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Title: Effects of state opioid prescribing cap laws on opioid prescribing after surgery

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Structured abstract

Objective: To evaluate the effects of state opioid prescribing cap laws on opioid prescribing after surgery.

Data sources: OptumLabs® Data Warehouse administrative claims data covering all 50 states from July 2012 through June 2019.

Study Design: We included individuals from 20 states that had implemented prescribing cap laws without exemptions for postsurgical pain by June 2019 and individuals from 16 control states plus the District of Columbia. We used a difference-in-differences approach accounting for differential timing in law implementation across states to estimate the effects of state prescribing cap laws on postsurgical prescribing of opioids. Outcome measures included filling an opioid prescription within 30 days after surgery; filling opioid prescriptions of specific doses or durations; and the number, days' supply, daily dose, and pill quantity of opioid prescriptions. To assess the validity of the parallel counterfactual trends assumption, we examined differences in outcome trends between law-implementing and control states in the years preceding law implementation using an equivalence testing framework.

Data Collection/Extraction methods: We included the first surgery in the study period for opioid-naïve individuals undergoing one of eight common surgical procedures.

Principal Findings: State prescribing cap laws were associated with 0.109 lower days' supply of postsurgical opioids on the log scale (95% Confidence Interval (CI): -0.139, -0.080) but were not associated with the number (Average treatment effect on the treated (ATT): -0.011; 95% CI: -0.043, 0.021) or daily dose of postsurgical opioid prescriptions (ATT: -0.013; 95% CI: -0.030, 0.005). The negative association observed between prescribing cap laws and the probability of

filling a postsurgical opioid prescription (ATT: -0.041; 95% CI: -0.054, -0.028) was likely

spurious, given differences between law-implementing and control states in the pre-law period.

Conclusions: Prescribing cap laws appear to have minimal effects on postsurgical opioid

prescribing.

Keywords: opioid, law, postsurgical pain, difference-in-differences, causal inference

What is known on this topic:

- Single-state studies have found that state opioid prescribing cap laws have reduced the

  prescribing of opioids for postsurgical pain.

- No study has evaluated the overall effects of state opioid prescribing cap laws on

  postsurgical opioid prescribing across all states with such laws in the U.S.

What this study adds:

- State opioid prescribing cap laws have led to minimal reductions in the days' supply of

  postsurgical opioid prescriptions but have not affected the number nor the daily dose of

  postsurgical opioid prescriptions.

- State opioid prescribing cap laws may have limited to no effects on the postsurgical

  prescribing of opioids.

Introduction

Higher doses and longer durations of opioid prescriptions are associated with greater risks of long-term opioid therapy, non-medical opioid use, and opioid overdose.[1,2] To reduce the potential negative consequences of opioid prescribing, many states have implemented prescribing cap laws limiting the allowable dose or duration of opioid prescriptions. Thirty-nine states had implemented such a law through 2019.[3] These laws vary in stringency and the prescriptions to which they apply. For example, some laws limit just the duration, while others limit both the dose and duration.[3] While all laws concern acute pain, some apply limits only to the initial prescription.[3] Most laws exempt certain groups of patients (e.g., cancer patients), and many allow providers to override the limits according to their professional judgment.[3]

Studies on prescribing cap laws conducted using general population samples have reported null or small effects on opioid prescribing.[4,5] However, because the laws pertain to restricted sets of prescriptions, analyses of their effects in the overall population may mask their effects in pertinent subgroups. One subgroup of interest is people receiving opioids to manage postsurgical pain. One study estimated that the incidence of long-term opioid therapy following initial postsurgical exposure was 6%.[6] Furthermore, many opioids prescribed for postsurgical pain are never taken.[7,8] Yet opioids may be necessary to control some patients' postsurgical pain adequately. Recent clinical guidelines emphasize caution in the use of opioids to treat postsurgical pain and recommend the use of nonopioid analgesics when appropriate.[9,10] Some state prescribing cap laws subject opioid prescriptions for postsurgical pain to the same restrictions as other prescriptions for acute pain; other state prescribing cap laws exempt or provide different restrictions for postsurgical prescriptions.

The emerging literature on the effects of these laws on postsurgical opioid prescribing has suggested they have reduced the amount of opioids prescribed.[11-21] Most studies evaluated a single state's law using data from a single institution. No study has evaluated the overall effects of prescribing cap laws on postsurgical prescribing across all states that have implemented them.

Many aspects of the policy context threaten the validity of such a study. Opioid prescribing has been scrutinized given its role in the overdose crisis, and prescribing practices are changing for reasons other than prescribing cap laws, such as changing clinical guidelines and professional norms.[22,23] Moreover, the extent of these changes varies across states.[24,25] States that have implemented laws have done so on different dates for reasons unknown to us. In this study, we examined whether state prescribing cap laws enacted by June 2019 had on average caused changes in the prescribing of opioids to manage postsurgical pain. In this article, we highlight the challenges inherent to this evaluation, explicate the reasons for our methodological decisions, then report and discuss the results of our analyses.

