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Assessment of COVID-19–Driven Changes in an Integrated OBGYN-Addiction Treatment Clinic and Future Implications

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Journal of Addiction Medicine Assessment of COVID-19-Driven Changes in an Integrated OBGYN-Addiction Treatment Clinic and Future Implications --Manuscript Draft--

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Abstract:	Objective: The COVID-19 pandemic prompted healthcare delivery changes, but the associated impacts on substance use disorder treatment outcomes among pregnant and parenting people are unknown. This study aims to 1) describe COVID-19-driven clinical practice changes, 2) evaluate clinic-level visit attendance patterns, and 3) compare patient-level treatment engagement outcomes across three COVID-19 pandemic phases in an OBGYN-addiction treatment clinic. Methods: COVID-19 phases include: preCOVID-19 (August 2019-February 2020), earlyCOVID-19 (March 2020-December 2020), and COVID-19-vaccine (January 2021-July 2021). OBGYN-addiction treatment clinical practice changes were summarized. Clinic-level attended medical provider visits were analyzed. Patient-level treatment engagement outcomes (buprenorphine continuation, visit attendance, and virtual visits) were assessed in a cohort of pregnant and parenting people enrolled in a clinic research registry. Mixed level logistic regression models determined the relationship between the COVID-19 phases and the patient-level outcomes. Results: The study site made several COVID-19-driven clinical visits. Clinic-level medical provider appointments increased between the first and second COVID-19 phases and remained high in the third phase. Among participants included in patient-level outcome analyses (N=27), there were no differences in the earlyCOVID-19 phase compared to preCOVID-19 (p <.05). Virtual visits increased between the first

two phases and remained high during the third. Conclusion: Within our OBGYN-addiction treatment clinic, implementation of tailored, patient-centered treatment strategies supported clinic- and patient-level treatment engagement throughout the pandemic.

Assessment of COVID-19-Driven Changes in an Integrated OBGYN-Addiction Treatment Clinic and Future Implications

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Abstract

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24	impacts on substance use disorder treatment outcomes among pregnant and parenting people are
25	unknown. This study aims to 1) describe COVID-19-driven clinical practice changes, 2) evaluate
26	clinic-level visit attendance patterns, and 3) compare patient-level treatment engagement
27	outcomes across three COVID-19 pandemic phases in an OBGYN-addiction treatment clinic.
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28	Methods: COVID-19 phases include: preCOVID-19 (August 2019-February 2020),
29	earlyCOVID-19 (March 2020-December 2020), and COVID-19-vaccine (January 2021-July
30	2021). OBGYN-addiction treatment clinical practice changes were summarized. Clinic-level
31	attended medical provider visits were analyzed. Patient-level treatment engagement outcomes
32	(buprenorphine continuation, visit attendance, and virtual visits) were assessed in a cohort of
33	pregnant and parenting people enrolled in a clinic research registry. Mixed level logistic
34	regression models determined the relationship between the COVID-19 phases and the patient-
35	level outcomes.

Results: The study site made several COVID-19-driven clinical practice changes, including 36 implementing a hybrid virtual/in-person system for medical visits. Clinic-level medical provider 37 appointments increased between the first and second COVID-19 phases and remained high in the 38 third phase. Among participants included in patient-level outcome analyses (N=27), there were 39 40 no differences in the earlyCOVID-19 phase compared to preCOVID-19 phase in buprenorphine continuation, any visits, or medical visits. There was a decrease in all patient-level outcomes in 41 the COVID-19-vaccine phase compared to preCOVID-19 (p <.05). Virtual visits increased 42 between the first two phases and remained high during the third. 43

- 44 Conclusion: Within our OBGYN-addiction treatment clinic, implementation of tailored, patient-
- 45 centered treatment strategies supported clinic- and patient-level treatment engagement
- 46 throughout the pandemic.

Introduction

48	Within the United States, the COVID-19 pandemic has caused over one million deaths,
49	significantly decreasing the average life expectancy particularly among Black and Latinx
50	communities. ^{1,2} Additionally, the pandemic has had substantial medical and social impacts,
51	including dramatic increases in substance use. ³ Among people with substance use disorders
52	(SUD), COVID-19 incidence, COVID-19-related morbidity and mortality are high. ^{4,5} People
53	with opioid use disorder (OUD) are particularly vulnerable to the negative impacts of COVID-19
54	given the pandemic emerged amid the opioid overdose epidemic. Between 2019-2020, the
55	United States recorded the highest number of overdose deaths in a 12-month period. ⁶ Overdose
56	deaths have continued to increase rapidly each year during the COVID-19 pandemic ⁷ due to both
57	the direct effects and psychosocial challenges of COVID-19.8,9 For this high-risk patient
58	population, accessible healthcare is crucial.

59 In order to prioritize patient and provider safety during the nationwide COVID-19 pandemic 60 lockdown, many healthcare systems transitioned to virtual modalities, offering patients remote 61 visits as alternatives to in-person visits. While the shift to a telehealth system improved access for some individuals, it has exacerbated challenges for others. Patient challenges include lack of 62 63 access to secure technologies, limited technology literacy, social isolation, and perceived loss of therapeutic rapport.^{10,11} Evidence-based SUD treatments, including medication for opioid use 64 disorder (MOUD) and mental health treatment, reduce overdose risk and improve quality of 65 life.^{12,13} However, only 1 in 10 people with SUD receive specialized SUD treatment, even before 66 COVID-19.¹⁴ Although the conversion to telehealth coinciding with the COVID-19 pandemic 67 has encouraged continuity of care broadly, there is concern that telehealth has made access to 68 SUD treatment more difficult for many people.^{10,11,15} 69

70	Pregnant and parenting people, a high priority addiction treatment population, are exceptionally
71	vulnerable to the risks associated with both COVID-19 and the overdose epidemic. Overdoses,
72	largely by opioids, have become a leading cause of pregnancy-associated deaths, with the largest
73	proportion occurring in the 7-12 months after delivery and among birthing people not
74	consistently receiving MOUD. ^{16,17} Barriers like lack of insurance coverage, lack of
75	transportation, conflict with wait/travel time, and childcare insecurity may place pregnant and
76	parenting people at risk of not accessing or having lapses in life-saving SUD treatment. ^{18,19} In
77	addition, pregnant people are highly prone to pandemic-related stressors associated with feeling
78	unprepared for birth in the pandemic and fears of perinatal COVID-19 infection. ²⁰ Given the
79	complexities that surround SUD, pregnancy/parenting, and the COVID-19 pandemic, it is vital
80	to maintain healthcare access and optimize recovery support for this vulnerable population.
81	Data describing the impact of COVID-19-driven healthcare delivery changes on SUD treatment
82	outcomes is limited. Among Medicaid beneficiaries with OUD in Wisconsin, patients in office-
83	based settings retained access to buprenorphine during COVID-19 at similar levels as
84	preCOVID-19 despite decreases in on-site services like urine drug tests. ²¹ Another study
85	analyzed COVID-19-driven shifts in a youth outpatient addiction treatment program and found
86	that the visit attendance rates increased from approximately 60% to 70% after converting to
87	telehealth. ²² To our knowledge, only one study has been conducted among pregnant people with
88	OUD. Authors found that with the shift to telehealth at the beginning of the pandemic, group
89	therapy attendance decreased and MOUD doses increased secondary to cravings. ²³
00	As talebaalth moves into a more permanent place in our bealthears system, we need to consider
90	As telehealth moves into a more permanent place in our healthcare system, we need to consider
91	the impact of COVID-19-driven transitions in healthcare delivery on our most vulnerable
0.2	nonvlations. To our knowledge, no study has evaluated how nondemic driven shanges in sere

92 populations. To our knowledge, no study has evaluated how pandemic-driven changes in care,

including use of virtual modalities, have affected treatment outcomes among pregnant and
parenting people with SUD. This study aims to (1) describe COVID-19-driven changes in
clinical practices employed by an integrated, interdisciplinary OBGYN-addiction clinic, (2)
evaluate clinic-level medical provider visit attendance patterns across three defined phases of the
COVID-19 pandemic, and (3) compare patient-level SUD treatment engagement outcomes
among a cohort of pregnant and parenting people receiving buprenorphine for OUD across three
COVID-19 pandemic phases.

100

Methods

101 Design

102 This study describes COVID-19-driven clinical practice changes within an OBGYN-addiction 103 treatment clinic and assesses their impact on two levels: (1) clinic-level and (2) patient-level. 104 Both clinic-level and patient-level outcomes were assessed in three phases. The first phase is the 105 preCOVID-19 phase (August 2019-February 2020) which coincides with standardization of clinic procedures and operations due to onboarding of new nurse management. The next phase is 106 107 the earlyCOVID-19 phase (March 2020-December 2020) which is marked by the World Health 108 Organization's declaration of COVID-19 as a global pandemic in March 2020. The third phase is the COVID-19-vaccine phase (January 2021-July 2021) which coincided with Phase 1c of the 109 110 CDC's vaccine distribution plan allowing our patient population the option to receive the first 111 dose.²⁴ The independent variable for all three aims was the COVID-19 phases.

112 Setting

113 The OBGYN-addiction outpatient treatment clinic is affiliated with a large academic medical 114 center in a Medicaid-expanded southern state. The medical center serves as a safety net for the region and treats predominately low-income, racially and ethnically minoritized people. On-site 115 116 addiction medicine physicians are board-certified obstetrician-gynecologists, and nursing staff are credentialed in both women's health and addiction. Most patients are referred from within the 117 118 academic medical center (e.g., inpatient consults, primary care physicians). At the initial clinic 119 visit, providers complete a comprehensive assessment. All patients diagnosed with OUD are 120 offered buprenorphine. A comprehensive, recovery-oriented care model is utilized throughout 121 treatment in which patients have access to psychiatric, mental health, case management, and 122 social work services. The clinic prioritizes a low-threshold, harm reduction approach, meaning that established patients with recurrence of substance use are not excluded from treatment, but 123 124 instead provided with increased wrap-around support. For patients who initiate SUD treatment during pregnancy, there is no time limitation on how long patients can continue SUD treatment 125 with the clinic after delivery. 126

127 Sample and Data Sources

128 Primary aim: Describe COVID-19-driven changes in clinical practices

129 COVID-19-driven clinical practice methods were summarized across three phases by the

130 research team using clinic-level management records. Summarized COVID-19-driven clinical

131 changes were reviewed and approved by a group of representative stakeholders from the study

site including physicians, nurses, and behavioral health providers.

