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Changes in methadone take-home dosing before and after COVID-19

Ofer Amram^{a,b,*}, Solmaz Amiri^a, Emily L. Thorn^c, Robert Lutz^{a,c}, Paul J. Joudrey^d

^a Department of Nutrition and Exercise Physiology, Elson S. Floyd College of Medicine, Washington State University, Spokane, WA 99202, USA

^b Paul G. Allen School for Global Animal Health, Washington State University, Pullman, WA 99164, USA

^c Department of Medical Education and Clinical Sciences, Elson S. Floyd College of Medicine, Washington State University, Spokane, WA 99202, USA

^d Yale Program in Addiction Medicine, Department of Internal Medicine, Yale School of Medicine, New Haven, CT 06520, USA

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ABSTRACT

Introduction: In response to the COVID-19 pandemic, a federal exemption allowed stable and less stable patients greater take-home doses of methadone. We assessed the adoption of increased take-home medication during COVID-19 and whether increased take-home doses is associated with clients' characteristics.

Methodology: We completed a pre-post study of adults receiving methadone for OUD from an OTP in Spokane, Washington. Our outcome was the change in the number of take-home methadone doses three months before and three months after the March 2020 take-home medication exemption. Clients' characteristics included age, gender, ethnicity, education level, homelessness, spatial access to the clinic, and methamphetamine use.

Results: The study included 194 clients in treatment for a median of three years. All study participants experienced an average increase in take-home medication of 41.4 in the three-month period after the COVID-19 exemption. In the final adjusted models, clients who reported using methamphetamine in the last 30 days experienced a significantly larger increase in take-home dosage (55.6 days) compare to clients who did not use methamphetamine ($p \leq 0.001$). Most of the clients who reported using methamphetamine were also likely to be homeless. All other variables were not associated with a change in take-home doses.

Conclusion: These results suggest that the Spokane OTP quickly expanded take-home medication dosing in response to the COVID-19 exemption and broadly expanded take-home dosing among established clients. Clients with concurrent methamphetamine use were allowed fewer take-home doses prior to COVID-19, but after the exemption the clinic provided them the same number of take-home doses as clients who had not used methamphetamine.

1. Introduction

Opioid overdose (OD) remains the leading cause of accidental death in the United States and emerging evidence suggests drug overdose events rose further during the COVID-19 pandemic (Ochalek, Cumpston, Wills, Gal, & Moeller, 2020). Opioid agonist medications (methadone or buprenorphine) are the Center for Disease Control and Prevention's recommended method for the treatment of opioid use disorders (OUD) (Nielsen et al., 2017). Opioid agonist medications reduce OD-related mortality, and are associated with improved measures of drug use, crime, and high-risk sexual behaviors such as unprotected sex, which tend to occur more often with injection drug use (Corsi et al., 2009; Deck et al., 2009; Nosyk et al., 2013). However, social distancing and lockdown measures resulting from COVID-19 and the increased risk of COVID-19 among patients with OUD led to changes in the delivery of

methadone (Wang et al., 2020).

In the United States, methadone can only be administered (in-person dosing) and dispensed (take-home dosing) for OUD at federally certified opioid treatment programs (OTP). Federal, state, and local regulations require that OTPs provide comprehensive treatment (medical evaluation, methadone administration, toxicology testing, and behavioral treatment), which is effective in reducing rates of OD mortality (Davoli et al., 2007; Kresina et al., 2009). Federal regulations require clients to present for methadone administration six days a week for at least the first 90 days, with increasing take-home allowance as appropriate (Joudrey et al., 2020). In March 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) recognized public health and safety issues surrounding COVID-19 and created an exemption from these administration requirements ((SAMHSA), S. A. a. M. H. S. A., 2020). It gave OTPs permission to provide up to 28 days of take-home

* Corresponding author at: Washington State University, 412 E Spokane Falls Blvd, Spokane, Washington 99202, USA.

E-mail address: ofer.amram@wsu.edu (O. Amram).

