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Did drug use increase following COVID-19 relaxation of methadone take-out regulations? 2020 was a complicated year

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ABSTRACT

Background: Relaxation of federal regulations for methadone take-out dosing during the COVID-19 pandemic is unprecedented. The impact of this change on drug use is unknown. This study explores the impact of the federal take-out variance on drug use in one urban opioid treatment program as measured by drug testing.
Methods: This study collected drug test results from 613 patients receiving methadone from July 2020, following COVID-19-related take-out dose adjustments, and July 2019 for comparison. Using a generalized linear mixed model, we computed the average estimated probability of a positive drug test for each year for each take-out phase. To isolate the effect of changing take-out, we removed the main effect of year, while retaining the main effect of take-out phase and the interaction between year and phase.
Results: The percent of drug tests positive for opiates, benzodiazepines, and methamphetamine was greater in July 2020 than in July 2019 ($p < 0.001$ for each), while the percent of tests negative for methadone increased ($p < 0.001$). Oxycodone, barbiturate, and cocaine positive tests remained stable. In a separate analysis of opioid and non-opioid test results, take-out phase was associated with both opioid and non-opioid positive results ($p < 0.001$, each outcome). The association of take-out phase with opioid and non-opioid positive results differed in the two years (year-by-phase interaction $p < 0.025$, each outcome). After removing the year main effect, the rate of positive tests was lower in 2020 for the smallest number of take-out doses, higher for a moderate number of take-out doses, and about the same for the highest number of take-out doses.
Conclusions: Positive opioid and non-opioid drug tests increased following the federal variance allowing more methadone take-out doses, but these findings cannot fully be attributed to alterations in the take-out schedule.

1. Introduction

The novel coronavirus disease-2019 (COVID-19) pandemic has disproportionately affected people with substance use disorder, especially those with opioid use disorder (OUD) (Wang et al., 2021). Medications for OUD (MOUD) are the standard of care for treating OUD, yet in the United States delivery of MOUD through opioid treatment programs (OTP) requires mandated frequency of visits that conflict with recommended public health measures to control the spread of COVID-19 (e.g., social distancing) (Substance Abuse and Mental Health Services Administration, 2015). Recognizing this conflict, on March 16, 2020, U. S. federal agencies issued an emergency variance allowing stable patients receiving methadone treatment to receive up to a 28 day supply of medication for unsupervised self-administration, hereafter referred to as take-out medication, and less stable patients to receive up to 14 days of take-out medication (Substance Abuse and Mental Health Services Administration, 2020a).

The Hennepin Healthcare Addiction Medicine Program, located in Minnesota's largest safety-net health system, began to adjust methadone take-out schedules on March 1, 2020, and accelerated this once the federal government issued its variance. For example, on March 1, 2020, of the clinic's roughly 545 patients, 6 came to clinic only one time per month and by April 1, this number had increased to 189.

The purpose of this brief article is to explore the impact on drug use of the COVID-19 federal variance on methadone take-out dosing in a single urban OTP as measured by drug testing.

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2. Methods

The Hennepin Healthcare Addiction Medicine OTP maintains a patient census between 540 and 600 patients with more than 95% receiving methadone and the remaining receiving OTP-based buprenorphine. All patients undergo random drug testing at least 8 times per year with 99% undergoing at least monthly testing. This brief article presents drug test results from July 2019 and from July 2020 after the OTP had implemented new COVID-19 workflows. The study team selected July 2020 to use the newest data following the federal regulations and resumption of drug testing in the clinic. We selected July 2019 as a comparator to reduce seasonal effects. The study includes results from all patients receiving methadone. The study restricted results to patients receiving methadone only, as the frequency of buprenorphine take-out dosing follows less restrictive regulations than methadone and is, therefore, subject to less impact by the March 16, 2020, guidance.

