the project ended.

Data Collection

A chart review of aggregate intake information for the participants was done to determine demographic and baseline characteristics. The SureAdhere Dashboard allowed determination of patient compliance with VDOT, that is, number of doses observed divided by the number of videos expected. Missing or aberrant videos were characterized as such. A monthly report listed patient’s compliance, technology issues, cumulative duration of time in the project, and reasons for starting or stopping.

Retrospective chart reviews examined take-home status (if already in the OTP), medication type (buprenorphine or

methadone), the duration of time in treatment before VDOT enrollment, retention in treatment and disposition (OTP, OBOT, drop out due to taper, prison, leaving voluntarily or against medical advice) 12 months after starting VDOT, method of transportation to clinic, time and one-way distance from the clinic, and maintenance or initiation of employment or other prosocial activity (homemaking, caregiving, classroom or other learning, looking for work or self-help activities). Reasons for participation were gathered from initial request paperwork completed by clinical staff. Round trip daily travel cost to the clinic estimates were \$0.50/ mile for personal car, \$2.00 for public buses and \$30.00 for Medicaid paid transportation. Travel time and distance calculations used Google maps travel estimator. Retention was defined as dosing in the OTP or, if transferred, OBOT, continuously for 12 months after intake for VDOT participants.

Data Analysis

Calculated frequencies and percentages for categorical variables and, where sample size permitted, treatment outcome measures were compared across groups using chi-square statistics with $P < 0.05$

Project-related Costs

Monthly staff costs were broken down by department with hours and full-time equivalents (FTE) then multiplied by hourly wage for total costs per month with fringe benefits added. Staff recall was used for training in the use of dispenser/smartphone app, project coordination, data management, and video or dispenser problem-solving. Time-in motion studies for filling dispensers and monitoring videos were generated rather than staff recall to be precise. The one-time purchases of dispensers and VDOT time were included in the total cost to generate a monthly cost per VDOT participant.

RESULTS

Participants ($N = 58$) enrolled in the project were 43% female, average age 36 years (range 20–70 years), 85% used heroin, 84% used by injection, 90% used more than one substance, 79% were engaged in employment/prosocial activities, and 60% lived mean distance 12 miles (range 2–38 miles) from OTP. Seventeen patients were on buprenorphine and 41 on methadone with 83% having no take-homes either due to not enough time in treatment (<6 months) or concerns about drug use, diversion, or incomplete callbacks (Table 1).

Participants joined 50% of the time because of work schedule or transportation issues. About 56% were in treatment >12 months at project start. Meantime in project was 11.4 months (range 0.5–36 months). One VDOT patient dropped out of treatment at 11 months. Comparing OTP 3- and 12-month retention rates of 65% and 55%, 100% of VDOT participants were in treatment at 3 months and 98% remained in treatment ($P < 0.001$) in either the OTP or OBOT 12 months after entering the project (Table 2).

The 847 drug and alcohol tests for participants show 43% of participants accounted for positive tests with cocaine being most common. We expected 15,831 individual videos and received 15,581 with 250 missing videos scattered amongst participants. A total of 192 of the received videos

TABLE 1. Demographics and Baseline Characteristics at Clinic Intake

	VDOT Total N = 58
Variables	n (%)
Sex	
Female	25 (43%)
Male	33 (57%)
Employed/prosocial activities (employed, school, homemaker, caregiver, self-help work)	46 (79%)
Injection use	49 (84%)
Non injection	9 (16%)
Heroin use	49 (85%)
Prescription opioids	9 (15%)
>1 drug used (opioid, stimulant, benzodiazepine, alcohol)	52 (90%)
Distance one way to clinic (miles)	
0–5	23 (40%)
6–15	21 (36%)
16–25	8 (14%)
26–38	6 (10%)
Take-home status at time study began	
Yes	10 (17%)
No	48 (83%)
Medication type	
Methadone	41 (71%)
Buprenorphine	17 (29%)

were of poor quality/inadequate with 10 of those showing medication noncompliance and only 1 showing definite diversion -missing pills on the table when videoing (Table 3).

