Substance Abuse and Rehabilitation

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ORIGINAL RESEARCH

Community-Based Medications First for Opioid Use Disorder - Care Utilization and Mortality Outcomes

Caleb J Banta-Green[1–3], Mandy D Owens[1,4], Jason R Williams[1], Anthony S Floyd[1], Wendy Williams-Gilbert[1], Susan Kingston[1]

[1]Addictions, Drug & Alcohol Institute, Department of Psychiatry and Behavioral Sciences, School of Medicine, University of Washington Seattle, Seattle, WA, USA; [2]Department of Health Systems and Population Health, School of Public Health, University of Washington Seattle, Seattle, WA, USA; [3]Department of Epidemiology, School of Public Health, University of Washington Seattle, Seattle, WA, USA; [4]Department of Psychology, University of Washington, Seattle, WA, USA

Correspondence: Caleb J Banta-Green, Addictions, Drug & Alcohol Institute, Department of Psychiatry and Behavioral Sciences, School of Medicine, University of Washington, NE Pacific St Box 356560, Seattle, WA, 98195, USA, Email calebbg@uw.edu

Video Abstract

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Purpose: A large treatment gap exists for people who could benefit from medications for opioid use disorder (MOUD). People OUD accessing services in harm reduction and community-based organizations often have difficulty engaging in MOUD at opioid treatment programs and traditional health care settings. We conducted a study to test the impacts of a community-based medications first model of care in six Washington (WA) State communities that provided drop-in MOUD access.

Participants and Methods: Participants included people newly prescribed MOUD. Settings included harm reduction and homeless services programs. A prospective cohort analysis tested the impacts of the intervention on MOUD and care utilization. Intervention impacts on mortality were tested via a synthetic comparison group analysis matching on demographics, MOUD history, and geography using WA State agency administrative data.

Results: 825 people were enrolled in the study of whom 813 were matched to state records for care utilization and outcomes. Cohort analyses indicated significant increases for days' supply of buprenorphine, months with any MOUD, and months with any buprenorphine for people previously on buprenorphine (all results $p<0.05$). Months with an emergency department overdose did not change. Months with an inpatient hospital stay increased ($p<0.05$). The annual death rate in the first year for the intervention group was 0.45% (3 out of 664) versus 2.2% (222 out of 9893) in the comparison group in the 12 months; a relative risk of 0.323 (95% CI 0.11–0.94).

Conclusion: Findings indicated a significant increase in MOUD for the intervention group and a lower mortality rate relative to the comparison group. The COVID-19 epidemic and rapid increase in non-pharmaceutical-fentanyl may have lessened the intervention impact as measured in the cohort analysis. Study findings support expanding access to a third model of low barrier MOUD care alongside opioid treatment programs and traditional health care settings.

Keywords: opioid use disorder, medications for opioid use disorder, multi-site study, low-barrier care, harm reduction

Background and Aims

A large treatment gap exists between those who have opioid use disorder (OUD) and the proportion receiving medications for OUD (MOUD), which are the most effective and evidence-based treatment for OUD.[1,2] Methadone and buprenorphine also significantly reduce opioid and all-cause mortality providing substantial harm reduction benefit in addition to supporting recovery according to findings from multiple large studies in diverse populations.[3,4] Most people with OUD want to stop or reduce their use and are interested in MOUD.[5] While many people with OUD access an array of services in harm reduction and other community-based organizations, many also have difficulty starting or engaging in care at traditional substance use disorder (SUD) treatment clinics or primary care clinics.[6,7]

Received: 19 June 2024
Accepted: 4 September 2024
Published: 14 September 2024

In recent years clinical efforts to increase low-barrier, rapid access to buprenorphine have expanded. Some programs initiate medications at harm reduction programs and transition quickly to primary care.[8] Hospital infrastructure and proximity to emergency departments (ED) and primary care clinics have been leveraged to create "bridge clinics".[9] Rapid Access Addiction Medicine clinics are being scaled up in parts of Canada showing positive outcomes on care utilization and mortality.[10] Care models are sometimes focused on specific populations, such as those who are unhoused. One such model is the Boston Roundhouse, which utilized buprenorphine and also made substantial use of methadone via the 72-hour rule in preparation for continuing care at an opioid treatment program.[11] Some existing SUD treatment programs have lowered barriers to initiating and continuing care.[12] Telemedicine has been shown to improve access and reduce costs for MOUD.[13]

