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Evaluating buprenorphine prescribing and opioid-related health outcomes following the expansion the buprenorphine waiver program

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Abstract

Aims: To evaluate associations between new types of buprenorphine waivers (nurse practitioner and physician assistant [NP/PA]; 275-patient limit [MD/DO-275]) and both buprenorphine prescribing and health outcomes.

Methods: Using comprehensive county-level data from California 2010–2018, we modeled quarterly associations between numbers of NP/PA and MD/DO-275 waivers and rates of buprenorphine prescribing, opioid-related deaths, emergency department (ED) visits, and hospitalizations among all counties and separately among metropolitan and nonmetropolitan counties using Poisson regression models with county and quarter fixed effects and adjusting for time-varying covariates.

Results: Each additional NP/PA and MD/DO-275 waiver was associated with a 2.6% (95%CI: 1.1–4.1%) and 5.8% (4.1–7.4%) increase in buprenorphine prescribing among nonmetropolitan counties, respectively. Each additional MD/DO-275 waiver was associated with a 2.8% (1.0%–4.6%) increase in buprenorphine among metropolitan counties. There were no

statistically significant associations between NP/PA waivers and buprenorphine prescribing among metropolitan counties or among either waiver type and opioid-related health outcomes.

Conclusions: NP/PA waivers were associated with increased buprenorphine prescribing among nonmetropolitan counties and MD/DO-275 waivers were associated with increased buprenorphine prescribing among both metropolitan and nonmetropolitan counties.

Keywords

Opioid use disorder; Opioid agonist treatment; Buprenorphine; Buprenorphine waiver program

1. Introduction

The United States continues to grapple with an unprecedented opioid overdose epidemic. Nearly half a million people have died from opioid-related drug overdoses since 1999 and provisional estimates suggest further increases in mortality from 2018 to 2019 (Ahmad, Rossen, & Sutton, 2020; Centers for Disease Control and Prevention National Center for Health Statistics, 2018). Expanding access to treatment for opioid use disorder (OUD) has been a key priority in the national response to the epidemic (American Medical Association Opioid Task Force, 2014; Behavioral Health Coordinating Committee, 2013; National Governors Association, 2016; President's Commission on Combating Drug Addiction and the Opioid Crisis, 2017; Volkow, Frieden, Hyde, & Cha, 2014). Medications for opioid use disorder (MOUD), such as methadone and buprenorphine, are the most effective treatment available for OUD and have been shown to decrease opioid use and related mortality and increase retention in treatment (Connery, 2015; Mattick, Breen, Kimber, & Davoli, 2009, 2014). However, MOUD are extensively underutilized (C. M. Jones, Campopiano, Baldwin, & McCance-Katz, 2015; Lembke & Chen, 2016; Saloner & Karthikeyan, 2015; Wu, Zhu, & Swartz, 2016). Although the reasons for underutilization are varied and complex, several studies have identified major gaps between treatment need and capacity (C. M. Jones et al., 2015; H. K. Knudsen, 2015; Olfson, Zhang, Schoenbaum, & King, 2020; Rosenblatt, Andrilla, Catlin, & Larson, 2015; Sigmon, 2014).

While methadone for OUD can only be dispensed through highly structured and federally regulated opioid treatment programs, buprenorphine can be prescribed by qualified providers in outpatient settings and dispensed by pharmacies. The prescription of buprenorphine for OUD is regulated through a federal waiver program. Buprenorphine waivers grant providers the permission to administer, dispense, and prescribe buprenorphine but also limit the number of patients that they can treat. Prior to 2016, physicians who underwent training and applied for a waiver could prescribe buprenorphine for OUD to up to 30 or 100 patients. In 2016, two additional policy changes were made in an effort to expand buprenorphine prescribing capacity: [1] a final rule from the Substance Abuse and Mental Health Services Administration (SAHMSA) increased the patient limit from 100 to 275 for physicians who prescribed buprenorphine to 100 patients for at least one year and met additional credential or practice criteria (MD/DO-275); and [2] the Comprehensive Addiction and Recovery Act (CARA) extended the ability to prescribe buprenorphine for OUD to nurse practitioners and physician assistants (NP/PA).

