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Research Paper

“Get in and get out, get on with life”: Patient and provider perspectives on methadone van implementation for opioid use disorder treatment

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ABSTRACT

Background: Expanding access to opioid use disorder (OUD) treatment, including methadone, is imperative to address the US overdose crisis. In June 2021, the Drug Enforcement Administration announced new regulations allowing all opioid treatment programs (OTPs) to deploy mobile medication units, or methadone vans, to dispense OUD medication treatment outside of clinic walls, ending a 13-year moratorium. We conducted a qualitative study evaluating one opioid treatment program’s experience, including benefits and challenges with implementing a methadone van, to inform future policy and clinical practice.

Methods: We recruited staff and patients receiving OUD medication treatment from an OTP in San Francisco, CA. The OTP had one operating van before March 2020 and began operating an additional van in response to COVID19-related efforts to de-populate clinic settings. We interviewed 10 providers and 20 patients from August to November 2020. We transcribed, coded, and analyzed all interviews using modified grounded theory methodologies.

Results: Both patients and providers perceived significant benefits with receiving OUD medications using methadone vans. Patients preferred dosing at the van over the clinic because they were able to “get in and out” faster. Both staff and patients appreciated being able to use phone counseling to connect with counselors which helped reduce in-person visits and streamline workflows. Providers also noted van implementation challenges, including daily van set up, urine drug testing, and delivering counseling to patients who lacked phones.

Conclusions: Eased restrictions on methadone van implementation represent a new strategy for expanding OUD treatment access. In our qualitative study, patients and staff were satisfied with methadone van implementation, though the OTP still faced implementation challenges. Audio-only counseling and other workflow solutions helped facilitate implementation, and several policy considerations like maintaining audio-only counseling flexibilities are key to ensuring future van success. Methadone vans offer the potential to expand treatment uptake, while prioritizing patient-centered care.

Introduction

Increasing access to medication treatment for opioid use disorder (OUD) remains a critical part of the United States' response to ending the overdose crisis. Despite rising overdose death rates in 2021 (Ahmad et al., 2021), the treatment gap is stark, with less than 20 % of individuals with OUD in the United States accessing medication for OUD (Krawczyk, Rivera, Jent et al., 2022). Methadone remains one of the most effective treatment options (National Academies of Sciences, Engineering & Medicine, 2019), though in the United States, it can only be accessed through opioid treatment programs (OTPs). OTPs are a highly regulated system of "methadone clinics" separated from the rest of the healthcare system, with an estimate of over 420,000 patients receiving care across nearly 2000 OTPs across the country (Knopf, 2021). Most individuals accessing methadone are required to present to clinic daily for several months before meeting criteria (e.g., adequate treatment adherence, drug abstinence, and stable housing and shelter) for unsupervised take-home doses of methadone. Many state OTP regulations also limit the number of clinics per state or pose barriers to opening new ones, and existing OTPs are often located far away from where individuals with OUD live (Kleinman, 2020; The Pew Charitable Trusts, 2022). The time and cost related to travel, especially when undertaken daily, is also an onerous burden for patients (Englander et al., 2023). All these factors combined make methadone challenging to access.

Overdose deaths only accelerated during COVID-19, creating a syndemic of COVID-19 and overdose public health emergencies. However, COVID-19 federal regulatory flexibilities introduced in March 2020, such as guidelines easing restrictions on counseling, unsupervised methadone take-homes, and allowing telehealth to be used to fulfill mandatory counseling requirements for the first time, afforded government agencies the opportunity to evaluate the impact of loosened regulations. Emerging research has found that these flexibilities led to improved patient treatment experiences, treatment retention, patient and provider satisfaction (Adams et al., 2023; Hunter et al., 2021; Krawczyk et al., 2023; Levander et al., 2021; Suen, Castellanos et al., 2022). In 2021, compelled by the need to expand treatment access, federal agencies responsible for regulating methadone treatment, including the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA), also announced new regulations re-allowing OTPs to establish mobile medication units, or methadone vans, thereby ending a 13-year moratorium (Office of the Federal Register, 2021). Methadone vans are vehicles that travel daily from the clinic to a pre-approved location and deliver medication treatment to OTP patients for several hours before returning to the clinic, expanding OTP service area and increasing access for potential patients outside of clinic walls. Government agencies in New York, Pennsylvania, and California have started examining guidance and implementation policies for expanding the use of

methadone vans (Hazelton, 2023). SAMHSA in December 2022 further released new proposed changes to federal law, essentially codifying many of the flexibilities introduced during COVID-19, such as allowances for telehealth, counseling, and further clarifying allowances and accreditation for methadone vans (Substance Abuse and Mental Health Services Administration (SAMHSA), 2022).

