Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Assessing the impact of social distancing measures implemented during COVID-19 pandemic on medications for opioid use disorder in West Virginia

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ABSTRACT

Introduction: This study evaluates if social distancing measures instituted during the novel coronavirus SARS-CoV-2 (COVID-19) pandemic were associated with a reduction in Medication for Opioid Use Disorder (MOUD) prescribing in West Virginia. The COVID-19 pandemic necessitated the quick implementation of public health interventions such as social distancing. This led to the use of telemedicine in the clinical setting however implementing telemedicine involves system level and infrastructure level changes within a healthcare environment. This could cause a barrier to MOUD delivery as it is often provided concomitantly with other face to face substance use and mental health services. The purpose of this study is to determine whether social distancing was associated with a reduction in MOUD prescribing in West Virginia, with the goal of adding to the knowledge of how COVID-19 and COVID-19-related mitigation strategies have impacted patients with OUD.

Methods: Prescription monitoring data were requested from the West Virginia Board of Pharmacy. We applied interrupted time series modeling to investigate MOUD prescribing practices before and after social distancing took effect. Gabapentin prescriptions were utilized as a control for comparison.

Results: Our study assessed state-wide buprenorphine and Suboxone prescriptions as compared to a control medication and found an increase in dosage of both medications and an increase in number of buprenorphine prescriptions, but a small decrease in buprenorphine/naloxone prescription number related to the dates of implementation of social distancing. Taken together, overall this indicates an increase in prescription number of MOUD prescriptions as well as an increase in dosage.

Conclusion: This study suggests that social distancing measures were associated with an increase in both the number of MOUD prescriptions and the number of doses in each prescription. Significant alterations to MOUD delivery in the clinical setting were implemented in a short timeframe with the COVID-19 pandemic. Understanding the implementation of clinical measures to accommodate social distancing measures may provide benefit to transformation of future delivery of MOUD.

1. Introduction

Opioid use disorder (OUD) is a prime public health concern of this decade, with over 1.9 million people reporting OUD in the previous year (Han et al., 2017). Medication for Opioid Use Disorder (MOUD) includes the administration of medications such as buprenorphine, naltrexone, or methadone, often provided concomitantly with other substance use and mental health services. A variety of West Virginia (WV) clinic have implemented MOUD treatment. MOUD treatment has been implemented in a hub and spoke model to build organizational capacity in compliance with state law. The model used to expand buprenorphine treatment in WV is the Comprehensive Opioid Addiction Treatment (COAT) model, which centers on interdisciplinary care (Lander et al., 2020; Winstanley et al., 2020). Common delivery methods for this

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model include: patients attending group medical management visits, group-psychosocial counseling, and community level peer support meetings, in addition to medication treatment.

The novel coronavirus SARS-CoV-2 (COVID-19) is a new communicable respiratory disease that has spread across the globe in a matter of months. The World Health Organization (World Health Organization, 2020) declared this rapidly spreading virus a pandemic on March 11, 2020. Public health quickly employed non-pharmacologic interventions to reduce the transmission of respiratory illness in pandemic and non-pandemic environments. These public health interventions include simple methods such as: hand washing, personal protective measures or personal distancing, as well as "social distancing." Social distancing is defined as a strategy of reducing the number and duration of social contacts to slow the spread of illness (Faherty et al., 2019). The state government of WV instituted social distance guidelines even before the state registered its first case of COVID-19, on March 17, 2020 (Office of the Governor Jim Justice, n.d.). Group peer recovery meetings and group medical visits were no longer held in-person with implementation of social distancing directives. This implementation of social distancing directives provided an opportunity to study the effect of social distancing and downstream effects on MOUD accessibility in a rural environment.

Social distancing measures transformed the delivery of healthcare during this time. Some accommodations were made to enable care during social distancing, specifically the 1135 waiver authority (Centers Centers for Medicare & Medicaid Services, 2021), and the Coronavirus Preparedness and Response Supplemental Appropriations Act (Senate and House of Representatives & Congress the United States of America in, 2020), allowing alternative medical visit delivery and treatment by way of telemedicine. Traditionally, telemedicine delivery of a controlled substance must be established during an in-person visit, in accordance with 21 U.S.C.802 (54)(D). Controlled substance delivery can be initiated in a telemedicine visit when a public health emergency is declared by the Secretary of Health and Human Services (Knopf, 2020).