133 Secondary aim: Evaluate clinic-level medical provider attendance patterns across the COVID134 19 pandemic

135 The clinic provides outpatient addiction services for over 180 adults, serving approximately 63 136 patients per month, with nearly all patients being pregnant and/or parenting people with SUD. All OBGYN-addiction clinic medical provider visits from August 2019 to July 2021 were 137 138 included in the deidentified clinic-level dataset. Number of visits each month was pulled from the health system appointment scheduling database. For this aim, protected health information 139 140 was not used which limited our access to clinic-level demographics across the COVID-19 phases. However, on average, 66% of the clinic patients identify as White and 34% as Black 141 with a mean age of 30.3 years. Most of the patients have at least one comorbid psychiatric 142 143 diagnosis, and 90% are receiving buprenorphine for OUD. Approximately 87% of the patients 144 are insured with Medicaid, 3% with private insurance, and 10% are uninsured.

145 Tertiary aim: Compare patient-level SUD treatment engagement outcomes across the COVID-19
146 pandemic

147 For patient-level outcomes, a secondary analysis of a cohort of participants from the OBGYN-148 addiction treatment clinic research registry was conducted. All patients are invited to participate 149 in the clinic-wide research registry (85% recruitment rate). For registry participants, monthly (30-day) chart abstractions are conducted starting from their initial visit including basic 150 151 demographics, medical diagnosis, medication history, visit attendance, socioeconomic changes, and comorbidities. The registry is approved by the university's Institutional Review Board. 152 153 For the current study analyses, registry participants were included if they initiated buprenorphine 154 treatment by January 2020 and had an OUD diagnosis. Analyses included data from the 30-day periods within the study timeframe for N=27 pregnant and parenting people receiving 155 buprenorphine for OUD. 156

157 Clinical Variables

158 *Primary aim:*

The clinical practice methods were categorized by department: medical, behavioral health, andcare coordination (e.g., clinic management and procedures).

161 Secondary aim:

The dependent variable for the clinic-level data was the total number of medical provider visits
for the OBGYN-addiction treatment clinic per month, including both virtual and in-person visits.
All appointments coded as "arrived" were counted as attended and included in the number of
appointments.

166 *Tertiary aim:*

Demographic, psychosocial, and clinical variables were abstracted from the initial intake visit and included race, age, insurance type, employment status, living situation, number of children in custody, comorbid SUD diagnosis, smoking tobacco (yes/no), psychiatric comorbidity (yes/no) and psychotropic medication (yes/no). Duration of treatment episode was calculated from the initial intake visit to the start of the study (August 2019) in months. Pregnancy status was determined for individual participants for each of the three COVID-19 phases; if a participant was pregnant at any time during a phase, status was coded as pregnant.

Patient-level treatment engagement outcomes were buprenorphine continuation, total visit
attendance (behavioral health and medical provider visits), medical provider visits, behavioral
health visits, and proportion of total attended visits that were virtual for each of the 30-day

periods over the three study phases. Buprenorphine continuation (yes/no) was coded as "yes" if the individual started or continued buprenorphine during that 30-day period. Any visit attendance (yes/no) was coded as "yes" if the individual had at least one behavioral health or medical provider visit during the 30-day period. Additionally, medical provider visits (yes/no) and behavioral health provider visits (yes/no) were coded as two separate variables. For all 30-day periods with at least one visit, the percent of medical provider and behavioral health visits attended virtually was calculated.

184 Data Analysis

185 *Primary aim:*

186 A qualitative description is provided for clinical practices and COVID-19-driven clinical187 changes in each category for the study phases.

188 Secondary aim:

The mean (and standard deviation) number of attended medical provider visits in each COVID-189 19 phase was calculated. Interrupted time series design was used to analyze differences by 190 191 COVID-19 phases in the monthly counts of attended visits from August 2019 to July 2021. ITS design was chosen because we have a specific date of "intervention" (COVID-19), include a 192 193 repeated measure (visit count per month) that did not change in data collection practices over the study period, and use a consistent interval between measurements (month's duration). This 194 analysis method is similar to that used by other studies evaluating the impact of events that are 195 abrupt and temporary.²⁵ 196

197 *Tertiary aim:*

198	Cohort characteristics at study enrollment are described. For the outcomes of buprenorphine
199	continuation, total visit attendance (including behavioral health and medical provider visits), and
200	percent of visits attended virtually, mixed level logistic regression models with a person level
201	random intercept and random slopes for COVID-19 phases were used due to the heterogeneity of
202	the outcomes throughout COVID-19 phases in each individual. Similar models have been used in
203	work exploring longitudinal datasets and outcomes in questions concerning COVID-19.26
204	Models controlled for fixed effects of pregnancy and duration of treatment episode. ²⁷ Percent of
205	visits attended virtually are described descriptively. Analysis for aims 2 and 3 were conducted
206	using STATA 16C with statistical significance set at 0.05.
207	Results
208	Primary aim: Describe COVID-19-driven changes in clinical practices
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209 210 211 212 213 214 215	COVID-19-driven clinical practice changes in the OBGYN-addiction treatment clinic are described in Table 1, with a few that supported continued patient engagement highlighted here. During the earlyCOVID-19 and COVID-19-vaccine phases, medical providers continued to offer limited in-person appointments while behavioral health primarily offered virtual options. Patient care policies were modified. In the preCOVID-19 phase, patients were required to attend at least one in-person medical provider visit and provide a toxicology test every 30-days to receive MOUD and medication for alcohol use disorder prescriptions. In the earlyCOVID-19 and

During the earlyCOVID-19 and COVID-19-vaccine phases, virtual capabilities increased in
clinic management. Interdisciplinary plan of care meetings were held virtually which increased
attendance and interprofessional communication. HIPAA compliant and synchronized cloud file
hosting service was implemented to store and share clinically relevant information.

Secondary aim: Evaluate clinic-level medical provider attendance patterns across the COVID-19 pandemic

- 225 The number of medical provider visits attended in the OBGYN-addiction treatment clinic per
- 226 month over the three COVID-19 phases are shown in Figure 1. On average, the clinic had 69.7
- (SD=11.2) attended appointments in the preCOVID-19 phase, 86.6 (SD=13.8) in the
- earlyCOVID-19 phase, and 71.1 (SD=6.9) in the COVID-19-vaccine phase. No significant
- changes in the number of visits each month were identified in the interrupted time series analysis(Appendix 1).

Tertiary aim: Compare patient-level SUD treatment engagement outcomes across the COVID-19 pandemic

Participants (N=27) identified as Black (48.2%) or White (51.9%) with a mean age of 31 years
(SD=4.0). Most participants had Medicaid insurance (81.5%), were unemployed (66.7%), and
living in their homes (81.5%; Table 2). Over 95% of the participants had a mental health
comorbidity, and about half were prescribed psychotropic medications (51.9%). Approximately
59% of participants were pregnant in the preCOVID-19 phase. Fewer participants were pregnant
in the latter two phases. Over half (51.8%) of participants were receiving treatment in the clinic
before the study started.

The number of participants for the patient-level treatment engagement outcomes varied by monthas the inclusion criteria was initiation of care by the end of the first phase (August-October 2019)

n=16, November 2019 n=20, December 2019 n=21, all other months n=27).

- In both unadjusted and adjusted models, buprenorphine continuation in a 30-day period was
- significantly lower in the COVID-19-vaccine phase (74.5%) compared to preCOVID-19

245 (96.5%), but not significantly different between early COVID-19 (91.9%) and preCOVID-19

246 phase (96.5%; Figure 2, Table 3).

In both unadjusted and adjusted models, any visit attendance in a 30-day period was significantly

lower in COVID-19-vaccine phase (64.4%) compared to the preCOVID-19 phase (89.5%;

249 Figure 2, Table 3).

250 In both unadjusted and adjusted models, medical provider visit attendance was significantly

lower in the COVID-19-vaccine (63.9%) phase compared to preCOVID-19 (86.7%), but not

- significantly different between earlyCOVID-19 (78.9%) and preCOVID-19 phase (86.7%;
- 253 Figure 2, Table 3).

In both unadjusted and adjusted models, behavioral health visit attendance in a 30-day period

was significantly lower in both the early (18.2%) and COVID-19-vaccine (6.5%) phases

compared to the preCOVID-19 phase (32.2%;Figure 2, Table 3).

257 The average percentage of behavioral health visits attended virtually increased between the first

two phases and remained high during the third (2.7%, 91.5%, 91.1%). A similar trend was seen

- for the average percentage of medical provider visits attended virtually (0.0%, 42.8%, 34.7%).
- Additional information for all full regression analyses can be found in Appendices 2-3.

Discussion

This study describes COVID-19-driven clinical changes in an OBGYN-addiction treatment 262 263 clinic and summarizes patterns in clinic-level and patient-level outcomes throughout the pandemic. During the unprecedented COVID-19 pandemic and nationwide shutdown, the study 264 265 site promptly adapted to a hybrid telehealth/in-person system to prioritize safety and patient 266 needs. With these changes, clinic-level visits remained consistent over three COVID-19 phases. 267 Although treatment engagement by participants in our small cohort of pregnant and parenting people decreased over the study timeframe, engagement with medical providers remained 268 relatively high, especially in the context of similar reported treatment retention rates for this 269 unique patient population.^{21,26} These clinic- and patient-level findings support that healthcare 270 271 accessibility can be achieved for this vulnerable population in a hybrid telehealth/in-person 272 system.

