Appendix

Table 19A.1. Studies Evaluating Changes in Methadone Take Home Doses during COVID-19 from March 2020 to September 2021

Study (cited in text)	Type of Study	Types of Data or Dataset	Sample Size	Race/Ethnicity	Sex (M/F)	Age Group	Population	Relevant Study Outcomes	Co-use of Other Substances	Geographic Location	Summary of Findings
Amram et al. (2021) ¹	Epidemiologic	Patient survey data and OTP medical records	N = 194 patients enrolled in Spokane, Washington OTP	Non-Hispanic White (72%) Other (20%)*	M & F	Ages 18 and older	Persons receiving methadone for OUD at an OTP in Spokane, Washington	Change in number of methadone THDs three months before and three months after the SAMHSA waiver in March 2020	Methamphetamine	Spokane, Washington	All survey participants received an average increase of 41.4 THDs in the three-month period after the SAMHSA waiver. Participants who self-reported use of methamphetamine in the past thirty days received a significantly larger increase in THDs compared to those who did not disclose methamphetamine use. Other variables (e.g., race, gender, housing insecurity, level of education, and transportation access) were not associated with a change in THDs.
Brothers, Viera, and Heimer (2021) ²	Epidemiologic and qualitative	State-wide survey, Office of Chief Medical Examiner autopsy data on confirmed accidental opioid- involved deaths	Total amount of providers who completed survey not stated in paper; (N = 24,261 represents patients—not providers— across eight OTP sites)	Not included	Not included	Ages 18 and older	OTP providers and persons receiving methadone at OTPs across Connecticut	OTP providers' responses to methadone treatment during COVID-19; comparison of opioid-involved overdose deaths and overdose deaths involving methadone before and after COVID-19	N/A	Connecticut	OTP providers in Connecticut reported that the percent of patients receiving 28-day THDs increased from 0.1% pre-COVID-19 to 16.8% during COVID-19. Furthermore, 14-day THDs increased from 14.2% to 26.8%. Three of the eight OTPs provided only 25% or more of their patients 28-day THDs during COVID-19. Methadone-only nor methadone-involved fatal overdoses did not increase from April to August 2020 compared to the same period in the previous five years.

¹ Ofer Amram et al., Changes in Methadone Take-Home Dosing Before and After COVID-19, 133 J. Substance Abuse Treatment art. 108552, at 1-5 (2021).

² Sarah Brothers et al., Changes in Methadone Program Practices and Fatal Methadone Overdose Rates in Connecticut During COVID-19, 131 J. Substance Abuse Treatment art. 108449, at 1-6 (2021).

Study (cited in text)	Type of Study	Types of Data or Dataset	Sample Size	Race/Ethnicity	Sex (M/F)	Age Group	Population	Relevant Study Outcomes	Co-use of Other Substances	Geographic Location	Summary of Findings
Andraka- Christou et al. (2021) ³	Qualitative	Individual state policy responses listed on Single State Agencies for Substance Abuse Services websites on SUD treatment during COVID-19	N = 220 documents from 45 states and Washington, D.C.	N/A	N/A	N/A	N/A	Identify qualitative themes in state policy responses to SUD treatment including increases in methadone THDs at OTPs across the United States	N/A	United States	One of the eight common policy changes to SUD treatment during COVID-19 was the extension of methadone THDs to patients who had not previously earned them or were "unstable." Many state policies also stated that OTP patients with earned methadone THDs were permitted the maximum amount of THDs during COVID-19, and THDs were allowed for patients with COVID-19 or at risk of developing more severe symptoms from COVID-19.
Figgat et al. (2021) ⁴	Epidemiologic	Survey data from patients enrolled in OTPs	N = 104 patients enrolled in OTPs across North Carolina	Hispanic/Latino (1.0%), Non-Hispanic Black (7.8%), Non-Hispanic White (88.2%), Other (2.9%)*	M & F	Ages 18 and older	Persons receiving methadone at OTPs across North Carolina	Change in number of methadone THDs, self- reported diversion of methadone THDs	N/A	North Carolina	Before March 2020, the percent of patients receiving THDs at each of the three OTPs in North Carolina ranged from 56% to 82%. Since COVID-19, these increased from 78% to 100%. The percentage of patients receiving a THD supply of > 6 days since COVID-19 ranged from 11% to 56%. 71.3% of patients receiving THDs reported storing doses in a locked container. Only six participants (6.9%) receiving THDs since COVID-19 reported selling or sharing their THDs. Among all survey participants (regardless of whether they received THDs), the most reported hypothetical reasons for giving away doses were needing money or drugs, helping someone else, and saving up for travel.