The implementation of telemedicine in any medical facility requires both infrastructure and system-level changes. Furthermore, some forms of telemedicine may be inaccessible to certain populations, such as those with OUD, particularly if they do not have access to electronic devices and/or broadband internet (Scott Kruse et al., 2018; Uscher-Pines et al., 2020). As a result, medical facilities may have experienced gaps in care due to social distancing measures. Although, an increase in care delivery due to telemedicine reach to marginalized populations, may also be found (Hughes, Verrastro, Fusco, Wilson, & Ostrach, 2021).

There are some expected challenges to prescribing MOUD through telemedicine in WV. Efficacy in our population has been demonstrated with face to face administration of the COAT model for prescribing MOUD (Lander et al., 2020; Winstanley et al., 2020). Social distancing directives amidst the COVID-19 pandemic necessitated rapid conversion to telehealth delivery for continued buprenorphine treatment. This change to telehealth delivery may significantly impact buprenorphine availability. Retention in MOUD treatment is associated with decreased drug use, improved social functioning and quality of life, and reduced mortality (Bart, 2012; Fullerton et al., 2014; Stotts, Dodrill, & Kosten, 2009); adding to the importance of continued access to MOUD treatment, despite the change in delivery of the program.

The purpose of this exploratory study is to determine whether social distancing was associated with a reduction in MOUD prescribing in WV, with the goal of adding to the knowledge of how COVID-19, and specific COVID-19-related mitigation strategies have impacted patients with OUD. A majority (64%) of the WV population lives in rural locations, most WV residents are white (93.5%), and about 16% of the population lives in poverty and a median household income around $46,000 (United States Census Bureau, n.d.). West Virginia has the highest percentage of non-institutionalized adults with disability benefits in the United States, 19.1% versus 12.6 respectively (United States Census Bureau, 2020). The state also has a high rate of opioid-related drug overdose deaths (42.2 per 1,000,000) people compared to the US (20.7 per 1,000,000) (National Institute on Drug Abuse, 2020). There is still limited access to MOUD in WV (Sheppard, Young, Davis, & Moran, 2021). We hypothesized that social distancing measures caused an initial decrease in MOUD prescribing. To this end, our group utilized a quasi-experimental Interrupted Time Series (ITS) model, utilizing the state Prescription Drug Monitoring Program (PDMP) data to investigate MOUD prescribing practices (both number of prescriptions and daily dose per prescription), before and after social distancing took effect. Gabapentin prescriptions were utilized as a control for comparison, as the state PDMP also collects information for this medication, but without the same prescribing requirements as MOUD. Gabapentin prescribing does not follow the same COAT clinical model, as it may be refilled or initiated without a clinical visit, at times prescribed via telephone or other methods, etc. Utilizing the state PDMP as the information source, we were able to assess the impact across multiple groups of patients, including private and publicly insured patients, as well as uninsured patients, lending external validity to our results for broad populations.

2. Methods

2.1. Data management and variables

The study team requested PDMP data from the WV Board of Pharmacy (WVBOP) for the time period from September 15, 2019 to September 19, 2020. The PDMP database stores data on all Schedule II-V controlled substances (and other drugs that require identification to purchase, such as pseudoephedrine) that are dispensed by practitioners to WV residents, with the exception of correctional facilities, the Indian Health Services, and tribal pharmacies. The data are required to be submitted to the WVBOP every 24 h. Data requested included the number of buprenorphine prescriptions (both buprenorphine alone and combined buprenorphine/naloxone), as well as the daily doses. The analysis included generic and brand name formulations including Bunavail, Sublocade, and Zubsolve. The analysis excluded transdermal formulations of buprenorphine, as this formulation has been designated primarily for the treatment of pain rather than OUD. These variables were monitored daily for 25 weeks prior to the WV Governor's social distancing mandate, enacted on March 12, 2020, and for the 25 weeks following the order. A second social distancing mandate on March 25, 2020 was analyzed, as a separate timepoint within the analysis. Identical data was obtained for gabapentin to serve as a control. The study team also collected descriptive data. This study had institutional review board (IRB) approval (Protocol #2005017367).