Similar to many healthcare facilities, our OBGYN-addiction clinic quickly transitioned care to a 273 telehealth platform at the beginning of the pandemic.²⁸ Provision of interdisciplinary virtual care 274 275 alongside reduced capacity in-person medical care (1) provided flexibility for individualized care plans tailored to meet patients' needs and (2) helped ease anxiety about COVID-19 exposure, a 276 277 heightened concern among pregnant and parenting people.²⁰ However, the telehealth-based system had some drawbacks. Patients were no longer able to combine interdisciplinary service 278 279 appointments into a single clinic visit. Instead, patients had to schedule multiple separate visits. Given the many barriers to care patients face, including childcare responsibilities, lack of 280 transportation, and stigma,²⁹ removing the ability to combine appointments may have inhibited 281 282 some people from initiating or continuing interdisciplinary services (e.g., contraception, 283 behavioral health, social work support).

284 The COVID-19-driven telehealth platform was beneficial for clinical coordination within the integrated OBGYN-addiction clinic as evidenced by more standardized intra-clinical 285 correspondence. Best practices for the care of pregnant and parenting people with SUD include 286 integrating perinatal care, mental health, and trauma-informed services with SUD treatment.³⁰ 287 288 Within an integrated care model, maintaining intra-clinical communication between interdisciplinary team members is key. Our OBGYN-addiction treatment program established 289 290 new modes of communication (i.e., weekly meetings) and information storage platforms using virtual capabilities to help ensure that intra-clinical communication was maintained within the 291 292 hybrid telehealth/in-person model.

293 The novelty of the pandemic limits the availability of SUD treatment outcomes research, 294 particularly among pregnant and parenting people. Current study findings supplement the limited existing literature, suggesting that offering virtual visits can increase the frequency of clinic 295 visits likely due to increased accessibility of care.²² Importantly, the study clinic did not cease in-296 297 person medical visits to ensure the clinic continued to offer services suitable for all patients. It is 298 commendable that the OBGYN-addiction clinic continued treating pregnant people with SUD 299 and incorporating patient-centered approaches to support treatment retention as many SUD 300 treatment clinics do not employ tailored care approaches for pregnant people, and the number of MOUD clinics accepting pregnant people decreased during the pandemic.³¹ 301

Patient-level treatment engagement outcomes from our small cohort demonstrated that many
participants continued taking buprenorphine, their primary OUD treatment, during the COVID19 pandemic. Our buprenorphine continuation rate of over 70% for all three COVID-19 phases
is similar to or above the rate of other MOUD populations before COVID-19,³² including
postpartum patients.^{21,27} One COVID-19-driven strategy that supported participant

buprenorphine continuation was implementation of home buprenorphine induction, which has
been found to be safe and effective among pregnant people.³³

309 Medical provider visit attendance decreased over the three COVID-19 phases yet remained relatively high; this is especially notable when considering the unique challenges pregnant and 310 parenting people with SUD face.^{14,34} We hypothesize that our expansion of patient-centered, 311 312 recovery-oriented strategies, like flexibility in visit type, contributed to the relatively high 313 treatment engagement across the COVID-19 phases. Notably, many participants were pregnant in the first phase, but not in the third phase, which likely contributed to the decrease in medical 314 provider visits independent of COVID-19 because visit frequency typically decreases 315 postpartum.³⁵ Similar to previous work, within the primarily virtual behavioral health model, 316 attendance decreased dramatically and remained low.²³ Given that barriers to care for birthing 317 people increase after delivering an infant, a decrease in utilization of adjunctive services 318 319 (behavioral health) postpartum was somewhat expected among our cohort, as the percent of pregnant participants decreased over time.³⁵ However, the drastic decrease in attendance may 320 have also been due to perceived loss of therapeutic rapport in a primarily virtual platform.^{11,36} In 321 322 response to these findings, the clinic has established a hybrid telehealth/in-person model for 323 behavioral health appointments.

324 Clinical Practice Implications

Findings underscore that a hybrid model, offering virtual and in-person options, may be a preferable method of interdisciplinary care provision for this population.³⁷⁻³⁹ Moving forward, integrating these COVID-19-driven changes into long-term practice may reduce patient and provider burden as well as improve patient SUD outcomes. The study clinic site continues to use 329 a hybrid telehealth/in-person model and low-threshold, flexible buprenorphine prescribing 330 options. Improving clinical communication and workflow with virtual capabilities may help improve wellbeing among healthcare workers, as burnout is a growing concern.^{34,40}

Limitations 332

331

333 This study assessed a unique OBGYN-addiction treatment clinic. Changes that worked within 334 this clinic may not work in other treatment settings. COVID-19-driven changes occurred rapidly, 335 and some changes may not have been captured in our review of clinical practices. The study site 336 is trainee-based; thus, some COVID-19-driven changes, especially for behavioral health services, 337 were largely dictated by institution-wide regulations limiting student attendance in clinic. 338 Additionally, the health system scheduling data used for the secondary aim may reflect a slightly 339 inflated count of attended appointments because virtual appointments were marked as "arrived" at the beginning of the clinic shift; some 'no show' appointments may not have been coded 340 341 appropriately by overburdened clerical staff. Additionally, behavioral health appointments were not captured in our clinic-wide scheduling database during the study timeframe. For patient-level 342 outcomes, participants were selected from those who consented to research registry participation, 343 introducing selection bias and limiting generalizability. The chart abstraction is subject to 344 information bias and offers constrained information, especially for psychosocial factors (e.g., 345 child welfare involvement). Given the small sample size, these findings are preliminary and 346 347 intended to inform future research that can build upon this study by incorporating toxicology reports and pregnancy outcomes among larger samples to better understand the impact of 348 349 COVID-19 changes on this vulnerable patient population. Despite these limitations, this study is 350 the first to describe COVID-19-driven clinical practice changes and SUD outcomes among pregnant and parenting people in integrated outpatient OB/GYN-addiction treatment. 351

Conclusions

359	Acknowledgment
358	approaches in addiction medicine.
357	investigate how COVID-19-driven care adaptations can be cultivated to advance personalized
356	incorporating similar clinical changes into permanent practice. Addiction researchers should
355	individuals' needs. Clinics treating pregnant and parenting people with SUD may benefit from
354	populations with SUD using a hybrid telehealth/in-person system that tailors care approaches to
353	Our findings support ways healthcare accessibility can be achieved for vulnerable patient

Acknowledgment

Not applicable 360

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Figures

- 477 Figure 1. Total number of clinic-wide medical provider visits attended by month over three
- 478 COVID-19 phases in an OBGYN-Addiction clinic
- 479 Figure 2. Patient-level trends in treatment engagement outcomes by month across three COVID-
- 480 19 phases for study cohort receiving buprenorphine for opioid use disorder in the integrated
- 481 OBGYN-Addiction clinic

Assessment of COVID-19-Driven Changes in an Integrated OBGYN-Addiction Treatment Clinic and Future Implications

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Abstract

Objective: The COVID-19 pandemic prompted healthcare delivery changes, but the associated
impacts on substance use disorder treatment outcomes among pregnant and parenting people are
unknown. This study aims to 1) describe COVID-19-driven clinical practice changes, 2) evaluate
clinic-level visit attendance patterns, and 3) compare patient-level treatment engagement
outcomes across three COVID-19 pandemic phases in an OBGYN-addiction treatment clinic.
Methods: COVID-19 phases include: preCOVID-19 (August 2019-February 2020),
earlyCOVID-19 (March 2020-December 2020), and COVID-19-vaccine (January 2021-June
July 2021). OBGYN-addiction treatment clinical practice changes were summarized. Clinic-
level attended medical provider visits were analyzed. Patient-level treatment engagement
outcomes (buprenorphine continuation, visit attendance, and virtual visits) were assessed in a
cohort of pregnant and parenting people enrolled in a clinic research registry. Mixed- <u>level effect</u>
logistic regression models determined the relationship between the COVID-19 phases and the
patient-level outcomes.

Results: The study site made several COVID-19-driven clinical practice changes, including 36 37 implementing a hybrid virtual/in-person system for medical visits. Clinic-level medical provider appointments increased between the first and second COVID-19 phases and remained high in the 38 third phase. Among participants included in patient-level outcome analyses (N=27), there were 39 no differences in the earlyCOVID-19 phase compared to preCOVID-19 phase in buprenorphine 40 continuation, any visits, or medical visits. There was a decrease in all patient-level outcomes in 41 the COVID-19-vaccine phase compared to preCOVID-19 (p <.05). Virtual visits increased 42 between the first two phases and remained high during the third. 43

- 44 Conclusion: Within our OBGYN-addiction treatment clinic, implementation of tailored, patient-
- 45 centered treatment strategies supported clinic- and patient-level treatment engagement
- 46 throughout the pandemic.

Introduction

48	Within the United States, the COVID-19 pandemic has caused over one million deaths,
49	significantly decreasing the average life expectancy particularly among Black and Latinx
50	communities. ^{1,2} Additionally, the pandemic has had substantial medical and social impacts,
51	including dramatic increases in substance use. ³ Among people with substance use disorders
52	(SUD), COVID-19 incidence, COVID-19-related morbidity and mortality are high. ^{4,5} People
53	with opioid use disorder (OUD) are particularly vulnerable to the negative impacts of COVID-19
54	given the pandemic emerged amid the opioid overdose epidemic. Between 2019-2020, the
55	United States recorded the highest number of overdose deaths in a 12-month period. ⁶ Overdose
56	deaths have continued to increase rapidly each year during the COVID-19 pandemic ⁷ due to both
57	the direct effects and psychosocial challenges of COVID-19.8,9 For this high-risk patient
58	population, accessible healthcare is crucial.

