# Reduction in Oregon's Medication Dosing Visits After the SARS-CoV-2 Relaxation of Restrictions on Take-home Medication

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To slow the spread of SARS-CoV-2 in opioid treatment programs (OTPs), SAMHSA notified State Opioid Treatment Authorities that stable patients could receive up to 27 days of take-homes, less stable patients could receive up to 13 days with fewer take-homes for other patients. An analysis assessed how the relaxed standards affected the number of patient dosing visits and the amount of take-home medications dispensed in Oregon's 20 public, nonprofit, and for-profit OTPs.

OTPs reported the number of patients receiving take homes pre and post federal policy change at 3 time points: pre SARS-CoV-2 (February or first half of March), post 1 SARS-CoV-2 (March, April, or May), and post 2 SARS-CoV-2 (April, May, or June). The patients receiving each quantity of take-homes were counted and means calculated for visits and take-homes per patient per month. A negative binomial mixed-effects regression model assessed change in mean dosing visits per patient.

During the pre SARS-CoV-2 period, OTPs served 7792 patients monthly with 120,513 medication visits and dispensed 44,883 take-home doses. Mean patient visits per month were 15.5 with 5.8 take-homes per patient per month. Following the policy change, medication visits declined 33% and take-home medication increased 97% with 10.4 mean visits per patient and 11.3 mean take-homes per patient. The negative binomial mixed-effects regression model estimated a 54% reduction in mean visits per patient. The policy change had the intended effect. More research is needed to assess unintended consequences associated with increased access to take-home medication.

**Key Words:** buprenorphine, methadone, opioid treatment programs, SARS-CoV-2, take-home doses

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The regulations governing opioid treatment programs (OTPs) restrict the use of methadone for the treatment of opioid use disorder to OTPs and inhibit access to take-home doses.[1] Patients new to care, may receive a single take-home dose per week during the first 90 days of care. Take-homes increase with retention in care. After 1 year, take-homes may increase to a 2-week supply and to a month's supply after 2 years.[1] States may set more restrictive take-home limits.

OTP medical directors must consider 8 criteria before increasing a patient's take-home medication: (1) no recent drug or alcohol use, (2) regular clinic attendance, (3) presence of behavioral problems, (4) recency of criminal involvement, (5) home environment stability, (6) duration of treatment, (7) ability to store medication safely, and (8) that the rehabilitative benefit exceeds the diversion potential.[1] The clinical record must document the reasons for take-home changes.

Because of limited access to take-home medication, most patients receiving methadone attend an OTP multiple times each week to receive medication. Long lines and crowded waiting rooms are common. On March 16, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) notified State Opioid Treatment Authorities (SOTAs) that to minimize risks of SARS-CoV-2 infections, SOTAs were permitted to grant blanket exceptions in their jurisdictions. Stable patients could receive up to 27 days of take-home doses, less stable patients could receive up to 13 days of take-home medication, more frequent dosing was required for the remaining patients.[2]

SAMHSA also approved the use of telemedicine to minimize in-clinic visits for counseling and education.[3] Medicare payments for telemedicine services were authorized and

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Health Insurance Portability and Accountability Act requirements were relaxed to facilitate use of telemedicine.[4,5]

The substantial regulatory changes impacting OTP operations created research opportunities. A rapid analysis examined the impact of the take-home relaxation on the reduction in patient visits and increases in take-home medication dispensed in Oregon's OTPs.

## METHODS

Oregon's SOTA requested SAMHSA's permission to allow Oregon's 20 OTPs to expand access to take-home medication. The SOTA required OTPs to provide a safety plan to reduce the spread of SARS-CoV-2 and the number of patients receiving 0 to 6 take-homes per week, 13 take-homes every 2 weeks, and 18, 21, 24, or 27 take-homes per month. Dosing was based on a 28-day month with the maximum take-home at 27 doses (plus one observed dose). OTP dosing reports were not standardized and varied on the day of the month data were reported. The OTPs provided counts for (a) a day in February or the first half of March (pre-SARS-COV-2), (b) a day in March, April, or May (post-1 SARS-COV-2) and (c) a day in April, May, or June (post-2 SARS-COV-2). Oregon's OTPs follow the federal methadone regulations for patients receiving take-home buprenorphine. The OTP take-home reports did not consistently differentiate methadone and buprenorphine patients. One OTP reported that 9% of their patients received buprenorphine. Based on his experience, Oregon's SOTA reported most patients received methadone.

A spreadsheet recorded the OTP owner, location, date of the count, and count of patients receiving each number of take-homes on the day reported. An analysis calculated number of patients served on the day of the report, patient visits and take-homes per month, and mean visits and mean take-homes per patient. In response to a request for determination, the Oregon Health and Science University Institutional Review Board confirmed the study was not human subject research.