³ Barbara Andraka-Christou et al., Common Themes in Early State Policy Responses to Substance Use Disorder Treatment During COVID-19, 47 Am. J. Drug & Alcohol Abuse 486, 486-96 (2021).

⁴ Mary C. Figgatt et al., Take-Home Dosing Experiences Among Persons Receiving Methadone Maintenance Treatment During COVID-19, 103 J. Substance Abuse Treatment art. 108276, at 1-4 (2021).

Study (cited in text)	Type of Study	Types of Data or Dataset	Sample Size	Race/Ethnicity	Sex (M/F)	Age Group	Population	Relevant Study Outcomes	Co-use of Other Substances	Geographic Location	Summary of Findings
Hunter et al. (2021) ⁵	Qualitative	Semi- structured telephone interviews with OTP clinicians	N = 20 OTP clinicians	Not included	M & F	Not included	OTP clinicians (physicians, physician assistants, nurse practitioners) at OTPs across 13 states	on changes in OTP policies during COVID-19, including	N/A	United States	Of the OTP clinicians interviewed, 72% stated that there was a change in the frequency of methadone dispensing during COVID-19. There was a high degree of variability in how clinicians implemented the SAMHSA waiver with 28% of clinicians stating that their OTP had not implemented any changes to methadone THDs. While many clinicians reported satisfaction with increases in methadone THDs, a few expressed reservations about liability and patient risk of overdose and diversion from THDs.
Joseph et al. (2021) ⁶	Retrospective chart review	OTP clinician and counselor notes, inpatient hospital admission notes, discharge summaries, family reports	N = approximately 3,600 patients enrolled in Bronx OTPs	Latinx (65%), Non-Hispanic Black (17%), no other race or ethnicity reported	Not included	Not included	Patients receiving methadone at OTPs in the Bronx	Changes in the frequency of scheduled OTP visits during COVID-19; non-fatal and fatal overdoses during COVID-19	N/A	Bronx, New York	Between March 9 and March 22, 2020, the percent of patients who had to travel to an OTP 5-6 times/week was reduced from 47.2% to 9.4%, reflecting increases in methadone THDs. From March 1 to May 21, 2020, patients on methadone (regardless of whether they received increases in THDs) experienced six non-fatal overdoses and zero fatal overdoses compared to two non-fatal overdoses and one fatal overdose between January 1 and March 15, 2020.

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⁵ Sarah B. Hunter et al., Clinical Perspectives on Methadone Service Delivery and the Use of Telemedicine During the COVID-19 Pandemic: A Qualitative Study, 124 J. Substance Abuse Treatment art. 108288, at 1-6 (2021).

⁶ Giliane Joseph et al., Reimagining Patient-Centered Care in Opioid Treatment Programs: Lessons from the Bronx During COVID-19, 122 J. Substance Abuse Treatment art. 108219, at 1-3 (2020).

Study (cited in text)	Type of Study	Types of Data or Dataset	Sample Size	Race/Ethnicity	Sex (M/F)	Age Group	Population	Relevant Study Outcomes	Co-use of Other Substances	Geographic Location	Summary of Findings
Kidorf et al. (2021) ⁷	Retrospective chart review	Data from OTP medical charts, Medminder pillbox data, nursing medication records	N = 42 patients enrolled in a Baltimore OTP	White (57.1%), Non-White (42.9%)	M & F	Not included	Patients receiving increases in methadone THDs during COVID-19 deemed high- risk for mismanaging THDs at an OTP in Baltimore	Pre-pillbox vs. post-pillbox changes in number of delivered THDs, percent of THDs dispensed within and outside of scheduled windows, evidence of possible tampering with THDs	N/A	Baltimore, Maryland	Prior to COVID-19, patients received 11 methadone THDs/month and 25.6 after the pillbox intervention which patients started to use about one month after SAMHSA's waiver. This represents a mean increase of about 14-15 more THDs per month. Almost all (99.3%) of THDs were dispensed from the pillbox in the scheduled window of time (three hours), and <1% of patients missed THDs. The average number of patients suspected of tampering with doses was 2.5. No patients reported overdose during the study period.
McIlveen et al. (2021) ⁸	Retrospective chart review	OTP dosing reports	N = 7792 patients (pre- COVID-19), N = 7,882 patients (post-COVID- 19 time point 1), N = 7,774 patients (post COVID-19 time point 2)	Not included	Not included	Not included	Patients on methadone across 20 Oregon OTPs	Changes in the number of patients receiving methadone THDs at three time points:	N/A	Oregon	Pre-COVID-19, mean patient OTP visits/month were 15.5 with 5.8 THDs/patient/month. At post-1 COVID-19, medication visits decreased by 33% and THDs increased 97% with 10.4 mean visits/patient and 11.3 mean THDs/patient. The changes in medication visits remained the same at the post-2 COVID-19 time point. A negative binomial mixed-effects regression model estimated an overall 54% reduction in mean OTP visits/patient when comparing pre-COVID-19 time point to the first post-COVID-19 time point. The Oregon State Opioid Treatment Authority did not report any deaths related to increasing THDs.