59 In order to prioritize patient and provider safety during the nationwide COVID-19 pandemic 60 lockdown, many healthcare systems transitioned to virtual modalities, offering patients remote 61 visits as alternatives to in-person visits. While the shift to a telehealth system has improved access for some individuals, it has exacerbated challenges for others. Patient challenges include 62 63 lack of access to secure technologies, limited technology literacy, social isolation, and perceived loss of therapeutic rapport.^{10,11} Evidence-based SUD treatments, including medication for opioid 64 use disorder (MOUD) and mental health treatment, reduce overdose risk and improve quality of 65 life.^{12,13} However, only 1 in 10 people with SUD receive specialized SUD treatment, even before 66 COVID-19.¹⁴ Although the conversion to telehealth coinciding with the COVID-19 pandemic 67 has been encouraging for the healthcare system encouraged continuity of care broadly, there is 68

concern that telehealth has made access to SUD treatment even-more difficult for many
people.^{10,11,15}

71 Pregnant and parenting people, a high priority addiction treatment population, are exceptionally vulnerable to the risks associated with both COVID-19 and the overdose epidemic. Overdoses, 72 largely by opioids, have become a leading cause of pregnancy-associated deaths, with the largest 73 proportion occurring in the 7-12 months after delivery and among birthing people not 74 consistently receiving MOUD.^{16,17} Barriers like lack of insurance coverage, lack of 75 transportation, conflict with wait/travel time, and childcare insecurity may place pregnant and 76 parenting people at risk of not accessing or having lapses in life-saving SUD treatment.^{18,19} In 77 addition, pregnant people are highly prone to pandemic-related stressors associated with feeling 78 unprepared for birth in the pandemic and fears of perinatal COVID-19 infection.²⁰ Given the 79 80 complexities that surround SUD, pregnancy/parenting, and the COVID-19 pandemic, it is vital to maintain healthcare access and optimize recovery support for this vulnerable population. 81 Data describing the impact of COVID-19-driven healthcare delivery changes on SUD treatment 82 outcomes is limited. Among Medicaid beneficiaries with OUD in Wisconsin, patients in office-83 based settings retained access to buprenorphine during COVID-19 at similar levels as 84 85 preCOVID-19 despite the decreases in on-site services like urine drug tests.²¹ Another study 86 analyzed COVID-19-driven shifts in a youth n-outpatient addiction treatment program for youth 87 and found that the visit attendance rates increased from approximately 60% to 70% after 88 converting to telehealth.²² To our knowledge, only one study so far has been conducted among pregnant people with OUD. Authors found that with the shift to telehealth at the beginning of the 89 90 pandemic, group therapy attendance decreased and MOUD doses increased secondary to cravings in this small sample.²³ 91

92 As telehealth moves into a more permanent place in our healthcare system, we need to consider the impact of COVID-19-driven transitions in healthcare delivery on our most vulnerable 93 populations. To our knowledge, no study has evaluated how pandemic-driven changes in care, 94 95 including use of virtual modalities, have affected treatment outcomes among pregnant and parenting people with SUD. This study aims to (1) describe COVID-19-driven changes in 96 97 clinical practices employed by an integrated, intermultidisciplinary OBGYN-addiction clinic, (2) evaluate clinic-level medical provider visit attendance patterns across three defined phases of the 98 COVID-19 pandemic, and (3) compare patient-level SUD treatment engagement outcomes 99 100 among a cohort of pregnant and parenting people receiving buprenorphine for OUD across three COVID-19 pandemic phases. 101

102

Methods

103 Design

104 This study describes COVID-19-driven clinical practice changes within an OBGYN-addiction treatment clinic and assesses their impact on two levels: (1) clinic-level and (2) patient-level. 105 106 Both clinic-level and patient-level outcomes were assessed in three phases. The first phase is the 107 preCOVID-19 phase (August 2019-February 2020) which coincides with- standardization of The start of this phase was selected because the clinic procedures and operations became more 108 109 standardized due to onboarding of new nurse management. The next phase is the earlyCOVID-110 19 phase (March 2020-December 2020) which is marked by the World Health Organization's 111 declaration of COVID-19 as a global pandemic in March 2020. The third phase is the COVID-112 19-vaccine phase (January 2021-Julyune 2021) which coincided . The start of this phase 113 coincided with Phase 1c of the CDC's vaccine distribution plan allowing our patient population

the option to receive the first dose.²⁴ the time during which COVID-19 vaccines were readily
 available for the clinic's patient population. The independent variable for all three aims was the
 COVID-19 phases.

117 Setting

118 The OBGYN-addiction outpatient treatment clinic is affiliated with a large academic medical 119 center in a Medicaid-expanded southern state. The medical center serves as a safety net for the 120 region and treats predominately low-income, racially and ethnically minoritized people. On-site 121 addiction medicine physicians are board-certified obstetrician-gynecologists, and nursing staff 122 are credentialed in both women's health and addiction. Most patients are referred from within the 123 academic medical center (e.g., inpatient consults, primary care physicians). At the initial clinic 124 visit, providers complete a comprehensive assessment. All patients diagnosed with OUD are 125 offered buprenorphine. Throughout treatment at the clinic, a A comprehensive, recovery-oriented 126 care model is utilized throughout treatment in which patients have access to psychiatric, mental 127 health, case management, and social work services. The clinic prioritizes a low-threshold, harm reduction approach, meaning that established patients with recurrence of substance use are not 128 excluded from treatment, but instead provided with increased wrap-around support. For patients 129 130 who initiate SUD treatment during pregnancy, there is no time limitation on how long patients 131 can continue SUD treatment with the clinic after delivery.

132 Sample and Data Sources

133 Primary aim: Describe COVID-19-driven changes in clinical practices

Clinic-level management records were reviewed for COVID-19-driven clinical practice methods
 were and summarized across three phases by the research team using clinic-level management
 records. Summarized COVID-19-driven clinical changes were reviewed and approved by a
 group of representative stakeholders from the study site including physicians, nurses, and
 behavioral health providers.

139 Secondary aim: Evaluate clinic-level <u>medical provider</u> attendance patterns across the COVID140 19 pandemic

141 The clinic provides outpatient addiction services for over 180 adults, serving approximately 63 142 patients per month, with nearly all patients being pregnant and/or parenting people with SUD. 143 All OBGYN-addiction clinic medical provider visits from August 2019 to Julyne 2021 were 144 included in the deidentified clinic-level dataset. Number of visits each month was pulled from the health system appointment scheduling database. For this aim, protected health information 145 146 was not used which limited our access to clinic-level demographics across the COVID-19 phases. However, on average, 66% of the clinic patients identify as White and 34% as Black 147 148 with a mean age of 30.3 years. Most of the patients have at least one comorbid psychiatric 149 diagnosis, and 90% are receiving buprenorphine for OUD. Approximately 87% of the patients 150 are insured with Medicaid, 3% with private insurance, and 10% are uninsured.

151 Tertiary aim: Compare patient-level SUD treatment <u>engagement</u> outcomes across the COVID-19
152 pandemic

For patient-level outcomes, a secondary analysis of a cohort of participants from the OBGYNaddiction treatment clinic research registry was conducted. All clinic-patients are invited to
participate in the <u>clinic-wide</u> research registry (85% recruitment rate). For registry participants,

156 monthly (30-day) chart abstractions are conducted starting from their initial visit including basic

- 157 demographics, medical diagnosis, medication history, visit attendance, socioeconomic changes,
- and comorbidities. The registry is approved by the university's Institutional Review Board.
- 159 For the current study analyses, registry participants were included if they initiated buprenorphine
- treatment by January 2020 and had an OUD diagnosis. Analyses included data from the 30-day
- 161 periods within the study timeframe for N=27 pregnant and parenting people receiving
- 162 buprenorphine for OUD.

163 Clinical Variables

164 *Primary aim:*

The clinical practice methods were categorized by department: medical, behavioral health, andcare coordination (e.g., clinic management and procedures).

167 Secondary aim:

168 The dependent variable for the clinic-level data was the total number of medical provider visits

169 for the OBGYN-addiction treatment clinic per month, including both virtual and in-person visits.

170 All appointments coded as "arrived" were counted as attended and included in the number of

appointments.

172 *Tertiary aim:*

173 Demographic, psychosocial, and clinical variables were abstracted from the initial intake visit

and included race, age (in years), insurance type, employment status, living situation, number of

175 children in custody, comorbid SUD diagnosis, smoking tobacco (yes/no), psychiatric

comorbidity (yes/no) and psychotropic medication (yes/no). Duration of treatment episode was
calculated from the initial intake visit to the start of the study (August 2019) in months.
Pregnancy status was determined for individual participants for each of the three COVID-19

179 phases; if a participant was pregnant at any time during a phase, status was coded as pregnant.

180 Patient-level treatment engagement outcomes were buprenorphine continuation, total visit 181 attendance (behavioral health and medical provider visits), medical provider visits, behavioral 182 health visits, and proportion of total attended visits that were virtual for each of the 30-day periods over the three study phases. Buprenorphine continuation (yes/no) was coded as "yes" if 183 the individual started or continued buprenorphine during that 30-day period. Any visit attendance 184 (yes/no) was coded as "yes" if the individual had at least one behavioral health or medical 185 186 provider visit during the 30-day period. Additionally, medical provider visits (yes/no) and 187 behavioral health provider visits (yes/no) were coded as two separate variables. For all 30-day 188 periods with at least one visit, the percent of medical provider and behavioral health virtual visits 189 attended virtually was calculated.

190 Data Analysis

191 *Primary aim:*

A qualitative description is provided for clinical practices and COVID-19-driven clinical
 changes in each category for the three COVID-19study phases.

