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Opioid-overdose laws association with opioid use and overdose mortality

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HIGHLIGHTS

- We conducted a national study of the impact of naloxone access and overdose Good Samaritan laws on opioid overdose deaths.
- Naloxone access and Good Samaritan laws are associated with 14% and 15% reductions, respectively, in opioid overdose deaths.
- Among African-Americans, naloxone and Good Samaritan laws reduce opioid overdose deaths by 23% and 26% respectively.
- Neither of these harm reduction measures result in increases in non-medical opioid use.
- These measures should be considered an important component of the strategy used to address the opioid overdose epidemic.

ARTICLE INFO

ABSTRACT

Introduction: Since the 1990's, governmental and non-governmental organizations have adopted several measures to increase access to the opioid overdose reversal medication naloxone. These include the implementation of laws that increase layperson naloxone access and overdose-specific Good Samaritan laws that protect those reporting overdoses from criminal sanction. The association of these legal changes with overdose mortality and non-medical opioid use is unknown. We assess the relationship of (1) naloxone access laws and (2) overdose Good Samaritan laws with opioid-overdose mortality and non-medical opioid use in the United States.
Methods: We used 2000–2014 National Vital Statistics System data, 2002–2014 National Survey on Drug Use and Health data, and primary datasets of the location and timing of naloxone access laws and overdose Good Samaritan laws.
Results: By 2014, 30 states had a naloxone access and/or Good Samaritan law. States with naloxone access laws or Good Samaritan laws had a 14% (p = 0.033) and 15% (p = 0.050) lower incidence of opioid-overdose mortality, respectively. Both law types exhibit differential association with opioid-overdose mortality by race and age. No significant relationships were observed between any of the examined laws and non-medical opioid use.
Conclusions: Laws designed to increase layperson engagement in opioid-overdose reversal were associated with reduced opioid-overdose mortality. We found no evidence that these measures were associated with increased non-medical opioid use.

1. Introduction

Non-medical use of opioids, including heroin and prescription opioid analgesics, is a major and growing public health concern in the United States, as evidenced by increasing numbers of emergency department visits (Cai, Crane, Poneleit, & Paulozzi, 2010), treatment admissions (Ling, Mooney, & Hillhouse, 2011), hospitalizations (Owens, Barrett, Weiss, Washington, & Kronick, 2006), and fatal overdoses (Centers for Disease Control and Prevention, 2016; Rudd, 2016). While non-medical prescription opioid use has declined, the

continued growth in adverse outcomes and the growing risk posed by illicitly produced synthetic opioids highlights the importance of efforts to address the epidemic (Green & Gilbert, 2016; Jones, 2017).

Naloxone is an opiate antagonist that quickly and effectively reduces overdose if given in time (Chamberlain & Klein, 1994). First approved by the United States Food and Drug Administration (FDA) in 1971, it has long been used to reverse opioid overdose in clinical settings, and two formulations approved and labeled specifically for layperson use have recently become available (Davis, Burris, Beletsky, & Binswanger, 2016). Evidence from communities with naloxone access programs suggests overdose mortality declines after implementation and that naloxone can be administered by laypersons with little or no formal training (Doe-Simkins et al., 2014; Walley et al., 2013). The United States Department of Health and Human Services considers expanded access of naloxone to be among the most important policy initiatives to reduce opioid-overdose mortality (Department of Health and Human Services & Assistant Secretary for Planning and Evaluation, 2015).

Despite overwhelming support for increased naloxone access by groups including the Centers for Disease Control and Prevention, the American Medical Association, and the American Pharmacists Association (Lim, Bratberg, Davis, Green, & Walley, 2016), concerns have been raised that expanded naloxone access might inadvertently lead to more non-medical opioid use (Bazazi, Zaller, Fu, & Rich, 2010; Kim, Irwin, & Khoshnood, 2009). Some critics argue that if the increased availability of naloxone reduces the probability of overdose death, some individuals may perceive drug use as less harmful and be more likely to use as a result (Bazazi et al., 2010; Kim et al., 2009). It is important that policymakers, clinicians, and other stakeholders base decisions regarding increasing naloxone access on data regarding the benefits or potential negative impacts of increased naloxone access.