To date, research has not examined downstream effects of NP/PA or MD/DO-275 waivers. National studies have documented increases in the number of waivered providers, including those with NP/PA and MD/DO-275 waivers, and the number of buprenorphine prescriptions in recent years (Andrilla, Moore, Patterson, & Larson, 2019; Ghertner, 2019; Hannah K. Knudsen, Lin, & Lofwall, 2019; Olfson et al., 2020). In addition, multiple studies have highlighted the potential for NP/PA and MD/DO-275 waivers to expand access to OUD treatment and help to close the gap between capacity and need (Barnett, Lee, & Frank, 2019; Knudsen et al., 2019). Although one study examined and found a positive state-level association between the total number of waivered providers and rates of buprenorphine prescribing among Medicaid enrollees prior to the 2016 policy changes (Wen, Hockenberry, & Pollack, 2018), no studies have investigated the associations between the number of NP/PA or MD/DO-275 waivers and population-level buprenorphine prescribing rates or opioid-related health outcomes. Each policy represents a distinct strategy for expanding access to buprenorphine: the MD/DO-275 policy sought to expand the prescribing capacity of prescribers already focused on buprenorphine provision whereas the NP/PA policy sought to expand the number of prescribers. Evaluating the impacts of these two policies can inform ongoing efforts to expand access to treatment for OUD.

Using statewide administrative data sources from California, we examined the uptake of NP/PA and MD/DO-275 waivers and their associations with buprenorphine prescribing, opioid-related mortality, emergency department visits, and hospitalizations.

2.   Materials and methods

2.1.   Overview and data sources

We described trends in the number and type of buprenorphine waivers in California and leveraged variability at the county-level to examine associations between the number of NP/PA and MD/DO-275 waivers and both buprenorphine prescribing and opioid-related health outcomes from 2010 to 2018.

We obtained administrative data covering the entire state of California from several sources: [1] counts of buprenorphine waivers by type, month, and county from SAMHSA; [2] individual-level buprenorphine and other opioid prescription data from California's controlled substance monitoring program (Controlled Substance Utilization and Evaluation System; CURES 2.0); [3] individual-level opioid-related mortality data from the California Department of Public Health; and [4] individual-level opioid-related emergency department visit and hospitalization data from the California Office of Statewide Health Planning and Development. Additional details regarding data sources are provided in the Appendix.

All analysis measures were calculated by county and calendar quarter.

2.2.   Exposures

Our two exposures of interest were the buprenorphine prescribing capacity rates (per 100,000 residents) associated with NP/PA and MD/DO-275 waivers. These rates correspond to the total number of patients permitted to be prescribed buprenorphine under each waiver

type. The NP/PA waiver measure included both 30-patient and 100-patient waivers, the latter of which were introduced in 2018. Additional details are provided in the Appendix.

The available waiver data had three limitations. First, only current service addresses were available for waivered providers. Thus, if a provider changed service addresses between when they obtained their first waiver and when the data were obtained (March 2020), the duration of time providing service at the current address and any prior service addresses were unknown. Second, for retired waivers, the date of retirement was not available. As of the time the data were obtained, 504 MD/DO-30 and MD/DO-100 waivers had been retired, which do not affect our primary exposures. Third, if a provider had multiple service addresses that spanned multiple California counties, the waiver was assigned to each county in full, thus inflating the buprenorphine prescribing capacity in affected counties. Among waivered California providers present in publicly available treatment locator data in February 2021, only 1.3% of providers had multiple service addresses that spanned multiple counties (Substance Abuse and Mental Health Services Administration, 2021); thus, we do not expect this third limitation to have a substantial effect on our estimates.

Regarding the first two limitations, in the main analysis, we assigned waivers to counties based on the providers' current service addresses and did not account for possible past moves or waiver retirements. However, both of these limitations were addressed in a sensitivity analysis described below.

2.3. Outcomes

Our seven outcomes were the rates of unique buprenorphine prescribers, unique buprenorphine patients, total buprenorphine prescriptions, total opioid-related health events (including deaths, emergency department visits, and hospitalizations), and each of the individual types of health events separately. Detailed definitions of each outcome are provided in the Appendix.