2.2. Statistical analysis

In order to assess the impact of social distancing on the variables under investigation, including the control, we performed an Interrupted Time Series (ITS) analysis utilizing an Autoregressive Integrated Moving Average (ARIMA) model (Box, Jenkins, Reinsel, & Ljung, 2015; McDowall, McCleary, & Bartos, 2019). Our group has previously utilized a similar methodology to assess the impact of a restrictive opioid prescribing law on opioid prescribing practice (Sedney et al., 2021). This modeling method is commonly used in healthcare research (Bernal, Cummins, & Gasparrini, 2017; Lagarde, 2012) to evaluate interventions (Biglan, Ary, & Wagenaar, 2000; Penfold & Zhang, 2013), and is well-equipped to account for pre-intervention trends in comparison to post-intervention trends, where the intervention was implemented on an exact date and sufficient data points are available. Thus, it represents a quasi-experimental methodology which can discern intervention effect, while accounting for other trends and variables within the data. Corresponding weekday regressors (Sun-Fri) were included in the model to address different patterns. The analysis included regressors corresponding to outliers, additive outliers, and innovation outliers as

previously reported by Chang and colleagues (Chang, Tiao, & Chen, 2012). Intervention effect is described for each medication in terms of either a sudden, immediate change (brief level change, permanent level change, and weekend level change), and/or a trend effect over time (permanent slope change and temporary arc change), as well as the combined effect of both slope and level changes, expressed as a percentage change of the expected value that can be calculated from the pre-intervention trend, in order to determine the magnitude of the change. Statistical analysis was done using R version 4.0.0. Detailed information for time series models can be found in Appendix 1.

3. Results

The overall prescriptions for the study period included 64,476 total buprenorphine prescriptions, and 499,340 buprenorphine/naloxone prescriptions. The results of buprenorphine without naloxone, and buprenorphine with naloxone (Suboxone) final modeling, are reported in Table 1 with only significant regressors.

Appendix 1 presents the detailed results of the ARIMA model, with the intervention effect isolated and presented below in Figs. 1 and 2. The vertical lines identify the timepoints of the first and second interventions. Buprenorphine prescription numbers increased after the second social distancing directive (19.9, 95% CI [8.8,31.0], $p < 0.001$), and this increase was equal to 3.24% of the expected pre-intervention value. This finding returned to preintervention baseline value. Buprenorphine dosage also increased by 8.43% of the expected value, with a similar trend (1523.0, 95% CI [1200.9, 1845.1], $p < 0.001$).

Buprenorphine/naloxone (Suboxone) prescription number decreased suddenly (−114.1, 95% CI [−179.7, −48.5], $p < 0.001$) after the second social distancing directive, then started to increase (192.5, 95% CI [80.4, 304.6], $p < 0.001$). In considering both the level change and the slope change (the sudden level decrease and slope increase), prescription number diminished by 0.75% compared to the expected number of prescriptions before the interventions. However, buprenorphine/naloxone (Suboxone) dosage increased (3369.6, 95% CI [1422.9, 5316.2], $p < 0.001$) after the second intervention. In total, compared to expected doses before the intervention this slope change increased dosage by 3.06% and this increase was sustained.

3.1. Gabapentin control

There were no significant regressors for gabapentin prescription numbers or doses. Furthermore, gabapentin prescription number and doses did not change significantly after either intervention (Fig. 2).

4. Discussion

The findings of this study support an expected initial disruption of buprenorphine/naloxone prescriptions. This initial disruption may correlate to the strain of continuing office-based treatment in compliance with social distancing requirements, and the subsequent loss of the face-to-face encounters, as previously mentioned. After the initial disruption in prescriptions there was a rebound in prescribing. This change rebound in prescription supports that despite the COVID-19 pandemic and social distancing requirements, with policy adjustments and clinical practice evolution, prescribers in WV were only temporarily inhibited in the distribution of MOUD. This rebound in prescribing, after telemedicine and social distancing measures are put in place, can be expected as previous studies on telemedicine delivery of MOUD show improved retention of patients with OUD (Hughes et al., 2021; Wang et al., 2021).