TABLE 2. VDOT Project Times, Reasons for Project Enrollment and Disposition at 12 months

	VDOT Total N = 58
Variables	n (%)
Time in treatment before project (months)	
<6	19 (33%)
6–12	8 (14%)
13–24	7 (12%)
>24	24 (41%)
Duration of time in project (months)	
≤6	19 (32%)
6–12	23 (40%)
13–24	8 (14%)
>24	8 (14%)
Reason for participation	
Work schedule	17 (29%)
Transportation issue	12 (21%)
Distance to clinic	7 (12%)
Diversion history	6 (10%)
Anxiety	5 (9%)
Frequent absences	4 (7%)
Night shift	3 (5%)
Distance and work	2 (3%)
Not enough time in treatment	1 (2%)
Homelessness	1 (2%)
Disposition after 12 months of project	
Opioid Treatment Program	49 (84%)
Office Based Opioid Treatment	8 (14%)
Taper out/Jail/left on own	1 (1.7%)

TABLE 3. Results for Videos and Urine Drug Screens

Videos expected	15831
Videos collected	15581 (98.4%)
Videos missing	250 (1.6%)
Types of Videos collected	
Aberrant/inadequate	192 (1.2%)
Medication Non-compliance	10 (0.064%)
Overt Diversion	1 (0.0064%)
Urine Drug Screens for 58 VDOT patients	847
Cocaine	43 (5%)
Opioids	21 (2.5%)
Benzodiazepines	20 (2.4%)
Amphetamine	5 (0.6%)
Alcohol breathalyzer	2 (0.2%)
# of participants w/ positive screens	25 (43%)

Weekly clinic attendance reduced costs by 86% and median weekly travel time saved was 5.5 hours (range 1.8–12) with monthly time saved 22 hours (5.5 hours/wk × 4 weeks). Transportation was by private vehicle 72% of the time. Median daily transportation costs were \$12 (range \$2.00–\$40.00) with monthly cost savings of \$312.00 (\$12.00/d × 26 days/mo). For Vermont Medicaid, transportation costs were reduced by \$780.00 (\$30.00/d × 26 days/mo). Prosocial activities increased from 79% to 93% by the end of the 12 months with 4 people not reporting from baseline. Some data points are lacking due to missing chart data (Table 4).

The monthly OTP cost for one person using the dispenser and VDOT was \$675.53. Calculated monthly cost

TABLE 4. Time, Transportation Mode, Travel Costs, Employment

Travel hours per week saved N = 55	0–2 (17) 3–5 (9) 6–8 (19) 9–12 (10) No answer (3)
Mode of transport N = 57	Car (41) Bus (8) Walk (2) Medicaid cab (6) No answer (1)
Dollars saved/day N = 49	0–5 (17) 6–10 (13) 11–20 (7) 21–30 (7) 31–40 (5) No answer (9)
Type of prosocial activity baseline N = 58	Employment (38) School (0) Homemaker (6) Caregiving (2) Self-help (0) Seeking work (0) No answer (0)
Type of prosocial activity project N = 54	Employment (41) School (1) Homemaker (8) Caregiving (2) Self-help (1) Seeking work (1) No answer (4)

TABLE 5. Costs of Dispensers, VDOT and Staff and Duties

Staff	Hours/mo	FTE/mo	Cost/mo N = 31	Cost Per Person/mo	Duties
Nursing	36	0.24	\$1008.00		Fill wheels
Site Coordinators	21	0.14	\$580.02		Enroll/training for app and dispenser use
Security	15	0.1	\$241.80		Monitor videos
Administrative	8	0.055	\$141.84		Problem solving
Clinicians	4.5	0.03	\$110.79		Feedback to participants
Data Manager	3	0.02	\$73.11		VDOT compliance monitoring
Medical	2	0.01	\$216.00		Oversight/exemptions
Staff cost less benefits			\$2371.56	\$76.50	
Benefits (35%)			\$830.05	\$26.78	
Total Staff costs			\$3201.61	\$103.28	
Video app (n = 31)			\$1178.00	\$38.00	
Total cost			\$4379.61	\$141.27	
Med-wheel Safe/Secure	\$375.00		\$31.25	\$31.25	
	one-time cost				
Total VDOT/dispenser cost				\$172.53	
OTP costs				\$500.00	
Total OTP cost with VDOT/dispenser				\$672.53	
Cost reductions					
Societal savings				-\$1138.33	
Total OTP costs less societal savings				-\$465.80	
Mean cost savings of transportation/26 days			(\$12.00/d x 26 days)	-\$312.00	
Total OTP costs less total savings				-\$777.80	
Cost savings Medicaid transportation/26 days			(\$30.00/d x 26 days)	-\$780.00	
Total OTP cost less Medicaid transport savings				-\$1245.80	

Month is calculated as 30 days.