Analyses of outcomes that included ICD-9 and ICD-10 codes (total opioid-related health events, emergency department visits, and hospitalizations) were restricted to the period from Q4 2015 through the end of 2018 to align with the transition from ICD-9 to ICD-10 codes on October 1, 2015. The transition from ICD-9 to ICD-10 resulted in notable discontinuities in trends of opioid-related health events identified using ICD codes (Heslin et al., 2017; Moore & Barrett, 2017). Analysis of these outcomes was restricted to the period after this transition to eliminate the risk of bias due to differential changes in coding practices across counties.

2.4. Statistical analysis

To examine the association between NP/PA and MD/DO-275 waiver capacity and each outcome, we fit 14 separate Poisson regression models with county and quarter fixed effects and a population offset (Wooldridge, 1999). The county fixed effects control for all time invariant differences between counties, whereas quarter fixed effects control for all county invariant differences over time (i.e., the secular trend). We employed a one quarter lag between independent and dependent variables for two reasons. First, a lag ensures correct temporal ordering between our exposures and outcomes, mitigating the possibility of reverse

causality. Second, we hypothesized a delay between the receipt of a waiver and the outcomes of interest and, absent any published data on the duration of this delay, a three month (i.e., one quarter) is both plausible and the shortest possible lag given our quarterly timescale. Thus, we modeled the association between waiver capacity measured in one quarter and outcomes measured in the subsequent quarter. Below, we refer to the quarter associated with the exposure as the exposure quarter and the subsequent quarter as the outcome quarter.

Each model controlled for the buprenorphine prescribing capacity rate associated with all waiver types other than the exposure waiver type during the exposure quarter, and unemployment rate (obtained as a monthly measure from the Bureau of Labor Statistics), percentage of residents with health insurance (obtained as an annual measure from the U.S. Census Bureau Small Area Health Insurance Estimates Program), and the non-buprenorphine opioid prescription rate in the quarter prior to the exposure quarter. Monthly unemployment rates were mapped to quarters by taking the mean monthly rate within each quarter; annual health insurance percentages were mapped to quarters by assigning annual values to each quarter of that year. To account for the possibility of confounding by past numbers of waivers, each model also controlled for the average value of the main exposure in the four prior quarters.

To control for county-level implementation of three concurrent initiatives that aimed to expand access to buprenorphine for the treatment of OUD in California, each model included indicator variables set to one from the quarter of implementation onwards and zero otherwise. A limitation of this approach is the assumption that implementation of these initiatives was the same across participating counties and that implementation occurred immediately without any meaningful ramp-up period; however, a more nuanced treatment of these initiatives was not feasible as part of this analysis. Details regarding the initiatives and implementation times for each county are provided in the Appendix (Table A.1).

The introduction of the new waivers coincided with increasing fentanyl-related mortality in California and, due to its high potency and erratic adulteration of other illicit substances, fentanyl presents challenges for existing overdose prevention strategies (e.g., lay naloxone distribution) (Fairbairn, Coffin, & Walley, 2017; Raheemullah & Andruska, 2019). To control for possible confounding by the presence of fentanyl for each of the four health outcomes, these models controlled for the proportion of opioid-related deaths involving fentanyl in the quarter prior to the exposure quarter. Here, we are using the proportion of opioid-related deaths involving fentanyl as a proxy for the presence of fentanyl in the illicit drug supply, for which there was no direct measure available.

We applied one quarter lags to all county-level covariates (except for the buprenorphine prescribing capacity rate associated with all waiver types other than the exposure waiver type and the three buprenorphine initiatives) to ensure that covariates preceded exposures and thus could not reside on the pathway between exposure and outcome.

In order to better capture associations between a single new NP/PA or MD/DO-275 waiver and our outcomes, regression coefficients associated with NP/PA waiver capacity were scaled to correspond to a 30-patient capacity increase in a median-sized California county

(186,620.5 residents), and those associated with MD/DO-275 waiver capacity were scaled to correspond to a 175-patient capacity increase. These numbers were selected because the majority of NP/PA waivers were new 30-patient limit waivers, and MD/DO-275 waivers correspond to a 175 patient increase from a 100-patient limit waiver. Examples of these calculations are provided in the Appendix. 95% confidence intervals and p-values were calculated using fully robust standard errors obtained from heteroscedasticity-consistent covariance matrices (Huber, 1967; White, 1980).