### Analysis

A negative binomial mixed-effects regression model assessed change in mean dosing visits per patient before and after take-home policies were relaxed, controlling for urban location (yes, no) and for-profit status (yes, no) with location and owner treated as random effects and location nested within owner. The ImerTest package in the R statistical package was used to fit the regression model.[6,7]

## RESULTS

Table 1 summarizes the changes in mean patient visits per month and monthly take-home medication. Pre-SARS-CoV-2, Oregon's OTPs served 7792 patients monthly with 120,513 medication visits and dispensed 44,883 take-home doses with 15.5 mean visits per month and 5.8 mean take-homes. The modal number of take-homes was 1 (range = 0 to 27) (Supplemental Figure 1, http://links.lww.com/JAM/A240). At post-1 SARS-CoV-2, OTPs served 7822 patients with 81,983 medication visits (a 33% reduction in visits from the pre-SARS report) and dispensed 88,513 doses of take-home medication (a 97% increase) with 10.4 mean visits per patient and 11.3 mean take-homes per patient (range: 0–27). The distribution of take-home medication became bi-modal with peaks at one and 27 doses (Supplemental Figure 2, http://links.lww.com/JAM/A240). The changes in medication visits were maintained in the post-2 SARS-CoV-2 reporting period with a continued decline in medication visits and increase in take-home medication (compared to the pre-SARS-CoV-2 report) (Supplemental Figure 3, http://links.lww.com/JAM/A240).

The negative binomial mixed-effects regression model estimated a 54% reduction in mean visits per patient (comparing the pre-SARS-CoV-2 report to the post-1 SARS-CoV-2 policy change, $P < 0.001$). The reduction was sustained relative to the pre-SARS-COV-2 report) at the post-2 SARS-CoV-2 policy change (Table 2). The for-profit and urban covariates did not significantly influence mean visits per patient.

## DISCUSSION

Relaxation of the federal take-home restrictions had the intended effect in Oregon's OTPs – a 54% reduction in monthly medication visits (comparing the pre-SARS-CoV-2 and the post-1 SARS-CoV-2 report). A similar 50% reduction in daily dosing was reported from a single large OTP in Washington state.[8]

At the same-time, take-home doses of opioid agonist therapy expanded from less than 45,000 to more than 88,000 per month. The Oregon SOTA has not been informed of any deaths related to increasing or changing access to take-home medication. Additional research is required to confirm this using state vital statistics data. More complete data on the

**TABLE 1.** Total OTP Patients, Medication Visits and Take-homes Per Month and Visits and Take-homes Per Patients

| Period | Patients Per Month | Visits Per Month | Take-homes Per Month | Mean Visits Per Patient | Mean Take-homes Per Patient |
|---|---|---|---|---|---|
| Pre SARS-CoV-2 | 7792 | 120,513 | 44,883 | 15.5 | 5.8 |
| Post1 SARS-CoV-2 | 7822 | 81,338 | 88,513 | 10.4 | 11.3 |
| Post 2 SARS-CoV-2 | 7774 | 74,983 | 81,454 | 9.6 | 11.8 |

Pre SARS-CoV-2 is before SAMHSA's relaxation of take-home medication restrictions in February or March (OTPs varied in reported dates).
Post 1 SARS-CoV-2 reflects services in March, April, or May (OTPs varied in reporting dates).
Post 2 SARS-CoV-2 reflects services in April, May, or June (OTPs varied in reporting dates).
Counts based on a 28-day month.
Oregon's 20 OTPs provided at least 3 take-home medication reports (ie, pre-SARS-CoV-2, post 1 SARS-CoV-2, and post 2 SARS-CoV-2).

**TABLE 2.** Negative Binomial Mixed-effects Regression Model Results for Monthly Mean Medication Visits Per Patient Per Month (Logarithmic Scale)

| **Random Effects:** | | | |
|---|---|---|---|
| **Groups** | **Name** | **Variance** | **Std.Dev.** |
| Location:Owner | (Intercept) | 0.024 | 0.155 |
| Owner | (Intercept) | 0.041 | 0.201 |
| Number of Observations: 60, groups: Location:Owner, 20; Owner, 8 | | | |

| **Fixed Effects:** | | | | |
|---|---|---|---|---|
| | **Beta Coefficient** | **Std. Error** | ***z* Value** | **Pr(>\|z\|)** |
| (Intercept) | 2.841 | 0.170 | 16.665 | <0.001 |
| Profit (Yes) | −0.085 | 0.179 | -0.476 | 0.634 |
| Urban (Yes) | −0.071 | 0.149 | -0.480 | 0.631 |
| Post 1 SARS-CoV-2 | −0.542 | 0.063 | -8.618 | <0.001 |
| Post 2 SARS-CoV-2 | −0.543 | 0.063 | -8.641 | <0.001 |

diversion and safety of take-home doses are critical to assessing this policy change.

Study limitations include unstandardized reports from the OTPs, variation in reporting periods, reliance on administrative records, and inability to differentiate methadone and buprenorphine visits. The data reflect services provided between February and June rather than specific moments in time because OTPs provided the data voluntarily and varied in responsiveness to requests for reports. Data, moreover, are from one state with a relatively low SARS-CoV-2 infection rate. A study strength is the inclusion of data from the state's 20 for-profit and nonprofit OTPs (federally operated OTPs are exempt from state oversight). Subsequent analyses can provide additional detail on the stability of the change overtime, data on the use of telemedicine technology for patient counseling and education, and linkage to state Medicaid and vital statistics data to assess rates of COVID-19 diagnoses and overdose fatalities.

## Clinical Implications

Data from Oregon's OTPs document change in OTP visits and patient access to take-home medication following the modification of federal policy and relaxation of take-home medication restrictions. OTPs and their patients can benefit from careful analysis of the intended and unintended effects of the enhanced access to take-home medication. Future research should include an analysis of national data to compare variation and implementation of this policy change across states.

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