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Acceptability, feasibility, and outcomes of a clinical pilot program for video observation of methadone take-home dosing during the COVID-19 pandemic

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ABSTRACT

Background: Methadone is one of the most utilized treatments for opioid use disorder. However, requirements for observing methadone dosing can impose barriers to patients and increase risk for respiratory illness transmission (e.g., COVID-19). Video observation of methadone dosing at home could allow opioid treatment programs (OTPs) to offer more take-home doses while ensuring patient safety through remote observation of ingestion.

Methods: Between April and August 2020, a clinical pilot program of video observation of methadone take-home dosing via smartphone was conducted within a multisite OTP agency. Participating patients completed a COVID-19 symptom screener and submitted video recordings of themselves ingesting all methadone take-home doses. Patients who followed these procedures for a two-week trial period could continue participating in the full pilot program and potentially receive more take-home doses. This retrospective observational study characterizes patient engagement and compares clinical outcomes with matched controls.

Results: Of 44 patients who initiated the two-week trial, 33 (75 %) were successful and continued participating in the full pilot program. Twenty full pilot participants (61 %) received increased take-home doses. Full pilot participants had more days with observed dosing over a 60-day period than matched controls (mean = 53.2 vs. 16.6 days, respectively). Clinical outcomes were similar between pilot participants and matched controls.

Conclusions: Video observation of methadone take-home dosing implemented during the COVID-19 pandemic was feasible. This model has the potential to enhance safety by increasing rates of observed methadone dosing and reducing infection risks and barriers associated with relying solely on face-to-face observation of methadone dosing.

1. Introduction

Opioid use disorder (OUD) continues to be a major cause of morbidity and mortality in the United States (US) (Mathers et al., 2008; National Institute on Drug Abuse, 2021; Nelson et al., 2011). The COVID-19 pandemic has exacerbated the OUD crisis, with national data indicating that rates of fatal and nonfatal overdoses rose significantly during the first year of the pandemic (Ahmad et al., 2021; Soares et al., 2021).

Methadone has been a cornerstone of OUD treatment in the United

States since the early 1970s, with >1800 opioid treatment programs (OTPs) currently operating in the United States (Substance Abuse and Mental Health Services Administration, 2022a). For persons with severe OUD, methadone may be the most commonly received treatment; for example, a recent survey of people who inject drugs found that nearly twice as many people reported past-year treatment with methadone than past-year treatment with buprenorphine (39 % vs. 22 %) (Poorman et al., 2021).

In the United States, daily or frequent supervised treatment with visual confirmation of ingestion, also called direct-observed therapy, is

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the standard of care for methadone treatment in federally licensed OTPs and is mandated by federal regulations to mitigate risk of methadone diversion to illicit markets (Federal Opioid Treatment Standards, 2015). However, requiring in-person direct-observation of methadone dosing also presents major barriers to accessing treatment for many patients (Frank et al., 2021) and has imposed challenges to infection control during the COVID-19 pandemic by requiring patients and staff to regularly interact in clinical spaces.

Smartphone technologies can potentially provide opportunities to make observed dosing of methadone treatment more flexible by allowing video observed dosing, where patients video-record themselves ingesting prescribed medications at home and securely submit those videos to clinic staff for review (Godersky et al., 2020, 2019; Schramm et al., 2020; Tsui et al., 2021). Prior research on video-observed dosing for buprenorphine found that it was acceptable and feasible for confirming medication adherence (Godersky et al., 2020, 2019) and suggested that it did not produce positive or negative effects on opioid use or treatment retention compared to usual care (Tsui et al., 2021).

The COVID-19 pandemic prompted many OTPs to take definitive steps to offer patients more nonobserved take-home doses (Amram et al., 2021; Peavy et al., 2020). In March 2020, SAMHSA released adjusted rules governing OTPs, allowing states to request blanket exceptions for most patients to receive more frequent take-home doses when OTP clinicians believe such increases are safe (Substance Abuse and Mental Health Services Administration, 2020). Subsequent to these policy changes, observational studies showed that patients who received increased methadone take-home doses during the pandemic had lower risk of opioid overdose, treatment discontinuation, and treatment disruption (Brothers et al., 2021; Gomes et al., 2022). In response to the benefits of this blanket exception, SAMHSA extended this exception and will allow OTPs to offer increased take-home doses for up to one year after the expiration of the COVID-19 public health emergency (Substance Abuse and Mental Health Services Administration, 2022b). However, more frequent take-home dosing also imposes new challenges to OTP providers (Hatch-Maillette et al., 2021), including potential concerns about risk for medication diversion, drug poisonings (i.e., overdose), and negative impacts on patient care and outcomes (Madden et al., 2021).

Within that context, from April to August 2020, an OTP agency in Washington State conducted a quality improvement initiative in which a clinical pilot program used smartphone-based video observation of methadone take-home dosing and remote COVID-19 symptom screening to increase patient and staff safety. The current study aims to characterize the pilot program, including its acceptability and feasibility, and to compare the clinical outcomes and service utilization of patient participants and matched controls. To our knowledge, this is the first study to evaluate the feasibility, acceptability, and engagement with smartphone-based video observation of methadone take-home dosing paired with remote COVID-19 symptom screening among patients in an OTP.