On March 17, 2020, the Hennepin Healthcare OTP practice manager (RR) and OTP physicians consulted with OTP counselors and nurses to review the entire clinical census to assess four risk factors: 1) risk of overdose, 2) risk of methadone diversion, 3) risk of medical or mental health decompensation, and 4) risk for COVID-19-related mortality. To balance patient and community safety, the team adjusted methadone take-out doses based on clinical impression of these risks. Prior drug test results could inform these criteria but we did not base decisions regarding take-out doses on these results. While we did not base our decisions solely on objective measures, the team reached consensus on these clinical decisions. As the clinic was developing new workflows, it suspended drug testing of all patients between March and June. Table 1 shows distribution of take-out doses on March 1, 2020, before our COVID-19 response; on April 6, 2020, after we had fully implemented the COVID-19 response; and on July 1, 2020, when the OTP resumed drug testing.

The team collected all drug test specimens randomly in clinic. Staff did not observe urine collection, but the specimen was immediately subject to temperature checks for validation, then analyzed on-site by a Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists certified laboratory. The assays tested for amphetamine, benzodiazepine, barbiturates, cocaine (and metabolite), opiates, methadone metabolite, and oxycodone using commercial assays (Roche KIMS, Montclair, NJ and Thermo Scientific DRI, Fremont, CA). The lab measured urine creatinine as a validation. Approximately 10 patients with renal failure undergo oral fluid drug testing. The OTP did not routinely test for fentanyl, as fentanyl and its analogues are mostly mixed into the local heroin supply rather than sold as stand-alone products. The clinic required patients refusing to provide a urine specimen to visit the clinic daily until they provided a urine specimen, after which they could resume their take-out schedule. These analyses exclude patients who refused to provide urine specimens; imputing refusals as positive did not substantively alter the main results.

The clinic generated automated census reports for July 2019 and 2020 for clinical demographics, methadone take-out schedules, and urine drug testing results. While results from July 2020 are of primary interest in this report, results from July 2019 served as a comparator. This study also used results from February 2019 and February 2020 (just before COVID-19 changes) to confirm that the July 2019 distribution of take-out doses and drug test results were generalizable to other pre-COVID-19 months. These analyses were part of a clinical quality improvement project and we conducted them using deidentified data. The Hennepin Healthcare Research Institute Human Subjects Research Committee did not consider this human subjects research.

The analyses considered patients with a confirmed prescription for a tested drug (e.g., opioid, benzodiazepine, amphetamine) to have a "negative" result for that substance. For the outcome "positive test" (yes/no), we used a generalized linear mixed model with person as the random effect, to capture the correlation between tests in July 2019 and 2020 for people who had both ($n = 407$). Some persons had more than one test in July 2019 or 2020; we included all available tests for each person. For testing changes in positive rates for individual drugs, the only fixed effect was year (2019 vs. 2020). In separate analyses for opioid (opiates or oxycodone) and for non-opioid drugs, fixed effects were year (2019 vs. 2020), take-out schedule, and the interaction of year and take-out schedule, as well as patient age and sex. The main effect of year is intended to adjust for confounding by year by capturing the difference between years in overall level of positive test results, distinct from differences arising from changes in take-out schedule. Because of the person-specific random effect, the fitted model gave an estimated probability of testing positive for each person in each year. We computed the average estimated probability of a positive test for each year for each take-out phase. To isolate the effect of changing take-out schedule, apart from the many other ways in which 2020 differed from 2019, we then removed from the estimated probabilities the main effect of year, while maintaining the main effect of take-out phase and the interaction between year and phase, and again averaged the resulting estimated probabilities of a positive test for each year and take-out phase. The research team divided take-out phase into four categories: 1–2/week, 3–5/week, 6/week, and > 6/week. These analyses used the R system (version: 3.6.1) and the "glmer" function in package "lme4" (version 1.1.23) (Bates et al., 2015; R Core Team, 2019).

Table 1
Impact of COVID-19 on methadone clinic schedule.