Studies evaluating methadone van implementation are few, showing patients who receive methadone treatment through vans have similar if not improved treatment retention compared to clinic patients (Breve et al., 2022; Chan et al., 2021; Gibbons et al., 2022; Hall et al., 2014). Further, methadone vans increase access to treatment for patients facing structural challenges such as homelessness, disability, lack of or underinsurance (Chan et al., 2021; Gibbons et al., 2022; Hall et al., 2014). Reports from urban cities in the Netherlands, India, and Canada have also found similar benefits, with methadone vans lowering barriers, facilitating access, and increasing retention for marginalized populations facing geographic and other sociodemographic challenges (Buning et al., 1990; Luce, 2011; Rao et al., 2021). As interest in using methadone vans to increase access is growing in the United States, studies evaluating clinician and patient perspectives on methadone van implementation, including benefits and challenges, are needed. We conducted a qualitative evaluation of provider and patient experience with methadone treatment delivery from a single OTP located in San Francisco during COVID-19, which included implementing new methadone van services for patients. We sought to understand the perspectives and impact of methadone van implementation on patients and OTP providers. Here we present qualitative findings related to the clinic's expansion of their methadone van program to guide future policy and clinical recommendations.

Methods

Clinic setting

We recruited OTP providers and patients with OUD from a single OTP that is located on the campus of an urban, academic public hospital in San Francisco, CA. The clinic serves as one of the city's main methadone providers and operates as a partnership between the San Francisco Department of Public Health and the Division of Substance Abuse and Addiction Medicine at the University of California San Francisco. The clinic furnishes both methadone and buprenorphine for OUD treatment, substance use and mental health counseling, HIV and Hepatitis C treatment, and serves patients with all types of insurance, including private, Medicaid, Medicare, and uninsured. The majority of clinic's patient population face structural challenges, including homelessness as well as mental and physical health conditions leading to comorbid disabilities.

Prior to 2020, the OTP had one methadone van operating about five miles from its brick-and-mortar clinic site, with 70 out of the 580 (12 %) clinic patients receiving methadone at the van starting in March 2020. In mid-March 2020, the OTP responded to the COVID-19 pandemic and need to de-congregate their main clinic, by requesting and receiving permission from the California Department of Health Care Services to operate an additional methadone van, physically located in a hospital parking lot that is inaccessible to outside visitors. OTP clinic leadership divided the patient population into two groups: 1) patients with less stability in their OUD treatment based on

OTP clinician judgement and receiving daily dosing or less than 6 take-homes per week – representing most of the clinic population, these individuals were required to visit the van for direct observation of methadone dosing (see Fig. 1); and 2) patients with OUD treatment stability receiving 6 or more take-homes each visit (i.e., coming into the OTP weekly or less) – these individuals would pick-up their take home doses from the clinic. Patients receiving greater than 6 take home doses remained at the clinic because it required more time to prepare a larger number of doses, and this would result in longer lines if it were van-based. Decisions of clinical stability were made on a case-by-case basis, and the most common determinants of clinical instability included ongoing non-prescribed opioid use, active alcohol or benzodiazepine use disorder, untreated serious mental illness, and currently experiencing homelessness preventing safe storage of methadone.

The clinic van was open seven days a week from 7 am to 11 am, and 12:30 pm to 2 pm daily. The van was staffed by a nurse and counselor, with additional clinical support available over the phone from the brick-and-mortar clinic. Over time, additional features were added to the van site, including two counseling booths (for Zoom sessions with remote counselors and medical providers) and a portable bathroom with handwashing availability for urine drug testing that was accessible for all individuals including those with disabilities.

Qualitative data collection and analysis

Our methods have been previously described,(Suen, Castellanos et al., 2022) where the current study draws from unpublished data related to methadone vans from the original study. Briefly, we recruited OTP staff from a variety of job disciplines, and patients with OUD with diverse OUD treatment experiences and stability. We oversampled patients new to the clinic to increase likelihood of exposure to regulatory changes including using the new methadone van. We interviewed 20 patients and 10 OTP staff (five substance use counselors, two physicians, and three nurse practitioners). KRK conducted all 20–40-min interviews from August to September 2020, using a semi-structured interview guide focusing on OUD treatment access, experiences, and utilization before and during COVID-19, impact of regulatory changes on methadone delivery, and recommendations for future clinical and policy practices. Analysis used a thematic approach based on modified grounded theory methodologies. Modified grounded theory is an approach within qualitative research and ethnography that builds upon the traditional grounded theory method developed by sociologists Barney Glaser and Anselm Strauss in the 1960s (Strauss & Corbin, 2008; Strauss & Glaser, 2017). Traditional grounded theory aims to develop theories directly from the data collected during the research process, rather than fitting data into pre-existing theoretical frameworks. Modified grounded theory involves adaptations or modifications to the original grounded theory approach to better suit the research context, questions, or the evolving understanding of the research process (Kambaru, 2018; Strauss & Glaser, 2017). In this study, we used modified ground theory to understand the social and clinical processes that informed the emergence and consequences of new care practices resulting from COVID-19. We modified our analysis to focus specifically on the implementation, utilization, and impacts of van methadone delivery rather than to derive theories about new phenomena.

Our collaborative research team brought together diverse expertise in addiction medicine, implementation science, and medical anthropology. Led by KRK, a medical anthropologist who has

conducted qualitative research on harm reduction service provision since 1995, the research team was comprised of a group of addiction medicine specialists, implementation scientists, and clinical research coordinators to collectively offer a multidimensional understanding of the research subject. SC and NJ coded all transcripts and iteratively discussed with the study team to ensure comprehensive revision of existing codes. KRK and LWS reviewed interview transcripts, coding, and quotes related to van implementation and compiled potential themes. Themes were iteratively discussed between all study researchers (SS, BS, KRK, LWS, BL) until they reached consensus. We did not collect demographic data on providers to protect their anonymity, and patient participant demographics have been previously described. (Suen, Castellanos et al., 2022)

This study was approved by the University of California San Francisco institutional review board (IRB # 20-31509).