Policy changes have been enacted to expand buprenorphine prescriber types, patient capacity, and tele-medicine access, but it is not clear that they are increasing access in general let alone for marginalized populations who may be at particular risk for overdose and face additional challenges accessing health care systems.[14–16] The Substance Abuse and Mental Health Services Administration indicated their support for low-barrier access to buprenorphine in a "Dear Colleague" letter about the medication first model in 2023.[17] The United States Department of Health and Human Services and the Drug Enforcement Administration (DEA) have published rules to continue COVID-19 era temporary policies to lessen barriers to starting and staying on methadone; these include options to reduce clinic-observed dosing frequency and to start at higher initial doses, which helps address higher tolerances associated with non-pharmaceutical fentanyl (NPF) use.[18]

Recent efforts have expanded the utilization of MOUD, typically buprenorphine, in emergency departments, jails, and even by emergency medical services in the field.[19–21] These inductions likely significantly reduce mortality risk in the short-term, but given that these patients are often marginalized and/or unhoused, connection to ongoing care can be a challenge for the patient to initiate and maintain.[22] In many areas of the United States homelessness has increased in recent years just as NPF availability has increased, a dangerous combination given that being unhoused has been shown to significantly increase fatal overdose risk.[23,24] Unfortunately, some prescribers may be more reluctant to accept these unhoused patients who may be seen as less "motivated" to stop using opioids (and other substances) or less likely to "embrace recovery".[25]

Staffing models that incorporate nurse care managers in office-based opioid treatment, primarily utilizing buprenorphine, have been shown to increase the number of providers who prescribe buprenorphine as well as the number of patients to whom they prescribe; nurse care managers provide structured clinical support to prescribers utilizing MOUD.[26,27] More recently, other supportive staff have been added to the care team with roles and titles such as care navigators, peer support specialists, and community health workers; research is ongoing on the potential additive impact of these support staff.[28,29]

A low-barrier buprenorphine clinic at a downtown Seattle, WA syringe services program located at a public health department was implemented in 2017 utilizing a nurse care manager model. Research on this clinic found that the care model was feasible, in high demand by clients, had good retention, and significantly reduced illicit opioid use.[30] The current study adapted that care model by adding care navigators and implementing it in multiple, diverse sites across WA State, in a community-based medications first (CBMF) model of care delivery.

In this context, community-based means care is located at community-based agencies that have a harm reduction philosophy and are either primarily a harm reduction organization that provides safer use supplies, among other supplies and services, or provides services to unhoused people. Said another way, community-based sites are not located in traditional health care or SUD treatment programs, thus providing a potential third model of care. Medications "first" does not necessarily mean medications "only". Medications first is predicated upon buprenorphine and methadone being strongly preventative of fatal overdose[3,4] and therefore trying to induce and stabilize people on medications as the first step in the care process. It is also in response to the predominant models for accessing buprenorphine in the traditional health care system and specialty addiction treatment that are appointment-based with multiple requirements and appointments prior to receiving MOUD. Counseling, while clearly beneficial to some, has not been proven to have significant additive benefit to medications.[31,32] CBMF also acknowledges that substance use often persists throughout treatment and recovery and that this is, in fact, a manifestation of opioid use disorder and a reason to continue to engage

people in care, not discharge them from it.[33] Ongoing engagement in care is a primary goal of CBMF, and harm reduction services and supplies can provide a reason for initially engaging in a care relationship and a reason to stay engaged if substance use continues, with or without continuation of MOUD. An engagement-oriented, harm reduction-supportive care model and philosophy is integral. Parallel to our work, others have used similar medications first terminology in the context of reducing barriers and supporting engagement in specialty addiction treatment (eg, outpatient and inpatient OUD treatment services that may or may not utilize MOUD). The rationale for a medications first approach and elements of the various barriers have been well articulated.[34,35] Further details on the rationale, staffing model, and evolution of this care model are available in our protocol paper for this study.[36]

Our primary aim is to test the impact of the CBMF intervention on emergency department utilization, hospitalization, and mortality outcomes. Other aims include testing whether housing status modifies the impact of the intervention and the impact of the intervention on MOUD utilization.