2. Materials and methods

2.1. Setting and sample

This is a retrospective observational study of patients who participated in a clinical pilot program of video observation of methadone take-home dosing and remote COVID-19 symptom screening. Patients who participated were receiving methadone treatment from one of three sites within a single OTP agency in the Puget Sound region in Washington State. The OTP served patients from a primarily urban and suburban geographic area, including a high proportion of patients who were homeless and/or had co-occurring substance use disorders in addition to OUD (e.g., methamphetamine use disorder). Patients invited to participate in the pilot program were ≥ 18 years old, received care from one of five counselors who agreed to be involved in the pilot program, and

qualified for an increased number of take-home doses based on SAMHSA's COVID-19 blanket exception for OTPs (SAMHSA, 2020) but had not demonstrated enough treatment stability to receive the maximum number of take-home doses allowed under the revised SAMHSA guidelines.¹ All patients who participated had smartphones; however, options to obtain free smartphones through a state program were also available. The study also included matched control patients who did not participate in the clinical program for analyses of clinical outcomes and service utilization.

2.2. Intervention

From April to August 2020, the participating OTP agency initiated the clinical pilot program in response to the urgent need for remote therapeutic monitoring systems during the COVID-19 pandemic. The patient-facing smartphone application and provider-facing platform used in the pilot were developed by emocha Mobile Health®. Fig. 1 depicts the primary technological components of the program.

OTP providers agreed that counselors would be the appropriate clinicians to invite patients to participate in the pilot program and deliver the intervention due to their frequent interactions with patients (typically weekly) and their accessibility and ability to respond to urgent clinical scenarios that could arise over asynchronous communications. Five counselors were invited and agreed to participate in the pilot program based on supervisor recommendations, which were driven primarily by counselors' availability, comfort with technology, and the perceived compatibility of their patient panels with the program.

Counselors introduced the pilot program to their patients during in-person clinic visits. Counselors assisted patients in downloading the mobile application and instructed them in how to use it, including help with navigating the mobile application, answering COVID-19 symptom screening questions, steps for completing video recordings (i.e., showing the unopened medication bottle and patient label, stating their name and dose amount, opening the bottle and cap and seal, ingesting the medication, and speaking after the medication was ingested), and utilizing the two-way chat feature.

Counselors were trained to review the uploaded videos through a provider portal and to accept or reject each video based on whether enough information was available to confirm correct dosing (e.g., the video was of high enough quality and the patient completed all required steps for video-observed dosing). Counselors were instructed to review videos and respond to patient messages daily; however, they could potentially review videos and respond to patient messages more or less frequently at their own discretion.

Patients who volunteered to participate in the clinical pilot were required to complete a two-week trial to demonstrate their ability to complete the tasks required for video-observed dosing. Patients who did not submit all expected videos during the two-week trial were not subsequently invited to participate in the full pilot program. We invited patients who submitted all expected videos during the two-week trial to continue participating in the full program until the pilot ended in August 2020, unless they withdrew or were withdrawn by their counselors.

No counselors or patients received financial incentives for their participation in this clinical pilot program. However, the pilot study did inform patients that video-observed dosing could provide additional evidence of treatment stability that would be factored into their treatment team's assessments for receiving additional take-home doses. As with all patients in the OTP, the treating provider, with consultation from the care team, ultimately made the decisions to increase take-home

¹ The 2020 blanket exception allowed OTPs to provide up to 28 days of take-home doses for "stable" patients and up to 14 days of take-home doses for "less stable" patients that OTPs believed could safely handle this level of take-home medication. However, the 2020 blanket exception did not provide specific criteria for determining which patients were "stable" or "less stable".

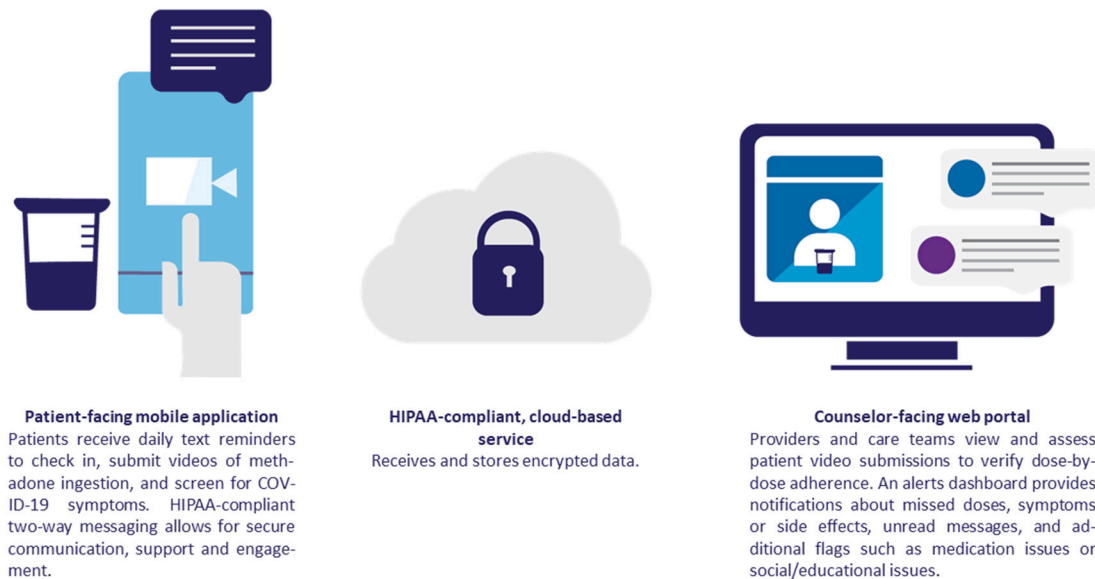


Fig. 1. Summary of technological components included in the platform used for asynchronous video-observed dosing of methadone take-home doses.

doses.