To remove barriers to naloxone access and emergency overdose care, the majority of states have enacted overdose-related laws making it easier for laypeople to access naloxone (naloxone access laws) and provided legal protection for those who report opioid overdoses for the purpose of getting medical assistance (overdose Good Samaritan laws). Naloxone access laws, by enabling wider distribution of naloxone, attempt to increase the likelihood that the opioid antagonist is close at hand so it can be quickly administered in the event of an overdose. Similarly, overdose Good Samaritan laws are designed to increase the likelihood that emergency services will be called, thereby giving the overdose victim a higher chance of surviving the overdose. To date, no studies of which we are aware have examined the influence of naloxone laws or overdose Good Samaritan laws on opioid-related mortality or non-medical opioid use at the national level.

In this study, we utilized state-level variation in the dates of naloxone law and overdose Good Samaritan law enactment to investigate relationships among these laws and opioid-overdose mortality and non-medical opioid use at the national level (Paulozzi, 2006).

2. Methods

2.1. Study population

Our study population consisted of (a) all individuals in the 50 states and District of Columbia from 2000 to 2014 for the mortality outcomes and (b) estimates of noninstitutionalized individuals 15 years of age or older from 2002 to 2014 for the opioid-use outcomes.

2.2. Data sources

We used three different data sources: (a) opioid-overdose mortality, as captured in the National Vital Statistics System from 2000 to 2014; (b) numbers of people who use heroin or opioid pain relievers nonmedically, as estimated in the National Survey on Drug Use and Health (NSDUH) from 2002 to 2014; (c) naloxone access laws and Good Samaritan laws from 2000 to 2014.

Following prior work (Rudd et al., 2016), we determined the number of opioid-overdose deaths by state from the 2000 to 2014 National Vital Statistics System (NVSS) multiple cause-of-death mortality files (additional detail on our opioid mortality classification strategy can be found in the appendix). Opioid-overdose deaths were combined with state census population estimates obtained from the U.S. Census Bureau (United States Census Bureau) to estimate mortality rates.

We identified the number of respondents using opioids non-medically in the past month using the 2002 to 2014 NSDUH, which is conducted by the Substance Abuse and Mental Health Services Administration annually (Substance Abuse and Mental Health Services Administration, 2016). We excluded respondents younger than 15 years of age.

We created a database of naloxone access laws and Good Samaritan laws to capture characteristics and effective dates of these laws. We identified, reviewed, and coded all relevant laws that were enacted in any U.S. state or the District of Columbia on or before December 31, 2014 (Wagenaar & Burris, 2013). Building on a previous database of such laws, we first searched the Westlaw database, a subscription legal resource commonly used for legal research that contains all state laws and regulations that were in effect during the study period, for all statutes and regulations containing the terms "naloxone," "opioid antagonist," "opiate antagonist," "overdose," "medical amnesty," and "Good Samaritan" (Davis & Carr, 2015), and reviewed them for relevance. Naloxone access laws were included if they were designed to increase layperson naloxone access. Good Samaritan laws were included if they provided criminal immunity protection to an individual who reports an overdose.

Results were cross-referenced with a database of naloxone access and Good Samaritan laws maintained by the Prescription Drug Abuse Policy System (Prescription Drug Abuse Policy System, 2016). Divergences were minor and were resolved by consensus. In addition to overall naloxone access laws and Good Samaritan laws, we examined specific provisions of each law for each state and year (Table 1). For

Table 1
Characteristics of Naloxone Access Laws and Overdose Good Samaritan Laws and their provisions.