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⁷ Michael Kidorf et al., Use of an Electronic Pillbox to Increase Number of Methadone Take-Home Doses During the COVID-19 Pandemic, 126 J. Substance Abuse Treatment art. 108328, at 1-5 (2021).

⁸ John McIlveen et al., Reduction in Oregon's Medication Dosing Visits After the SARS-CoV-2 Relaxation of Restrictions on Take-Home Medication, 15 J. Addiction Med. 516, 516-18 (2021).

Study (cited in text)	Type of Study	Types of Data or Dataset	Sample Size	Race/Ethnicity	Sex (M/F)	Age Group	Population	Relevant Study Outcomes	Co-use of Other Substances	Geographic Location	Summary of Findings
Meteliuk et al. (2021) ⁹	Epidemiologie	Data from national opioid agonist therapy (OAT) registry		Not included	Not included	Not included	Patients enrolled in OAT programs in Ukraine	Changes in methadone delivery during two 60-day time periods in 2020: (1) pre-COVID-19 guidance from January 1 to March 1, 2020 and (2) post-COVID-19 guidance from April 1 to June 1, 2020	N/A	Ukraine	Prior to COVID-19, 57.5% of 12,837 patients received methadone THDs. By June 1 2020, 82.2% of 13,097 patients were receiving methadone THDs. This represents a 35.9% net increase in THDs. Of note, Ukraine legislation requires patients to have documented six months of "sobriety" before granted THDs; this policy was not followed in the context of COVID-19. Annualized mortality during this period did not change. Fifteen fatal overdoses were reported from April 1 to June 1, 2020.
Russell et al. (2021) ¹⁰	Qualitative	Telephone- based interviews with people who use drugs (PWUD) across Canada during COVID-19 between May and July 2020	N = 196 PWUD in Canada	White (59.2%), Indigenous (29%), Other (11.2%)*	M & F	Ages 18 and older	PWUD in Canada who are either actively using psychoactive substance and/or enrolled in an OAT program (methadone or buprenorphine)	How COVID- 19 has impacted access to harm reduction services, OAT, withdrawal management, and treatment services	Opiates, stimulants, cannabis, alcohol, benzodiazepines, hallucinogens	Canada	Of the people enrolled in OAT programs, 30% expressed positive views on loosening regulations relating to methadone THDs. One participant stated that having control over methadone doses actually reduced substance use. However, many participants indicated a lack of standardization in terms of relaxing regulations across OAT programs in Canada.

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⁹ Anna Meteliuk, Rapid Transitional Response to the COVID-19 Pandemic by Opioid Agonist Treatment Programs in Ukraine, 121 J. Substance Abuse Treatment art. 108164, at 1-4 (2021).

¹⁰ Cayley Russell et al., Identifying the Impacts of the COVID-19 Pandemic on Service Access for People who Use Drugs (PWUD): A National Qualitative Study, 129 J. Substance Abuse Treatment art. 108374, at 1-10 (2021).