Methods

Study methods are described here, with additional details about the clinical intervention and study design available in our protocol paper.[36]

Clinical Intervention

The CBMF intervention is rapid, typically same-day, access to medications; convenient, non-appointment-based care; no exclusions for polysubstance use; no counseling mandates (but services readily available); ongoing, easy-to-access care. The model is intended for people who may have barriers to appointment-based care, including those who are unhoused. Staffing for CBMF utilized project-funded care teams comprised a nurse care manager and care navigators, as well as a prescriber's time to oversee clinical activities. CBMF staff were often co-located at syringe services programs to facilitate linkage. COVID-19 precautions necessitated some clinics to move to appointment-based care for portions of the study period.

Ongoing implementation support was provided by the study team to clinic sites. The study's clinical intervention support team (CBG, MDO, WWG, SK) provided initial training and ongoing, twice-monthly and ad hoc technical assistance and clinical consultation for nurse care managers and care navigators. Clinical support was provided to prescribers in monthly video conference calls. Site administrators met with the study team twice monthly to discuss administrative, clinical, and research issues (the clinical support team along with ASF).

Settings

Settings included syringe services programs, health departments, a federally qualified health center with a small primary care office on a highway adjacent to mobile harm reduction services, and programs for unhoused people. Table 1 provides an overview of each of the sites. The goal of this project was to provide care where people with OUD already receive other services and often have established trusting relationships with staff and volunteers. The six sites were purposefully selected to represent different types of organizations and provide geographic variability. Three of the sites were in Eastern Washington (Spokane, Walla Walla, Kennewick) and three in Western Washington (Tacoma, Seattle, Centralia).

Study Participants

People with OUD, per clinician assessment, who were interested in starting on an FDA-approved medication for OUD were eligible for the study if they were also between the ages of 18–70 and willing to provide access to state records data including substance use treatment records along with identifiers needed to link to records data. Potential participants were approached about study involvement and provided consent to participate in the study *after* their initial CBMF service encounter when they had already been informed and been prescribed MOUD. The clinical intervention, study recruitment, and enrollment began August 2019. The last month of new client enrollment was September 2021. At least 12 months of follow-up data from the date of beginning the clinical intervention were utilized.

Table 1 Site Locations and Characteristics

Site	Service Providers	SSP Services Located:	OUD Services Located:	Care Navigator Located:
Tacoma	-Tacoma Needle Exchange/ Dave Purchase Project -Tacoma Pierce County Health Department	Parked van outside health department. Later inside an adjacent building	Inside health department	Van, inside SSP, inside health department
Spokane	-Spokane Regional Health District syringe services program (SSP) -Frontier Behavioral Health –Compassionate Addiction Treatment (CAT)	Inside health department and CAT	Inside health department and CAT	Inside all locations. Provided by Frontier Behavioral Health.
Centralia	–Gather Church	Mobile van	Inside agency	SSP van and inside agency
Walla Walla	–Blue Mountain Heart to Heart*	Inside agency	Inside agency	Inside agency
Kennewick*		Inside agency	Inside agency	Inside agency
North Seattle	–Neighborcare Health –Aurora Commons –SSP outreach/delivery by The People's Harm Reduction Alliance	Nearby street outreach, mobile delivery	Inside adjacent primary care clinic and later also at community drop-in center	At both indoor locations

Notes: *also operated a mobile SSP van with referrals into CBMF.

A potential comparison group derived from state records was identified via a variable indicating a history of OUD based on documented history of a diagnosis for OUD or diagnoses indicating health complications attributed to opioid use in state Medicaid data.

Data Sources

At the time of study enrollment personal identifiers (for data linkage), demographics, and housing status were collected from participants. Secondary, administrative data were obtained from the WA State Department of Social and Health Services' Research and Data Analysis (RDA) office including: health care, buprenorphine, and naltrexone utilization documented in state Medicaid data, monthly Medicaid eligibility, mortality data (indicating that a death from any cause occurred in a specific month), county of residence in a given month, arrests, Prescription Monitoring Program data for buprenorphine prescriptions, and methadone provided by publicly-funded opioid treatment programs.