The COVID-19 pandemic required social distancing restrictions and prompted widespread adoption of telehealth for the provision of MOUD. Relaxation of prescription limitations and requirements allowed implementation of Telemedicine delivery of MOUD. There was initial distress over access amongst MOUD users with the onset of social distancing requirements (Krawczyk et al., 2021). However, the conversion to telehealth possibly had a neutralizing impact for MOUD access. Telemedicine is effective for opioid agonist therapy delivery (Morin, Parrotta, Eibl, & Marsh, 2021), including the induction of therapy (Tofighi et al., 2019). Hughes and colleagues, report that primary care-based MOUD visits increased with telehealth (Hughes et al., 2021). A phone-based MOUD telehealth program was similarly effective in San Francisco (Mehtani et al., 2021). Some academic authors have now called for permanent easement of face to face delivery restrictions on MOUD delivery (Stringer, Langdon, Mckenzie, Brockmann, & Marotta, 2021).

Prescription rates are affected by the use of telemedicine to access to MOUD care. While Jones and colleagues note that the national number of patients dispensed buprenorphine were within forecasted numbers (Jones, Guy, & Board, 2021), more nuanced variations have also been reported amongst specific populations. For instance, Caton and colleagues reported on primary care clinics in California, who experienced increased patient demand for services, as well as increased duration of MOUD prescriptions (Caton et al., 2021). In Texas, a group that also utilized PDMP information demonstrated a decrease in prescriptions, but an increase in the overall number of patients receiving the prescriptions and an increase in duration without corresponding dosage change (Cance & Doyle, 2020). Our study assessed state-wide buprenorphine and buprenorphine/naloxone (Suboxone) prescriptions as compared to a control medication, and found an increase in dosage of both medications, and an increase in number of buprenorphine prescriptions, but a small decrease in buprenorphine/naloxone (Suboxone) prescription number related to the dates of implementation of social distancing. Overall, this indicates an increase in prescription number of MOUD and an increase in dosage. These results add to the better understanding of how policy changes can affect MOUD availability.

Our study has several limitations. We do not include clinical data regarding patient diagnoses, symptoms (which may be particularly important given symptom-driven dosing), or assess downstream consequences of the findings we report. Our dataset did not include other confounders that could affect the results include patient demographics, insurance coverage for telemedicine, and OUD diagnosis. Similarly, because our methodology is associated with specific dates only, not simultaneous events on those dates, we cannot differentiate between the effect of social distancing with that of the implementation of telemedicine using this methodology. Our modeling did not show that gabapentin sustained unanticipated changes in availability related to social distancing – thus we feel that the selection of gabapentin as a control strengthens our findings and adds rigor to our methodology.

Our work demonstrates an association of social distancing implementation in WV with increased dispensation of MOUD, both in number of prescriptions, and in amount of medication per prescription. It is believed that this association relates to the concomitant relaxation of restrictions to allow telemedicine during social distancing, but importantly, our methods are insufficient to verify this belief. Further investigation using other methodologies may aid in supporting this hypothesis. Moreover, given the growing evidence that the substance use epidemic has been exacerbated during this time, placing our findings into the broader environment of substance use disorder in WV during the COVID-19 pandemic is key (Khoury, Preiss, Geiger, Anwar, & Conway, 2021; Niles, Gudin, Radcliff, & Kaufman, 2021; Striley & Hoeflich, 2021).

5. Conclusions

This study suggests that social distancing measures were associated with an increase in the number of MOUD prescriptions and the number of doses in each prescription. Significant alterations to MOUD delivery in the clinical setting were implemented in a short timeframe with the onset of the COVID-19 pandemic, allowing the application of telemedicine. Understanding the implementation of clinical measures to

