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Impact of California Statute on Naloxone Availability and Opioid Overdose Rates



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Introduction: Ensuring that people at risk of overdosing on opioids have easy access to naloxone is an essential part of the fight against the opioid crisis. This study evaluates the impact of the 2016 California law (CA AB1535) permitting pharmacies to dispense this life-saving medication without a physician's prescription.

Methods: California counties were categorized on the basis of population density (rural, suburban, urban), rate of opioid-related deaths by population density (high, medium, low), and rate of opioid prescriptions by population density (high, medium, low). Ten diverse pharmacies from each category were selected for inclusion. In a brief 1-minute interview conducted between July and August 2021, pharmacists from 146 California pharmacies were surveyed regarding their knowledge of CA AB1535, their practice of dispensing naloxone without a physician's prescription, and whether they normally stock naloxone. Chi-square tests were used to compare responses.

Results: Although almost all pharmacies interviewed (94%) were aware of the law and most of them (64%) dispensed naloxone without a physician's prescription, few statistically significant differences were found between surveyed categories. There were no significant relationships between naloxone availability at pharmacies and overdose death rates.

Conclusions: Our results suggest that the number of California pharmacies dispensing naloxone without a physician's prescription has continued to increase since the implementation of CA AB1535. However, despite increased access to naloxone at pharmacies, opioid overdose rates have continued to rise since 2016, indicating the need for a multifaceted harm reduction approach.

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INTRODUCTION

In the U.S., the number of opioid overdose deaths has steadily increased over the past 2 decades. In 2000, the incidence of opioid overdose deaths nationwide was under 10,000. That number increased to 21,089 in 2010 and 47,600 in 2017.¹ In 2020, 75% of the 68,630 drug overdose deaths in the U.S. were related to opioid use.¹

In California, there were 17,576,679 prescriptions for opioid analgesics, 11,767 emergency department visits related to opioid overdoses, and 3,244 deaths resulting

from opioid overdoses in 2019.² Unfortunately, the rate of opioid overdoses has risen substantially since the onset of the coronavirus disease 2019 (COVID-19)

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pandemic, and in 2020, there were 14,867,426 prescriptions for opioid analgesics, 16,537 emergency department visits related to opioid overdoses, and 5,502 deaths related to opioid overdoses (3,946 of which were related to fentanyl) in California—changes of -15% , $+41\%$, and $+70\%$, respectively, compared with those in 2019.² These numbers suggest that although opioid prescription rates decreased while COVID-19 restrictions were in place, the incidence of opioid-related emergency department visits and overdose deaths increased.

One way to treat an opioid overdose is with a medication called naloxone. Naloxone works by reversing the lethal effects of opioid overdoses, namely respiratory depression.^{3,4} It competitively antagonizes opioid receptors in the central nervous system, reversing overdose symptoms.^{3,4} Naloxone has the highest affinity for μ -opioid receptors, but it binds to κ - and γ -opioid receptors as well.³ It can be administered as an intravenous injection; intramuscular injection; or, most commonly in California, nasal spray.⁴ Naloxone has no effect on someone who is not using opioids⁴ and is considered safe for pregnant women,⁵ so the drawbacks to administering this medication to someone who is potentially overdosing are negligible.

With adequate public health education and intervention, naloxone can be an effective tool in the fight against the opioid epidemic. In a study conducted in 19 communities in Massachusetts, areas with state-supported overdose education and nasal naloxone distribution programs had lower incidences of opioid-related deaths and hospitalizations than communities that did not implement such programs.⁶ This suggests that naloxone has the potential to improve health outcomes and combat the growing opioid epidemic with adequate distribution, education, and government support. This effect could be further amplified by an increase in treatment engagement that may arise with the implementation of these measures.

In January 2016, California began allowing pharmacists to dispense naloxone without a physician's prescription with the passage of CA AB1535.⁷ This bill was introduced in 2014 to address the need for improved accessibility and distribution of naloxone to those at risk of overdosing on opioids.⁷ Before the bill's passage, there was a large discrepancy between opioid and naloxone prescriptions in California. For example, there were 1.08 naloxone prescriptions per 100,000 Californians in the second quarter of 2015, compared with 595 opioid prescriptions per 1,000 Californians in that same time frame.^{2,8}

In a study conducted on 2,292 pharmacies in 7 California counties (Plumas, Lake, Lassen, Humboldt, Shasta, Fresno, and San Diego) in 2017, it was concluded

that despite the passage of legislation permitting pharmacies to dispense naloxone without a prescription, naloxone had not become broadly available in the selected counties, and out-of-pocket costs were highly variable between pharmacies.⁹ In a study conducted by Puzantian et al. in early 2018, only 23.5% of sampled retail pharmacies in California were dispensing naloxone without a prescription, and only 50.6% maintained a stock of nasal naloxone. They noted several reasons for the lack of implementation, including "lack of knowledge of legislation," "lack of required training," and "stigma about substance use disorder."¹⁰ In a follow-up study, Puzantian et al. surveyed pharmacies again in early 2020 and found that 42.4% of pharmacies dispensed naloxone without a prescription and that 81.9% kept nasal naloxone in stock.¹¹ Importantly, this study took place before the start of the COVID-19 pandemic and only a few years after the implementation of CA AB1535. It also had an underrepresentation of rural California pharmacies.