The full specification of the regression models is provided in the Appendix. This analysis was not pre-registered and results should be considered exploratory.

2.5. Subgroup analysis

To investigate differences in associations between each waiver type and our outcomes among metropolitan and nonmetropolitan counties, we fit models that included an interaction term between county metropolitan status and the primary exposure. Metropolitan status was defined using the United States Office of Management and Budget 2013 metropolitan and nonmetropolitan categories, which attempt to capture "urban" and "rural" counties (United States Department of Agriculture Economic Research Service, 2019; United States Office of Management and Budget, 2010). From these models, we present associations between exposures and outcomes separately among metropolitan and nonmetropolitan counties as well as the p-value for the interaction term.

2.6. Sensitivity analyses

To explore the associations between NP/PA and MD/DO-275 waiver capacities and our outcomes at an alternative timescale with less measure variability, we also fit models using six-month periods rather than quarters.

We used a probabilistic approach to assess the sensitivity of our results to the two limitations of the waiver data described above. Specifically, we used Census data to stochastically simulate provider moves and retirements over 1000 iterations and reported the 2.5% and 97.5% quantiles of the distributions of each exposure-outcome association estimate. Details are provided in the Appendix.

Lastly, one California county with a population of approximately 3000 residents had a single MD/DO-275 waiver. This single waiver corresponded to an associated prescribing capacity of over 9000 patients per 100,000 residents, nearly three times larger than the total prescribing capacity of any other county. To assess whether this single county was driving the results of our MD/DO-275 models in both the main and subgroup analyses, we also fit these models excluding this county.

2.7. Randomization inference

As an alternative approach to assessing the probability that our estimates were due to chance, we conducted a randomization inference procedure, which is described in the Appendix.

2.8. Multiple comparisons

We adjusted for multiple comparisons using the Benjamini-Hochberg (BH) method (Benjamini & Hochberg, 1995), which is described in the Appendix. For all estimates, we present the point estimates, 95% confidence intervals, and p-values as described above, and indicate whether the null hypothesis can be rejected at $p < 0.05$ after adjusting for multiple comparisons.

3. Results

3.1. Buprenorphine waivers in California

The cumulative number and number of new buprenorphine waivers by type and calendar quarter from 2010 to 2018 in California are presented in Fig. 1. The total number of buprenorphine waivers increased over the study period, with more rapid increases following the introduction of NP/PA and MD/DO-275 waivers. There were an average of 96.8 (SD = 32.3) new waivers per quarter before Q3 2016 when MD/DO-275 waivers were first introduced, and an average of 301.8 (SD = 58.2) new waivers per quarter from Q3 2016 through the end of 2018. Following their introductions, there were an average of 98.6 (SD = 18.1) and 22.9 (SD = 24.0) new NP/PA and MD/DO-275 waivers, respectively, per quarter across the state. At the end of 2018, there were 720 and 229 active NP/PA and MD/DO-275 waivers, respectively.

The total patient prescribing capacity rate (across all waiver types) at the end of the first quarter of 2010 and the end of the fourth quarter of 2018 for each county are presented in the Appendix (Fig. A.1). The total patient prescribing capacity rates segmented by waiver type for each county at the end of 2018 are also presented in the Appendix (Fig. A.2). There was extensive heterogeneity in the number and type of waivers across counties. The total prescribing capacity rate at the end of 2018 ranged from 120.1 to 3291.0 patients per 100,000 population across counties. The percentage of the total waiver capacity rate accounted for by NP/PA waivers ranged from 0% to 100% (Mean = 13.8; SD = 17.0), whereas that accounted for by MD/DO-275 waivers ranged from 0% to 82% (Mean = 18.2; SD = 19.5). These county-level summaries exclude the single outlier county that is also excluded in a sensitivity analysis.