Methods

Data

We used de-identified administrative claims from the OptumLabs® Data Warehouse (OLDW), which includes enrollment records and medical and pharmacy claims for more than 200 million commercial and Medicare Advantage enrollees.[26] The data include beneficiaries from all 50 U.S. states plus the District of Columbia (DC).

Exposure

To determine which of the 50 states and DC had implemented prescribing cap laws and to characterize those laws, we used state law data previously collected by two public health attorneys.[3] This data was collected and updated for this study using standard legal research methods, including searches in the Westlaw legal database of each state's statutes and regulations. These methods have been described elsewhere.[3,27,28]

We identified 38 states that had implemented opioid prescribing cap laws for adults by 12/31/2019 (Appendix A). We excluded 12 implementing states whose laws exempted postsurgical prescriptions. Because our analytic strategy (described below) required that states implemented laws contemporaneously with other states, we further excluded the 2 states that implemented laws before 7/1/2016. We classified the 4 states that implemented laws after 6/30/2019 as non-implementing states. We therefore included 20 states as law-implementing states and 16 states plus DC as non-implementing states.

Sample

We used Scully et al.'s algorithm of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology codes to identify individuals from the 36 included states and DC undergoing one of the following eight surgical procedures between 7/1/2012 and 6/30/2019: cholecystectomy, appendectomy, inguinal hernia repair, anterior cruciate ligament reconstruction, rotator cuff repair, discectomy, mastectomy, and hysterectomy.[29] Author M.C.B., a chronic pain specialist, mapped the ICD-9-

CM codes to ICD-10 Procedure Coding System codes. We included only the first surgery per individual during this period that had not occurred within two days of another surgery. Individuals with continuous medical and pharmacy coverage over the 60 days preceding and the 30 days following the surgery date were eligible for inclusion. To exclude individuals who may have been on long-term opioid therapy, we excluded a surgery from the sample if the individual had filled an opioid prescription 31-60 days before the procedure.

Outcomes

For each individual/surgery, we defined 13 opioid-related outcomes. We identified opioid medications for inclusion and defined their morphine milligram equivalents (MME) conversion factors using the Centers for Disease Control and Prevention Opioid and Oral MME Conversion File.[30] We excluded buprenorphine-naloxone products and the buprenorphine products Probuphine and Subutex because they are primarily used to treat opioid use disorder instead of pain. We measured the receipt of any opioid prescription to manage postsurgical pain, defined as an opioid prescription filled within 30 days before or after the surgery date. We included prescriptions filled within 30 days before the surgery because surgeons often prescribe opioids to patients preoperatively.[6,31-34] The other outcomes were measured only for individuals who filled an opioid prescription. We calculated the total number of opioid prescriptions filled, the total pill quantity, the total days' supply (adjusting for days with more than one prescription), and the average MME per day. We measured whether any of the opioid prescriptions had greater than 3, 5, 7, or 30 days' supply, and whether any of the opioid prescriptions averaged greater than 30,

50, 90, or 200 MME per day. These cutpoints were chosen because clinical guidance has highlighted their association with risk of opioid misuse and overdose.[2]

Notation and Estimand

We now describe the analysis we repeated for each outcome. Let Law_j indicate whether state j implemented a prescribing cap law, $Time_t = \{pre, post\}$ indicate whether individual i's surgery occurred before or after law implementation, and define $Y_{i,j,post}(1)$ and $Y_{i,j,post}(0)$ as the individual's potential outcomes in the post period had they been exposed and unexposed to the law, respectively. For ease of exposition, we interchangeably refer to the law as the treatment and individuals from law-implementing states as the treated or treatment group.

Our estimand is the average difference between the two potential outcomes among individuals from law-implementing states — i.e., the average treatment effect on the treated (ATT):

$$ATT = E[Y_{i,j,post}(1) - Y_{i,j,post}(0) \mid Law_j = 1]. \quad (1)$$

Difference-in-differences identification strategy

Among those with $Law_j = 1$ in our sample, $Y_{i,j,post}(0)$ is unobserved, so we must identify a proxy for $E[Y_{i,j,post}(0) \mid Law_j = 1]$. We do not understand thoroughly the factors that both motivate states to enact prescribing cap laws and influence providers' opioid prescribing. We prefer an identification strategy, then, that does not require the assumption that we have

observed all such confounders. The difference-in-differences design instead requires us to identify a control group of individuals unexposed to a prescribing cap law and whose average change in outcome from the pre-law period to the post-law period represents the average change that would have occurred for the treatment group over the corresponding period.