Take-out schedule	Number of patients (%)		
	March 1	April 6	July 1
1/week	157 (29)	0	23 (4)
2/week	45 (8)	0	38 (7)
3/week	37 (7)	0	3 (1)
4/week	27 (5)	143 (27)	124 (22)
5/week	47 (9)	25 (5)	32 (6)
6/week	83 (15)	79 (15)	86 (15)
14/2-weeks	105 (19)	91 (17)	78 (14)
21/3-weeks	37 (7)	9 (2)	4 (1)
28/month	6 (1)	189 (35)	183 (32)

3. Results

Drug tests from July 2019 and 2020 include results from 613 unique individuals, 407 of whom had results in both years. Mean patient age was 49 years (SD 14); 49% were female; 23% Black, 15% American Indian, 9% Asian, 46% Caucasian, and <1% Latinx. Sixteen percent were employed either full or part time. The mean daily methadone dose was 74 mg (SD 34).

Less than 25% of drug test results were positive for an illicit substance across both years (Table 2). The proportion of tests positive for opiates, amphetamines, or benzodiazepines was significantly higher in 2020 ($p < 0.001$ for each), while tests positive for barbiturates, cocaine, or oxycodone were relatively stable across years. The proportion of tests negative for methadone was higher in 2020 ($p < 0.001$). Few positive test results were due to legitimately prescribed controlled substances, but the proportion of positive tests due to prescribed benzodiazepines or oxycodone was lower in 2020.

The percentage of opioid positive urine drug tests was higher in July 2020 than in July 2019 for all methadone take-out phases (Table 3, "Actual"). The average odds of having a positive opioid test in 2020 (i.e., the year main effect) was 2.34 (95% CI 1.78, 3.07) times higher than the average odds of being positive across both years, and that of non-opioid drugs was 2.48 (95% CI 1.89, 3.25) times higher. While opioid positive results decreased with each phase of take-out methadone in 2019, 2020 saw little difference in positive results for patients receiving less than weekly take-outs. Results for non-opioid drug positives were also higher in July 2020, with similar findings for differences between 2019 and 2020 as seen for opioids (Table 3).

A significant main effect of take-out phase existed on both opioid and

Table 2
Drug test results 2019 versus 2020.

Drug test	7/2019	7/2020
	$N = 568$	$N = 602$
Methadone*		
NEG	11 (1.9%)	24 (4.0%)
POS	557 (98%)	578 (96%)
Opiate*		
NEG	486 (86%)	467 (78%)
POS	78 (14%)	135 (22%)
Rx	4 (0.7%)	0 (0%)
Amphetamine*		
NEG	508 (89%)	508 (84%)
POS	58 (10%)	94 (16%)
Rx	2 (0.4%)	0 (0%)
Barbiturate		
NEG	566 (100%)	600 (100%)
POS	1 (0.2%)	2 (0.3%)
Rx	1 (0.2%)	0 (0%)
Benzodiazepine*		
NEG	509 (90%)	528 (88%)
POS	36 (6.3%)	68 (11%)
Rx	23 (4.0%)	6 (1.0%)
Cocaine		
NEG	508 (89%)	529 (88%)
POS	60 (11%)	73 (12%)
Oxycodone		
NEG	545 (96%)	581 (97%)
POS	15 (2.6%)	19 (3.2%)
Rx	8 (1.4%)	2 (0.3%)

"N" is the number of drug tests; an individual could have more than one drug test.
NEG negative test result, POS positive test result, Rx confirmed prescription.
* $p < 0.001$ for 2020 versus 2019.

Table 3
Predicted versus actual positive drug test results.

Take-out doses	2019			2020		
	Fitted (with year)	Fitted (without year)	Actual	Fitted (with year)	Fitted (without year)	Actual
Opioids						
1–2/ week	0.277	0.435	0.303	0.344	0.202	0.364
3–5/ week	0.096	0.187	0.129	0.366	0.226	0.381
6/week	0.028	0.060	0.044	0.228	0.121	0.260
>6/ week	0.012	0.027	0.020	0.075	0.036	0.107
Non-opioid drugs						
1–2/ week	0.426	0.587	0.437	0.561	0.398	0.551
3–5/ week	0.106	0.187	0.140	0.529	0.377	0.524
6/week	0.062	0.119	0.089	0.270	0.161	0.302
>6/ week	0.023	0.049	0.041	0.081	0.040	0.119