3.2. Associations between NP/PA and MD/DO-275 waiver capacity and outcomes

Each additional NP/PA waiver (scaled to correspond to a median-sized county) was associated with a 2.2% (incidence rate ratio = 1.022, 95% confidence interval = 1.009–1.035) increase in the buprenorphine prescriber rate, a 1.4% (1.014, 1.001–1.027) increase in the buprenorphine patient rate, and a 1.9% (1.019, 1.003–1.035) increase in the total buprenorphine prescription rate in the subsequent calendar quarter (Fig. 2 and Table A.2). When scaled to the median California population size and outcome rates in Q4 2018, these point estimates correspond to an average increase of 0.97 buprenorphine prescribers, 6.9 buprenorphine patients and 12.8 buprenorphine prescriptions for each additional NP/PA waiver. After adjusting for multiple comparisons, only the prescriber rate was statistically significant at $p < 0.05$.

Each additional MD/DO-275 waiver was associated with a 3.1% increase in the buprenorphine prescriber rate (1.031, 1.015–1.047), a 4.1% increase in the buprenorphine patient rate (1.041, 1.028–1.053), and a 5.0% increase in the total buprenorphine prescription rate (1.050, 1.036–1.064). These point estimates correspond to an average increase of 1.4 buprenorphine prescribers, 20.1 patients receiving buprenorphine and 34.1 buprenorphine prescriptions for each additional MD/DO-275 waiver. After adjusting for multiple comparisons, all three associations were statistically significant at $p < 0.05$.

There were no statistically significant associations between NP/PA or MD/DO-275 waiver capacity and opioid-related health outcomes before or after adjusting for multiple comparisons. All unscaled regression coefficients and 95% confidence intervals for these primary models are present in Appendix (Table A.7).

3.3. Subgroup analysis

The results of our subgroup analysis among metropolitan and nonmetropolitan counties are presented in the Appendix (Table A.3). NP/PA waiver capacity was associated with an increase in the buprenorphine prescriber rate (1.026, 1.013–1.039), patient rate (1.021, 1.009–1.033), and total prescription rate (1.026, 1.011–1.041) among nonmetropolitan counties but not among metropolitan counties.

MD/DO-275 waiver capacity was associated with an increase in the buprenorphine prescriber rate (1.056, 1.039–1.073) among nonmetropolitan counties only, but was associated with the patient rate (metropolitan: 1.024, 1.009–1.040; nonmetropolitan: 1.047, 1.032–1.061) and total prescription rate (metropolitan: 1.028, 1.010–1.046; nonmetropolitan: 1.058, 1.041–1.074) among both metropolitan and nonmetropolitan counties.

The interaction terms representing the difference in exposure-outcome associations between metropolitan and nonmetropolitan counties were statistically significant at $p < 0.05$ for all buprenorphine prescription outcomes after adjusting for multiple comparisons.

3.4. Sensitivity analyses

Estimates obtained using six-month time periods were qualitatively similar to the main estimates obtained using quarters and are presented in the Appendix (Table A.4).

The results of our probabilistic sensitivity analysis were largely consistent with our main analysis results and are presented in the Appendix (Table A.5).

The results of the MD/DO-275 models excluding the single outlier county were nearly identical to the results of the main MD/DO-275 models as well as those stratified by metropolitan status (data not shown).

3.5. Randomization inference

The results of our randomization inference procedure were largely consistent with inference using robust standard errors and are presented in the Appendix (Table A.6 and Fig. A.3). However, the results suggest a > 0.05 probability that the associations between both NP/PA

(p = 0.080) and MD/DO-275 (p = 0.171) waiver capacities and the buprenorphine prescriber rate and between MD/DO-275 waiver capacity and buprenorphine prescriber rate were due to chance.

4. Discussion

We found that the number of waivered providers and the overall buprenorphine prescribing capacity increased substantially in California following the implementation of new national policies introducing the MD/DO-275 and NP/PA waivers, with extensive variability across counties. We also found positive associations between NP/PA waivers and buprenorphine prescribing among nonmetropolitan counties and positive associations between MD/DO-275 waivers and buprenorphine prescribing among both metropolitan and nonmetropolitan counties, though found no associations between these new waivers and opioid-related health outcomes. This is the first study to examine links between these novel buprenorphine waivers and buprenorphine prescribing and the first to examine links between any type of buprenorphine waiver and opioid-related health outcomes, which have implications for ongoing efforts to expand access to buprenorphine for the treatment of OUD.