Several features of our data setting complicate the study design. Differential trends in opioid prescribing have been observed across states during the years preceding the introduction of prescribing cap laws.[24,25] While the difference-in-differences design does not require that the pre-law trends of the treatment and control groups are parallel,[35] demonstrating such parallelism supports the validity of the assumption that, absent the law, the trends would have continued on the same trajectory in the post-law period.

Furthermore, in the classic difference-in-differences setup, all units have the same pre and post period. The 20 law-implementing states in our study, however, enacted their laws on 17 unique dates. In such instances of staggered treatment adoption, investigators typically estimate treatment effects using models that include fixed effects for states and for time periods. These models can have "static" specifications with one treatment effect parameter or "dynamic" specifications with treatment effect parameters for each time period relative to treatment initiation (i.e., event studies). Recent studies have demonstrated the static estimator is biased when treatment effects are heterogeneous across states or time,[36-38] and the estimate of each relative time effect in the dynamic estimator is contaminated by the effects in the other relative periods.[39] Hence, methodologists have developed improved estimators that divide states implementing the treatment simultaneously into separate cohorts, estimate treatment effects separately for each cohort, then average the cohort-specific effects across cohorts.[39,40]

However, surgeries from less populous states are infrequent enough in our data that we do not think some of the state-level averages are reliable measurements of state-level opioid prescribing. Were we to form separate cohorts for the 17 distinct implementation dates, the sample sizes for some cohorts would be too small to ensure reliable outcome measurements and assess confidently whether pre-law trends were parallel.

Defining cohort-specific and overall effects

To address the issue of staggered adoption in a way that preserves adequately large sample sizes, we create cohorts of states that implemented their laws during the same interval of time instead of on the same date. For each cohort, we then estimate a cohort-specific ATT using a two-group, two-period difference-in-differences design.

Before we discuss details of the cohort-specific designs, including how we define the study periods and construct the treatment and control groups, we explain our strategy for estimating the cohort-specific effects and the overall effect.

We define c in $1, \dots, C$ such that ATT_c is the cohort-specific ATT and V_c is the variance of ATT_c for cohort c. We use the following difference-in-differences estimator to estimate each ATT_c:

$$\widehat{ATT_c} = \{E[Y_{ijt}|\ Law_j = 1, Time_t = post] - E[Y_{ijt}|\ Law_j = 1, Time_t = pre]\} -$$
$$\{E[Y_{ijt}|\ Law_j = 0, Time_t = post] - E[Y_{ijt}|\ Law_j = 0, Time_t = pre]\} . (2)$$

We assume each $\widehat{ATT_c}$ estimates the *ATT* defined in (1). We therefore adopt methods from common-effect meta-analysis to aggregate the cohort-specific estimates. Were the cohort-specific effects independent, the maximum likelihood estimate of the common effect would be the inverse-variance-weighted average of the cohort-specific effects: $\widehat{ATT} = \sum_c w_c ATT_c$, with $w_c = V_c^{-1}$. Since the implementation dates are near one another and the number of potential control states is limited, the control groups will likely overlap across cohorts, in which case the cohort-specific ATTs will be correlated. When study-specific effects are correlated, the linear estimator of the common effect with the smallest asymptotic variance instead uses the weights:

$$w_c = \mathbf{1}^T \widehat{\Omega}^{-1} / \mathbf{1}^T \widehat{\Omega}^{-1} \mathbf{1}, \qquad (3)$$

where $\mathbf{1}$ is the c-vector of 1s and $\widehat{\Omega}$ is the estimated covariance matrix of the cohort-specific ATTs.[41,42]

Defining the cohorts

For each cohort, we must choose a baseline demarcating the pre and post periods. Since the implementation dates among the states in the cohort differ, the chosen baseline will fall in the actual pre or post period for most states. Dividing the law-implementing states into separate cohorts thus requires a balance between grouping together only those states whose implementation dates are near one another and grouping together enough states to attain adequately large samples.

By dividing the law-implementing states into three cohorts and defining the baselines to be the same distance apart as the length of the pre and post periods, we attempt this balance in a way that allows us to derive an estimator for the covariance between the cohort-specific ATTs of adjacent cohorts. Specifically, we set baseline for Cohorts 1, 2, and 3 to be 7/1/2016, 7/1/2017, and 7/1/2018, respectively. We allocate the 6 states that implemented laws between 7/1/2016 and 4/1/2017 to Cohort 1, the 7 states that implemented laws between 5/16/2017 and 1/1/2018 to Cohort 2, and the 7 states that implemented laws between 7/1/2018 and 1/1/2019 to Cohort 3. For states whose true implementation date differs from their cohort's baseline, we exclude surgeries occurring between those two dates. We otherwise include surgeries occurring in the year before baseline in the pre period and surgeries occurring in the year following baseline in the post period.