Study Design

A prospective cohort study design was conducted to test the impacts of the intervention on subsequent MOUD and emergency department utilization and hospitalization. For care utilization outcomes we restricted analyses to those with complete Medicaid eligibility in the 12 months prior to and following receiving CBMF to maximize complete data.

To test the impact of the intervention on mortality, a synthetic comparison group analysis, based upon a statistically matched group from WA State agency administrative data sources, was conducted. In the first stage of creating a comparison group, members of the large comparison data pool were assigned the treatment group member's start date and matched on key broad indicators of OUD history and county of residence. In the second stage, propensity score matching was implemented with more fine-grained history variables, including MOUD utilization, opioid poisonings, all-cause hospital emergency department visits and inpatient hospitalizations, and arrest history, to match and balance the samples; details are provided in the Supplement.

Analyses

Descriptive statistics for demographics, MOUD utilization, arrests, and emergency department and inpatient hospitalization are presented for all study participants enrolled and matched to state data, the subset of study participants included in the synthetic comparison group analysis for mortality, and those with complete Medicaid data. Propensity score matching for the comparison analysis was conducted with a 24-month pre-period, for a slightly different set of characteristics (see Supplement) and resulted in all weighted standardized mean differences being less than 0.06 standard deviations (data not shown).

For the prospective cohort study analyses, pre-post comparison of rates of care utilization based on days' supply of buprenorphine or number of months within which an event occurred was tested with an unadjusted model regressing change score on housing status. Specifically, the value for the 12 months before induction into CBMF was subtracted from the value for the 12-month follow-up period, and this change score regressed on whether the participant reported having stable housing at induction. For example, a client who had 2 opioid poisonings treated at an emergency department in the post period and 3 in the pre period would have a change score of −1. Post-hoc contrasts determined significant change scores (whether the model intercept differs from 0) or whether this depends on housing status.

For the synthetic comparison group analysis, the all-cause mortality rate difference between the intervention and comparison groups was tested in a logistic regression model that accounted for propensity score weighting and included history variables used in estimating the propensity score as covariates, followed by marginal effects estimation to calculate an average risk ratio. Details are provided in the Supplement. All analyses were conducted in R statistical software, using the MatchIt package for propensity score matching and weighting and the marginaleffects package for g-computation of the marginal risk ratio.[37–39]

Results

A total of 1325 people received the CMBF clinical intervention. 825 people were enrolled in the study, of whom 813 were matched to state records by RDA. Those who received CBMF services had generally similar age and gender as those enrolled in the study and whose data were analyzed (Table 2). Data indicated that those with complete Medicaid eligibility were similar to all of those enrolled in the CBMF study except they had higher rates of each care measure, likely because they had more time with complete data. The group with complete eligibility for Medicaid had lower rates of arrest, which is likely due at least in part to the fact that people lose Medicaid eligibility if they are incarcerated. The group with complete Medicaid data had a somewhat smaller proportion who were unstably housed/unhoused, 41% versus 44%.

Impact of CBMF on MOUD Utilization and Health Care Utilization

For care utilization outcomes, we restricted analyses to those with complete Medicaid eligibility in the 12 months prior to and following receiving CBMF and complete housing data (n=446). Table 3 compares the year before and after starting CBMF. Not all measures depended on Medicaid eligibility; however, we narrowed analyses to this group as health care and some MOUD utilization data elements were constructed from Medicaid health system data.

Analyses indicated significant increases for days' supply of buprenorphine, months with any OUD medication, and months with any buprenorphine overall (n=446) and for both housed and unhoused people. Those housed had a significantly greater increase than those unhoused. Both months with an emergency department poisoning visit (eg, opioid overdose) and with a non-poisoning-related emergency department visit did not change. The months with an inpatient hospitalization stay increased significantly, with no difference by housing status. Among those who had any buprenorphine in the pre-period (n=243), the change in buprenorphine days' supply increased significantly from a mean of 81.5 days to 136.5 days ($p<0.05$).