Results

Both patient and provider participants highlighted several benefits and challenges of methadone van implementation. Themes and exemplary quotes are summarized in Table 1, including themes of 1) efficiency and convenience: methadone delivery at vans were more streamlined with easier access to patients, creating a less stressful and chaotic environment compared to OTP clinic settings; 2) reduced time in the traditional clinical setting: vans removed some of the undesirable aspects of accessing methadone treatment by existing outside of the usual clinic or hospital settings; 3) impact of telehealth counseling: telehealth facilitated van implementation though still had logistical challenges; and 4) additional challenges: including methadone medication set up and urine drug testing. Based on these findings, recommendations for future consideration are summarized in Table 2.

Less crowding and chaos at the van streamlined efficiency and improved experiences

Many participants accessing methadone van services highlighted how by being parked outside in the parking lot, methadone delivery was less crowded. Beyond the benefit of reducing COVID-19 risk, the more spacious and relaxed van environment contrasted with the chaotic, crowded environment of the clinic that patients had previously experienced before the pandemic. Van participants highlighted how there were often many steps to accessing methadone in the brick-and-mortar clinic, and the time pressure to complete all the steps before the clinic closed increased patient anxiety and stress. The clinic was often crowded, especially right before closing time, which increased the chaotic atmosphere.

Like going into the building, you got to go upstairs, you got to put masks on and all that shit, and then you got to go upstairs, get in line and give them your name and then you got to sit down and wait for them to call you and, it's kind of a pain in the ass. Being out at the van, you just roll in. [...] There's a handful of people there, three or four nurses there passing it [methadone] out, so you can get it quicker and get in and get out, get on with life. I like that. [Patient Participant I]

Patients with significant comorbidities and disabling conditions likely gained the most benefits, through easier access to methadone by not having to travel further distances to the brick-

and-mortar clinic and being able to communicate with their counselors and meet counseling requirements through telehealth. As patients with disabilities are more likely to face severe complications from COVID-19, they further benefitted by having van dosing take place outdoors and thereby lowering their risk of infection.

By shifting most patients to dosing at the van, the clinic not only de-populated the clinic to reduce COVID-19 spread, but it also increased efficiency, because patients could simply walk up to the line at the van, receive their methadone dose, and leave. This change reduced anxiety and tension for both patients and staff.

You can't overstate how much more anxiety, tension, agitation there would be if we didn't have it [the van]. Because on a bad day, like on a tough day, we would have 30 people in the waiting area extending into the outside if things got backed up. And that's when we didn't have a horrible pandemic. [...] [The van] has benefits beyond just the COVID control aspect. Some other things that the patients have said that they like is they come in, they get a dose, and they go. [...] Those are the things that are the biggest advantages from my perspective. It keeps people moving. [Staff Participant H]

By streamlining access to methadone treatment, patients and staff perceived less stress and higher quality of care at the OTP.

Vans were more positive environments than clinics

Because the van was outside and away from the brick-and-mortar clinic setting, patients remarked on how they perceived this as beneficial, due to not having constant reminders of their OUD.

"[The van] was different and it wasn't so overwhelmingly depressing, because when you go to the hospital, there's somebody who's died every day, and they put up a little plaque [memorial message]. [...] I like the fact that we don't have to go to the [clinic] [...] It's just strange, it's like it's a hospital you know. And it makes you feel really sick. I know I'm sick [have OUD] and I know that. It becomes debilitating you know at times. [...] Going to a hospital every day, it reinforces something in my head, at least it makes me feel like there is something seriously wrong with me." [Patient Participant L]

Being constantly reminded about the morbidity and mortality of having OUD made participants desire a setting that was separated from the usual clinic milieu, and the vans offered an alternative treatment setting. Patients and providers were also able to reimagine what treatment spaces could look like outside of clinic walls. They created communities to foster mutual aid, and the decreased surveillance and austerity usually associated with clinic environments meant that patients could help reshape the setting into more joyous, healing spaces:

Pretty much a lot of the people, they're respectful toward each other. Everybody gets along. They try to help each other out when it comes to, even if it's food, if it's you need a blanket. [...] Sometimes like we'll group together to where we meet here in the back. [...] We'll have lunch and we'll let out everything that we need to let out. [Patient Participant B]

Telehealth counseling facilitated van implementation but came with challenges

Providers and patients emphasized how being allowed to use telehealth for counseling, particularly audio-only counseling, was crucial to reducing in-person visits and benefitted both patients and staff. Patients liked telehealth counseling paired with dosing at the van, because they could get in and out at the van quickly and counseling outside of visits were more convenient:

I love [the van]. Much quicker in and out. I just feel like you go in, you get your methadone, and you leave. Your counselor's there. I don't feel by any stretch that my counselor has been removed from me or that I can't get access to him. [Patient Participant G]

It's easier for me. I don't have to stop what I'm doing to go to an interview or an appointment. It's just one less thing that I have to stop doing, so I can keep doing what I'm doing, and I could be on the phone, I could talk to her. It's not a big deal. [Patient Participant I]

OTP staff appreciated the flexibility of offering multiple modalities for counseling. Phone visits reduced work burdens. It also shifted communication toward the practice of more frequent, shorter touch points, which benefitted relationships.