2.3. Data sources

This study obtained data from the OTP's electronic health records (EHRs) and records generated by the mobile application used for the clinical pilot program. The University of Washington Institutional Review Board approved the use of these clinical data sources for the current retrospective observational study.

The study used EHR data to obtain information about patient demographics, primary treatment site, methadone dosing, and duration of current treatment episodes. Records of scheduled doses (in-person and take-home doses), in-clinic observed doses, changes in take-home dosing schedules, visits with counselors and medical providers, and discharges from the OTP were obtained for the 60-day period after enrolling in the pilot and over a yoked 60-day period for matched control patients. For each pilot participant, the study identified a matched control who did not participate in the pilot but was matched by age group, treatment site, gender (when known), homelessness (when known), and duration of their current treatment episode, using one-to-one exact matching for each of these measures. The structure of the data utilized for this study precluded us from using patients' initial in-clinic dosing frequency as a matching variable for selecting matched controls.

The study used data from the mobile application to identify video submissions, counselor determinations of videos (i.e., acceptable or unacceptable), and COVID-19 symptom screens completed over the 60 days after starting the pilot. A 60-day observation period was selected, starting from the day the pilot participant started the clinical pilot (or for a yoked 60-day period for matched controls), to create a uniform observation window for all participants.

2.4. Measures and analytic plan

Primary analyses characterized the acceptability and feasibility of the service model used in the clinical pilot. We defined the primary *acceptability* measure as the percentage of patients who agreed to use the clinical program out of those known to be offered it by an OTP counselor. We defined the primary *feasibility* measures as the percentage of days with scheduled methadone take-home doses in which patients uploaded videos that were accepted by counselors and the percentage of those days in which COVID-19 symptom screenings were completed among patients in the pilot program. The research team and OTP

stakeholders established a priori thresholds of 50 % for each measure and for concluding whether the program was acceptable or feasible (e.g., the program would be considered acceptable if ≥ 50 % of patients who were offered the program agreed to use it and would be considered feasible if patients in the pilot program uploaded videos for ≥ 50 % of their take-home doses).

We characterized clinical services and outcome measures for pilot participants and matched control patients. OTP-related clinical service measures included *visits with counselors*, *visits with medical providers*, *days without medication coverage* (i.e., days without in-person dosing or take-home doses available), and *days with an observed dose* (in-person or by video) over the first 60 days in the pilot (pilot participants) or a yoked 60-day period (matched controls). The study used *t*-tests to compare pilot participants and matched controls on these measures. Clinical outcome measures included *retention in the OTP*, *graduation to additional take-home doses*, *experiencing ≥ 4 consecutive days without medication coverage*, *overdose* (i.e., recorded hospitalization for a non-fatal or fatal drug overdose), and *death* based on data from the EHR during the 60-day observation period. Because the incidence for these measures was low, these outcomes were characterized descriptively and we did not perform inferential statistical tests comparing pilot participants to matched controls.

3. Results

3.1. Acceptability and success in the two-week trial

Fig. 2 summarizes the flow of patients through the pilot program. Counselors offered ninety patients the opportunity to participate. Sixty patients agreed to start the two-week trial (i.e., 67 % of those who were offered; primary acceptability outcome). Forty-four patients uploaded at least one video during the two-week trial (i.e., 73 % of patients who agreed to start the two-week trial), all of whom submitted at least one video that was accepted by a counselor. Thirty-three patients were successful in the two-week trial (i.e., 75 % of those with at least one video submitted, or 55 % of those who agreed to start the two-week trial) and were invited to continue participating in the full clinical pilot beyond the two-week trial period. These 33 patients composed the full pilot sample used for the remaining analyses below. The eSupplement includes a table comparing these 33 patients to the 27 patients who agreed to start the two-week trial but did not continue onto the full pilot; these two groups did not significantly differ on any demographic