194 Secondary aim:

- 195 The mean (and standard deviation) number of attended medical provider visits in each COVID-
- 196 19 phase was calculated. Interrupted time series design was used to analyze differences by

197 COVID-19 phases in the monthly counts of attended visits from August 2019 to Julyne 2021.

198 ITS design was chosen because we have a specific date of "intervention" (COVID-19), include a

199 repeated measure (visit count per month) that did not change in data collection practices over the

200 <u>study period, and use a consistent interval between measurements (month's duration).</u> This

analysis method is similar to that used by other studies evaluating the impact of events that are

abrupt and temporary.²⁵

203 *Tertiary aim:*

204 Cohort characteristics at study enrollment are described. For the outcomes of buprenorphine 205 continuation, total visit attendance (including behavioral health and medical provider visits), and 206 percent of virtual-visits attended virtually, mixed level logistic regression models with a person 207 level random intercept and random slopes for COVID-19 phases were used due to the 208 heterogeneity of the outcomes throughout COVID-19 phases in each individual. Mixed effect 209 linear models with the same variables were used to assess the percent of virtual visits. Similar 210 models have been used in work exploring longitudinal datasets and outcomes in questions concerning COVID-19.26 Models controlled for fixed effects of pregnancy and duration of 211 treatment episode.²⁷ Percent of visits attended virtually are described descriptively. All 212 213 analyses Analysis for aims 2 and 3 were conducted using STATA 16C with statistical significance set at 0.05. 214

215

Results

216 Primary aim: Describe COVID-19-driven changes in clinical practices

217 COVID-19-driven clinical practice changes in the OBGYN-addiction treatment clinic are 218 described in Table 1, with a few that supported continued patient engagement highlighted here. 219 During the earlyCOVID-19 and COVID-19-vaccine phases, changes were made in care delivery 220 method with both medical provider and behavioral health visits shifting to telehealth platforms. 221 mMedical providers continued to offer limited in-person appointments while behavioral health primarily offered virtual options. Patient care policies were modified. In the preCOVID-19 222 223 phase, patients were required to attend at least one in-person medical provider visit and provide a toxicology test every 30-days to receive MOUD and medication for alcohol use disorder 224 225 (MAUD) prescriptions. In the earlyCOVID-19 and COVID-19-vaccine phases, this toxicology 226 testing was extended to every 90-days. The patient care policy was incorporated into a new "Patient Care Agreement" and reviewed with patients by nursing staff during appointments. 227 During the earlyCOVID-19 and COVID-19-vaccine phases, virtual capabilities increased in 228 229 clinic management. Interdisciplinary plan of care meetings were held virtually which increased 230 attendance and interprofessional communication among all departments working with clinic 231 patients, and a HIPAA compliant and synchronized cloud file hosting service was implemented 232 to store and share clinically relevant information.

Secondary aim: Evaluate clinic-level <u>medical provider</u> attendance patterns across the COVID-19 pandemic

The mean-number of medical provider visits attended in the OBGYN-addiction treatment clinic per month over the three COVID-19 phases are shown in Figure 1. On average, the clinic had 69.7 (SD=11.2) attended appointments in the preCOVID-19 phase, 86.6 (SD=13.8) in the earlyCOVID-19 phase, and 71.10 (SD=6.97.5) in the COVID-19-vaccine phase. No significant

changes in the number of visits each month were identified in the interrupted time series analysis(Appendix 1).

Tertiary aim: Compare patient-level SUD treatment <u>engagement</u> outcomes across the COVID-19 pandemic

Participants (N=27) identified as Black (48.2%) or White (51.9%) with a mean age of 31 years
(SD=4.0). Most participants had Medicaid insurance (81.5%), were unemployed (66.7%), and
living in their homes (81.5%; Table 2). Over 95% of the participants had a mental health
comorbidity, and about half were prescribed psychotropic medications (51.9%). Approximately
59% of participants were pregnant in the preCOVID-19 phase. Fewer participants were pregnant
in the latter two phases. Over half (51.8%) of participants were receiving treatment in the clinic
prior tobefore the beginning of the study periodstarted.

The number of participants for the five-patient-level treatment engagement outcomes varied by
month as the inclusion criteria was initiation of care by the end of the first phase (. Months
August-October 2019 included-n=16-, participants, November 2019 included n=20-participants,
December 2019 included n=21, participants. aAll other months included n=27-) participants.

In both unadjusted and adjusted models, buprenorphine continuation in a 30-day period was
significantly lower in the COVID-19-vaccine phase (74.54.6%) compared to preCOVID-19
(96.5%), but not significantly different between early_COVID-19 (91.92%) and preCOVID-19
phase (96.5%, 91.2%, 74.6 of 30-day periods in each phase respectively; Figure 2, Table 3).

258	In both unadjusted and adjusted models, any visit attendance in a 30-day period was significantly
259	lower in COVID-19-vaccine phase (64.41%) compared to the preCOVID-19 phase (89.57%)
260	79.9%, 64.1% of 30 day periods in each phase respectively; Figure 2, Table 3).
261	In both unadjusted and adjusted models, medical provider visit attendance was significantly
262	lower in the COVID-19-vaccine (63.96%) phase compared to preCOVID-19 (86.79.9%), but not
263	significantly different between earlyCOVID-19 (78.99%) and preCOVID-19 phase (86.79%)
264	78.0%, 63.6% of 30-day periods in each phase respectively; Figure 2, Table 3).
265	In both unadjusted and adjusted models, behavioral health visit attendance in a 30-day period
266	was significantly lower in both the early (18.29.4%) and COVID-19-vaccine (6.57.7%) phases
267	compared to the preCOVID-19 phase (32.21.7%; 19.4%, 7.7% of 30 day periods in each phase
268	respectively; Figure 2, Table 3).
269	The average percentage of behavioral health visits attended virtually increased between the first
270	two phases and remained high during the third (2.7%, 91.5%, 91.1%). A similar trend was seen
271	for the average percentage of medical provider visits attended virtually (0.0%, 42.8%, 34.7%).
272	Percentage of virtual visits increased significantly between the first two phases and remained
273	high during the third (0.9%, 47.3%, 40.2%; Table 3). Additional information for all full
274	regression analyses can be found in Appendices $2-\underline{34}$.
275	Discussion
276	This study describes COVID-19-driven clinical changes in an OBGYN-addiction treatment

- 277 clinic and summarizes patterns in clinic-level and patient-level outcomes throughout the
- 278 pandemic. During the unprecedented COVID-19 pandemic and nationwide shutdown, the study

279 site promptly adapted to a hybrid telehealth/in-person system to prioritize safety and patient 280 needs. With these changes, number of clinic-level visits remained consistent over three COVID-281 19 phases. Although treatment engagement by participants in our small cohort of pregnant and 282 parenting people decreased over the study timeframe, engagement with medical providers-it remained relatively high, especially in the context of similar reported treatment retention rates 283 for this unique patient population.^{21,26} These clinic- and patient-level findings support that 284 healthcare accessibility can be achieved for this vulnerable population in a hybrid telehealth/in-285 person system. 286

Similar to many healthcare facilities, our OBGYN-addiction clinic quickly transitioned care to a 287 telehealth platform at the beginning of the pandemic.²⁸ Provision of inter-multidisciplinary 288 289 virtual care alongside reduced capacity in-person medical care (1) provided flexibility for individualized care plans tailored to meet patients' needs and (2) helped ease anxiety about 290 COVID-19 exposure, a heightened concern among pregnant and parenting people.²⁰ However. 291 292 the telehealth-based system had some drawbacks. For instance, pPatients were no longer able to 293 combine multidisciplinary interdisciplinary service appointments into a single clinic visit. 294 Instead, patients had to schedule multiple separate visits. Given the many barriers to care patients face, including childcare responsibilities, lack of transportation, and stigma,²⁹ removing the 295 296 ability to combine appointments may have inhibited some people from initiating or continuing 297 multidisciplinary interdisciplinary services (e.g., contraception, behavioral health, social work 298 support).

The COVID-19-driven telehealth platform was beneficial for <u>clinical-care</u> coordination within the integrated OBGYN-addiction clinic<u>as evidenced by more standardized intra-clinical</u> correspondence. Best practices for the care of pregnant and parenting people with SUD include

integrating perinatal care, mental health, and trauma-informed services with SUD treatment.³⁰
Within an integrated care model, maintaining intra-clinical communication between
multidisciplinary interdisciplinary team members is key. Our OBGYN-addiction treatment
program established new modes of communication (i.e., weekly meetings) and information
storage platforms using virtual capabilities to help ensure that intra-clinical communication was
maintained within the hybrid telehealth/in-person model.

308 The novelty of the pandemic limits the availability of SUD treatment outcomes research, 309 particularly among pregnant and parenting people. Current study findings supplement the limited existing literature, suggesting that offering virtual visits can increase the frequency of clinic 310 visits likely due to increased accessibility of care.²² Importantly, the study clinic did not cease in-311 person medical visits to ensure the clinic continued to offer services suitable for all patients. It is 312 commendable that the OBGYN-addiction clinic continued treating pregnant people with SUD 313 314 and incorporating patient-centered approaches to support treatment retention as many SUD 315 treatment clinics do not employ tailored care approaches for pregnant people, and the number of MOUD clinics accepting pregnant people decreased during the pandemic.³¹ 316

Patient-level <u>treatment engagement</u> outcomes from our small cohort demonstrated that many participants continued taking buprenorphine, their primary OUD treatment, during the COVID-19 pandemic. Our buprenorphine continuation rate of over 70% for all three COVID-19 phases is similar to or above the rate of other MOUD populations before COVID-19,³² including postpartum patients.^{21,27} One COVID-19-driven strategy that supported participant buprenorphine continuation was implementation of home buprenorphine induction, which has been found to be safe and effective among pregnant people.³³

324 Similarly, mMedical provider visit attendance decreased over the three COVID-19 phases yet, 325 remained relatively high; this is especially notable when considering the unique challenges pregnant and parenting people with SUD face.^{14,34} We hypothesize that our expansion of patient-326 327 centered, recovery-oriented strategies, such aslike flexibility in visit type, likely contributed to the relatively high treatment engagement across the COVID-19 phases. Notably, many 328 329 participants were pregnant in the first phase, but not in the third phase, which likely contributed 330 to the decrease in medical provider visits independent of COVID-19 because visit frequency typically decreases postpartum.³⁵ Similar to previous work, within the primarily virtual only-331 option behavioral health model, attendance decreased dramatically and remained low.²³ Given 332 that barriers to care for birthing people increase after delivering an infant, a decrease in 333 utilization of adjunctive services (behavioral health) postpartum was somewhat expected among 334 our cohort, as the percent of pregnant participants decreased over time.³⁵ However, the drastic 335 decrease in attendance may have also been due to perceived loss of therapeutic rapport in a 336 primarily virtual-only platform.^{11,36} Importantly, iIn response to these findings, the clinic has 337 338 now established a hybrid telehealth/in-person model for behavioral health appointments.