An advantage is that we can call our clients, and that counts as counseling. I have a lot of really good conversations with my clients on the phone. And so for my job specifically that's been great. [Staff Participant E]

When you tell clients, "This is my work cell phone, you can text me on it, you can call me on it, you know, any time of day, I won't answer it after office hours," all the counselors have been saying that their clients have been reaching out to them more frequently for less time [...] There's more frequency of communication between the counselors and the clients than there was before, which is surprisingly helpful. [Staff Participant I]

However, counselors still faced challenges with telehealth counseling, particularly for people who lacked phones. This was exacerbated by increased difficulty reaching patients in-person at the van, as patients were often "in and out". For patients they couldn't reach, counselors relied on "stop dosing," flagging patients so they could not receive their methadone until they met with their counselor in clinic:

Because before I had the luxury of having the person come into the office and I could do face-to-face and start to get to know them. And now sometimes when people come to the van, they come at the last minute. And so, they have to dose and then you might not get in touch with them at all. So, then you have to stop dose them and some people don't react well to being stop dosed. [Staff Participant C]

Therefore, stop dosing was seen as necessary by counselors to complete mandatory counseling requirements. This may have been detrimental to the relationship by forcing the patient to participate in counseling that they may have found unhelpful or unnecessary, as not all patients desired counseling as a part of their treatment.

“[At the van], they don’t need to talk to you as much, I ain’t gotta see no counselor. You just take your dose and go and there’s no nothing, none of that.” [Patient Participant E]

Another challenge to overcome was connecting patients with their assigned counselor at the van, since most counselors were located at the brick-and-mortar site. In response, the OTP created the counselor of the Day at the van site, whose role was to provide contact between patients at the van and their counselors or physicians located back at the clinic, as well as help address any administrative paperwork to simplify workflows.

We weren’t able to get a hold of a lot of clients because of the lack of phones a lot of the clients had, so I was down at the van site like every day for a few hours each shift [...] trying to connect clients to their counselors within, with a centralized phone that we had. [Staff Participant B]

Most patients preferred to maintain the option for phone counseling, while OTP staff were mixed about their preference to return to entirely in-person versus relying mostly on telehealth:

We don’t have the capacity and time to spend with those clients like we used to before, which is a huge thing. Like if clients don’t feel engaged to the clinic, they’re going to drop out easily [...] So in some ways logistically [phone counseling] works, but in terms of like actual treatment and being connected to your counselors, I think that makes a huge difference of not being able to face-to-face and meet them face-to-face. [Staff Participant A]

If [telehealth counseling] helps me help my clients and they seem happier and the only difference is I don’t sit in the room with them [...] I would just keep doing this because it’s working so well. [Staff Participant I]

Van implementation included other logistical challenges, including with medication set up and urine drug testing

Because the new methadone van was implemented relatively rapidly and under the pressures and uncertainty of the COVID-19 pandemic, OTP staff faced other logistical challenges. Federal regulations set by the Drug Enforcement Administration require methadone be stored only within clinics behind locked doors, and therefore medication had to be set up and transported back and forth from the van to the clinic every day with the accompaniment of an armed guard. There was also a long and cumbersome process to establish secure Wi-Fi connectivity and allow access to the clinic’s electronic health record within the methadone van for medication dispensing.

There’s been a lot of problems with just getting set up in the mornings and then just breaking everything down in the afternoons. Each day, we still have to set up all the medications we need, the methadone, the buprenorphine, the directly observed therapy that we’re giving other medications to. [...] And then we have to make sure we’re walking over there with the guard. And at the site just getting that set up, all the computers set up, the methadone pumps set up, and connected to the WIFI connection, the secure connection to the hospital. There’s a lot of different parts to it physically. [Staff Participant D]

One patient remarked how the van computers were not working one day, and how many people had to be directed to dose at the clinic, increasing the sense of chaos and crowding on site:

One day the, the computers went down in the vans, right, so I had to go inside the clinic and it feels strange because it's so crowded in there, you wouldn't believe, I mean, I'm sure you would believe but it is so many people on the dose. [Patient Participant I]

Urine drug testing was also a challenge. Prior to COVID-19, urine collection happened inside the clinic, where the physical patient, existing systems, and staffing made it relatively easy. Clinical staff had to check each urine drug sample for appropriate temperature and pH to ensure lack of tampering. During COVID-19, urine drug testing was initially suspended in the first half of 2020 and reinitiated at the outdoor van site in the latter half of 2020 presented new challenges for clinic staff and patients. With the transition to the outdoor site, patients had access to only a single portable bathroom (which required repeated cleaning throughout the day). Lack of other staff at the site required nurses at the van to try to manage urine collection which slowed down the ability to provide methadone and prolonged waiting times.

The clinic created several innovations to address challenges over time. Clinic leadership purchased a portable bathroom that was compliant with the American with Disabilities Act and had handwashing on site, and additional non-nursing staff became available and designated with handling urine drug testing to streamline workflows.