We use the same 16 states plus DC as the control group for each cohort. Table 1 and Appendix C display the surgeries included in each cohort. Note the surgeries comprising the control group in the post-law period for Cohort 1 are the same surgeries that comprise the control group in the pre-law period for Cohort 2. Otherwise, the ATTs for Cohorts 1 and 2 are estimated using different data. Their covariance, then, equals the covariance of the mean outcome among the post-period control group surgeries in Cohort 1 and the mean outcome among the pre-period control group surgeries in Cohort 2; this covariance is negative because per (2), we subtract the former to estimate ATT_1 and add the latter to estimate ATT_2. As these two subgroup means are equal in expectation, their covariance is equal to the negatives of each of their variances; it can thus be estimated using the variances of the parameters used to estimate the subgroup means. ATT_2 and ATT_3 covary in the same manner; ATT_1 and ATT_3 are independent.

Estimating the cohort-specific and overall ATTs

For each outcome within each cohort, we fit a linear regression model including indicators for treatment group, post-law period, and their interaction, which estimates the cohort-specific ATT. We estimated the variances of the cohort-specific ATTs and the control-subgroup parameters by nonparametrically bootstrapping each cohort. We estimated the overall ATT and its variance using the weights defined in (3).[42] As the covariance of the ATTs for the adjacent cohorts can be estimated in either cohort, we used the average of the two estimates in the covariance matrix used to estimate the overall ATT. All analyses were performed using R version 4.0.3.

Equivalence testing

To examine our assumption that the control groups provide adequate counterfactuals for the treatment groups, we statistically assessed how parallel their trends were during the 3 years before baseline. Specifically, we replicated our analysis using three artificial baseline dates during the pre-law period: 24 months, 18 months, and 12 months before baseline, respectively. If the pre-period trends are parallel, the three estimated pre-period ATTs should be zero. Collectively, they inform us of differential pre-period trends we might expect to continue in the post period.

We tested these three pre-period ATTs using an equivalence testing framework.[43,44] Equivalence testing provides a stricter test of whether pre-law trends are parallel than difference testing. The null hypothesis in the equivalence test is that the pre-period ATT is nonzero. Thus,

demonstrating it is zero or negligibly nonzero (i.e., equivalent) yields stronger evidence of parallel pre-law trends.

Because an equivalence test at significance level α corresponds with the 100(1-2α)% confidence interval for the ATT, we can avoid the subjective exercise of choosing equivalence bounds for the test. Using $\alpha = .05$, the bound of the 90% confidence interval with the greater absolute value is the minimum equivalence bound we could choose that would lead us to reject the null hypothesis of no difference. We thus have evidence at the .05 level that the true pre-period ATT of interest does not exceed this value; the smaller the value, the stronger the evidence the trends are parallel over that period. By providing the smallest equivalence range supported by the data, we let the reader judge whether the pre-period ATT is meaningfully different from zero.[43]

Robustness checks

We performed four separate robustness checks. First, to examine whether the effects of prescribing cap laws differ according to whether they impose dose restrictions, we stratified the 20 law-implementing states according to whether they limit just the duration (n=12) or both the dose and duration (n=8) of opioid prescriptions, then replicated the main analyses within each stratum. Second, in case we had inadvertently included patients on long-term opioid therapy, we excluded individuals who had been prescribed an opioid 61-180 days before their surgery, then replicated the main analyses. Third, since some states have recently implemented other laws designed to affect opioid prescribing (i.e., pill mill laws and mandatory prescription drug monitoring program (PDMP) query laws),[27] we restricted our sample to individuals from the 9

law-implementing and 12 control states plus DC that had not implemented such laws during the

two-year study period of any cohort in which they were included (Appendix B), then replicated

the main analyses. Fourth, to examine whether the results are sensitive to potential state-level

confounding, we included terms for the following state-level covariates in our outcome models:

proportion of adults 18-64 below the federal poverty level; proportion uninsured; proportion

white; and proportion of adults without a 4-year college degree.[45] Since after conditioning on

covariates we could no longer estimate the covariance of the cohort-specific ATTs using the

variances of the subgroup mean parameters, we estimated these covariances empirically by

nonparametrically bootstrapping the entire dataset.

Results

We included 55,966 surgeries in our main analyses, 10,152 and 9,569 of which were for

individuals from law-implementing states during the pre-law and post-law periods, respectively.