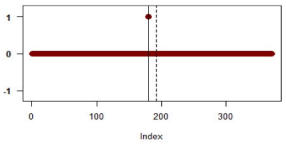
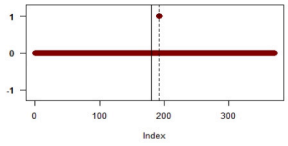
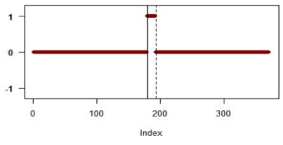
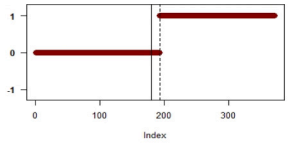
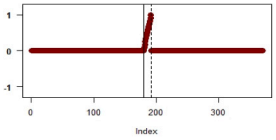
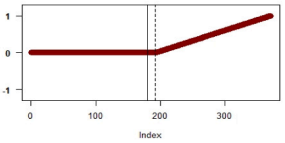
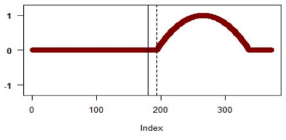
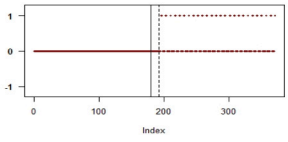
Table 1
Significant regressors of Buprenorphine and Buprenorphine/naloxone model (a) with graphical explanation of each regressor (b).

(a)Significant regressors of mode. f is first intervention and s is second intervention

Medication / Regressor	Buprenorphine		Buprenorphine/Naloxone	
	Mean [95% CI]	*p value*	Mean [95% CI]	*p value*
RX				
Pulse s	-	-	-	-
Step s	-	-	−114.1 [−179.7, −48.5]	<0.001*
Ramp s	-	-	192.5 [80.4, 304.6]	<0.001*
Curve s	19.9 [8.8, 31.0]	<0.001*	-	-
Pulse f	-	-	-	-
Step f	-	-	-	-
Ramp f	-	-	-	-
Weekends	-	-	-	-
Dose				
Pulse s	-	-	-	-
Step s	-	-	-	-
Ramp s	-	-	3369.6 [1422.9, 5316.2]	<0.001*
Curve s	1523.0 [1200.9, 1845.1]	<0.001*	-	-
Pulse f	-	-	-	-
Step f	-	-	-	-
Ramp f	-	-	-	-
Weekends	−797.9 [−1101.9, −493.8]	<0.001*	-	-

* P-value<0.05 deemed significant.

(b)Graphical explanation of different potential intervention effects and corresponding regressors examined above:

Intervention / Changes (Regressor)	First intervention (f)	Second intervention (s)
Brief level change (pulse)		
Permament level change (step)		
Permament slope change (ramp)		
Temporary change (curve)	Preclude	
Weekend level change (weekend)	Preclude	