339 Clinical Practice Implications

Findings underscore that a hybrid model, offering virtual and in-person options, may be a
preferable method of <u>multidisciplinary-interdisciplinary</u> care provision for this <u>complex and</u>
vulnerable SUD-population.³⁷⁻³⁹ Additionally, findings suggest that flexible buprenorphine
prescribing policies and lenient toxicology test timelines can support treatment engagement,
especially for patients who have been on a stable recovery path. Moving forward, integrating
these COVID-19-driven changes into long-term practice may reduce patient and provider burden
as well as improve patient SUD outcomes. The study clinic site continues to use a hybrid

telehealth/in-person model and low-threshold, flexible buprenorphine prescribing options.

348 Improving clinical communication and workflow with virtual capabilities may help improve

349 wellbeing among healthcare workers, as burnout is a growing concern.^{34,40}

350 Limitations

351 This study assessed a unique OBGYN-addiction treatment clinic. Changes that worked within 352 this clinic may not work in other treatment settings. COVID-19-driven changes occurred rapidly, 353 and some changes may not have been captured in our review of clinical practices. The study site 354 is trainee-based; thus, some COVID-19-driven changes, especially for behavioral health services, 355 were largely dictated by institution-wide regulations limiting student attendance in clinic. Additionally, the health system scheduling data used for the secondary aim may reflect a slightly 356 357 inflated count of attended appointments because virtual appointments were marked as "arrived" 358 at the beginning of the clinic shift; some 'no show' appointments may not have been coded 359 appropriately by overburdened clerical staff. Additionally, behavioral health appointments were 360 not captured in our clinic-wide scheduling database during the study timeframe. For patient-level outcomes, participants were selected from those who consented to research registry participation, 361 introducing selection bias and limiting generalizability. The chart abstraction is subject to 362 information bias and offers constrained information, especially for psychosocial factors (e.g., 363 364 child welfare involvement) of this small sample size. Given the small sample size, these findings are preliminary and intended to inform future research that can build upon this study by 365 incorporating toxicology reports and pregnancy outcomes among larger samples to better 366 understand the impact of COVID-19 changes on this vulnerable patient population. Despite these 367 368 limitations, this study is the first to describe COVID-19-driven clinical practice changes and

369 SUD outcomes among pregnant and parenting people in integrated outpatient OB/GYN-370 addiction treatment.

371

Conclusions

372 SUD treatment facilities and providers have demonstrated resiliency and creativity as they have cultivated new care provisions to meet patient needs during unprecedented circumstances. Our 373 findings support ways healthcare accessibility can be achieved for vulnerable patient populations 374 375 with SUD using a hybrid telehealth/in-person system that tailors care approaches to individuals' 376 needs. Clinics treating pregnant and parenting people with SUD may benefit from incorporating 377 similar clinical changes into permanent practice₁₇ and aAddiction researchers should investigate 378 how COVID-19-driven care adaptations can be cultivated to advance personalized approaches in 379 addiction medicine.

380

Acknowledgment

381 Not applicable

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Figures

- 498 Figure 1. Total number of clinic-wide medical provider visits attended by month over three
- 499 COVID-19 phases in an OBGYN-Addiction clinic
- 500 Figure 2. Patient-level trends in <u>treatment engagement</u> outcomes by month across three COVID-
- 501 19 phases for study cohort receiving buprenorphine for opioid use disorder in the integrated
- 502 OBGYN-Addiction clinic

Type of		PreCOVID-19	Early COVID-19	COVID-19-
care	Service	Phase	Phase	Vaccine Phase
Medical	Visit modality	In-person	Both in-person	Both in-person and
			and virtual (via	virtual (via
			Doximity &	Doximity & phone)
	Buprenorphine	In-person at clinic	phone) In-person at clinic	In-person at clinic
	initiation modality	visit	visit or home	visit or home
	initiation modulity	VISIC	induction of	induction of
			buprenorphine	buprenorphine
			option without an	option without an
			initial in-person	initial in-person
			visit per provider	visit per provider
			discretion	discretion
			Patient provided	Patient provided
			handout with	handout with
			instructions	instructions
	Frequency of	In-person visit	In-person visit	In-person visit with
	toxicology testing	with toxicology	with toxicology	toxicology every
	requirement for	every 30 days	every 90 days	90 days with virtual
	30-day MOUD or MAUD		with virtual visits	visits every 30 days in between
	prescription		every 30 days in between	III between
	Patient care	Patients verbally	Clinic	Team members
	expectations	advised by	expectations were	collaboratively
		provider on how	not standardized	developed a
		often and for what	nor routinely	"Patient Care
		reasons they	reviewed with	Agreement" and
		would need to	patients	reviewed
		have clinic visit		expectations with
		with their		all new and current
		addiction provider.		patients
Behavioral	Individual visit	In-person	Primarily virtual	Primarily virtual
Health (BH)	modality (trainee-	appointments	(via Zoom &	(via Zoom &
	led appointments)		phone)	phone)
	Group visit	In-person offered	appointments Virtual (via	appointments Both in-person
	modality (Mom's	weekly	Zoom) offered	(with reduced
	Recovery Group:	weekiy	weekly	(whill reduced capacity) and
	registration-free,		WEEKIY	virtual (via Zoom)
	financially free,			offered weekly
L			1	stiered weekig

Table 1. Description of changes in clinical practice methods across three COVID-19 phases in an interdisciplinary OBGYN-addiction treatment clinic

	baby/toddler			
	welcome) Scheduling system	By nurse coordinator and BH trainees on paper schedule	By nurse coordinator and BH trainees by phone or text and added to schedule in HIPAA compliant shared OneDrive	By nurse coordinator, BH trainees, or Patient Access Representative by phone, text, or via patient portal into electronic medical record
Care Coordination	Appointments with clinical team members from different disciplines	Coordinated appointments. Interdisciplinary providers rotate through the same medical exam room for all contacts with one patient.	Separate appointments. Interdisciplinary providers required to schedule appointments for specific service.	Separate appointments. Interdisciplinary providers required to schedule appointments for specific service.
	Provider meeting modality	Weekly interdisciplinary plan of care meeting held in- person at hospital for OB/GYN, Nursing, Research, and BH	Weekly interdisciplinary plan of care meeting held virtually via Zoom and expanded to additional disciplines (OB/GYN, Nursing, Research, BH, social work, pediatrics, and interpersonal violence advocates)	Weekly interdisciplinary plan of care meeting held virtually via Zoom and expanded to additional disciplines (OB/GYN, Nursing, Research, BH, social work, pediatrics, and interpersonal violence advocates)
	Information sharing	Pertinent information shared in person between team members present in clinic	Pertinent information shared between disciplines via virtual interdisciplinary plan of care meetings and in real time on	Pertinent information shared between disciplines via virtual interdisciplinary plan of care meetings and in real time on HIPAA compliant

Information	No centralized	HIPAA compliant shared OneDrive during clinic	shared OneDrive during clinic
Information storage	No centralized location for resources, schedules, and patient tracking information.	HIPAA compliant shared OneDrive folder created to house resources for patients, providers, and schedulers and was updated regularly.	HIPAA compliant shared OneDrive folder housed resources for patients, providers, and schedulers, and was updated regularly.
Patient resource modality	Interdisciplinary care coordination and referrals (pediatric, nutrition, interpersonal violence advocates) given in-person, via nurse phone triage, and during clinic day or at interdisciplinary plan of care meeting	Interdisciplinary care coordination and referrals provided via impromptu phone calls or messages in the electronic medical record	Interdisciplinary care coordination and referrals provided via impromptu phone calls or messages in the electronic medical record

Abbreviations: MOUD, medication for opioid use disorder; MAUD, medication for alcohol use disorder; BH, behavioral health

Demographic and psychosocial characteristics	% (n)
	n=27
Race	
Black	48.2 (13)
White	51.9 (14)
Age (mean years \pm SD)	31.0 <u>+</u> 4.0
Insurance	
Medicaid	81.5 (22)
Private	11.1 (3)
Uninsured	7.4 (2)
Employment	
Employed	29.6 (8)
Unemployed	66.7 (18)
Not reported	3.7 (1)
Living situation	
Home	81.5 (22)
Residential treatment	11.1 (3)
Jail	7.4 (2)
Number of children in the individual's custody [median (range)] ^a	1 (0-8)
Co-morbid substance use disorder	
Cannabis	7.4 (2)
Stimulant	18.5 (5)
Alcohol	7.4 (2)
Smoking tobacco	63.0 (17)
Receipt of any psychotropic medication	51.9 (13)
Any comorbid psychiatric diagnosis	92.6 (25)
Pregnant	
PreCOVID-19	59.3 (16)
Early COVID-19	37.0 (10)
COVID-19-Vaccine	22.0 (6)
Duration of treatment episode [months; median (range)]	0 (0-16)

Table 2. Patient-level demographic and psychosocial characteristics of study cohort receiving buprenorphine for opioid use disorder in the integrated OBGYN-Addiction clinic

Outcome Variable		Unadjusted model	Adjusted model ^a
		Odds ratio (95%	Odds ratio (95%
		CI)	CI)
Buprenorphine	PreCOVID-19 phase	Ref	Ref
continuation	Early COVID-19 phase	.26 (.03, 2.46)	.37 (.04, 3.59)
	COVID-19 vaccine phase	.03* (.00, .30)	.05* (.005, .48)
Any visits	PreCOVID-19 phase	Ref	Ref
	Early COVID-19 phase	.29* (.07,.99)	.33 (.10, 1.10)
	COVID-19 vaccine phase	.11* (.03, .37)	.12* (.04,.41)
Medical	PreCOVID-19 phase	Ref	Ref
provider visits	Early COVID-19 phase	.38 (.13, 1.14)	.44 (.15,1.29)
	COVID-19 vaccine phase	.16* (.05, .48)	.18* (.06, .56)
Behavioral	PreCOVID-19 phase	Ref	Ref
health visits	Early COVID-19 phase	.16* (.03, .78)	.19* (.05, .70)
	COVID-19 vaccine phase	.02* (.00, .14)	.03* (.01, .16)

Table 3. Regression for patient-level treatment engagement outcomes across three COVID-19 phases for study cohort receiving buprenorphine for opioid use disorder in the integrated OBGYN-Addiction clinic

*significant at the p-value<.05; ^aadjusted for pregnancy during the observation month and duration of treatment episode (months).