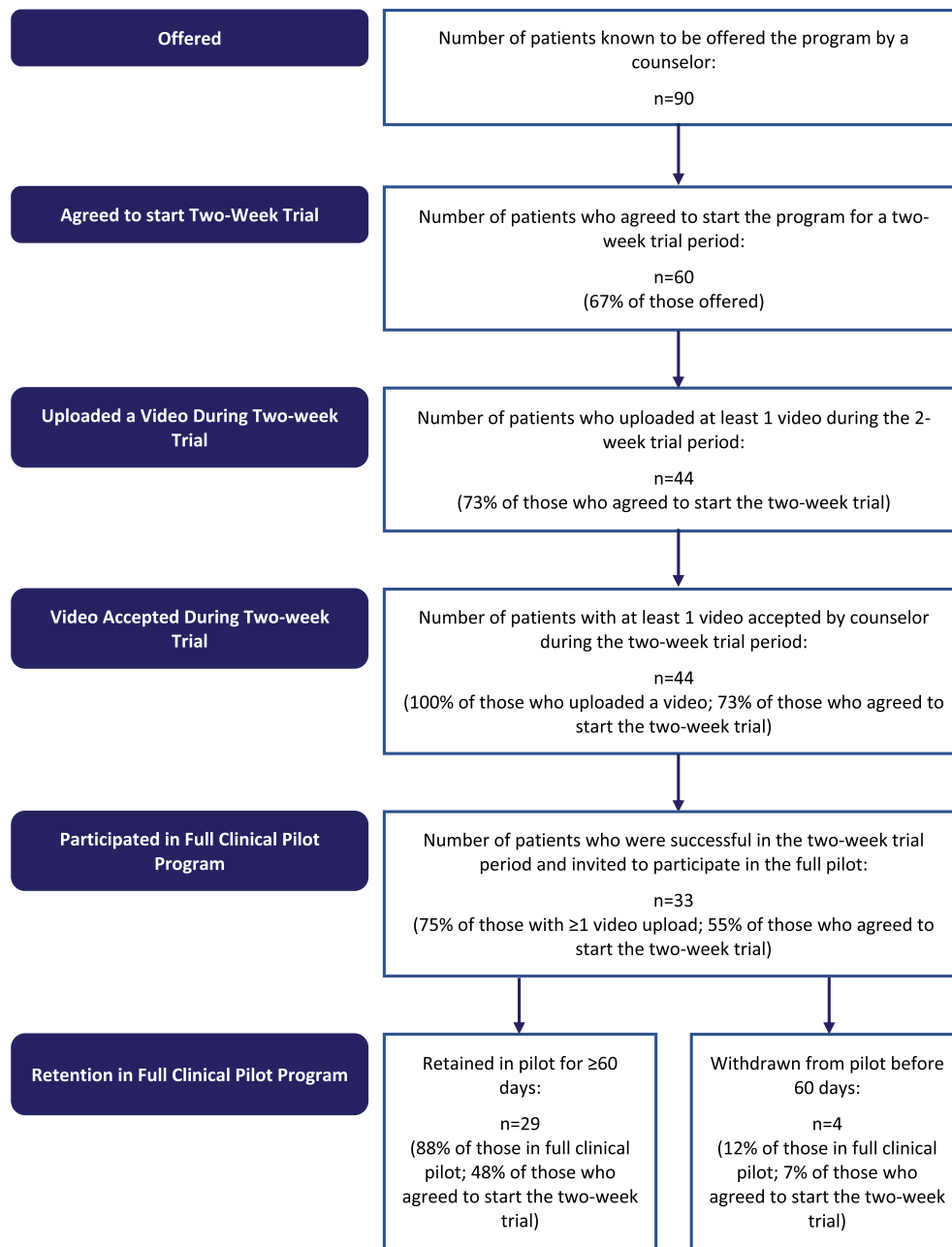


Fig. 2. Patient flow throughout the clinical pilot program.

measures, duration of treatment episode, methadone dose, or number of take-home doses at baseline.

Among the 33 pilot participants, 29 (88 %) continued the clinical pilot for at least 60 days. Four clinical pilot participants (12 %) discontinued the clinical pilot within 60 days and were reverted to their previous frequency of take-home dosing. This group included three patients who were disenrolled by counselors after multiple failures to submit expected videos and/or submitting videos that were not accepted and one patient who asked to be withdrawn despite high compliance out of a desire to not submit daily videos. These 4 individuals who discontinued the pilot within 60 days were retained in the primary sample of pilot participants ($n = 33$) described below.

3.2. Baseline characteristics of pilot participants and matched controls

Baseline characteristics of the 33 pilot participants and 33 matched

controls are shown in Table 1. Most pilot participants were between the ages of 30 and 49, male, white, and non-Hispanic/non-Latino. Most had Medicaid insurance, were receiving methadone doses >100 mg, and had a current treatment episode that was longer than one year. Twenty-one percent were homeless. Matched control patients did not significantly differ from pilot participants on any of these characteristics.

Most pilot participants had 3–4 take-home doses per week (70 % of sample) at the time they started the two-week trial (i.e., prior to any increase in take-home doses associated with the clinical pilot). In contrast, matched controls had more take-home doses over a yoked time period, with 27 % having 6 take-home doses per week and 27 % having 13 take-home doses every two weeks. This difference was expected and reflects counselors intentionally inviting patients into the pilot if they had not demonstrated enough treatment stability to receive the maximum number of take-home doses allowed under the revised guidelines.

Table 1
Description of patients who participated in the clinical pilot after a successful two-week trial period and matched controls.

		Pilot participants (n = 33)		Matched controls (n = 33)		p-val.		
		N	(%)	N	(%)			
Age	<30	5	15 %	6	18 %	0.64		
	30–49	17	52 %	16	48 %			
	50–64	11	33 %	9	27 %			
	65+	0	0 %	2	6 %			
Sex	Male	21	64 %	21	64 %	1.00		
	Female	12	36 %	12	36 %			
Race	American Indian or Alaskan Native	3	9 %	4	12 %	0.31		
	Asian or Pacific Islander	0	0 %	0	0 %			
	Black or African American	1	3 %	3	9 %			
	Native Hawaiian or other Pacific Islander	0	0 %	1	3 %			
	White	28	85 %	21	64 %			
	Unknown or another race	1	3 %	4	12 %			
	Ethnicity	Hispanic or Latino	2	6 %	2		6 %	0.49
		Not Hispanic or Latino	29	88 %	26		79 %	
		Unknown	2	6 %	5		15 %	
	Homeless		7	21 %	7		21 %	1.00
Medicaid insurance		28	85 %	24	73 %	0.37		
Prior duration of treatment episode	< 12 months	7	21 %	7	21 %	1.00		
	12–36 months	14	42 %	14	42 %			
	> 36 months	12	36 %	12	36 %			
Initial methadone dose	< 60 mg	1	3 %	4	12 %	0.49		
	60–100 mg	14	42 %	13	39 %			
	> 100 mg	18	55 %	16	48 %			
Scheduled frequency of take-home dosing at the start of pilot	1 take-home per week	0	0 %	2	6 %	0.001		
	3–4 take-home doses per week	23	70 %	13	39 %			
	6 take-home doses per week	10	30 %	9	27 %			
	13 take-home doses per two weeks	0	0 %	9	27 %			

Note. P-values reflect differences between pilot participants and matched controls and were estimated using Fisher's exact tests.