Mortality Analyses

The mortality analyses utilized a matched comparison group drawn from state records data. For the matched comparison analyses, intervention participants were included if they had an indication of a history of OUD based upon the presence of an OUD or opioid poisoning diagnosis and/or a previous indication of having received a medication for the treatment

Table 2 Participant Characteristics

	All Clients Served	Enrolled and Matched to State Data	Pre-post Cohort Analysis with Complete Medicaid Data	Matched Comparison Mortality Analysis
n=	1325	813	463	664
Demographics				
Age- mean		36.9	37.8	36.9
<20	2.10%	0.60%	0.40%	0.60%
20–29	24.90%	27.40%	25.30%	27.00%
30–39	36.60%	37.90%	36.70%	38.90%
40–49	18.80%	20.50%	21.40%	19.70%
50–59	10.00%	9.70%	12.10%	10.40%
60+	4.50%	3.80%	4.10%	3.50%
Missing	3.00%	0.00%	0.00%	0.00%
Female	41.00%	40.00%	49.00%	40.10%
Unstably housed/unhoused		44.10%	40.60%	45.90%
Medications for opioid use disorder utilization				
Buprenorphine - day's supply		32	42.8	38.7
Buprenorphine - any		52.30%	58.80%	63.3%
Buprenorphine - months with		2.35	3	22.83
Methadone - any		6.00%	8.20%	7.4%
Methadone - months with		0.27	0.38	0.33
Naltrexone - any		2.80%	3.20%	3.3%
Naltrexone - months with		0.07	0.08	0.08
Any OUD medication - months with		2.7	3.4	3.2
Any OUD medication		56.00%	63.70%	67.8%
Arrests				
Arrests - any		40.00%	34.60%	43.4%
Arrests - month with		0.91	0.71	0.97
Emergency department and inpatient hospital utilization				
ED poisoning - any		3.80%	4.10%	4.2%
ED poisoning - months with		0.044	0.045	0.048
ED non-poisoning - any		54.70%	65.00%	59.5%
ED non-poisoning - months with		1.42	1.71	1.55
Hospitalization - any		25.70%	30.00%	27.6%
Hospitalization - months with		0.48	0.57	0.53

Table 3 Changes Pre-Post Among Intervention Participants

	Fully Medicaid Eligible+		Fully Medicaid Eligible w/ Housing Data			Stably Housed at Baseline			Unstably Housed/ Unhoused at Baseline			Change by Housing Status
n=	463		446			265			181			
	Pre	Post	Pre	Post	p<0.05*	Pre	Post	p<0.05*	Pre	Post	p<0.05*	p<0.05*
Medications for opioid use disorder utilization												
Buprenorphine days' supply	42.76	107.85	43.64	111.02	*	45.18	121.27	*	41.38	96.02	*	*
OUD medication- months with any	3.43	7.07	3.47	7.15	*	3.42	7.55	*	3.54	6.57	*	*
Buprenorphine- months with any	3.02	6.35	3.06	6.46	*	3.08	6.95	*	3.03	5.75	*	*
Acute care utilization												
ED poisoning visit- months with any	0.05	0.04	0.05	0.04		0.02	0.03		0.08	0.07		
ED non-poisoning visit- months with any	1.71	1.6	1.71	1.6		1.51	1.45		2	1.81		
Any hospital stay- months with any	0.57	1.63	0.59	1.65	*	0.53	1.65	*	0.67	1.65	*	

Notes: +Noted as Medicaid eligible in all 12 months before and after the start month. *Significance tested in an unadjusted model regressing change score on housing status.

of OUD (n=670). (For the other 143, no indication of needing MOUD could be found in state records). The final comparison group was matched based upon multiple variables including geography/county, demographics, care utilization, and arrest history (n=664).

The observed annual death rate in the first year for the intervention group was 0.45% (3 out of 664) compared to 2.2% (222 out of 9893) in the comparison group in the 12 months, with a regression adjusted relative risk of 0.323 (95% CI 0.11–0.94). This can be interpreted as the CBMF intervention was associated with a significant reduction in the mortality rate with an estimated 68% reduction (95% CI 6%-89%) relative to the comparison group. Had the comparison group experienced mortality at the same rate as the intervention group, there would have been an estimated 45 deaths, or 177 potential deaths avoided.