Type of care	Service	PreCOVID-19 Phase	Early COVID-19 Phase	COVID-19-Vaccine Phase
Medical	Visit modality	In-person	Both in-person and virtual (via Doximity & phone)	Both in-person and virtual (via Doximity & phone)
	Buprenorphine initiation modality	In-person at clinic visit	In-person at clinic visit or hHome induction of buprenorphine option without an initial in- person visit per provider discretion	In-person at clinic visit or hHome induction of buprenorphine option without an initial in- person visit per provider discretion
			Patient provided handout with instructions	Patient provided handout with instructions
	Frequency of toxicology testing requirement (required for <u>30-day</u> MOUD or MAUD prescription)	In-person <u>visit with</u> <u>toxicology</u> every 30 days	In-person <u>visit with</u> <u>toxicology</u> every 90 days with virtual visits every 30 days in between	In-person <u>visit with</u> <u>toxicology</u> every 90 days withvirtual visits every 30 days in between
	Patient care expectations	Patients verbally advised by provider on how often and for what reasons they would need to have clinic visit with their addiction provider.	Clinic expectations were not standardized nor routinely reviewed with patients	Team members collaboratively developed a "Patient Care Agreement" and reviewed expectations with all new and current patients
Behavioral Health (BH)	Individual visit modality (trainee- led appointments)	In-person appointments	Primarily virtual (via Zoom & phone) appointments	Primarily virtual (via Zoom & phone) appointments
	Group visit modality (Mom's Recovery Group: registration-free, financially free, baby/toddler welcome)	In-person offered weekly	Virtual (via Zoom) offered weekly	Both in-person (with reduced capacity) and virtual (via Zoom) offered weekly
	Scheduling system	By nurse coordinator and BH trainees on paper schedule	By nurse coordinator and BH trainees by phone or text and added to schedule in HIPAA compliant shared OneDrive	By nurse coordinator, BH trainees, or Patient Access Representative by phone, text, or via patient portal into

Table 1. Description of changes in clinical practice methods across three COVID-19 phases in an <u>interdisciplinary</u> OBGYN-addiction treatment clinic

Care Coordination	Appointments with multidisciplinary clinical team members from different disciplines	Coordinated appointments. <u>Multidisciplinary</u> <u>Interdisciplinary</u> providers rotate through the same medical exam room	Separate appointments. <u>Multidisciplinary</u> <u>Interdisciplinary</u> providers required to schedule appointments for	electronic medical record Separate appointments. <u>Multidisciplinary</u> <u>Interdisciplinary</u> providers required to schedule appointments for
	Provider meeting modality	for all contacts with one patient. Weekly interdisciplinary plan of care meeting held in-person at hospital for OB/GYN, Nursing, Research, and BH	specific service. Weekly interdisciplinary plan of care meeting held virtually via Zoom and expanded to additional disciplines (OB/GYN, Nursing, Research, BH, social work, pediatrics, and interpersonal violence advocates)	specific service. <u>Weekly</u> interdisciplinary plan of care meeting held virtually via Zoom and expanded to additional disciplines (OB/GYN, Nursing, Research, BH, social work, pediatrics, and interpersonal violence advocates) Weekly interdisciplinary plan of care meeting held virtually via Zoom for all disciplines working with patients (OB/GYN, Nursing, Research, BH, social work, pediatrics and interpersonal violence advocates)
	Information sharing	Pertinent information shared in person between team members present in clinic	Pertinent information shared between disciplines via virtual interdisciplinary plan of care meetings and in real time on HIPAA compliant shared OneDrive during clinic	Pertinent information shared between disciplines via virtual interdisciplinary plan of care meetings and in real time on HIPAA compliant shared OneDrive during clinic
	Information storage	No centralized location for resources, schedules, and patient tracking information.	HIPAA compliant shared OneDrive folder created to house resources for patients, providers, and schedulers and	HIPAA compliant shared OneDrive folder housed resources for patients, providers, and schedulers, and

		was updated regularly.	was updated regularly.
Patient resource modality	Multidisciplinary Interdisciplinary care coordination and referrals (pediatric, nutrition, interpersonal violence advocates) given in-person, via nurse phone triage, and during clinic day or at interdisciplinary plan of care meeting	InterMultidisciplinary care coordination and referrals provided via impromptu phone calls or messages in the electronic medical record	Interdisciplinary care coordination and referrals provided via impromptu phone calls or messages in the electronic medical record

Abbreviations: MOUD, medication for opioid use disorder; MAUD, medication for alcohol use disorder; BH, behavioral health

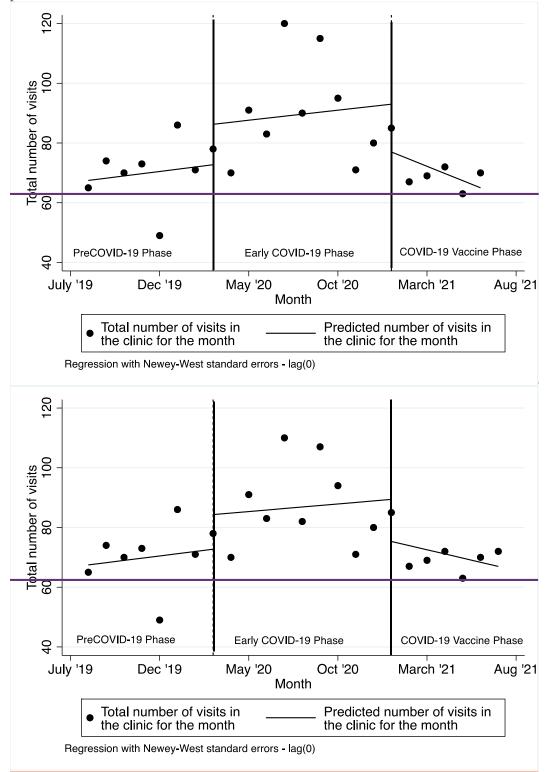


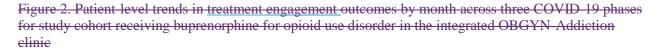
Figure 1. Total number of clinic wide medical provider visits attended by month over three COVID-19 phases in an OBGYN Addiction clinic*

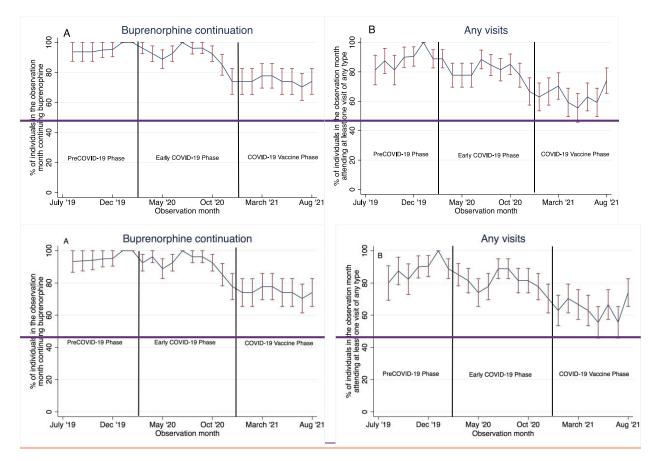
*No significant changes in the number of <u>medical provider</u> visits each month were identified in the interrupted time series analysis

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Demographic and psychosocial characteristics	% (n) n=27
Race	
Black	48.2 (13)
White	51.9 (14)
Age (mean years \pm SD)	31.0±4.0
Insurance	
Medicaid	81.5 (22)
Private	11.1 (3)
Uninsured	7.4 (2)
Employment	
Employed	29.6 (8)
Unemployed	66.7 (18)
Not reported	3.7 (1)
Living situation	
Home	81.5 (22)
Residential treatment	11.1 (3)
Jail	7.4 (2)
Number of children in the individual's custody [median (range)] ^a	1 (0-8)
Co-morbid substance use disorder	
Cannabis	7.4 (2)
Stimulant	18.5 (5)
Alcohol	7.4 (2)
Smoking tobacco	63.0 (17)
Receipt of any psychotropic medication	51.9 (13)
Any comorbid psychiatric diagnosis	92.6 (25)
Pregnant	
PreCOVID-19	59.3 (16)
Early COVID-19	37.0 (10)
COVID-19-Vaccine	22.0 (6)
Duration of treatment episode [months; median (range)]	0 (0-16)

Table 2. Patient-level demographic and psychosocial characteristics of study cohort receiving buprenorphine for opioid use disorder in the integrated OBGYN-Addiction clinic