Numbers expressed as proportion of positive tests.

non-opioid drug positive results ($p < 0.001$ for both). The interaction between take-out phase and year was also significant for opioid and non-opioid drug positive results ($p < 0.01$ for both), i.e., the pattern across take-out phases in positive test results differed in the two years. The fitted model including year slightly attenuated the 2020 opioid and non-opioid drug positive results across each take-out phase with greater attenuation of 2019 results (Table 3, "Fitted [with year]"). In the fitted model without the year main effect (Table 3, "Fitted [without year]"), which captures the effect of change in take-out schedule while removing other potential differences between 2019 and 2020, estimated opioid positive results were lower for those receiving 1–2 take-outs per week and higher for all other take-out phases in 2020 compared to 2019. Fitted non-opioid positive results were also lower in 2020 than 2019 for those receiving 1–2 take-outs per week but relatively similar across years for those receiving one week or more of take-outs.

Besides the effect of year and take-out schedule on drug test results, older age was associated with higher odds of testing opioid positive (OR 1.33, 95% CI 1.02, 1.73), while being female was associated with higher odds of testing non-opioid drug positive (OR 1.37, 95% CI 1.05, 1.78).

4. Discussion

The unprecedented change in OTP regulations during the COVID-19 pandemic provides a unique opportunity for research and, potentially, regulatory reform (Hatch-Maillette et al., 2020; Livingston et al., 2020). Consistent with other reports (Morin et al., 2021), we found that the absolute percent of positive opioid and non-opioid drug tests increased following the federal variance that allowed more methadone take-out doses, but we also found that this result cannot be fully attributed to alterations in the take-out schedule.

General population surveys or OTP specific data on drug use trends during COVID-19 are lacking. Our finding of increased drug tests positive for methamphetamine, opiates, and benzodiazepines in 2020 may be consistent with pre-pandemic trends in self-reported drug use by patients entering substance use disorder treatment with the intention of starting MOUD (Substance Abuse and Mental Health Services Administration, 2020c) and pandemic-era drug testing reports of increased positive rates for opiates and benzodiazepines (Niles et al., 2021). These increases are of particular interest given the disruption of medical care and surgical procedures during the pandemic and the resultant decrease in opioid and benzodiazepine prescriptions in circulation (Downs et al., 2021). That we saw no change in cocaine positive drug tests in our sample may be a result of sample size and differs from national trends for patients seeking MOUD (Substance Abuse and Mental Health Services Administration, 2020c); however the finding is consistent with reports of stable treatment admission rates for cocaine in Minnesota between 2017 and 2019 (Substance Abuse and Mental Health Services Administration, 2020b). We also found that drug tests negative for methadone increased in 2020. We are not able to determine whether this signifies increased methadone diversion. Further studies should evaluate the extent to which COVID-19 disrupted access to MOUD, thereby increasing risk for methadone diversion. While the North Central High Intensity Drug Trafficking Area Overdose Response Strategy Team did not report an increase in local law-enforcement reports of methadone diversion during this period (Hayley McCarron, MPH personal communication), 2020 saw increases in methadone-associated deaths nationally (Ahmad et al., 2021).

In our fitted model without the effect of year, we found that the predicted probability of a positive drug test (opioid or non-opioid) was lower in 2020 than in 2019 for those receiving the fewest take-outs, whereas the study found the opposite for those receiving more take-outs. While this finding may seem counter-intuitive, we speculate that it is a result of flexible decision-making during the emergency variance. Before the emergency variance, eligibility for take-out medication was federally determined under 42 CFR Part 8 and included length of time in treatment and ongoing drug use as factors that influence take-out medication eligibility (Medication Assisted Treatment for Opioid Use Disorders, 2001). Therefore, by regulation, patients receiving the fewest take-out doses of medication were either within their first 90 days of OTP treatment (a group likely to have ongoing drug use) or clinically unstable, as defined under the federal rule's 8-point criteria. In 2020, with the emergency variance, clinical staff were not bound by the specifications of 42 CFR Part 8 and could determine the frequency of take-out medication based on their own definition of instability. Our definition of instability warranting fewer take-outs may have included a population whose identified risks (e.g., medical and psychiatric decompensation) were mostly independent of drug use and that our

definition of stability allowed for ongoing drug use in the presence of risk factors for poor COVID-19 outcome.