Discussion

Our findings indicated a statistically and clinically significant increase in medications for OUD after receiving CBMF and a significant decrease in mortality relative to the comparison group. We did not see a change in emergency department poisoning visits, but it is important to note that the rate of these visits is very low and that previous research indicated that many people who have an overdose do not seek medical care.[40] Not seeking care for an overdose was perhaps even more likely given the high rates of naloxone availability in the community (approximately 80% of people who use opioids reported having naloxone according to a WA State syringe services program survey) and the reluctance of people to go to the emergency department or hospital during COVID-19.[41,42] Conversely, there was a significant increase in inpatient hospitalizations which did not align with emergency department poisoning findings, perhaps due to COVID-19 or other unmeasured co-morbidities.

We aimed to provide services to housing-insecure people and at least 40% of participants studied were housing insecure. It is important to see that those who were unhoused also had a substantial and statistically significant increase in time on medications. We also wanted to test this model of care in multiple diverse communities, urban and rural, small and large, and the intervention was feasible in all settings. This study is not generalizable to all of WA State nor nationally due to purposeful community recruitment. However, findings suggest that the CBMF model is feasible outside of a large urban setting, such as Seattle, which was the forerunner of this model, which is important for ensuring broad accessibility. We believe that feasibility was increased by the relationship building and ongoing communication between CBMF sites and upstream and downstream referral partners as program successes and challenges were shared. These communication processes should be strongly considered by those planning to implement CBMF in the future.

CBMF added care navigators to the original Seattle-based model. Care navigators averaged 10 contacts/encounters per client during the first six months of care for the 1325 people who received services.[43] Even during COVID-19 restrictions the most common mode of communication was in-person, speaking to the dedication of staff and the significance of these encounters to clients. The most common topic of encounters was program retention, followed by clients' ongoing substance use. As one client said,

> You can't imagine how it feels to finally not have to lie or cheat to hide my drug use just to get some help. Here, they actually want to know about it! That seemed crazy to me at first but that's just really how it ought to be, isn't it?

Future research on CBMF would benefit from studying the potential impacts of different staffing models involving nurse care managers and care navigators, though the existing literature has shown that each can provide significant improvements in outcomes for people on buprenorphine.[26,28] Cost-effectiveness of the model will be important to analyze in the future. Roughly in the middle of the study period, NPF overtook heroin as the predominant opioid. The utility of the CBMF model for those with OUD and dependent on NPF is important to understand, particularly given greater medication induction challenges and some perceptions among people who use NPF of lower effectiveness of buprenorphine for NPF compared to heroin or pharmaceutical opioids such as oxycodone. Lastly, given the promise of long-acting injectable buprenorphine products for NPF, including growing uptake at several of our sites that continued services after the study ended, future research should incorporate these newer MOUD products.[44] There is also the possibility of rapid starts with long-acting injectable products.[45] For regions with geographic access to opioid treatment programs there is the potential for future CBMF programs to utilize the 72-hour rule for methadone to get a person quickly started on methadone, which, as a full agonist medication, may ease induction from fentanyl and help match new higher opioid tolerance levels seen with use of non-pharmaceutical fentanyl.[11,46]

Rationale for Study Design Modifications

We originally proposed a "6-month, induction-stabilization-transition" model, such that after 6 months of CBMF care clients would be transferred to ongoing care elsewhere, ideally primary care in traditional health care settings. However, this was difficult for many participants, and we did not enforce this 6-month limit as it would have potentially meant discontinuing buprenorphine for people with no other option. Therefore, the model of care we tested did not have a strict 6-month duration. When recruiting sites for the study, we asked them to identify a primary care provider willing to take clients stabilized on MOUD and all sites identified at least one provider. However, when it came time to refer clients from CBMF many community providers would not accept clients or quickly discharged them. This lack of referral acceptance or rapid care discontinuation was often explained as being due to ongoing substance use such as methamphetamine or benzodiazepines, even when clients were stable on buprenorphine and regularly attended their medical appointments. Some CBMF site administrators noted that community prescribers became more willing over time to accept referrals from CBMF programs. In addition, according to clinic staff, many unhoused clients found it difficult to get to an appointment with a primary care provider due to lack of transportation.