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doses to stable clients and up to 14 days of take-home doses to less stable clients (SAMHSA). Health care providers at OTPs have discretion to determine which clients are stable and less stable. Emerging research on the impact of COVID-19 on the provision of methadone has been mixed. A methadone clinic in Wuhan, China, observed a reduction in daily methadone administration while the number of new patients initiating methadone was unchanged at an OTP in Seattle, Washington, before and after COVID-19 community transmission (Jiang et al., 2020; Peavy et al., 2020). Other studies in both the United States and Spain that also examined the impact of an increase in take-home medication as a result of COVID-19 showed that rare or undetectable level diversion of take-home methadone has been occurring after take-home guidelines were loosened (Figgatt et al., 2021; Trujols et al., 2020). Furthermore, patient satisfaction with methadone treatment programs has improved after the new SAMHSA guidelines (Patton et al., 2021). However, research that examines how U.S. OTPs are implementing the COVID-19-related exemption is limited.

In this study, we examined how the COVID-19-inspired exemption from methadone administration regulations impacted the administration of methadone to clients at an OTP in Spokane County. More specifically, we assessed the change in take-home medication following the exemption and whether client characteristics were associated with the observed changes.

2. Methodology

2.1. Study sample

We completed a pre-post study at an OTP located at the Spokane Regional Health District (SRHD) located in Spokane County, Washington, before (December 1, 2019–February 29, 2020) and after (April 1, 2020–June 30, 2020) community transmission of COVID-19. Methadone is the primary option for the treatment of OUD at this facility. In this clinic, providers offer treatment in combination with behavioral treatment. Spokane is the second-most populous city in Washington State with approximately 220,000 residents (U.S. Census Bureau, 2017). The Spokane OTP started allowing increased take-home medication in response to the SAMHSA exemption on March 23, 2020.

This study recruited a convenience sample of 249 clients and surveyed the sample at the clinic in winter 2019 for a cross-sectional study examining transportation and travel burden among clients receiving methadone. From this sample, we included all English-speaking clients age 18 years and older receiving methadone for OUD at the Spokane County OTP. We linked the survey data to clients' medical records to obtain information on clients' methadone dosage and take-home doses before and after COVID-19. Our research team emphasized that study participation was voluntary and confidential, and that it would not affect their enrollment at this OTP. The study compensated participants \$15 for completing the survey. For this study, we only included clients who were in treatment during the seven-month period from December 2019 to June 2020. The Washington State University Ethics Review Committee approved this study.

2.2. Study variables

The study defined the primary outcome variable (continuous) as the change in the number of take-home methadone doses before and after the March 2020 SAMHSA take-home medication exemption. We included the three-month period before the take-home medication exemption (December, January, and February for a total of 91 days) and the three-month period after (April, May, and June for a total of 91 days). These data were collected and maintained by the OTP at the SRHD. As a secondary outcome, we created a categorical measure of change take-home methadone doses dichotomized using the change in take-home methadone median (monthly increase of up to 15 days per month, and monthly increase greater than 15, yes vs. no).

Covariates (additional variables) included age (continuous), gender (female vs. male), race/ethnicity (non-Hispanic white versus other), self-reported education level (high school diploma or equivalent, yes vs. no), self-reported home insecurity in the past 3 years (defined as living with sexual partner & children, with sexual partner alone, with children alone, with parents, with family, with friends or in controlled environment; yes vs. no), self-reported methamphetamine use in the past 30 days (yes vs. no, this variable was collected through our survey in 2019), and average methadone dose in milligrams during the three months before COVID-19 period (continuous). Based on our previous research, which showed a negative association between distance to the clinic and methadone treatment adherence in Spokane County, we identified clients with poor spatial access to the OTP (Amiri et al., 2018). We did this first by calculating the distance between a client's home address obtained from the clinic data and the OTP. The study classified clients who resided more than five miles from the OTP and also reported difficulty with transportation to the OTP as having poor spatial access to the clinic (yes vs. no) (Amiri et al., 2018).

2.3. Analysis

The study included descriptive statistics, with measures of central tendency and variability for continuous variables, and frequency distributions and percentages for categorical variables, to describe take-home doses before and after COVID-19 while controlling for covariates.