3.3. Feasibility and engagement

Measures of feasibility and engagement over the first 60 days after enrolling in the clinical pilot are summarized for pilot participants in Table 2. Pilot participants had a mean of 41.89 days with take-home doses available, out of which there was a mean of 37.12 days with a video uploaded and accepted by a counselor (i.e., 88.6 % of days in which a video was expected; primary feasibility measure). On average, patients had 1.15 days with videos submitted but not accepted by their counselor (i.e., 2.7 % of take-home days), 0.88 days with videos submitted but not reviewed by a counselor (i.e., 2.1 % of take-home days), and 2.70 days with videos not submitted (i.e., 6.4 % of take-home days). On average, patients completed dosing in-person at an OTP site on 16.03 days and missed a scheduled in-person dose on 0.67 days. The eSupplement provides additional information about the weekly rates of videos uploaded by patients and accepted by counselors, stratified according to patients' take-home dose frequency.

Patients completed a mean of 40.24 COVID-19 symptom screens (i.e., 96.1 % of take-home days; primary feasibility measure for remote

Table 2
Feasibility measures related to video observed methadone take-home dosing and remote COVID-19 symptom screening: Engagement over the 60-day period after starting the clinical pilot among the 33 patients who participated in the clinical pilot after a successful two-week trial.

	M	(SD)
Video observed dosing of methadone take-home doses		
Number of days with a video expected (i.e., take-home days), per patient	41.89	(10.34)
... days with a video submitted by patient and accepted by a counselor, per patient	37.12	(12.66)
... days with a video submitted by patient that was reviewed but not accepted by a counselor, per patient	1.15	(2.05)
... days with a video submitted by patient that was not reviewed by a counselor, per patient	0.88	(1.19)
... days without a video submitted, per patient	2.70	(3.88)
Number of days with an in-person dose completed, per patient	16.03	(7.42)
Number of days without medication coverage (i.e., due to missed in-person dosing or not having take-home doses), per patient	0.67	(2.10)
Median (range) number of days between first and last accepted video (within 60-day observation period only)	58	(22–59)
COVID-19 symptom screening		
Number of days with a COVID-19 symptom screen expected, per patient (i.e., number of take-home days)	41.89	(10.34)
Number of days with a COVID-19 symptom screen completed, per patient	40.24	(12.58)
Number of days with one or more COVID-19 symptoms reported on a symptom screen, per patient	0.76	(2.60)
Number (and percent) of patients reporting COVID-19 symptoms on any symptom screen	5	(15 %)

Note. Mean and SD values above reflect the mean and SD of the number of days meeting each described outcome, per patient, out of a 60-day observation period that started the day the patient joined the clinical pilot.

COVID-19 symptom screening). Five pilot participants reported one or more COVID-19 symptoms during the first 60 days of the pilot. No patients were known to be diagnosed with COVID-19 (see eSupplement).

3.4. OTP services and clinical outcomes

We show OTP service utilization measures in Table 3. Pilot participants and matched controls had a similar number of visits with counselors (mean = 2.18 and 1.70 visits per patient, respectively), visits with medical providers (mean = 0.36 and 0.67, respectively), and days without medication coverage (i.e., days without in-person dosing or take-home doses available; mean = 0.67 for both groups). Pilot participants had a significantly higher number of days with an observed methadone dose (in-person or by video) compared to matched controls (mean = 53.15 vs. 16.64 days, respectively; difference = 36.51 days, 95 % CI: 31.31–41.72 days), a difference that was almost entirely attributable to the pilot participants having take-home doses observed by video.

Table 4 summarizes clinical outcome measures. All pilot participants and matched controls were retained in the OTP for the first 60 days after the pilot or the yoked period. Twenty pilot participants (61 % of sample) graduated to increased take-home doses, whereas no matched controls did. One pilot participant had ≥4 consecutive days of methadone disruption; no pilot participants or matched controls died or had known overdoses. Additional clinical outcome results are available in the eSupplement for 17 pilot participants and 20 matched controls that had emergency department, hospitalization, and COVID-19 testing data available from a health information exchange.

4. Discussion

This study evaluated the acceptability, feasibility, and clinical outcomes associated with a novel clinical pilot program that used video

Table 3

OTP-related services for patients who participated in the clinical pilot after a successful two-week trial period and matched controls.

OTP-related service measure	Pilot participants (n = 33)		Matched controls (n = 33)		Difference	(95 % CI)	p-value
	M	(SD)	M	(SD)			
Visits with counselors	2.18	(1.04)	1.70	(1.94)	0.48	(-0.29, 1.26)	0.21
Visits with medical providers	0.36	(0.93)	0.67	(2.01)	-0.31	(-1.08, 0.47)	0.44
Days without medication coverage ^a	0.67	(2.10)	0.67	(1.34)	0.00	(-0.87, 0.87)	1.00
Days with observed dosing (in-person or by video)	53.15	(7.31)	16.64	(12.97)	36.51	(31.31, 41.72)	<0.001

^a Days without medication coverage could be due to missing in-person dosing or lacking take-home doses.

Table 4

Clinical outcome measures for patients who participated in the clinical pilot after a successful two-week trial period and matched controls.