Name	Description
Naloxone law	State has passed a law designed to increase layperson access to naloxone.
Third party	State law permits third-party prescription of naloxone.
Standing order	State law permits prescription of naloxone via standing order.
Possession	State law permits possession of naloxone without prescription.
Prescriber immunity	State law provides civil and/or criminal immunity to prescribers.
Dispenser immunity	State law provides civil and/or criminal immunity to dispensers.
Good Samaritan law	State has passed a Good Samaritan law that provides protection from arrest and/or prosecution for a person who reports an overdose.
Good Samaritan law possession	Good Samaritan law provides protection from arrest for possession of any controlled substance.
Good Samaritan law probation	Good Samaritan law provides protection from violation of probation and/or parole.

naloxone access laws, we examined whether each law permits the prescription of naloxone to a person with whom the prescriber does not have a provider-patient relationship ("third party"), whether the law permits naloxone to be prescribed via a nonpatient-specific or standing order ("standing order"), whether the law permits naloxone to be possessed without a prescription ("possession"), whether the law provides civil and/or criminal immunity to medical professionals who prescribe naloxone ("prescriber immunity"), and whether the law provides civil and/or criminal immunity to medical professionals who dispense naloxone ("dispenser immunity").

For Good Samaritan laws, we examined whether the law provides protection from arrest for possession of a controlled substance ("Good Samaritan law possession") and whether the law provides protection from probation or parole violations ("Good Samaritan law probation"). Section I of the supplementary appendix gives further details on the timing and adoption and implementation of these measures.

2.3. Data measures

The two outcome variables were (1) the number of opioid-overdose deaths and (2) an individual level indicator of those who use opioids non-medically in the past month. From the NVSS dataset, opioid-overdose deaths were counted at the state-level for each year from 2000 to 2014 for the full population and select subgroups. In addition to an overall aggregated number of opioid-overdose deaths, we disaggregated opioid-overdose deaths into the following categories: sex (male, female), age group (15 to 24, 25 to 34, 35 to 44, 45 to 54, 55 to 64, and 65 years of age or older), and race/ethnicity (non-Hispanic white, non-Hispanic black, and Hispanic). We chose these subgroups to align with published research regarding opioid-overdose mortality in the United States (Rudd et al., 2016). Further details on our opioid mortality classification strategy can be found in Section II of the appendix.

From the NSDUH dataset, opioid use was defined as any reported use of heroin or non-medical use of prescription pain relievers in the past month for years 2002 through 2014. Due to a significant redesign in 2002 of NSDUH, we decided not to extend the opioid use analysis to years prior to the redesign. Past-month non-medical opioid use was defined as the use of prescription pain relievers when the respondent did not have a prescription or took the medication only for the experience or feeling it caused. The wording of the NSDUH questionnaire did not allow us to distinguish the use of opioid pain relievers from the use of prescription nonopioid pain relievers. However, NSDUH respondents are asked to identify which prescription drugs they have ever used. The non-medical use of nonopioid prescription pain relievers appears to be extremely low, approximately one quarter of 1%.

Our primary explanatory variables of interest were (1) naloxone access laws and (2) overdose Good Samaritan laws. Variables for naloxone access laws and Good Samaritan laws were organized at the state level for each law according to year and provision. We assigned the state a value of zero in the years during which the law had not been enacted and zero in the year in which the law was enacted to account for a lagged effect on implementation. A value of 1 was assigned in all years for the state after the year the law was enacted.

2.4. Statistical analyses

To identify the effect of the naloxone access laws and Good Samaritan laws on the number of opioid-overdose deaths and the number of people who use opioids non-medically, we used a standard difference-in-differences approach in which for each year, states that had implemented the laws are considered as being exposed and those that have not implemented the laws are considered not exposed. The differential time and geographic implementation of the laws provided a natural experiment that allowed us to control for many potential cofounders. The comparison occurred between exposed and non-exposed states and within the exposed group before and after implementation.

As such, we compared the outcomes for the same population before and after implementation, accounting for changes in population distribution and opioid availability levels.

We used mixed-effects negative binomial regression models to examine the association of naloxone access laws and Good Samaritan laws with the number of opioid-overdose deaths. For this analysis, data were organized at the state level, and the models included random effects for state and fixed effects for year and exposure group. Hausman tests indicated that state random effects appropriately accounted for unobserved heterogeneity (Hausman, 1978). Using this same modeling approach, we also examined the association of naloxone access laws and overdose Good Samaritan laws with opioid-overdose mortality in subgroups defined by sex, race/ethnicity, and age categories.