Among the 36,245 surgeries included from control states, 18,888 were included in the pre-law

period in one cohort and the post-law period in another cohort, such that we included 27,087 and

28,046 surgeries for individuals from control states during the pre-law and post-law periods,

respectively. Summary measures of descriptive characteristics and outcomes for the individuals

in each of these four groups (law-implementing/control and pre-law/post-law) are presented in

Table 2. The groups were not substantially different in average age, proportion female,

prevalence of mental illness, prevalence of substance use disorder, and average Elixhauser

comorbidity score; all standardized mean differences between the law-implementing, pre-law

group and the other three groups were less than 0.15 (data not shown).

Probability and number of opioid prescriptions

The results of our main analyses and the pre-period equivalence testing are presented in Table 3. State prescribing cap laws were associated with a 0.041 lower probability of filling a postsurgical opioid prescription (95% Confidence Interval (CI): -0.054, -0.028). There was evidence of a negative trend in the years preceding law implementation: being from a law-implementing state was associated with a 0.033 lower probability of filling a postsurgical opioid prescription in the year before law implementation, and a difference as great as 0.044 during this time could not be ruled out. Trends in the probability of filling an opioid prescription for the law-implementing and control states are displayed for each cohort in Figure 1. There was no apparent difference in pre-period trends in the number of postsurgical opioid prescriptions (Appendix D Figure 1), and prescribing cap laws were not associated with a significant difference in the number of postsurgical opioid prescriptions (ATT: -0.011; 95% CI: -0.043, 0.021).

Dose-related outcomes

The estimated association between prescribing cap laws and log-transformed MME per day was not significantly different from zero (ATT: -0.013; 95% CI: -0.030, 0.005) and was similar to estimated differences in pre-law trends (Appendix D Figure 2). Prescribing cap laws were associated with a 0.022 lower probability of filling a postsurgical opioid prescription with greater than 30 MME per day (95% CI: -0.030, -0.006) and a 0.037 lower probability of filling a prescription with greater than 50 MME per day (95% CI: -0.053, -0.021). Pre-period trends were

similar between groups for the probability of a prescription with greater than 30 MME per day (Appendix D Figure 3). The between-group difference in pre-period trends for the probability of a prescription with greater than 50 MME per day (Figure 2) was smaller than the estimated association. Prescribing cap laws were not associated with the probability of filling a prescription with greater than 90 MME per day (ATT: -0.006; 95% CI: -0.014, 0.002). Their association with the probability of a prescription with greater than 200 MME per day was practically zero (ATT: 0.001; 95% CI: 0.000, 0.002).

Duration-related outcomes

State prescribing cap laws were associated with 0.109 lower days' supply of postsurgical opioids on the log scale (95% CI: -0.139, -0.080), which corresponds to a negative difference of about 10% in days' supply. This exceeded the difference in pre-law trends (Appendix D Figure 4), which was no greater than 0.032 according to the pre-period equivalence testing. Similarly, prescribing cap laws were associated with 0.117 fewer total pills prescribed on the log scale (95% CI: -0.146, -0.088), which exceeded the difference in trends before the law. Prescribing cap laws were negatively associated with the probability of filling an opioid prescription with greater than 3 days' supply (ATT: -0.083; 95% CI: -0.097, -0.069), 5 days' supply (ATT: -0.066; 95% CI: -0.083, -0.048), or 7 days' supply (ATT: -0.070; 95% CI: -0.086, -0.054) to an extent that exceeded any differences in trends in the years preceding the law (Figure 2 and Appendix D Figure 5). Prescribing cap laws were not associated with the probability of filling an opioid prescription with greater than 30 days' supply (ATT: -0.001; 95% CI: -0.003, 0.001).

Robustness checks

Associations between state prescribing cap laws limiting just the duration of opioid prescriptions and opioid prescribing outcomes were similar to those observed for all prescribing cap laws taken together (Appendix E). Among states with laws limiting both the dose and duration of opioid prescriptions, prescribing cap laws were associated with less log-transformed MME per day (ATT: -0.077; 95% CI: -0.116, -0.039) and lower probabilities of filling a prescription with greater than 30 MME per day (ATT: -0.053; 95% CI: -0.088, -0.018), 50 MME per day (ATT: -0.066; 95% CI: -0.101, -0.032), or 90 MME per day (ATT: -0.034; 95% CI: -0.052, -0.015). Estimated associations between laws limiting both the dose and duration of opioid prescriptions and the duration-related outcomes were negative but were attenuated relative to those in our main analyses and were usually smaller than the pre-period equivalence bounds (Appendix F). Results of the analyses restricted to states that did not implement a pill mill law or mandatory PDMP query law during the study period were similar to the results limited to states with laws limiting both the dose and duration of opioid prescriptions (Appendix G). Results of the analyses excluding patients prescribed an opioid during the 180 days before their surgery date (Appendix H) and the analyses controlling for state-level covariates (Appendix I) were similar to our main results.