The study used adjusted and unadjusted generalized linear models (GLM) (Gaussian function for the continuous model and binomial function for the binary outcome) to explore the association between clients' characteristics and change in take-home medication before and after COVID-19. We analyzed the data using R and set the significance level at 0.05 (two-tailed).

3. Results

Of the 249 clients who completed the survey, we included 194 in the study. We excluded 55 who discontinued treatment or transferred to another facility ($n = 22$), were deceased ($n = 3$), or for whom we could not verify missed doses post-COVID-19 exemption ($n = 30$). On average, clients had been in treatment for more than three years (Table 1). The participants' median age was 40 years (IQR 32–51), 109 (56%) were female, 54 (28%) reported using methamphetamine (variable collected in winter 2019) and 39 (20%) were non-Hispanic white. Ninety (46%) clients had at least a high school diploma or equivalent, 17 (9%) experienced home insecurity, and 20 (10%) resided more than five miles away from the clinic and reported difficulty with transportation. Finally, the median dose of methadone prior to COVID-19 was 105 mg/day (IQR: 84–131).

During the three-month period prior to the COVID-19 exemption, clients received an average of 39.2 take-home doses per 91 days. During the three-month period after the COVID-19 exemption, clients received an average of 80.6 take-home doses per 91 days, which corresponds to an average increase of 41.4 take-home doses. Prior to the COVID-19 exemption, clients reporting methamphetamine use during our survey in 2019 received a mean of 21.4 take-home doses per 91 days, while clients without reported methamphetamine use received a mean of 47.4 take-home doses. Clients who reported using methamphetamine during our survey in 2019 experienced the largest increase in take-home dosage per 91 days with an average increase of 55.6 compared to those not using methamphetamine with an average increase of only 35 take-home doses per 91 days ($p \leq 0.001$). Clients who reported home insecurity experienced an average increase of 49.7 take-home doses per 91 days compared to those reporting home security who experienced an increase of 40.0 in take-home per 91 days ($p = 0.11$). Clients without a GED experienced an increase of 39.8 in take-home doses per 91 days compared with those with a GED who experienced an increase of 41.2 in take-home doses per 91 days ($p = 0.92$). Male clients had an increase of

Table 1
Characteristics of clients at the Spokane Regional Health District methadone by change in methadone take home doses($n = 194$).

Characteristics	N = 194	Increase in take-home doses per 91 days Post COVID19 (Mean, SD)	P-Value
Dose Pre COVID-19 (Median, IQR)	105 mg (84–131)	–	
Age (Median, IQR)	41 (32–51)	–	
Gender			0.22
Male	76 (39%)	44.2 (21.1)	
Female	109 (56%)	39.8 (23.8)	
Non-Hispanic White			0.93
Yes	142 (72%)	41.5 (22.4)	
No	39 (20%)	40.1 (24.0)	
Home insecurity			0.12
Yes	17 (9%)	49.7 (22.9)	
No	177 (91%)	40.6 (21.2)	
High school diploma or equivalent			0.92
Yes	89 (45%)	40.4 (22.7)	
No	88 (45%)	41.9 (23.2)	
Residing 5Miles from the clinic and having difficulty accessing transportation			0.84
Yes	20 (10%)	42.1 (23.7)	
No	149 (77%)	41.5 (22.7)	
Self-reported methamphetamine use in the last 30 days			<0.001
Yes	54 (28%)	55.6 (16.4)	
No	121 (61%)	35.0 (22.4)	

43.5 while females experienced an increase of 39.3 in take-home doses per 91 days ($p = 0.25$). Non-Hispanic whites experienced an average increase of 41.2 in take-home doses compared to nonwhites who experienced an increase of 38.8 in take-home doses per 91 days ($p = 0.80$). Finally, clients who resided farther away from the clinic and reported transportation difficulty experienced an average increase of 42.1 in take-home doses per 91 days compared to those residing closer to the clinic who experienced an increase of 40.7 per 91 days in take-home doses ($p = 0.64$).