Survey-adjusted logit models were used to examine the association of the laws with the estimated number of people who used opioids nonmedically. In contrast to the mortality analysis, this analysis used pooled cross-sectional data and was conducted at the individual level, controlling for age, sex, race/ethnicity, education, income, state, year, and state-specific linear time trends. We provide additional details on the full empirical model and methods in Section III of the appendix.

While the differential time and geographic implementation of the laws in the difference-in-differences framework reduces bias from many potential confounders, this method is still susceptible to potential bias from other policy initiatives passed contemporaneously with the laws. For any specific intervention to be confounding, its implementation would have to be highly correlated with the explanatory and outcome measures. Arguably, the most closely related initiatives are prescription drug monitoring programs (PDMPs). PDMPs are state-level databases that capture data on many prescription controlled substances at the time of dispensing and make those data available to authorized users as permitted by law (Davis, Pierce, & Dasgupta, 2014). While these laws have been shown not to affect past year nonmedical opioid use (Ali, Dowd, Classen, Mutter, & Novak, 2017), if they impact opioid mortality and are correlated with the passage of naloxone and Good Samaritan laws, then they could confound our results. We assessed whether PDMPs confounded the main associations using a chi-squared analysis and found they were not associated with enactment of laws (p > 0.19 for each of them) during these years, so we did not include them in the model. The full analysis can be found in Section IV of the appendix. The results of this analysis suggest the exogenous variation in timing and geography of the passage of the measures we examined is sufficient to account for major sources of bias.

Standard errors for the mortality analyses are clustered by state. Standard errors for the drug use analyses are adjusted for NSDUH's complex survey design. Statistical significance was set at p < 0.05. All analyses were conducted using Stata software, version 14.1 (StataCorp).

3. Results

By the end of 2014, a total of 28 (55%) states had passed a naloxone access law (Fig. 1). Of these, 21 (41%) had third-party provisions, 16 (31%) had standing-order provisions, 16 (31%) had provisions for prescriber immunity, 16 (31%) had provisions for dispenser immunity, and 8 (16%) had possession without prescription provisions. A total of 21 (42%) states had passed overdose Good Samaritan laws, of which 8 (16%) had provisions that protected people who report an overdose from arrest for possession of controlled substances, and 7 (14%) had provisions protecting people from probation and/or parole violations. See Table S1 in the appendix for full details on the enactment year of the different provisions of the naloxone access laws and Good Samaritan laws by state.