Discussion

In this national sample of individuals insured through commercial or Medicare Advantage plans undergoing common surgical procedures, we found that state opioid prescribing

cap laws were associated with some measures of postsurgical opioid prescribing but not others. We found small negative associations between prescribing cap laws and the probability of receiving any postsurgical opioid prescription, the probability of an opioid prescription being for a dose greater than 30 or 50 MME per day, the days' supply of the opioid prescriptions, the probability of an opioid prescription having greater than 3, 5, or 7 days' supply, and the quantity of pills prescribed. We observed no association between prescribing cap laws and the number of postsurgical opioid prescriptions, the MME per day of opioid prescriptions, and the probability of receiving an opioid prescription for greater than 90 or 200 MME per day or for greater than 30 days.

Except for the probability of filling any opioid prescription, all outcomes evolved similarly between law-implementing states and control states in the years preceding law implementation. We are thus comfortable with our assumption that these outcome trends would have continued to evolve in parallel absent the law. Our findings therefore support causal interpretations of the observed associations between prescribing cap laws and all outcomes except the probability of filling any opioid prescription. We likewise conclude that prescribing cap laws did not affect the outcomes for which no associations were observed. As the negative association observed for the probability of filling any opioid prescription was consistent with the increasingly negative difference in the trend of this outcome between law-implementing states and control states in the years preceding the laws, we do not conclude that the negative association observed for this outcome represents a causal effect of prescribing cap laws.

These effects of prescribing cap laws on postsurgical opioid prescribing are consistent with the specific restrictions imposed by the law-implementing states. While all states limit the days' supply of opioid prescriptions, less than half limit the dose.[3] The observed effects on

duration-related outcomes may be attributable to the ubiquity of duration limits among the laws, whereas more restrictions on dose among states may be required to observe clinically meaningful reductions in dose-related outcomes. The results of our stratified analyses — in which laws limiting both the dose and duration of opioid prescriptions led to small reductions in dose-related outcomes, but laws limiting merely the duration did not — support this interpretation.

The results of this study are inconsistent with null findings from prior evaluations of the laws using general population samples,[4,5] but are broadly consistent with single-state evaluations that have concluded that prescribing cap laws have reduced the amount of opioids prescribed postsurgically.[11-21] The discrepancy in results may be because most laws are intended to govern prescriptions for acute pain like postsurgical pain, whereas general population samples include a mix of people being treated for acute and chronic pain. However, the reductions in postsurgical opioid prescribing observed in our study were minimal, and theories that have been offered to explain the lack of effects in general samples may apply to postsurgical prescriptions as well. For example, a qualitative study in which representatives from state agencies were interviewed identified the complexity of the laws and insufficient information technology infrastructure as barriers to implementation and enforcement of prescribing cap laws.[46] That the complexity of the laws has been identified as a limitation is important given concerns that the simple one-size-fits-all nature of the laws is insufficient for patient populations with heterogeneous pain needs.[47] Even when implemented and enforced as intended, the limits may be set at levels higher than providers would prescribe for most patients anyway; however, setting stricter limits increases the risk that pain is controlled inadequately for patients with greater need.

Because we used claims data in this study, we were not able to examine the effects of the laws on patient-reported pain outcomes that could inform these concerns about pain control.

Further, because the claims data covered only commercial and Medicare Advantage insurance plans, the results may not generalize to other populations such as those who are uninsured or are insured by Medicaid. Other limitations of our study include the one-year post-law period we used to measure outcomes, which precluded us from examining longer-term effects. Lastly, the definition of our cohorts entailed that certain law-implementing states contributed fewer than two years of data and that two law-implementing states were excluded from our analyses.

Conclusions

The implementation of opioid prescribing cap laws led to minimal reductions in the days' supply of postsurgical opioid prescriptions, but the laws did not affect the number or daily dose of these prescriptions. While incorporating more and stricter limits on the dosage of opioid prescriptions into the laws may lead to similarly minimal reductions in dose-related outcomes, prescribing cap laws are likely insufficient to eliminate high-risk postsurgical opioid prescribing.

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Table 1. States included in each cohort and ranges of surgery dates included in the sample for each state.