Discussion

Our qualitative study evaluating the impact of COVID-19 changes on methadone van treatment delivery elucidated several findings, including that some patients preferred the less chaotic, nontraditional clinical setting of the van compared to the brick-and-mortar clinic, and counseling flexibilities facilitated methadone delivery at the vans and became a key component of its success. OTP staff adapted workflows to meet patient needs, while patients appreciated the flexibility in which they could receive care. These findings parallel existing studies, which have highlighted how COVID-19 flexibilities (although most focused exclusively on take-home provision) have allowed for more individualized care and autonomy, promoting independence, and supporting treatment goals (Hunter et al., 2021; Levander et al., 2021; Suen, Castellanos et al., 2022).

To our knowledge, this is the first qualitative study examining the perspectives of patients and OTP clinicians on provision of methadone using methadone vans. One recent scoping review conducted key informant interviews with directors of federal agencies and OTPs which found strong support for proposed changes to methadone van regulations, particularly for geographic areas lacking treatment access such as rural communities and jails (Chan et al., 2021). Our study adds to this literature by emphasizing how the patient experience may be improved when offered the ability to dose in a methadone van setting, which could translate into improved treatment adherence and retention. These benefits may also be generalizable to other countries who face significant stigma in setting up methadone clinics, and allowing methadone delivery via vans may help address these barriers (Buning et al., 1990; Rao et al., 2021). Further, we found flexibilities related to counseling

during COVID-19 facilitated van implementation for patients and staff by easing the burdens of treatment requirements.

Our study found that the OTP was nimble in overcoming implementation challenges, such as developing a Counselor of the Day role to help with connecting patients with their assigned counselors and clinicians at the brick-and-mortar site and addressing on-site administrative needs. The OTP also quickly learned ways to streamline urine drug testing at the van, which can be a significant barrier to implementation.

The most significant facilitator to van implementation seemed to be allowance for telehealth counseling, especially audio-only. Prior to COVID-19, California had state requirements (Code of Regulations Title 9, Section 10,345(a)(b)) requiring OTP patients to participate in a minimum of 50 min of counseling services per calendar month, where counseling had to be done “face-to-face” with the patient. In March 2020, California regulators provided a blanket exemption to the “face-to-face” requirement, allowing telehealth counseling sessions via audio-only or video visual modalities. In our study, while some counselors missed having in-person visits in the clinic setting, both patients and staff reported satisfaction with being able to meet counseling requirements using audio-only telehealth, which increased frequency of communication between counselors and patients and improved relationships. By reducing in-person counseling time and removing barriers associated with a traditional brick-and-mortar clinic, van visits became more streamlined, reducing wait times and improving patient treatment experiences. Patients could be “in and out” dosing at the van and be freed to tend to other activities of their life. This was particularly meaningful for patients with chronic physical, medical, and mental disabilities. Mobile methadone vans could offer specific benefits for clients with physical disabilities that limit travel or easy mobility, as well as homeless participants whom risk losing their belongings if left unattended for long periods of time by offering a place where individuals could bring their belongings in a more spacious setting. Despite these benefits, challenges remained: patients who lacked phones did not benefit, and some patients had to be stop-dosed by counselors to ensure they met counseling requirements.

Implications and recommendations for state regulatory agencies

Many addiction treatment experts, including patients in methadone treatment, have questioned the utility of counseling requirements at OTPs in recent years, as studies reveal counseling (outside of contingency management) has not shown significant benefit over opioid agonist treatment alone (Carroll & Weiss, 2017; McCarty et al., 2021; Timko et al., 2016). SAMHSA recently proposed regulatory changes stating that many patients may not find benefit from counseling and stated patient refusal to participate in counseling should not be grounds for OTP discharge (Substance Abuse and Mental Health Services Administration (SAMHSA), 2022). However, almost half of US states, including California where this study’s OTP is located, have additional regulations imposing strict counseling schedules (e.g., minimum number or length of sessions) that are often tied to eligibility for take home medication (Pew Research Center, 2022). Further, some states including California have already moved away from audio-only allowances and now requiring video-enabled technologies for telehealth counseling (California Department of Health Care Services Narcotic Treatment Program, personal communication, December 29, 2022). As audio-only counseling was integral for the success of this OTP’s methadone van program,

making audio-only counseling an enduring part of methadone treatment should be strongly considered by state regulatory agencies to achieve a high level of efficacy and patient satisfaction. States can also consider going further by defaulting to federal methadone guidelines and removing requirements for counseling as a means of reduce barriers to treatment retention and access. In fact, because federal regulations are already substantial and detailed, states with additional regulations could consider eliminating them altogether in favor of the federal regulations.

OTPs also have financial incentives to require counseling, as most are reimbursed based on number of counseling visits, incentivizing quantity of counseling rather than quality or matching counseling to patient needs and preferences. Several states including Massachusetts and New York have moved to bundled Medicaid payments rather than paying for individual counseling visits to address this issue, and other state regulatory agencies can consider following suite to avoid misaligning financial incentives with patient treatment goals (New York State Office of Addiction Services & Supports, 2021; Suen, Coe et al., 2022; Wyatt et al., 2022).