For the United States population, opioid-overdose mortality increased from 2.71 per 100,000 people in 2000 to 8.43 per 100,000 people in 2014, and the estimated prevalence of past-month nonmedical opioid use was 1.89% (95% confidence interval [CI], 1.73 to 2.06) in 2002 and 1.75% (95% CI, 1.62 to 1.89) in 2014.
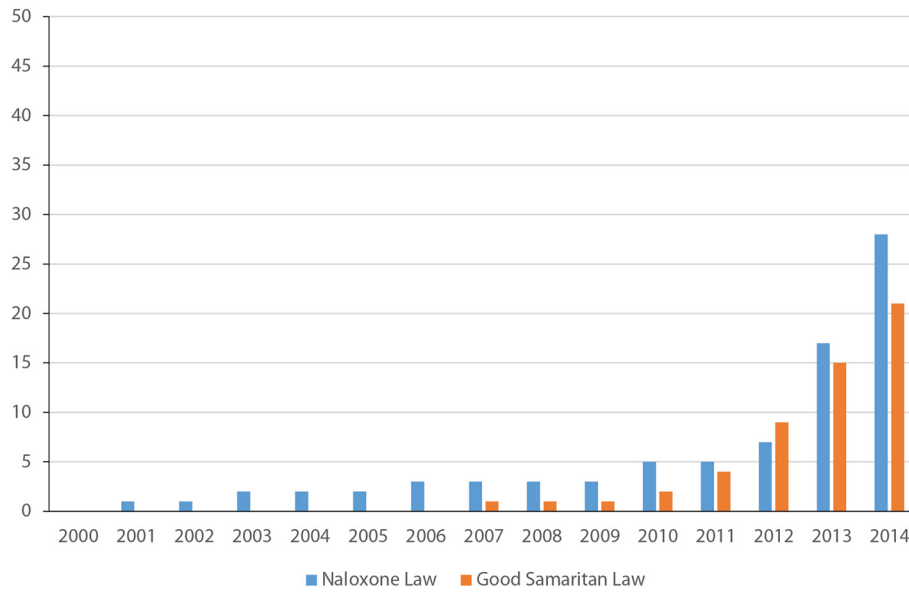
Fig. 1. Number of States with Naloxone Access Laws and Good Samaritan Laws through December 31, 2014.
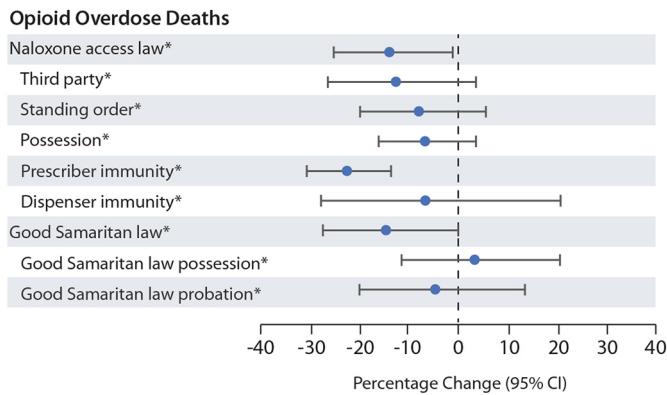

Fig. 2. Association of Naloxone Laws and Overdose Good Samaritan Laws with Opioid-Overdose Deaths, 2000–2014.
*State-level exposure and outcomes with state as a random effect and year as a fixed effect; 1-year lag from year law was passed.

After states enacted a naloxone access law, they had a 14% lower incidence of opioid-overdose deaths, as compared to when states did not have a naloxone law (p = 0.033). Similarly, after states enacted an overdose Good Samaritan law, they had a 15% lower incidence of opioid-overdose deaths, as compared to when states did not have an overdose Good Samaritan law (p = 0.050) (Fig. 2). With the exception of prescriber immunity, which is associated with a 23% (p < 0.001) reduction in deaths, no other statistically significant associations were observed between the specific provisions of these laws and opioid-overdose deaths.

In subgroup analyses, the existence of a naloxone access law was associated with a 14% lower incidence of opioid-overdose deaths among men (p = 0.048), a 23% lower incidence among the black non-Hispanic population (p = 0.001), and a 16% lower incidence among individuals 35 to 44 years of age (p = 0.016) (Fig. 3A). The existence of a Good Samaritan law was associated with a 26% lower incidence of opioid-overdose deaths among the black non-Hispanic population (p < 0.001), a 16% lower incidence among the Hispanic population (p = 0.009), a 17% lower incidence among those 35 to 44 years of age (p = 0.025), and a 19% lower incidence among those 55 to 64 years of age (p = 0.0025) (Fig. 3B).