Clinical outcome measure	Pilot participants (n = 33)		Matched controls (n = 33)	
	N	(%)	N	(%)
Retained in opioid treatment program	33	(100 %)	33	(100 %)
Graduation to additional take-home doses	20	(61 %)	0	(0 %)
≥4 consecutive days of methadone interruption	1	(3 %)	0	(0 %)
Overdose (fatal or nonfatal)	0	(0 %)	0	(0 %)
Death	0	(0 %)	0	(0 %)

observation of methadone take-home dosing and remote COVID-19 symptom screening. The clinical pilot was rapidly implemented starting in April 2020 in an effort to reduce the risk of viral transmission for patients and staff during the COVID-19 pandemic while offering a technology-supported approach for observing methadone take-home doses. Results from this study indicated that patients engaged with the program at rates that exceeded the agreed upon thresholds for adequate acceptability and feasibility. Most patients who were offered the program agreed to participate. Patients in the full pilot program (i.e., those who submitted videos consistently during a two-week trial period) had 88.6 % of their methadone take-home doses observed by counselors. Moreover, most participants in the full pilot program continued to use the program successfully for at least 60 days, and the 12 % who stopped providing video confirmation of take-home dosing were disenrolled from the clinical pilot and reverted back to their previous frequency of in-person dosing.

The results of this clinical pilot program suggest that video observation of methadone take-home dosing has the potential to improve patient safety in at least three ways. First, twenty out of 33 pilot participants received increased take-home dosing privileges, resulting in an estimated total of 113 fewer in-person dosing days in this sample, which potentially reduced COVID-19 transmission risk for patients and staff. Second, even with increased take-home doses, pilot participants on average had 53.15 out of 60 days with a methadone dose observed by a clinician (in-person or by video), which was markedly higher than matched controls who had 16.64 days with a methadone dose observed during the same period, suggesting that video observed dosing can increase assurance about methadone adherence, potentially help mitigate concerns about methadone poisonings or diversion, and help OTP providers obtain the assurance they often desire when increasing the number of take-home doses for some patients (Madden et al., 2021). Third, the ability to observe methadone take-home dosing remotely often led to increased take-home privileges that could potentially reduce barriers that some patients experience with in-person requirements (e.g., limited transportation, childcare or employment obligations, etc.) (Socías et al., 2020).

Collectively, our findings suggest that video observation of methadone take-home dosing may be a viable service model for increasing observation of methadone dosing and potentially increasing take-home dosing privileges for patients who qualify for increased take-home doses but have not demonstrated enough stability to receive the maximum

increase in take-home doses allowed by the revised SAMHSA guidelines. The field has a growing interest in testing service delivery models that can expand access to methadone treatment (Joudrey et al., 2021). Other studies have also supported the feasibility and acceptability of video observation of buprenorphine ingestion with and without financial incentives for confirmed buprenorphine adherence (Godersky et al., 2019; Holtyn et al., 2021; Tsui et al., 2021), electronically controlled pill dispensers for administering and monitoring methadone doses (Dunn et al., 2021; Kidorf et al., 2021), and video observed dosing plus electronically controlled pill dispensers for patients receiving methadone or buprenorphine in pill form (Brooklyn et al., 2021). Video observation of methadone take-home dosing could be one service model that supports greater flexibility to patients and OTP systems. Future research should further clarify patients' and clinicians' perspectives about video observation of methadone take-home doses as tools to support OTP services, including whether video observation helps to mitigate potential concerns about medication diversion, misuse, or nonadherence and ways that it can support service delivery.

This study has important limitations. The setting included three OTPs managed by a single agency, covering a largely urban and suburban area in Washington State. Acceptability and feasibility could vary for other OTPs, including those in rural areas where patients have less access to home internet or cellular data coverage and often travel farther to receive care. By design, the pilot program had a limited duration and sample size, and future research should evaluate the sustainability of engagement with the program that was tested and perform higher-powered analyses with patient measures. Counselors who participated in the pilot were purposefully selected based on their availability, comfort with technology, and patient panels; more extensive testing with a broader range of counselors may be warranted. Counselors invited their patients to participate and we cannot test whether that caused potential selection bias in the patients who were offered the program or accepted it. Although control patients were matched on several key variables impacting their likelihood of graduating to increased take-home doses, they were not matched by treating providers or treating teams even though this could be a source of heterogeneity in offering increased take-home doses. We attempted to obtain data on ED visits, hospitalizations, and COVID-19 test results from a health information exchange; however, these data were missing for approximately half of the pilot participants and matched controls and thus we could not make interpretable conclusions based on these measures (see eSupplement). Finally, matched controls had more frequent take-home doses at the start of the pilot than pilot participants, a difference that was attributable to the characteristics of patients who were eligible to participate in the pilot and our inability to select matched controls based on take-home dosing schedules using the data that were available. However, most pilot participants received increases in the number of their take-home doses during the 60-day observation period, which mitigated this initial difference in in-clinic dosing during the study period (i.e., pilot participants had a mean of 16.03 in-person dosing days and matched controls had a mean of 16.67 in-person dosing days; see Tables 2 and 3, respectively). Nonetheless, matched controls may have had somewhat greater treatment stability than pilot participants, in which case pilot participants could be expected to have somewhat worse outcomes than matched controls, which the study did not observe.

The study also has several strengths. In particular, a novel, technology-supported clinical service delivery model was rapidly implemented at the onset of the COVID-19 pandemic for the purpose of increasing observation of methadone dosing, reducing potential risk of COVID-19 transmission, and supporting patients' ability to obtain increased take-home doses and stay retained in methadone treatment. The study addresses an important research topic focused on reducing barriers to receiving methadone, a lifesaving OUD treatment. The sample included patients with variable experiences in homelessness and treatment duration. The design included careful analyses with datasets from multiple sources (EHR, mobile application, health information exchange) with a matched control design to compare dosing, OTP services, and clinical outcomes for patients who did not utilize the pilot program.