Arrest outcomes were not explored due to two major events: 1) the COVID-19 pandemic led to rapid and dramatic reductions in jail censuses beginning in March 2020 and 2) major legal changes to state drug possession laws. In February 2021 the WA State Supreme Court decided a case with the result that state drug possession laws were invalidated, the legislature subsequently passed ESB5476 making drug possession a misdemeanor with the first two arrests subject to diversion.[47] The net impact was that arrests and incarceration for possession virtually stopped until the law was changed in 2023 to make drug possession a gross misdemeanor.[48]

We also originally planned to use a comparison group approach for all analyses. However, we could not obtain housing management information system data from WA State as planned and thus had no measure of housing stability for the comparison group. Given that the intervention group was at least 40% unstably housed, we felt this could result in an unfair comparison such that the intervention may have outcomes that appeared worse due to their housing instability. Thus, we used a cohort pre-post analysis for MOUD and care utilization so that participants served as their own comparison to reduce confounding. We chose to use the comparison group approach for the mortality analysis as we felt this would result in conservative bias, with the intervention group likely having worse outcomes and elevated mortality if

not for the intervention.[23,49] The actual results indicated the intervention group had lower mortality, with the degree of mortality reduction associated with the intervention likely underestimated.

Limitations

For our pre-post cohort analyses we utilized data for clients who had continuous Medicaid eligibility for 24 months (12 months pre- and post-CBMF enrollment). The data indicated that this subset had somewhat lower rates of housing instability and arrests. It is likely, therefore, that the findings somewhat overestimated the impact of CBMF in these analyses relative to the entire population enrolled in the study.

Due to COVID-19 infection concerns beginning in March 2020 (8 months after the start of the study), some programs temporarily instituted appointment-based care to minimize the number of clients in clinic spaces; this had a substantial negative impact on study enrollment. However, the demographics of those who received services were generally very similar to those included in analyses (Table 1). Switching to appointment-based care for some intervention participants likely made the care model more similar to those in the comparison group. This conservative bias would most likely result in an underestimate of the impact of the intervention.

In preparing for this study, we estimated an annual mortality rate of 6%, based upon our previous research with those with opioid use seen for care in Seattle emergency departments as well as very similar findings in Boston.[4,50] In this case, it appears that the matched comparison, which had an extensive history of medication use for OUD, had a lower mortality rate than we anticipated, and yet the intervention group still had a significantly reduced mortality rate. We were only able to obtain all-cause mortality data, not opioid involved overdose specific mortality data from WA State. While it is possible that the intervention did not impact opioid involved mortality specifically, multiple studies have found consistent impacts of MOUD on reducing both all-cause and opioid specific mortality.[3,4] Further, one of the goals of the intervention was to reduce mortality, regardless of the cause.

We used an observational study design rather than a randomized controlled trial. Based on previous experience implementing a randomized controlled trial with a similar, high acuity population receiving care in fast paced, non-appointment-based care setting, we chose to emphasize including as many participants as possible by removing research burden on staff and clients.[50] The net result, we believe, is study findings that are likely representative of real-world care and a broad spectrum of clients and are less biased than a randomized controlled trial might have been.[51]

Conclusion

Given the persistent unmet need for MOUD and increasing challenges presented by NPF, the positive findings for CBMF warrant its inclusion among a growing third model of community-based care. This third care model is evolving across the United State and Canada to provide a medication-first, low-barrier model of care to provide access to buprenorphine alongside existing models in traditional health care settings and opioid treatment programs.

Ethics/Human Subjects Review

The University of Washington IRB determined that the application qualified for expedited review and approved it (IRB ID# STUDY00006623). The WA State IRB reviewed and approved the use of state-held secondary data records (Project # 2019-032). This study complies with the Declaration of Helsinki.

Acknowledgments

The authors acknowledge the kind, ethical, high-quality care provided by community-based providers during the COVID-19 pandemic. Their dedication and passion is greatly appreciated. Tremendous thanks to the clients who agreed to share their data for this study. We also thank Jeanne Sears PhD RN who provided expert consultation on statistical methods. A preliminary version of the study findings was presented as a poster at the College on Problems of Drug Dependence on June 20, 2023 and a copy is available online at: https://adai.uw.edu/wordpress/wp-content/uploads/community-based-meds-poster-2023.pdf

Funding

Funding for this research was provided by the Paul G. Allen Family Foundation which had no role in the design of the study and collection, analysis, and interpretation of data.

Disclosure

The authors declare no competing interests in this work.

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