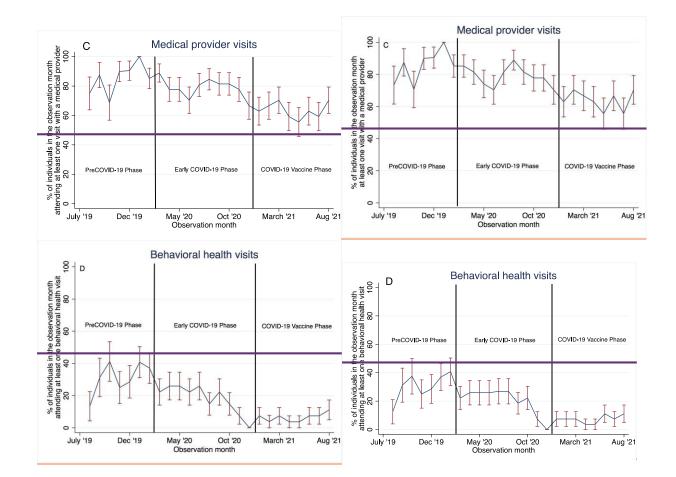


Table 3. <u>Regression for p</u>Patient-level <u>regression-treatment engagement</u> outcomes across three COVID-19 phases for study cohort receiving buprenorphine for opioid use disorder in the integrated OBGYN-Addiction clinic

Outcome	Variable	Unadjusted model Odds ratio (95% CI)	Adjusted model ^a Odds ratio (95% CI)
Buprenorphine	PreCOVID-19 phase	Ref	Ref
continuation	Early COVID-19 phase	.2 <u>6</u> 2 (.0 <u>3</u> 2, <u>2.46</u> 1.89)	. <u>3729 (.0<u>4</u>3, <u>3.59</u>2.80)</u>
	COVID-19 vaccine phase	.0 <u>3</u> 3* (.00, .30)	.05* (.005, . <u>48</u> 51)
Any visits	PreCOVID-19 phase	Ref	Ref
	Early COVID-19 phase	.2 <mark>98</mark> * (.0 <u>7</u> 8,.9 <u>9</u> 5)	.3 <u>3</u> 4 (. <u>10</u> 09, 1. <u>10</u> 02)
	COVID-19 vaccine phase	.1 <u>1</u> 0* (.03, .3 <u>7</u> 5)	.1 <u>2</u> +* (.0 <u>4</u> 3,. <u>41</u> 38)
Medical provider	PreCOVID-19 phase	Ref	Ref
visits	Early COVID-19 phase	.3 <u>8</u> 6 (.1 <u>3</u> 2, 1. <u>14</u> 01)	.4 <u>4</u> 1 (.1 <u>5</u> 4,1. <u>2</u> 19)
	COVID-19 vaccine phase	.1 <u>6</u> 5* (.05, .4 <u>8</u> 6)	.18* (.06, .5 <u>6</u> 3)
Behavioral health	PreCOVID-19 phase	Ref	Ref
visits	Early COVID-19 phase	. <u>1620* (.0<u>3</u>5, .<u>78</u>87)</u>	. <u>1922</u> * (.0 <u>5</u> 7, .7 <u>0</u> 5)
	COVID-19 vaccine phase	.0 <u>2</u> 3* (.0 <u>0</u> 4, .1 <u>4</u> 9)	.0 <u>3</u> 5* (.01, .1 <u>6</u> 9)
	Linear regression coefficients (95% CI) ^a		fficients (95% CI) ^a
% of medical	PreCOVID-19 phase	Ref	Ref
provider and	Early COVID-19 phase	.45* (.33, .58)	.44* (.32, .57)
behavioral health	COVID-19 vaccine phase	.38* (.26, .50)	.38* (.25, .50)
visits that were			
conducted			
virtually	 		

*significant at the p-value<.05; ^aadjusted for pregnancy during the observation month and duration of treatment episode (months).

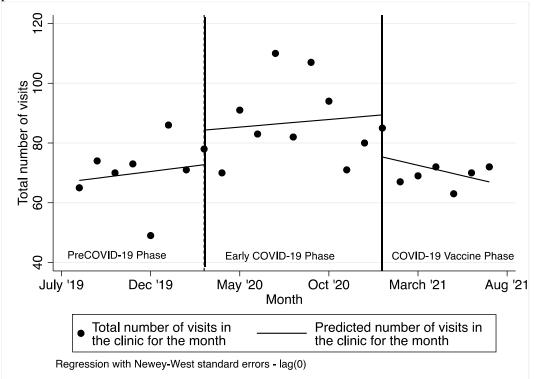
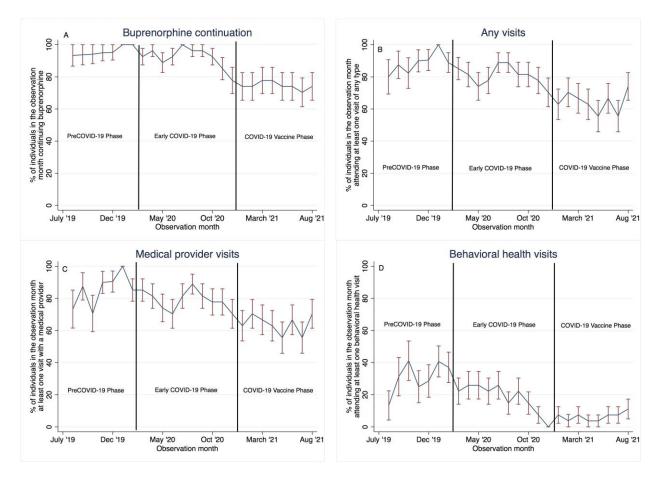


Figure 1. Total number of clinic-wide medical provider visits attended by month over three COVID-19 phases in an OBGYN-Addiction clinic^a

^aNo significant changes in the number of medical provider visits each month were identified in the interrupted time series analysis

Figure 2. Patient-level trends in treatment engagement outcomes by month across three COVID-19 phases for study cohort receiving buprenorphine for opioid use disorder in the integrated OBGYN-Addiction clinic



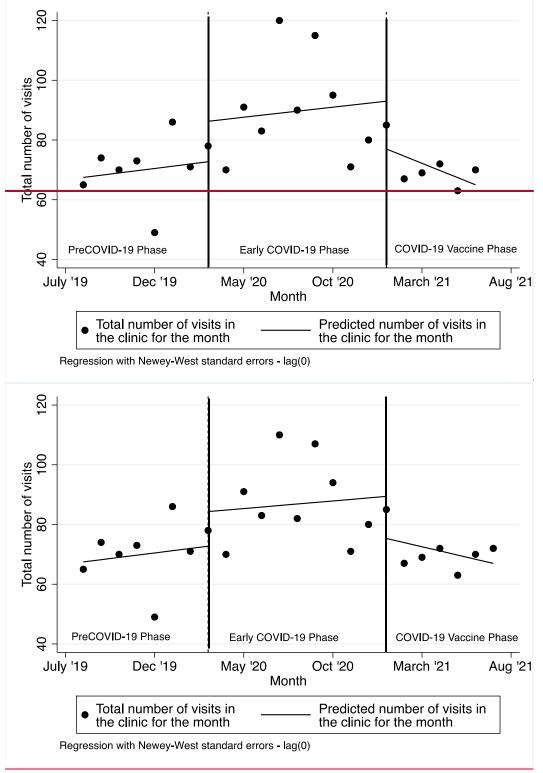
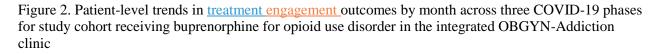
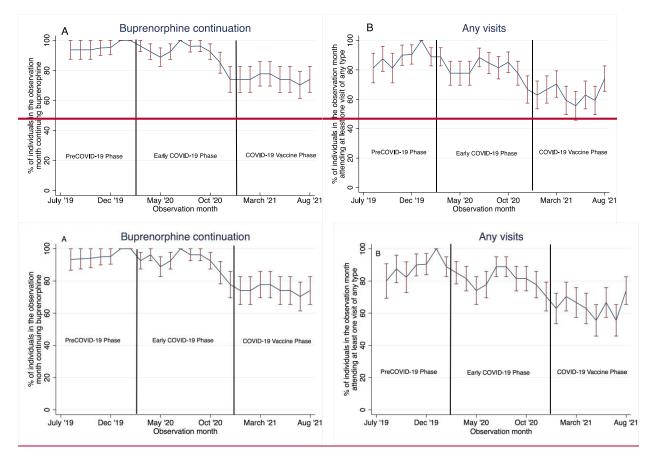
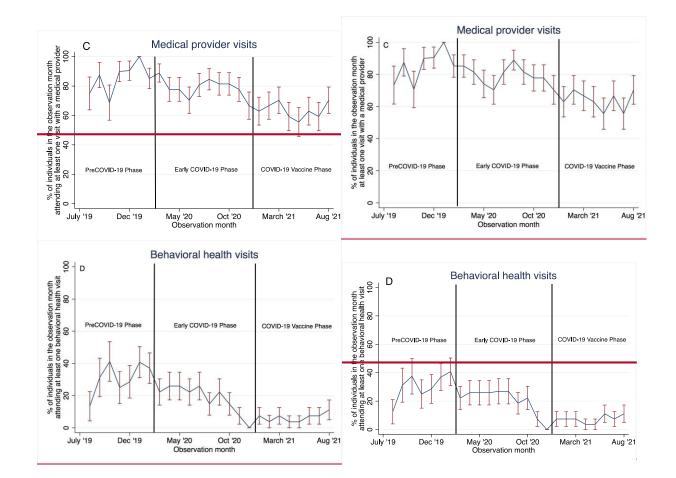


Figure 1. Total number of clinic-wide medical provider visits attended by month over three COVID-19 phases in an OBGYN-Addiction clinic^a

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