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...
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. 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 emoche 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., opening 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

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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”.
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.

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 \( \geq 50 \% \) 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 \( \geq 50 \% \) 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 \( \geq 4 \) 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

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-three 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 characteristics.
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 per week, 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.
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., 96.1 % of take-home days; primary feasibility measure for remote 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).

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 starting the clinical pilot among the 33 patients who participated in the clinical pilot after a successful two-week trial. Starting the clinical pilot among the 33 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 3 summarizes clinical outcome measures. All pilot participants and matched controls were retained in the OTP for the first 60 days after starting the clinical pilot among the 33 patients who participated in the clinical pilot after a successful two-week trial.
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 technology-supported approach for observing methadone take-home after a successful two-week trial period and matched controls.

Moreover, most participants in the full pilot program continued to use 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 provider, 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 (Brooklynn 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.

### Table 3

<table>
<thead>
<tr>
<th>Clinical outcome measure</th>
<th>Pilot participants (n = 33)</th>
<th>Matched controls (n = 33)</th>
<th>Difference (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graduation to additional take-home doses</td>
<td>20 (61%)</td>
<td>0 (0%)</td>
<td>20 (61%)</td>
<td>0.001</td>
</tr>
<tr>
<td>&gt;4 consecutive days of methadone interruption</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>1 (3%)</td>
<td></td>
</tr>
<tr>
<td>Overdose (fatal or nonfatal)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

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

### Table 4

<table>
<thead>
<tr>
<th>Clinical outcome measure</th>
<th>Pilot participants (n = 33)</th>
<th>Matched controls (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overdose (fatal or nonfatal)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

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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. Blacock: 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

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jsat.2022.108896.

References


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