All clients received an increase in take-home doses following the COVID-19 exemption, 94 (48%) clients received an increase of up to 15 take-home doses per month, and 100 (52%) received an increase of 15 and more take-home doses per month.

In both adjusted models (continuous and dichotomized), clients who reported using methamphetamine during our survey in 2019 experienced a significantly larger increase in take-home dosage compared to clients who did not use methamphetamine ($p \leq 0.001$). All other variables were not associated with a change in take-home doses [Table 2](#).

4. Discussion

In this pre-post study of clients receiving methadone for OUD at an OTP in Spokane Washington, we assessed the change in take-home doses after COVID-19 and its association with clients' characteristics. In our study of established methadone clients, we found all participants received an increase in the number of take-home doses following the COVID-19 exemption for methadone administration. Clients reporting methamphetamine use in the past 30 days received a greater increase in take-home methadone allowance following the exemption, while clients with longer travel distances and reporting transportation difficulty did

Table 2
Unadjusted and adjusted GLMs analyses of change in take-home doses before and after COVID-19 at the Spokane Regional Health District opioid treatment program ($n = 194$).

Variable	Change in Take-Home Doses							
	Continuous				Binary (≤ 15 or > 15 days per month)			
	Unadjusted		Adjusted		Unadjusted		Adjusted	
	Estimate (95%CI)	P-Value	Estimate (95%CI)	P-Value	Estimate (95%CI)	P-Value	Estimate (95%CI)	P-Value
Pre COVID-19 dose	-0.01 (-0.19–0.00)	0.051	-0.06 (-0.17–0.04)	0.235	-0.06 (-0.17–0.04)	0.063	0.99 (0.98–1.00)	0.088
Age	0.00 (-0.29–0.29)	0.993	-0.05 (-0.36–0.26)	0.775	-0.05 (-0.36–0.26)	0.592	1.00 (0.97–1.03)	0.979
Gender		0.236		0.441		0.289		0.402
Female (Ref)		–		–		–		–
Male	4.12 (-2.67–10.92)		2.82 (-4.33–9.98)	–	2.82 (-4.33–9.98)		1.24 (0.61–2.53)	
White		0.569		0.934		0.767		0.83
Non-White (Ref)		–		–		–		–
vWhite	2.38 (-5.80–10.55)		0.36 (-8.12–8.84)	–	0.36 (-8.12–8.84)		1.06 (0.47–2.43)	
Home insecurity		0.103		0.599		0.257		0.936
No (Ref)		–		–		–		–
Yes	9.62 (-1.97–21.20)		3.4 (-9.27–16.07)	–	3.4 (-9.27–16.07)		1.68 (0.44–7.15)	
High school diploma or equivalent		0.68		0.884		0.5		0.982
No (Ref)		–		–		–		–
Yes	-1.44 (-8.32–5.45)		0.53 (-6.55–7.61)	–	0.53 (-0.22–0.07)		0.87 (0.43–1.75)	
Residing 5Miles from the clinic and having difficulty accessing transportation		0.8		0.979		0.739		0.962
No		–		–		–		–
Yes	1.4 (-9.55–12.36)		-0.15 (-11.04–10.74)	–	1.31 (0.51–3.41)		1.44 (0.48–4.48)	
Self-reported methamphetamine uses in the last 30 days		<0.001		<0.001		<0.001		<0.001
No		–		–		–		–
Yes	18.12 (11.21–25.03)		18.15 (10.42–25.88)		6.9 (3.38–14.98)		5.54 (2.54–13.02)	

not receive a greater increase in take-home allowance. These results suggest that the COVID-19 exemption from administration rules resulted in rapid and widespread changes in take-home medication dosing at the Spokane OTP, and the OTP relaxed methadone administration the most for clients with concurrent methamphetamine use.