Our study is limited by its naturalistic design: the study did not prospectively randomize patients to a take-out schedule, nor did we collect drug tests with uniform frequency. A brief randomized trial of two versus five take-outs per week shortly after methadone initiation found little effect on drug test results over 8 weeks (Schmitz et al., 1998). Isolating the causal effect of the change in take-out schedules is difficult and may be impossible with the data available to us. The fundamental problem is confounding of the change in take-out schedule by the passage of time, which would also affect alternative analyses, e.g., considering the dynamics of take-out schedule in individuals over time. Another complication of our study is that take-out schedules were assigned purposively after the federal variance, which could be expected to confound the causal effect of interest. Inclusion of multiple clinics adopting different take-out schemes (e.g., no change in response to the federal variance to all patients receiving maximum allowed take-outs) will increase sample size and possibly allow for more robust statistical analyses than a single site allows. We did not collect information on methadone dose, time in treatment, psychiatric comorbidity, self-reported drug use, or other characteristics that can impact drug use. For those with legitimate prescriptions for a controlled substance, we could not determine if misuse or additional illicit use of a drug in the same class had occurred. Also, we have no measures of adherence to or diversion of the methadone take-out doses. Finally, statistical analysis is not always feasible for event rates near 0% or 100%, and *p*-values for these events (e.g., methadone-negative patients) must be scrutinized.

The COVID-19 pandemic is not the first disaster to impact OTP services. In the United States, natural disasters (e.g., hurricanes Katrina and Sandy) and the 9/11 terrorist attacks created significant disruption to OTP services and increased overall stress levels in the patient population (Carlisle Maxwell et al., 2009; McClure et al., 2014; Pouget et al., 2015; Tofighi et al., 2014). The response to such disasters historically has been implementation of guest dosing plans at alternate clinical sites rather than regulatory change in methadone take-out schedules. Research following these disasters indicates that stresses related to disrupted services, barriers to clinic access (e.g., loss of transit, transience due to displacement), and lack of clinical disaster planning resulted in increased drug use, especially when medication access was interrupted (Pouget et al., 2015).

5. Conclusion

COVID-19 was accompanied by economic stressors, social isolation, drug supply-chain disruptions, and fear (McGinty et al., 2020). Together, these and other disruptions of 2020 (e.g., economic disaster, the murder of George Floyd and subsequent civil unrest, political tensions) can be considered a “Big Event”, a term Friedman and others adopted to contextualize HIV risk amid vast social upheaval caused by war and other transitions that increase social vulnerability (S. Friedman et al., 2006). With the complexity of Big Events, analyses of risk, in this context, drug use, may require a multi-center dataset and network or more complex causal analyses to capture the social context of behavioral change and the impact of service/societal disruption on outcomes (S. R. Friedman et al., 2009). Future studies attempting to determine the impact of COVID-19 and OTP regulatory change on patient outcomes will need such analytic models as it is not clear that the benefits gained (e.g., reduced drug use) by the strict pre-pandemic regulation outweigh the lack of flexible decision-making that OTP providers and patients have experienced for decades prior to COVID-19. Our findings show that 2020 was a year likely marked by tremendous change and that increases in drug use in patients receiving methadone cannot be fully attributed to the relaxation of OTP regulations.

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Contributors

All authors had access to the data utilized in production of this manuscript. All authors have read and approve the final version of the manuscript. GB wrote the manuscript. GB and JSH designed the research. RR compiled the data. JSH and SW analyzed the data.

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