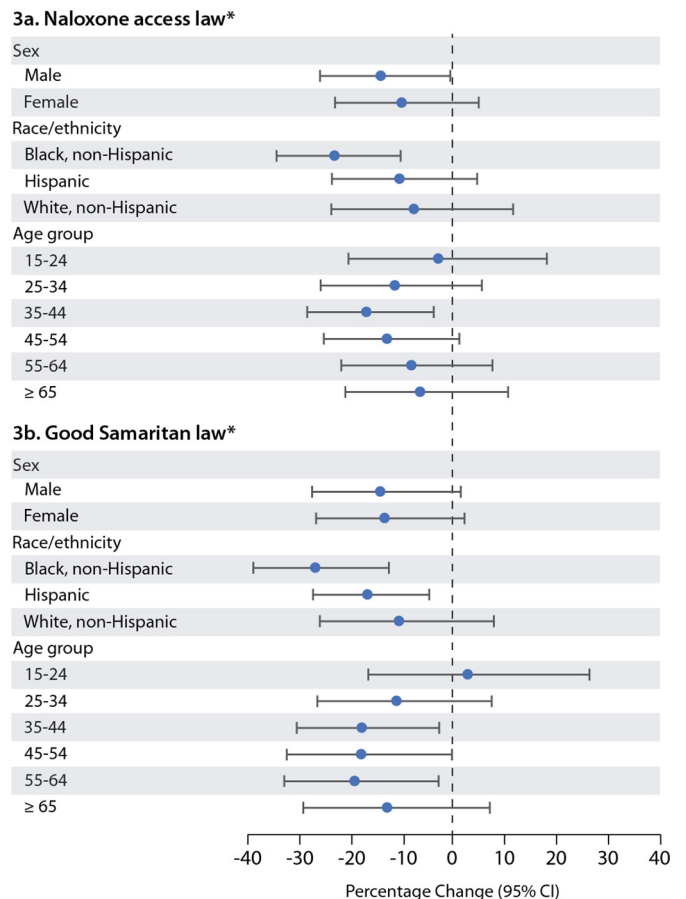There were no statistically significant increases in the prevalence of

Fig. 3. Associations of Naloxone Access Laws and Overdose Good Samaritan Laws with Opioid-Overdose Deaths, by Sex, Race/Ethnicity, and Age, 2000–2014.
*State-level exposure and outcomes with state as a random effect and year as a fixed effect; 1-year lag from year law was passed.
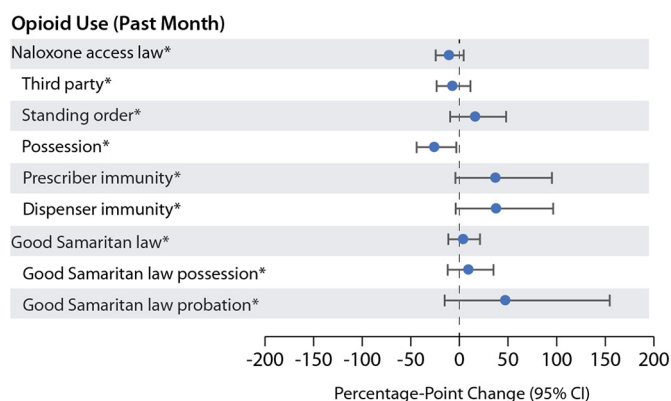
Opioid Use (Past Month)

Fig. 4. Association of Naloxone Access Laws and Good Samaritan Laws with Opioid Use in the Past Month, 2002–2014.
*Models include age, sex, race, education, income, state, year, and state-specific linear time trends; 1-year lag from year law was passed.

nonmedical opioid use after the enactment of naloxone access laws or Good Samaritan laws (Fig. 4).

4. Discussion

Laws designed to increase access to naloxone and encourage individuals to call for assistance in overdose situations were significantly associated with reduced opioid-overdose mortality. Other than prescriber immunity, no specific provision of these laws accounted for this association; rather, our results indicate that the general expansion of these laws is associated with fewer opioid-overdose deaths.

Examination of subgroups indicated naloxone access laws were primarily associated with reductions in mortality for African Americans, whereas Good Samaritan laws were associated with mortality reductions for African American and Hispanic populations.

There was no evidence that naloxone access laws or Good Samaritan laws were associated with increases in non-medical opioid use, as some have feared (Bazazi et al., 2010; Kim et al., 2009). In this respect, these measures were similar to other harm-reduction strategies used to address public health issues, such as needle exchanges (Lurie et al., 1993), which have reduced negative outcomes without increasing risk-taking behavior. However, our measure only captures prevalence of past-month use, not frequency of use, and therefore do not rule out additional use by current users. This finding could further be explored by future work examining more intensive measures of opioid use, such as substance use disorder prevalence, frequency of use, or potency of substances used.