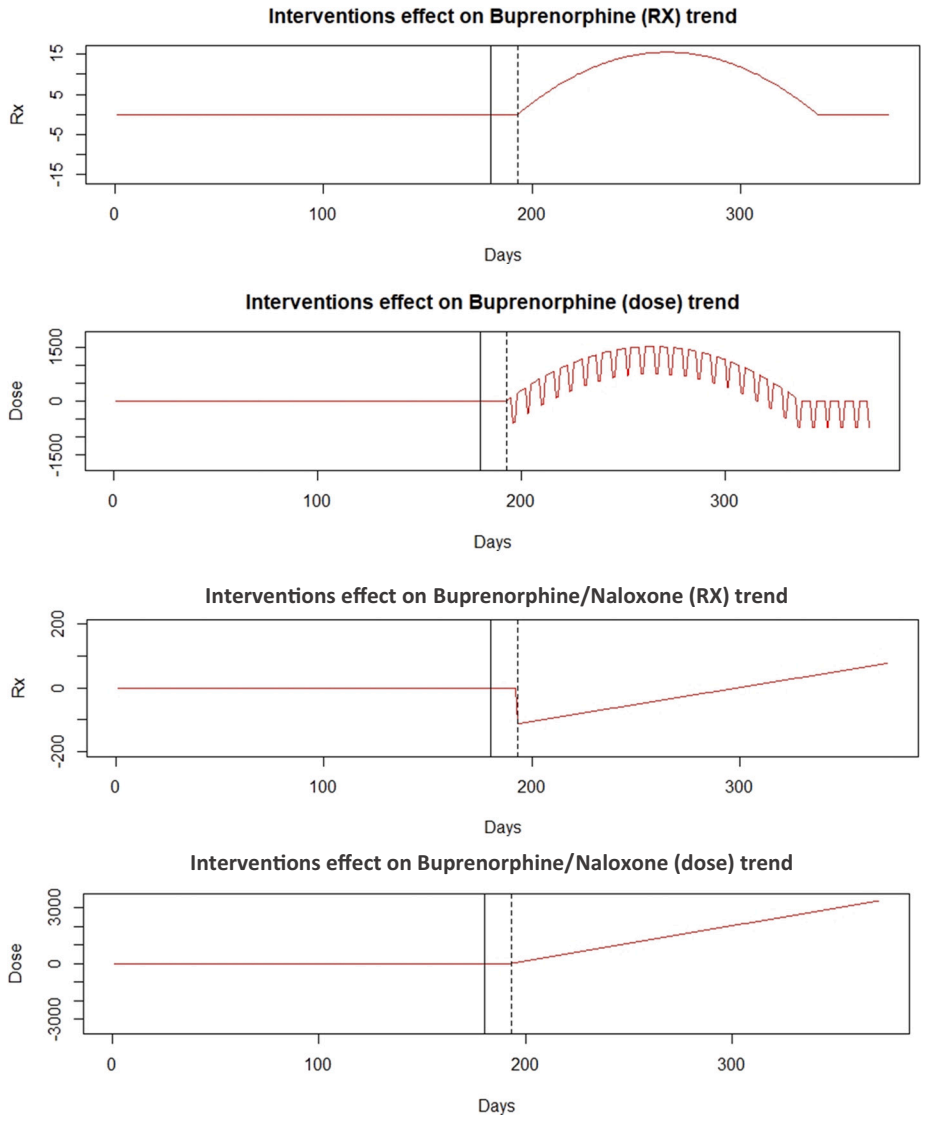


Fig. 1. Interventions effect on buprenorphine and buprenorphine/naloxone RX and dose.

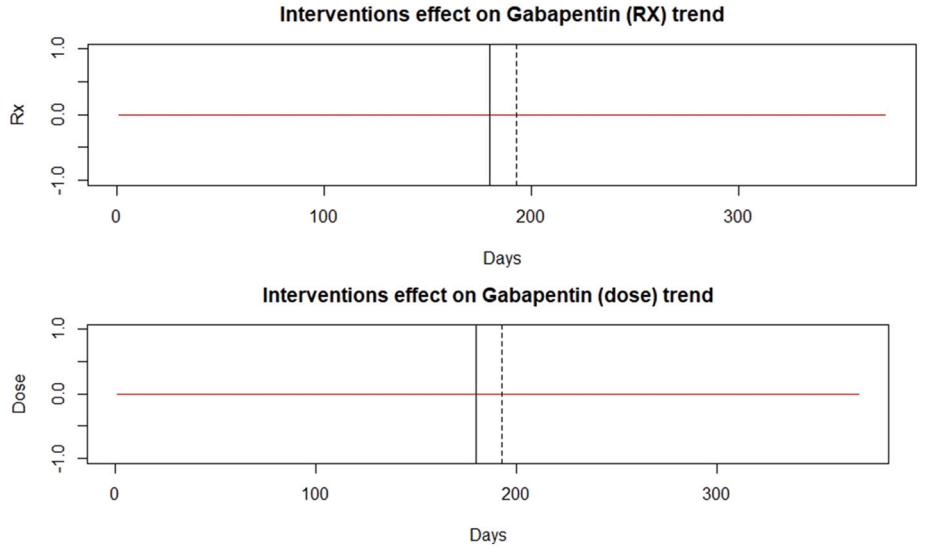


Fig. 2. Interventions effect on Gabapentin (control) RX and dose.

accommodate social distancing measures may benefit the transformation of future delivery of MOUD.

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CRediT authorship contribution statement

Treah Haggerty: Supervision, Methodology, Investigation, Writing original draft, Writing-review and editing. **Maryam Khodaverdi**: Formal analysis, Investigation. **Patricia Dekeseredy**: Writing-review and editing, project administration. **Nathan Wood**: Resources, Data curation, Investigation. **Brian Hendricks**: Methodology, Writing-review and editing. **Jason Peklinsky**: Writing-review and editing. **Cara L. Sedney**: Conceptualization, Methodology, Investigation, Writing original draft, Writing-review and editing.

Declaration of competing interest

None.

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Appendix A. Supplementary data

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