Implications and recommendations for federal regulatory agencies

OTP staff emphasized multiple logistic challenges with daily set up and break down of methadone van implementation, medication security, urine drug testing, and other logistical challenges with meeting DEA, SAMHSA, and California requirements for methadone van implementation as well as additional accreditation requirements. These results align with another study interviewing key informants which showed that the need for vans to deliver medication to a remote site and back to the brick-and-mortar site daily, often requiring vans to drive hours each day. These requirements pose a significant barrier to implementation and should be reconsidered.

It is important to note that the OTP already owning several vans that were DEA-approved is quite unusual and eased the burden of van implementation at this site. Methadone vans are burdensome and costly for OTPs (Breve et al., 2022; Gibbons et al., 2022; Pew Research Center, 2022), with estimated startup costs of \$150,000–250,000 (Gibbons et al., 2022). SAMHSA has announced federal funds to help clinics implement methadone vans, and local governments are also considering using opioid settlement funds to help support methadone van implementation (Gibbons et al., 2022; Hazelton, 2023). However, it is unclear if these funding sources are sustainable long-term, and further funding sources to support OTP clinics in expanding methadone van programs are therefore essential to program success.

Limitations

Our study had several limitations. Interviews were conducted at the end of 2020 during a time of rapid change in health care and methadone regulations, and it is unclear how this may have impacted findings. Because our results were limited to one OTP in California, generalizability to other OTPs especially in other states with different regulations is unclear. Underserved rural or remote areas are also present a major opportunity for methadone van services, and this study does not address some of the challenges and possibilities inherent in those settings. Despite these limitations, to our knowledge, ours is the first qualitative study evaluating the perspectives of patients and clinicians on methadone van implementation, and our results can help inform future implementation evaluation of methadone van programs.

Conclusion

Regulation of OTP clinics has undergone rapid changes in recent years, precipitated by the COVID-19 public health emergency and the urgent need to expand treatment access to address escalating overdose deaths. Methadone van programs offer one strategy for existing OTPs to expand access, and our study found patients and staff were satisfied with methadone delivery using vans, facilitated by telehealth counseling and reconfigurations of clinic workflow. Maintaining audio-only counseling flexibilities beyond COVID-19 public health emergency could help OTPs with methadone van implementation while aligning with goals toward supporting patient-centered care and autonomy.

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Ethical approval

All research was conducted in accordance with both the Declarations of Helsinki and Istanbul. This study was reviewed and approved by the Institutional Review Board (IRB) at University of California San Francisco (IRB # 20-31509).

CRedit authorship contribution statement

Leslie W. Suen: Scott Steiger: Writing – review & editing, Methodology, Conceptualization. Brad Shapiro: Writing – review & editing, Methodology, Conceptualization. Stacy Castellanos: Writing – review & editing, Software, Resources, Project administration, Data curation. Neena Joshi: Methodology, Formal analysis. Barrot H. Lambdin: Writing – review & editing, Conceptualization. Kelly R. Knight:

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

- Adams, A., Blawatt, S., MacDonald, S., Finnick, R., Lajeunesse, J., Harrison, S., Byres, D., Schechter, M. T., & Oviedo-Joekes, E. (2023). Provider experiences with relaxing restrictions on take-home medications for opioid use disorder during the COVID-19 pandemic: A qualitative systematic review. *The International Journal on Drug Policy*, 117, Article 104058. <https://doi.org/10.1016/j.drugpo.2023.104058>
- Ahmad, F. B., Rossen, L. M., & Sutton, P. (2021). Provisional drug overdose death counts. National Center for Health Statistics. <https://www.cdc.gov/nchs/nvss/vsrr/drug-o-verdose-data.htm>.
- Breve, F., Batastini, L., LeQuang, J. A. K., & Marchando, G. (2022). Mobile narcotic treatment programs: On the road again? *Cureus*, 14(3), Article e23221. <https://doi.org/10.7759/cureus.23221>
- Buning, E. C., Van Brussel, G. H. A., & Van Santen, G. (1990). The 'methadone by bus' project in Amsterdam. *British Journal of Addiction*, 85(10), 1247–1250. <https://doi.org/10.1111/j.1360-0443.1990.tb01598.x>
- Carroll, K. M., & Weiss, R. D. (2017). The role of behavioral interventions in buprenorphine maintenance treatment: A review. *American Journal of Psychiatry*, 174 (8), 738–747. <https://doi.org/10.1176/appi.ajp.2016.16070792>
- Chan, B., Hoffman, K. A., Bougatsos, C., Grusing, S., Chou, R., & McCarty, D. (2021). Mobile methadone medication units: A brief history, scoping review and research opportunity. *Journal of Substance Abuse Treatment*, 129, Article 108483. <https://doi.org/10.1016/j.jsat.2021.108483>
- Englander, H., Gregg, J., & Levander, X. A. (2023). Envisioning minimally disruptive opioid use disorder care. *Journal of General Internal Medicine*, 38(3), 799–803. <https://doi.org/10.1007/s11606-022-07939-x>
- Gibbons, J. B., Stuart, E. A., & Saloner, B. (2022). Methadone on wheels—a new option to expand access to care through mobile units. *JAMA Psychiatry*, 79(3), 187–188. <https://doi.org/10.1001/jamapsychiatry.2021.3716>
- Hall, G., Neighbors, C. J., Iheoma, J., Dauber, S., Adams, M., Culleton, R., Muench, F., Borys, S., McDonald, R., & Morgenstern, J. (2014). Mobile opioid agonist treatment and public funding expands treatment for disenfranchised opioid-dependent individuals. *Journal of Substance Abuse Treatment*, 46(4), 511–515. <https://doi.org/10.1016/j.jsat.2013.11.002>
- Hazelton, A. W. | L (2023). Mobile methadone clinics are among the initiatives Philly will fund with opioid settlement funds. January 5. Philadelphia Inquirer <https://www.inquirer.com/news/philadelphia-opioid-settlement-funds-kensington-overdose-crisis-2023-0105.html>.
- Hunter, S. B., Dopp, A. R., Ober, A. J., & Uscher-Pines, L. (2021). Clinician perspectives on methadone service delivery and the use of telemedicine during the COVID-19 pandemic: A