The positive correlation between prescriber immunity and reductions in overdose deaths corroborate prior findings in surveys that show that some prescribers are wary of prescribing naloxone to people who use drugs because of fear of legal consequences (Beletsky et al., 2007). While these fears are generally unfounded, naloxone laws that contain prescriber immunity provisions remove the possibility of such negative legal action, encouraging medical providers to prescribe the medication (Davis et al., 2016).

Expanded naloxone access may differentially affect African American and Hispanic populations for many reasons. Naloxone laws make it easier for naloxone to be accessed outside of the traditional prescriber-patient relationship. The laws may therefore disproportionately increase access among African American or Hispanic populations that use opioids non-medically, who may be less likely to access harm-reduction services from traditional providers, and who are more likely to be uninsured or underinsured compared to the white population with similar characteristics (Clemans-Cope, Kenney, Buettgens, Carroll, & Blavin, 2012). Additionally, many high-volume naloxone programs are located in cities, which are disproportionately

inhabited by African American or Hispanic communities. Because people of color have been disproportionally affected by the nation's war on drugs policies for the past four decades, they may differentially benefit from the additional assurances these laws provide in order to feel safe calling 911 during drug-related emergencies (Alexander, 2012). Similarly, if people of color are less likely to call 911 in the event of an overdose for fear of police interaction (Peck, 2015), then increased access to naloxone, even if equally distributed among racial/ethnic groups, may disproportionately reduce overdose mortality rates among people of color.

Because some states have yet to pass naloxone access or Good Samaritan laws, these measures offer an opportunity to significantly impact the ongoing opioid crisis at a relatively low cost. Our results suggest that, given 7008 opioid deaths in 2014 in states without naloxone access laws by the end of that year, universal adoption of these laws may be associated with approximately 981 fewer deaths per year. Similarly, with 12,641 opioid deaths in the states without Good Samaritan laws, approximately 1896 deaths may be avoided with full adoption of these laws.

Our study should be considered in light of a number of potential limitations. First, because the study design was observational in nature, it did not provide a definitive causal effect. In particular, we were not able to study all potential effect modifiers or confounding variables. For example, if opioid availability grew faster in non-adopting states than in adopting states resulting in more deaths due to increased opioid availability, our results would be biased. That stated, our analytical difference-in-differences approach essentially used each U.S. state as its own control by using data before and after enactment of laws. Additionally, we found no evidence of correlation between the measures we examined and the most pertinent policies (PDMP laws) designed to address opioid use during the study period.

Second, most of the laws were passed in the latter part of the study period. By using implementation of the law in the prior year as our exposure variable, some variation in the exposure variable is lost. While we also examined these laws with a contemporaneous indicator of implementation as our exposure variable and found qualitatively similar results (available upon request), these results may not measure the full impact and should be reanalyzed with additional years of data.

Next, the classification of opioid overdoses may be susceptible to mis-measurement by coroners and medical examiners. If this measurement is random, then it would result only in less precision in our estimates. If the measurement error is systemically related to adoption of the laws examined, then our estimates may potentially be biased. However, we believe that such correlation between cause of death misclassification and passed laws is improbable and therefore the potential for bias is low. Additionally, aggregation of deaths to the state level mitigate this potential mismeasurement.

Finally, we examined a relatively large number of hypotheses, which raises the potential that the statistically significant findings could be found by chance. Even with no relationship between the examined measures and outcomes, we would still expect 2 of the 40 models examined to give results significant at the 5% level by chance.

Opioid-overdose mortality has emerged as a highly significant public health concern. In response, states have implemented naloxone access laws and overdose Good Samaritan laws as harm reduction measures intended to curb overdose mortality. Our results show that these laws are associated with reductions in overdose mortality without leading to increases in the number of people who use opioids non-medically. Consequently, these measures should be considered an important part of the approach to address the opioid epidemic.

Conflict of interest

No conflict declared.

Disclaimer

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Appendix A. Supplementary information

Supplementary data to this article can be found online at https://doi.org/10.1016/j.addbeh.2018.03.014.

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