FTE is based on 37.50 hours per week/150 hours per month.

savings based on a review of the societal benefits of reduced crime, reduced health costs (including lives lost due to opioid overdose death) and increased employment wages was calculated at \$465.80. Total net savings with reduced personal transportation costs of \$312.00 would be \$777.80 per person per month whereas for Vermont Medicaid transportation the total savings would be \$1245.80 (Table 5).

DISCUSSION

This is the first project to our knowledge that combines medication dispensers with VDOT for observed ingestion of MOUD. Of the 15,581 observed videos, in only 1 was diversion noted- a highly favorable adherence rate for a novel technology combination never previously examined. We believe this protocol supports expanded provision of take-home doses in high-risk situations. OTP Medical Directors struggle to give take-homes to new treatment inductees, patients with ongoing substance use, history of diversion or medication misuse, or failed callbacks. In this project, 83% of participants did not meet “take-home” criteria, often due to the above reasons, yet had very high rates of medication compliance via VDOT. Significant reductions in travel time and costs, improved employment/prosocial activities, and high retention rates are noteworthy.

People who had to choose between work/home duties and clinic attendance could now do both. Some patients dosed in the middle of the night before or after work. We believe patients should be able to dose when they want to within their own schedule and not have to spend hours a day traveling for

treatment. We are unaware of any other disease in medicine that puts this burden on patients. A study published by the Vermont Results First Inventory & Benefit-Cost Analysis for Hubs and Spokes 2017³⁹ indicated the benefit-cost ratio in reduced crime, reduced health care costs, and increased employment wages in OTPs was between 1.12 and 1.66. This includes the cost of premature death from opioid overdose and translates to savings of \$13,660 per person per year. Spending the resources to provide VDOT and dispensers recaptures much of the costs of “dropping out” and we think our project can work in many OTPs. We encourage entities to consider this option.

There are several limitations. Cellular service can be a challenge in rural areas. Since VDOT is obtained asynchronously, patients with inadequate service could upload videos once a week and clinic response to missing videos would obviously lag in time. Fortunately, missing video accounted for 1.6% of all those expected. The cost of phone ownership, data plans, and device memory capacity are issues. In those who dropped out early, two-thirds cited issues with technology complexity. These same issues might limit the project for others with cognitive issues, older adults, and homeless populations. The participants represented a cross-section of the OTP population but the project was limited by the small size of the study group, lack of a control group, and randomization. Participants who enrolled were highly motivated, had higher rates of employment, and owned a smartphone and data plan. This can skew toward a higher retention rate but we believe there are a substantial number of patients in OTPs who

would benefit from VDOT and dispensers. Larger studies are needed to test the applicability of VDOT in other OTPs. Vermont OTPs are paid a monthly bundled rate and in other programs which are fee-for-service, studies like this may need modification. The cost to the clinic was significant, including start-up costs and purchasing the necessary hardware and software. Cost reductions in nursing duties could be achieved by pharmacy technicians or machines filling the dispensers. To our knowledge, there is no dispenser that can deliver liquid methadone or buprenorphine film.

Future Considerations

High-intensity programs that require constant contact, such as OTPs, can utilize mobile smartphone platforms to maintain interaction with the clinic,⁴⁰ increase 1-year retention rates⁴¹ and can be a way to bridge gaps in treatment access,^{42–44} especially in rural communities where they are stigmatized. Where buprenorphine diversion is a concern,^{45–49} pharmacies could work with community buprenorphine/telehealth providers to utilize the dispensers and VDOT. Mail-order pharmacies currently send injectable buprenorphine directly to providers with buprenorphine waivers and this could be considered with dispenser cassettes shipped with buprenorphine that could be swapped out at the provider office.

CONCLUSIONS

Overall, in this small, observational study these proof-of-concept findings highlight potential advantages for VDOT and dispensers with patients who may benefit from additional monitoring, especially early in treatment. Although promising, additional studies are needed to obtain more robust estimates of the impact of VDOT and dispensers on treatment outcomes and to identify potential differences in these outcomes associated with patient characteristics. We also believe that further models of cost savings can be explored to make this a feasible option for delivering MOUD. With COVID-19 changing the way that take-homes are dispensed, VDOT can expand the number of people with extended take-homes and ensure medication compliance.

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