- qualitative study. *Journal of Substance Abuse Treatment*, 124, Article 108288.
<https://doi.org/10.1016/j.jsat.2021.108288>
- Kambaru, A. (2018). Qualitative research and a modified grounded theory approach. *Tsuru University and Review*, 88, 47–58. <http://trail.tsuru.ac.jp/dspace/handle/trair/871>.
- Kleinman, R. A. (2020). Comparison of driving times to opioid treatment programs and pharmacies in the US. *JAMA Psychiatry*, 77(11), 1163. <https://doi.org/10.1001/jamapsychiatry.2020.1624>
- Knopf, A. (2021). OTP patient census information now being collected. *Alcoholism & Drug Abuse Weekly*, 33(19). <https://doi.org/10.1002/adaw.33067>, 6–6.
- Krawczyk, N., Rivera, B. D., Jent, V., Keyes, K. M., Jones, C. M., & Cerda, M. (2022). Has the treatment gap for opioid use disorder narrowed in the U.S.? A yearly assessment from 2010 to 2019. *International Journal of Drug Policy*, 110, Article 103786. <https://doi.org/10.1016/j.drugpo.2022.103786>
- Krawczyk, N., Rivera, B. D., Levin, E., & Dooling, B. C. E. (2023). Synthesising evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. *The Lancet Public Health*, 8(3), e238–e246.
[https://doi.org/10.1016/S2468-2667\(23\)00023-3](https://doi.org/10.1016/S2468-2667(23)00023-3)
- Levander, X. A., Hoffman, K. A., McIlveen, J. W., McCarty, D., Terashima, J. P., & Korthuis, P. T. (2021). Rural opioid treatment program patient perspectives on take-home methadone policy changes during COVID-19: A qualitative thematic analysis. *Addiction Science & Clinical Practice*, 16, 72. <https://doi.org/10.1186/s13722-021-00281-3>
- Luce, J. (2011). A cross-canada scan of methadone maintenance treatment policy developments. Centre for Addiction and Mental Health. <https://www.ceca-ccet.ca/pdf/CECA%20MMT%20Policy%20Scan%20April%202011.pdf>.
- McCarty, D., Chan, B., Bougatsos, C., Grusing, S., & Chou, R. (2021). Interim methadone – effective but underutilized: A scoping review. *Drug and Alcohol Dependence*, 225, Article 108766.
<https://doi.org/10.1016/j.drugalcdep.2021.108766>
- National Academies of Sciences, Engineering, and Medicine. (2019). Medications for opioid use disorder save lives. National Academies Press. <https://doi.org/10.17226/25310> New York State Office of Addiction Services and Supports. (2021). Medicaid billing guidance for nys opioid treatment programs (OTPs) programs operating during the COVID-19 emergency. New York State Office of Addiction Services and Supports. <https://oasas.ny.gov/system/files/documents/2021/04/medicaid-billing-guidance.pdf>.
- Office of the Federal Register, N. A. and R. A. (2021). 86 FR 33861—Registration requirements for narcotic treatment programs with mobile components [Government]. June 28. Govinfo.Gov; Office of the Federal Register, National Archives and Records Administration <https://www.govinfo.gov/app/details/FR-2021-06-28/https%3A%2F%2Fwww.govinfo.gov%2Fapp%2Fdetails%2FFR-2021-06-28%2F2021-13519>.