The associations between both NP/PA and MD/DO-275 waivers and buprenorphine prescribing were stronger among nonmetropolitan counties relative to metropolitan counties. These findings are encouraging given that non-urban areas have persistently poorer access to medications for the treatment of OUD, both via opioid treatment programs and providers with buprenorphine waivers (Andrilla et al., 2019; Ghertner, 2019; Joudrey, Edelman, & Wang, 2019; Rosenblatt et al., 2015). Our NP/PA findings complement multiple studies that have explored the role of NP/PA waivers in rural areas. Specifically, one study found that NP/PA waivers accounted for the majority of increases in the rate of waivered providers in rural areas from 2016 to 2019 (Barnett et al., 2019) and another projected that NP/PA waivers will increase the number of rural patients treated with buprenorphine by 15% (Andrilla, Patterson, Moore, Coulthard, & Larson, 2020). Alternatively, the new 275-patient limit waivers were associated with increased prescribing in both metropolitan and non-metropolitanx counties, suggesting that patient limits may act as a barrier to expanded buprenorphine prescribing across multiple settings. Indeed, a survey among waivered providers found that 8% of respondents with a 100-patient waiver were prescribing at or near their patient limit, with no variability by urbanicity detected in a multivariable analysis (Jones & McCance-Katz, 2019). Ultimately, our findings suggest that NP/PA and MD/DO-275 waivers are important tools for expanding buprenorphine prescribing in nonmetropolitan counties, where access is more constrained, while MD/DO-275 waivers also appear to be effective in metropolitan counties.

We found no statistically significant associations between either NP/PA or MD/DO-275 waivers and opioid-related health outcomes. Numerous studies have linked OUD treatment with methadone or buprenorphine with lower risk of opioid-related health encounters and mortality at the individual level (Krawczyk et al., 2020; Pearce et al., 2020; Samples, Williams, Crystal, & Olfson, 2020; Sordo et al., 2017; Williams, Samples, Crystal, & Olfson, 2020), but studies demonstrating meaningful population-level associations are limited (Schwartz et al., 2013). The translation of individual-level benefits to shifts in

population-level outcomes depends on a variety of factors, including the number of individuals that receive sustained treatment in a given population. The first MD/DO-275 and NP/PA waivers were granted in California in late 2016 and early 2017, respectively; thus, we were only able to assess outcomes during the first two years following the introduction of these waivers. As of September 2018, only 3.2% and 1.7% of all nurse practitioners and physician assistants, respectively, possessed waivers to prescribe buprenorphine, which both lag behind the 5.6% of physicians with waivers (Spetz, Toretsky, Chapman, Phoenix, & Tierney, 2019). Similarly, only 7% of all waivers carried a 275-patient limit as of February 2021 (Substance Abuse and Mental Health Services Administration, 2020). Delays between the introduction and broader utilization of these novel waiver types could explain the absence of associations with health outcomes; thus, it is important for future research to investigate these associations over a longer time-frame. Although we found no associations between these waivers and downstream health outcomes, medications for the treatment of OUD remain underutilized and our findings linking these waivers to increased buprenorphine prescribing are a promising indication that the policies have been effective.