Cohort	State	Range of surgery dates included	
		Pre-law period	Post-law period
Cohort 1	CT	07/01/2015 – 06/30/2016	07/01/2016 – 06/30/2017
(Baseline: 07/01/2016)	NY	07/01/2015 – 06/30/2016	07/22/2016 – 06/30/2017
	NH	07/01/2015 – 06/30/2016	01/01/2017 – 06/30/2017
	PA	07/01/2015 – 06/30/2016	01/03/2017 – 06/30/2017
	RI	07/01/2015 – 06/30/2016	03/22/2017 – 06/30/2017
	DE	07/01/2015 – 06/30/2016	04/01/2017 – 06/30/2017
	Control states[†]	07/01/2015 – 06/30/2016	07/01/2016 – 06/30/2017
Cohort 2	NJ	07/01/2016 – 05/15/2017	07/01/2017 – 06/30/2018
(Baseline: 07/01/2017)	MD	07/01/2016 – 05/24/2017	07/01/2017 – 06/30/2018
	AK, IN	07/01/2016 – 06/30/2017	07/01/2017 – 06/30/2018
	LA	07/01/2016 – 06/30/2017	08/01/2017 – 06/30/2018
	NC, NV	07/01/2016 – 06/30/2017	01/01/2018 – 06/30/2018
	Control states[†]	07/01/2016 – 06/30/2017	07/01/2017 – 06/30/2018
Cohort 3	FL, MI, TN	07/01/2017 – 06/30/2018	07/01/2018 – 06/30/2019
(Baseline: 07/01/2018)	AR	07/01/2017 – 06/30/2018	08/15/2018 – 06/30/2019
	MO	07/01/2017 – 06/30/2018	08/28/2018 – 06/30/2019
	MS	07/01/2017 – 06/30/2018	10/28/2018 – 06/30/2019
	WA	07/01/2017 – 06/30/2018	01/01/2019 – 06/30/2019
	Control states[†]	07/01/2017 – 06/30/2018	07/01/2018 – 06/30/2019

[†]Control states include AL, CA, DC, GA, IA, ID, KS, MN, MT, ND, NE, NM, OR, SD, TX, WI, WY.

Table 2. Descriptive characteristics and outcomes of the study sample grouped by whether subjects were from a law-implementing state and whether their surgery occurred before or after the law was implemented

	Law states, pre-law period (N=10,152)	Law states, post-law period (N=9,569)	Control states, pre-law period (N=27,087)	Control states, post-law period (N=28,046)
Descriptive characteristics				
Mean age	59.6	61.6	57.3	58.5
Percentage female	55.9	54.6	56.2	55.9
Percentage with any mental illness	16.7	17.6	15.3	16.3
Percentage with any substance use disorder	2.3	2.1	2.0	1.5
Mean Elixhauser comorbidity score	3.05	3.31	2.69	2.90
Outcomes				
Percentage prescribed any opioid	76.1	70.8	77.5	76.7
Mean number of opioid prescriptions[a]	1.50	1.48	1.57	1.56
Average MME/day[a,b]	46.0	41.9	46.9	44.2
Percentage with opioid rx[b] for >30 MME/day[a]	71.7	65.0	71.3	67.5
Percentage with opioid rx for >50 MME/day[a]	35.8	25.3	37.0	32.1
Percentage with opioid rx for >90 MME/day[a]	5.7	3.7	7.4	6.4
Percentage with opioid rx for >200 MME/day[a]	0.1	0.1	0.2	0.1
Average days' supply[a]	11.8	9.9	12.3	11.6
Percentage with opioid rx for >3 days' supply[a]	84.1	71.2	84.2	82.7
Percentage with opioid rx for >5 days' supply[a]	53.2	43.9	55.0	53.2
Percentage with opioid rx for >7 days' supply[a]	36.6	21.4	39.8	34.2
Percentage with opioid rx for >30 days' supply[a]	0.5	0.2	0.5	0.4
Average pill quantity[a]	67.4	53.9	74.6	68.2

[a]Measured among those prescribed an opioid.

[b]Abbreviations: MME=Morphine milligram equivalents; rx=prescription.

Table 3. Average effects of opioid prescribing cap laws on postsurgical opioid and nonopioid prescribing outcomes among surgery patients in 20 states that implemented a prescribing cap law between July 2016 and January 2019.