4.1. Conclusion

This study provided preliminary evidence that video observation of methadone take-home doses was acceptable, feasible, and can result in increased take-home dosing privileges. Video observation of methadone take-home dosing could help OTPs confirm adherence to take-home doses, potentially helping them to increase the provision of take-home doses that in turn could reduce significant barriers to treatment, reduce the risk of opioid overdose and respiratory illness transmission, and enhance the flexibility of methadone treatment for some patients. Future efforts should focus on testing video observation of methadone take-home dosing over longer durations and with larger samples to test the program's sustainability and impact on longer-term clinical outcomes and to identify subgroups of patients for whom such a program is most helpful.

CRedit authorship contribution statement

Kevin A. Hallgren: Methodology, Formal analysis, Writing – original draft, Writing – review & editing. **James Darnton:** Investigation, Writing – review & editing. **Sean Soth:** Investigation, Data curation, Writing – review & editing. **Kendra L. Blalock:** Formal analysis, Data curation, Project administration, Writing – review & editing. **Alyssa Michaels:** Visualization, Project administration, Writing – review & editing. **Paul Grekin:** Investigation, Writing – review & editing. **Andrew J. Saxon:** Investigation, Writing – review & editing. **Steve Woolworth:** Investigation, Writing – review & editing. **Judith I. Tsui:** Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision, Project administration, Funding acquisition.

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Appendix A. Supplementary data

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References

- Ahmad, F. B., Rossen, L. M., & Sutton, P. (2021). *Provisional drug overdose death counts*. National Center for Health Statistics.
- Amram, O., Amiri, S., Thorn, E. L., Lutz, R., & Joudrey, P. J. (2021). Changes in methadone take-home dosing before and after COVID-19. *Journal of Substance Abuse Treatment*, 113(108552), 1–5. [https://www.journalofsubstanceabusetreatment.com/article/S0740-5472\(21\)00278-6/fulltext](https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(21)00278-6/fulltext).