The introduction of NP/PA and MD/DO-275 waivers aimed to increase buprenorphine access by increasing the number and prescribing capacity of buprenorphine prescribers, respectively. However, the supply and prescribing capacity of prescribers are only two of a wide array of constraints that inhibit broader buprenorphine utilization. Several studies have also highlighted a lack of training and support among providers (Barry et al., 2009; Cunningham, Kunins, Roose, Elam, & Sohler, 2007; Cunningham, Sohler, McCoy, & Kunins, 2006; DeFlavio, Rolin, Nordstrom, & Kazal Jr., 2015; Gordon et al., 2011; Haffajee, Bohnert, & Lagisetty, 2018; Hutchinson, Catlin, Andrilla, Baldwin, & Rosenblatt, 2014; Mendoza, Rivera-Cabrero, & Hansen, 2016; Netherland et al., 2009; van Boekel, Brouwers, van Weeghel, & Garretsen, 2013; Yang, Arfken, & Johanson, 2013), poor care coordination (Barry et al., 2009; Cunningham et al., 2007; Gordon et al., 2011; Haffajee et al., 2018; Hutchinson et al., 2014; Mendoza et al., 2016; Netherland et al., 2009; Quest, Merrill, Roll, Saxon, & Rosenblatt, 2012; Yang et al., 2013), inadequate reimbursement (Arfken, Johanson, di Menza, & Schuster, 2010; Barry et al., 2009; Gunderson, Levin, Kleber, Fiellin, & Sullivan, 2006; Haffajee et al., 2018; Netherland et al., 2009; Quest et al., 2012), and stigma among both providers (Cunningham et al., 2007; DeFlavio et al., 2015; Gordon et al., 2011; Haffajee et al., 2018; Kissin, McLeod, Sonnefeld, & Stanton, 2006; Mendoza et al., 2016; Yang et al., 2013) and patients (Link, Struening, Rahav, Phelan, & Nuttbrock, 1997; Luoma et al., 2007) as key barriers to buprenorphine treatment. As such, isolated efforts addressing only single barriers are not likely to result in the large population-level increases in treatment utilization that are needed to combat the ongoing opioid crisis. For example, although Medicaid expansion has been linked to increased buprenorphine prescribing, one study found that this association may have been constrained by the number of waivered providers (Gertner et al., 2020; Saloner, Levin, Chang, Jones, & Alexander, 2018). Despite the likely limited effectiveness of singular interventions, we did find that the introduction of NP/PA and MD/DO-275 waivers was associated with increased buprenorphine prescribing. These findings highlight the possibility that further expansion of buprenorphine prescribing, possibly by way of deregulation (Davis & Carr, 2019; Fiscella, Wakeman, & Beletsky, 2019; Stancliff, Greene, & Zucker, 2019), could be an effective means to increase access.

Our study has several limitations. First, data are from administrative data sources, which are not collected for research purposes and may be subject to inaccuracies; however, leveraging these data are the only viable way to evaluate population-level associations and we have no specific reason to suspect the presence of systematic measurement error that would bias our findings. Second, our study is ecological in nature so we cannot confirm that the new NP/PA and MD/DO-275 waivered providers contributed directly to subsequent changes in individual outcomes. Third, we could not confirm where each provider practiced between their waiver date and when the data were obtained in 2020 or whether they retired, but we attempted to rigorously address this limitation in a sensitivity analysis and our results were unchanged. Fourth, our main exposures were inflated for some counties due to how the available data handled providers with multiple service addresses that spanned multiple counties; however, these providers appear to be rare and so we don't expect this to have a substantial effect on our estimates. Fifth, our results are specific to the state of California and not necessarily generalizable to other states or the U.S. overall.

5. Conclusion

The present study employed a rigorous analysis approach that incorporated temporal ordering and controlled for all time invariant, county invariant, and important time-varying confounders and found that NP/PA waivers were associated with increased buprenorphine among nonmetropolitan counties and MD/DO-275 waivers were associated with increased prescribing among both metropolitan and nonmetropolitan counties. These findings highlight the benefits of expanding the buprenorphine waiver program to include these new waiver types and suggest that efforts to increase their adoption may lead to increased buprenorphine utilization.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funding

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Fig. 1.
Parts A-B: (Part A) Total number of buprenorphine waivers and (Part B) number of new buprenorphine waivers by type and calendar quarter, California 2010–2018.

Fig. 2.

Fixed effects Poisson regression results estimating associations between waiver capacities and buprenorphine prescribing and opioid-related health outcomes, California, 2016–2018.
*Null hypothesis rejected at p<0.05 when accounting for multiple comparisons using Benjamini-Hochberg method.
†Single waiver corresponds to a 30 patient increase in prescribing capacity for NP/PA waivers and a 175 patient increase in prescribing capacity for MD/DO-275 waivers in a median-sized California county.