Study (cited in text)	Type of Study	Types of Data or Dataset	Sample Size	Race/Ethnicity	Sex (M/F)	Age Group	Population	Relevant Study Outcomes	Co-use of Other Substances	Geographic Location	Summary of Findings
Treitler et al. (2022) ¹¹	Qualitative	Semi- structured interviews conducted with MOUD providers between September and November 2020	N = 20 MOUD providers	Black or African American (10%), Hispanic/Latinx (10%), White (60%), Other (20%)*	M & F	Not included	MOUD providers in New Jersey	Identify MOUD practice changes that were implemented due to COVID-19, understand provider experiences with those changes, and analyze provider perspectives on whether changes should be permanent post-COVID- 19	N/A	New Jersey	Most providers increased methadone THDs after the waiver, but gradually reduced the amount of THDs patients received as the pandemic went on. A few providers described how increased THDs during COVID-19 improved treatment adherence (e.g., patients who got increased THDs in the beginning of the pandemic then qualified for THDs based on pre-pandemic requirements). Some providers stated that increases in THDs made it more difficult to use THDs for contingency management. A few providers noted that while they expected overdoses and diversion to increase with more THDs, this was not the case. All providers viewed the pre-pandemic regulations to be too strict and wanted increased THDs to extend into the future. No providers reported an increase in overdoses in their patients since the SAMHSA waiver and some observed a decrease in overdoses.
Trujols et al. (2020) ¹²	Epidemiologic	Program records from a MMT program in Barcelona	N = 102 patients enrolled in MMT program in Barcelona	Not included	Not included	Not included	Patients enrolled in MMT program in Barcelona	Changes in methadone THDs pre- COVID-19 (March 12, 2020) compared to COVID-19 (March 13 – May 12, 2020)	N/A	Barcelona, Spain	The number of patients on the maximum THD schedule (four weeks) increased significantly from the pre-COVID-19 time point to the COVID-19 time point. All amounts of THDs increased from pre-COVID-19 to COVID-19. There were no signs of diversion in patients as a result of increased THDs.

¹¹ Peter C. Treitler et al., Perspectives of Opioid Use Disorder Treatment Providers During COVID-19: Adapting to Flexibilities and Sustaining Reforms, 132 J. Substance Abuse Treatment art. 108514, at 1-10 (2021).

12 Joan Trujols et al., Increased Flexibility in Methadone Take-Home Scheduling During the COVID-19 Pandemic: Should this Practice be Incorporated Into Routine Clinical Care?, 119 J. Substance Abuse Treatment art. 108154, at 1-3 (2020).

Vicknasingam et al. (2021) ¹³		Semi- structured interviews from March 18 to August 31, 2020 and quantitative data from MMT program at Sungai Buloh Hospital in Selangor	N = 18 (N = 2, medical personnel of MMT programs; N = 3, medical personnel of HIV clinics; N=4, staff of nongovernmental organization (NGO) services; N = 9, MMT patients)	Not included	Not included	Not included	Patients and service providers in HIV and MMT clinics and NGOs in Malaysia	Explore programmatic and operational changes implemented by clinics in response to COVID-19 and how patients and providers felt about these changes	N/A	Malaysia	Physicians reported that methadone THDs were significantly relaxed in both clinics participating in this study compared to pre-COVID-19 guidelines (which required negative urine toxicology tests conducted randomly for at least a month before the allowance of THDs). Overall, patients preferred the relaxed rules for methadone THDs and would like them to continue after COVID-19 restrictions lifted. One patient did not have a place to store THDs and was worried about accidental overdoses from children at home. As of November 2020, one of the two MMT programs in the study continued to offer more flexible THDs and the other returned to the pre-COVID-19 regulations.
Front (2020) ¹⁴	Qualitative	Interviews with executives and administrative officials at OTPs across the country from June 4 through June 22, 2020	N = 142 OTPs across the United States (number of administrators interviewed not specified)	Not included	Not included	Not included	Executives and administrative officials at OTPs	Identify challenges that OTPs faced during the COVID-19 pandemic and how OTPs responded to these obstacles	N/A	United States	Most of the OTPs (127 of 142) reported increases in THDs during COVID-19, but at a lower level than SAMHSA's recommendations due to individual clinician discretion or state limitations. Some leaders stated they were unsure how to allow patients to get increased THDs and which patients qualified under SAMHSA's waiver. OTP leadership stated that they wanted SAMHSA's waiver on THDs to be extended after COVID-19.

^{*}Authors do not specify race/ethnicity

¹³ Balasingam Vicknasingam et al., COVID-19 Impact on Healthcare and Supportive Services for People Who Use Drugs (PWUDs) in Malaysia, 12 Frontiers in

Psychiatry art. 630730, at 1-7 (2021).

14 US Dep't Health & Hum. Serv. Off. Inspector Gen., Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken to Address Them 9-30 (2020).