- Brooklyn, J. R., Stothart, M., Stunell, M., Berman, V. M., Rylant, D., & Hanson, M. (2021). Characterizing the clinical use of a novel video-assisted dosing protocol with secure medication dispensers to reduce barriers to opioid treatment. *Journal of Addiction Medicine*. <https://doi.org/10.1097/ADM.0000000000000895>
- Brothers, S., Viera, A., & Heimer, R. (2021). Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19. *Journal of Substance Abuse Treatment*, 131, Article 108449. <https://doi.org/10.1016/j.jsat.2021.108449>
- Dunn, K. E., Brooner, R. K., & Stoller, K. B. (2021). Technology-assisted methadone take-home dosing for dispensing methadone to persons with opioid use disorder during the Covid-19 pandemic. *Journal of Substance Abuse Treatment*, 121, Article 108197. <https://doi.org/10.1016/j.jsat.2020.108197>
- Federal Opioid Treatment Standards. (2015). 42 CFR § 8.12.
- Frank, D., Mateu-Gelabert, P., Perlman, D. C., Walters, S. M., Curran, L., & Guarino, H. (2021). "It's like 'liquid handcuffs': The effects of take-home dosing policies on methadone maintenance treatment (MMT) patients' lives. *Harm Reduction Journal*, 18, 88. <https://doi.org/10.1186/s12954-021-00535-y>
- Godersky, M. E., Klein, J. W., Merrill, J. O., Blalock, K. L., Saxon, A. J., Samet, J. H., & Tsui, J. I. (2020). Acceptability and feasibility of a Mobile health application for video directly observed therapy of buprenorphine for opioid use disorders in an office-based setting. *Journal of Addiction Medicine*, 14, 319–325. <https://doi.org/10.1097/ADM.0000000000000608>
- Godersky, M. E., Saxon, A. J., Merrill, J. O., Samet, J. H., Simoni, J. M., & Tsui, J. I. (2019). Provider and patient perspectives on barriers to buprenorphine adherence and the acceptability of video directly observed therapy to enhance adherence. *Addiction Science & Clinical Practice*, 14, 11. <https://doi.org/10.1186/s13722-019-0139-3>
- Gomes, T., Campbell, T. J., Kitchen, S. A., Garg, R., Bozinoff, N., Men, S., Tadrous, M., Munro, C., Antoniou, T., Werb, D., & Wyman, J. (2022). Association between increased dispensing of opioid agonist therapy take-home doses and opioid overdose and treatment interruption and discontinuation. *JAMA*, 327, 846–855. <https://doi.org/10.1001/jama.2022.1271>
- Hatch-Mailette, M. A., Peavy, K. M., Tsui, J. I., Banta-Green, C. J., Woolworth, S., & Grekin, P. (2021). Re-thinking patient stability for methadone in opioid treatment programs during a global pandemic: Provider perspectives. *Journal of Substance Abuse Treatment*, 124, Article 108223. <https://doi.org/10.1016/j.jsat.2020.108223>
- Holtyn, A. F., Toegel, F., Novak, M. D., Leoutsakos, J.-M., Fingerhoo, M., & Silverman, K. (2021). Remotely delivered incentives to promote buprenorphine treatment engagement in out-of-treatment adults with opioid use disorder. *Drug and Alcohol Dependence*, 225, Article 108786. <https://doi.org/10.1016/j.drugalcdep.2021.108786>
- Joudrey, P. J., Bart, G., Brooner, R. K., Brown, L., Dickson-Gomez, J., Gordon, A., Kawasaki, S. S., Liebschutz, J. M., Nunes, E., McCarty, D., Schwartz, R. P., Szapocnik, J., Trivedi, M., Tsui, J. I., Williams, A., Wu, L.-T., & Fiellin, D. A. (2021). Research priorities for expanding access to methadone treatment for opioid use disorder in the United States: A National Institute on Drug Abuse clinical trials network task force report. *Substance Abuse*, 42, 245–254. <https://doi.org/10.1080/08897077.2021.1975344>
- Kidorf, M., Brooner, R. K., Dunn, K. E., & Peirce, J. M. (2021). Use of an electronic pillbox to increase number of methadone take-home doses during the COVID-19 pandemic. *Journal of Substance Abuse Treatment*, 126, Article 108328. <https://doi.org/10.1016/j.jsat.2021.108328>
- Madden, E. F., Christian, B. T., Lagisetty, P. A., Ray, B. R., & Sulzer, S. H. (2021). Treatment provider perceptions of take-home methadone regulation before and during COVID-19. *Drug and Alcohol Dependence*, 228, Article 109100. <https://doi.org/10.1016/j.drugalcdep.2021.109100>
- Mathers, B. M., Degenhardt, L., Phillips, B., Wiessing, L., Hickman, M., Strathdee, S. A., Wodak, A., Panda, S., Tyndall, M., Toufik, A., Mattick, R. P., & 2007 Reference Group to the UN on HIV and Injecting Drug Use. (2008). Global epidemiology of injecting drug use and HIV among people who inject drugs: A systematic review. *Lancet*, 372, 1733–1745. [https://doi.org/10.1016/S0140-6736\(08\)61311-2](https://doi.org/10.1016/S0140-6736(08)61311-2)
- National Institute on Drug Abuse. (2021). *Overdose death rates [WWW document]*. URL. National Institute on Drug Abuse <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>. (Accessed 6 January 2022).
- Nelson, P. K., Mathers, B. M., Cowie, B., Hagan, H., Des Jarlais, D., Horyniak, D., & Degenhardt, L. (2011). Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: Results of systematic reviews. *Lancet*, 378, 571–583. [https://doi.org/10.1016/S0140-6736\(11\)61097-0](https://doi.org/10.1016/S0140-6736(11)61097-0)
- Peavy, K. M., Darnton, J., Grekin, P., Russo, M., Green, C. J. B., Merrill, J. O., Fotinos, C., Woolworth, S., Soth, S., & Tsui, J. I. (2020). Rapid implementation of service delivery changes to mitigate COVID-19 and maintain access to methadone among persons with and at high-risk for HIV in an opioid treatment program. *AIDS and Behavior*, 24, 2469–2472. <https://doi.org/10.1007/s10461-020-02887-1>
- Poorman, E., Glick, S. N., Hiser, J. K. D., Bhatraju, E., & Tsui, J. I. (2021). Increased utilization of buprenorphine and methadone in 2018 compared to 2015 among Seattle-area persons who inject drugs. *Journal of Substance Abuse Treatment*, 129, Article 108375. <https://doi.org/10.1016/j.jsat.2021.108375>
- Schramm, Z. A., Leroux, B. G., Radick, A. C., Ventura, A. S., Klein, J. W., Samet, J. H., Saxon, A. J., Kim, T. W., & Tsui, J. I. (2020). Video directly observed therapy intervention using a mobile health application among opioid use disorder patients receiving office-based buprenorphine treatment: Protocol for a pilot randomized controlled trial. *Addiction Science & Clinical Practice*, 15, 30. <https://doi.org/10.1186/s13722-020-00203-9>
- Soares, W. E., Melnick, E. R., Nath, B., D'Onofrio, G., Paek, H., Skains, R. M., Walter, L. A., Casey, M. F., Napoli, A., Hoppe, J. A., & Jeffery, M. M. (2021). Emergency Department Visits for nonfatal opioid overdose during the COVID-19

- pandemic across six US Health Care Systems. *Annals of Emergency Medicine*. <https://doi.org/10.1016/j.annemergmed.2021.03.013>. S0196-0644(21)00226-2.
- Socias, M. E., Dong, H., Wood, E., Brar, R., Richardson, L., Hayashi, K., Kerr, T., & Milloy, M.-J. (2020). Trajectories of retention in opioid agonist therapy in a Canadian setting. *The International Journal on Drug Policy*, 77, Article 102696. <https://doi.org/10.1016/j.drugpo.2020.102696>
- Substance Abuse and Mental Health Services Administration. (2020). *Opioid Treatment Program (OTP) guidance*.
- Substance Abuse and Mental Health Services Administration. (2022a). *Opioid treatment program directory*.
- Substance Abuse and Mental Health Services Administration. (2022b). Methadone take-home flexibilities extension guidance [WWW document]. URL <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance>. (Accessed 5 May 2022).
- Tsui, J. I., Leroux, B. G., Radick, A. C., Schramm, Z. A., Blalock, K., Labelle, C., Heerema, M., Klein, J. W., Merrill, J. O., Saxon, A. J., Samet, J. H., & Kim, T. W. (2021). Video directly observed therapy for patients receiving office-based buprenorphine – a pilot randomized controlled trial. *Drug and Alcohol Dependence*, 227, Article 108917. <https://doi.org/10.1016/j.drugalcdep.2021.108917>