Outcome	Main results		Pre-period equivalence testing at 24, 18, and 12 months prior to baseline[a]	
	ATT[b]	95% CI[b]	Pre-period ATTs	Pre-period equivalence bounds
Opioid prescriptions				
Any opioid rx[b]	-.041	(-.054, -.028)	(-.012, -.029, -.033)	(.022, .040, .044)
Number of opioid rx	-.011	(-.043, .021)	(.000, .018, .011)	(.027, .045, .037)
Dose				
MME[b] per day (log)	-.013	(-.030, .005)	(-.003, -.019, -.011)	(.018, .034, .025)
> 30 MME	-.022	(-.038, -.006)	(.003, -.007, -.000)	(.015, .019, .012)
> 50 MME	-.037	(-.053, -.021)	(-.011, -.016, -.002)	(.025, .030, .015)
> 90 MME	-.006	(-.014, .002)	(-.003, -.003, -.005)	(.010, .011, .012)
> 200 MME	.001	(.000, .002)	(.000, .001, .000)	(.002, .002, .001)
Duration				
Days' supply (log)	-.109	(-.139, -.080)	(-.007, -.005, -.009)	(.030, .028, .032)
> 3 Days' supply	-.083	(-.097, -.069)	(.003, -.002, -.006)	(.013, .012, .016)
> 5 Days' supply	-.066	(-.083, -.048)	(-.003, -.007, -.005)	(.018, .021, .019)
> 7 Days' supply	-.070	(-.086, -.054)	(-.008, -.008, -.013)	(.022, .022, .027)
> 30 Days' supply	-.001	(-.003, .001)	(.000, .001, .000)	(.002, .003, .002)
Pill quantity (log)	-.117	(-.146, -.088)	(-.021, -.021, -.006)	(.044, .043, .030)

[a]The pre-period ATTs estimate the parallelism of the trends between the group of law-implementing states and the group of control states at different points in the pre-law period, and the pre-period equivalence bounds quantify our uncertainty about how similar the trends are. The main results are viewed in the context of these pre-period diagnostics that temper our confidence about the degree to which causality can be inferred from our design.
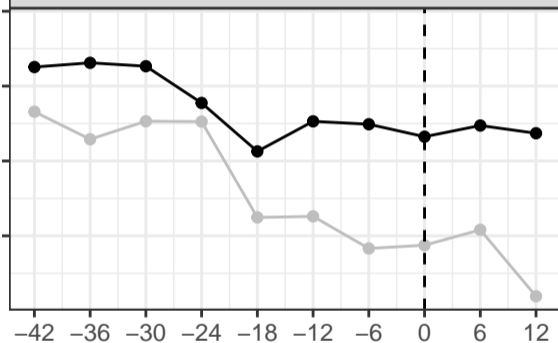
[b]Abbreviations: ATT=Average treatment effect on the treated; CI=Confidence interval; rx=prescription; MME=Morphine milligram equivalents.
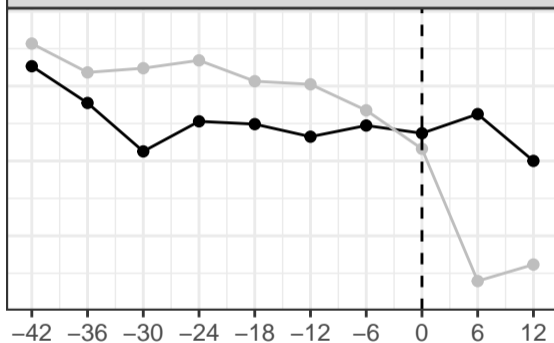
Figure Legends

Figure 1. Trends in the proportion of patients filling any postsurgical opioid prescription for each cohort from 4 years before to 1 year after law implementation. Data points represent the average value over the preceding 6 months.

Figure 2. Trends among patients filling any postsurgical opioid prescription in the proportion of patients filling a prescription with greater than 7 days' supply (Row 1) or a prescription with greater than 50 morphine milligram equivalents (MME) per day (Row 2) for each cohort from 4 years before to 1 year after law implementation. Data points represent the average value over the preceding 6 months.

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Cohort 1:
6 States that implemented laws between
July 2016 and April 2017
plus 16 control states & DC

Cohort 2:
7 states that implemented laws between
May 2017 and January 2018
plus 16 control states & DC

Cohort 3:
7 states that implemented laws between
July 2018 and January 2019
plus 16 control states & DC

Proportion

Months relative to baseline

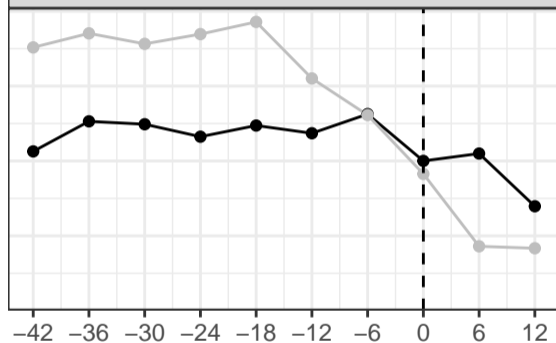Group ● Control states ● Law−implementing states

Cohort 1:
6 States that implemented laws between July 2016 and April 2017 plus 16 control states & DC

Cohort 2:
7 states that implemented laws between May 2017 and January 2018 plus 16 control states & DC

Cohort 3:
7 states that implemented laws between July 2018 and January 2019 plus 16 control states & DC

Any opioid rx >7 days

Any opioid rx >50 MME

Proportion

Months relative to baseline

Group — Control states — Law−implementing states