This study adds to the growing body of research examining the impact of SAMHSA exemptions implemented during the COVID-19 pandemic. Research has reported positive outcomes from post-COVID telemedicine buprenorphine-based treatment programs made possible through loosened restrictions (Hughes et al., 2021; Tofighi et al., 2021). Regulatory bodies were concerned with increase diversion as a result of increases in take home methadone doses. However, to date little evidence exists that increased diversion of take-home methadone occurred after take-home guidelines loosened (Figgatt et al., 2021; Trujols et al., 2020). In addition, patient satisfaction with methadone treatment programs has improved after the new SAMHSA guidelines (Patton et al., 2021).

These results suggest health professionals at the OTP were able to quickly implement take-home medication dosing expansion in response to COVID-19 and that health professionals elected to broadly expand take-home dosing among established clients. Before COVID-19, federal regulations required near daily clinic-based medication administration for clients starting or restarting methadone and at least weekly dispensing through the first year, and only if clients met specific requirements. Research has previously criticized this policy for its potential negative impact on treatment retention (Joudrey et al., 2020). Such a concern was greatest for vulnerable populations and for those who lived farthest away from the clinic (Lin et al., 2015; Shirinbayan et al., 2010). However, our results suggest factors such as travel burden, transportation difficulty, and home insecurity did not impact the change in take-home dosing during the study period and suggest health professionals were not considering these factors when deciding to increase take-home dosing for a patient.

Our results indicate that established methadone clients with concurrent methamphetamine use were most impacted by the COVID-19 exemption. These results indicate that clients with concurrent methamphetamine use received fewer take-home doses prior to COVID-19 but were given similar take-home medication allowance post COVID-19 to clients who did not report methamphetamine use. Together, these results suggest health professionals were allowing fewer take-home doses for clients with concurrent methamphetamine use prior to COVID-19 but after the exemption health professions provided the same number of take-home doses to all clients regardless of methamphetamine status. Therefore, concurrent methamphetamine use was a factor in the decision whether to increase take home medication. Interestingly, most of the clients who reported using methamphetamine were also likely to experience home insecurity. Given the ongoing rise in stimulant-related overdose deaths within the United States, our results suggest a need to further examine the impact of this change in providers' approach to patients with current methamphetamine use. For patients with concurrent methamphetamine use, increased take home medication allowance could improve methadone treatment retention by increasing methadone accessibility, but it could also increase the risk of diversion or overdose. Further research should examine if take-home dose practices change over time and the impact of these changes on treatment retention and overdose. Our results suggest that the exemption resulted in rapid and broad changes in take-home dosing for established patients. If demonstrated to be safe, take-home medication dosing could increase methadone availability and allow for more patient-centered care. Given the known shortage of OTPs and the burdens that current regulations place on patients, research should examine this changing landscape.

4.1. Strengths and limitations

This study has several limitations. First, our study examined changes

in take-home doses over a three-month period before and after COVID-19 and did not assess changes in the long term. Second, our convenience sample of established methadone clients has the potential to introduce a selection bias. Our study population may differ from patients initiating methadone treatment or patients unwilling to consent to study participation. Finally, we were not able to capture clients who were unstable during the study period. This study also has several strengths. First, the accurate locational data on clients' place of residence allowed us to examine the impact of changes in methadone treatment delivery as a result of COVID-19 for clients with poor access to the clinic. In addition, we conducted a survey and consented people to access their medical records in 2019, which enabled us to examine how differences in socio-demographic and individual characteristics impacted changes in take-home doses.

4.2. Conclusions

The results of this study show that in response to the COVID-19 exemption, a rapid expansion took place in the number of take-home doses of methadone given to established clients, including those with concurrent methamphetamine use. Given these findings, a critical need exists to understand how this exemption has impacted treatment outcomes and whether the continued use of take-home methadone doses will lead to improved outcomes for certain populations over the long term.

CRedit authorship contribution statement

OA: Conceptualization, Methodology, Writing- Original draft preparation, Data curation **Solmaz Amiri:** Data curation, Analysis **ET:** Data collection, Reviewing and preparation **RL:** Writing- Reviewing and Editing **PJ:** Writing- Reviewing and Editing, Conceptualization.

Declaration of competing interest

No conflict to declare.

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