- Pew Research Center. (2022). Overview of opioid treatment program regulations by state. Pew Charitable Trusts. <https://pew.org/3Qw8g8c>.
- Rao, R., Yadav, D., Bhad, R., & Rajhans, P. (2021). Mobile methadone dispensing in Delhi, India: Implementation research. *Bulletin of the World Health Organization*, 99 (6), 422–428. <https://doi.org/10.2471/BLT.20.251983>
- Strauss, A., & Corbin, J. (2008). *Basics of qualitative research: Techniques and procedures for developing grounded theory*. SAGE Publications, Inc. <https://doi.org/10.4135/9781452230153>
- Strauss, A., & Glaser, B. (2017). *Discovery of grounded theory: Strategies for qualitative research*. Routledge. <https://doi.org/10.4324/9780203793206>
- Substance Abuse and Mental Health Services Administration (SAMHSA). (2022). Medications for the Treatment of Opioid Use Disorder. <https://public-inspection.feder alregister.gov/2022-27193.pdf>.
- Suen, L. W., Castellanos, S., Joshi, N., Satterwhite, S., & Knight, K. R. (2022). The idea is to help people achieve greater success and liberty”: A qualitative study of expanded methadone take-home access in opioid use disorder treatment. *Substance Abuse*, 43 (1), 1143–1150. <https://doi.org/10.1080/08897077.2022.2060438>
- Suen, L. W., Coe, W. H., Wyatt, J. P., Adams, Z. M., Gandhi, M., Batchelor, H. M., Castellanos, S., Joshi, N., Satterwhite, S., Perez-Rodríguez, R., Rodríguez-Guerra, E., Albizu-Garcia, C. E., Knight, K. R., & Jordan, A. (2022). Structural adaptations to methadone maintenance treatment and take-home dosing for opioid use disorder in the era of COVID-19. *American Journal of Public Health*, 112(S2), S112–S116. <https://doi.org/10.2105/AJPH.2021.306654>
- The Pew Charitable Trusts. (2022). Overview of opioid treatment program regulations by state. Pew Charitable Trusts. <https://pew.org/3Qw8g8c>.
- Timko, C., Schultz, N. R., Cucciare, M. A., Vittorio, L., & Garrison-Diehn, C. (2016). Retention in medication-assisted treatment for opiate dependence: A systematic review. *Journal of Addictive Diseases*, 35(1), 22–35. <https://doi.org/10.1080/10550887.2016.1100960>
- Wyatt, J. P., Suen, L. W., Coe, W. H., Adams, Z. M., Gandhi, M., Batchelor, H. M., Castellanos, S., Joshi, N., Satterwhite, S., Perez-Rodríguez, R., Rodríguez-Guerra, E., Albizu-Garcia, C. E., Knight, K. R., & Jordan, A. (2022). Federal and state regulatory changes to methadone take-home doses: Impact of sociostructural factors. *American Journal of Public Health*, 112(S2), S143–S146. <https://doi.org/10.2105/AJPH.2022.306806>



Fig. 1. Photograph of the OTP van setting up in the morning for methadone delivery.

Table 1

Qualitative themes and exemplary quotes from patient and provider perspectives of methadone van implementation at a California opioid treatment program.

Theme	Exemplary quote
<i>Less crowding and chaos at the van streamlined efficiency and improved experiences</i>	<p><i>Because they don't have everybody in that [waiting] room together where everybody is stuck in there breathing on each other, people stinking and it's ugh! It's better out there [at the van] [...] You get your dose, and you leave. It's better like that. [Patient Participant E]</i></p> <p><i>I think anytime you got anything to do with something inside of a building, it's like more chaos; everybody got problems. If you're out [at the van] and you can get your little space and whatnot when you're all crammed up. [...] So [the van] is easier. [Patient Participant K]</i></p>
<i>Vans were more positive environments than clinics</i>	<p><i>I would like to be outside; I like it. I like having the van right there. You don't have to run all the way inside, because there's a lot of, because there's other medical stuff in this building. Yeah, I like it separate. [Patient Participant A]</i></p> <p><i>One of my patients [...] likes it because it just feels freer. He brings music and is into the scene basically. [Staff Participant H]</i></p>
<i>Telehealth counseling facilitated van implementation though came with challenges</i>	<p><i>It was easier for a lot of people to not have to sit at the clinic and see their counselor and wait due to ride situations or life. It was easier for them have more control over their treatment in that sense. [Staff Participant B]</i></p> <p><i>Both from a perspective of serving client needs and programmatically being able to deliver a service, we want to make it as simple as possible for someone to placed rapidly in contact with their counselor with minimum barriers and so that's what we're focused on over there. [Staff Participant G]</i></p>
<i>Van implementation included other logistical challenges, including with medication set up and urine drug testing</i>	<p><i>The only thing that I can think of that would be kind of a long-term problem with the way things are right now is having the urine samples. Because you have to have somebody get the urine sample, [...] check the temperature with the thermometer and then you know run it back to a medical assistant, put it in the fridge. And then somebody has to be cleaning the bathrooms [...] But that's the only thing other than weather that I feel might be difficult. [Staff Participant D]</i></p>

Table 2

Recommendations and considerations for state and federal agencies.

Recommendations for state agencies

- Audio-only telehealth counseling heavily facilitated methadone van program success. States should consider maintaining allowances for audio-only counseling toward minimum counseling requirements
- To avoid misaligning financial incentives that incentivize quantity of counseling over quality of treatment and patient progression in treatment goals, states can consider using bundled Medicaid payments to reimburse for counseling services as opposed to individual payments
- Minimum counseling requirements lack evidence and may pose as potential barriers to treatment. States agencies can reconsider imposing counseling requirements and instead defer to federal guidelines set by the Substance Abuse and Mental Health Services Administration

Recommendations for federal agencies

- The Drug Enforcement Agency should reconsider requirements for daily return of methadone medication to brick-and-mortar sites and reducing other onerous requirements to ease logistical challenges of van implementation
 - Substance Abuse and Mental Health Services Administration and other agencies should make clear what sources of long-term funding are available for OTPs to implement and evaluate methadone van programs
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