To further illuminate the status of naloxone availability in California pharmacies after the enactment of CA AB1535, we surveyed pharmacies throughout California, including pharmacies in rural counties, and analyzed naloxone availability in the context of regional opioid overdose incidences. Our study aims to assess the effectiveness of CA AB1535 by investigating pharmacist awareness of the law, whether pharmacies dispensed naloxone without a physician's prescription, barriers to dispensing naloxone without a prescription, and possible correlations between naloxone availability and opioid overdose incidences.

METHODS

This study was approved by the California Northstate University IRB Committee (Protocol Number 0115-02-016).

Study Sample

All counties in California were categorized on the basis of population density (rural, suburban, and urban, as defined by the California State Association of Counties¹²), incidence of opioid-related deaths by population density (low, medium, or high), and incidence of opioid prescriptions by population density (low, medium, or high). The latter 2 statistics are based on 2021 data from the California Opioid Overdose Surveillance Dashboard.² *High-overdose rates* were defined as >15 deaths per 100,000 individuals in a calendar year, *medium-overdose rates* were defined as 10–15, and *low-overdose rates* were defined as <10 . *High prescription rates* were defined as >500 prescriptions per 1,000 residents in a calendar

year, *medium* were defined as 400–500, and *low* were defined as <400.²

Researchers composed a list of all the pharmacies in each category of the 6,243 pharmacies located in California.¹³ A total of 27 categories were created through different combinations of the metrics mentioned earlier (e.g., rural, low-overdose deaths, high prescription rate, or suburban, medium-overdose deaths, low prescription rate). These categories are listed in [Appendix Table 1](#) (available online). Of these 27 categories, 10 diverse pharmacies from each category were selected by researchers for inclusion on the basis of the criteria described below. If there were fewer than 10 pharmacies in the category, all pharmacies were included. For categories that included multiple counties, an equal number of pharmacies was selected from each county whenever possible. Within the counties, pharmacies were selected from different cities and towns. Within each category, an equal number of privately owned pharmacies and pharmaceutical chains were selected for inclusion whenever possible, and no 2 pharmacies from the same chain were selected if possible. A total of 184 pharmacies were selected for inclusion in the study.

Measures

All data were collected between July and August 2021. Pharmacies that were selected for inclusion in the study were called and asked to participate. Pharmacists who verbally consented to participate were given a 1-minute survey assessing the awareness of CA AB1535, naloxone availability without a prescription, and whether naloxone was regularly in stock. If pharmacists offered an explanation as to why they did not dispense naloxone, those comments were recorded as well. Pharmacies that did not answer the phone call or asked to be contacted at a different time were called a second time. Several pharmacies declined to participate on the first phone call, and they were not contacted again. Pharmacies that did not participate after 2 phone calls were not contacted again. No personal identifying information was collected from the participating pharmacies or pharmacy staff. Only publicly available, deidentified information about the pharmacy, as an entity, was used during the survey process.

Statistical Analysis

Pharmacy response data were grouped by category (rural/suburban/urban, high/medium/low overdose death rate, high/medium/low prescription rate, and pharmaceutical chain/private), and chi-square tests were performed for each category grouping using IBM SPSS Statistics, Version 29. Statistical significance was considered as $p < 0.05$.

RESULTS

Of 184 Californian pharmacies that were asked to participate in the study, 146 (79%) agreed to take part in our survey. Of those 146 pharmacies, 136 (94%) were familiar with CA AB1535, 127 (86%) had naloxone in stock, and 94 (64%) dispensed naloxone without a physician's prescription per current law. We next grouped the California counties on the basis of population density, overdose rate, and prescription rate to examine whether there were differences between pharmacy awareness of CA AB1535, stocking of naloxone, and dispensing of naloxone without a prescription on the basis of these categories. Aggregated results from the study are shown in [Table 1](#). Chi-square tests were performed, and there were no statistically significant differences found between pharmacies in rural ($n=38$), suburban ($n=68$), and urban ($n=40$) counties on the basis of awareness of CA AB1535 (100%, 87%, 100%, respectively; nonsignificant), the percentage of pharmacies that dispensed naloxone without a prescription (68%, 63%, 63%; nonsignificant), or the percentage that regularly stocked naloxone (92%, 88%, 78%; nonsignificant).

There were also no statistically significant differences found between pharmacies in counties with high ($n=48$), medium ($n=59$), and low ($n=39$) overdose rates in awareness of CA AB1535 (98%, 92%, 92%, respectively; nonsignificant), percentage of pharmacies that dispensed naloxone without a prescription (65%, 68%, 59%; nonsignificant), or the percentage that regularly stocked naloxone (96%, 80%, 85%; nonsignificant). Finally, we also categorized pharmacies as having high ($n=42$), medium ($n=57$), and low ($n=47$) prescription rates on the basis of the California Opioid Overdose Surveillance Dashboard and also found no statistically significant differences in awareness of CA AB1535 (93%, 93%, 96%; nonsignificant), percentage of pharmacies that dispensed naloxone without a prescription (71%, 63%, 60%; nonsignificant), or the percentage that regularly stocked naloxone (88%, 82%, 89%; nonsignificant).

We next examined the differences in awareness of CA AB1535, the percentage of pharmacies that dispensed naloxone without a prescription, or the percentage that regularly stocked naloxone between pharmaceutical chains and private pharmacies. Of the 146 pharmacies that participated in the survey, 138 pharmacies were able to be categorized as pharmaceutical chains or private pharmacies. Of those 138 pharmacies, 46% were pharmaceutical chains, and 54% were private pharmacies. Responses attributed to each of these categories are shown in [Table 2](#). Chi-square tests were performed, and pharmaceutical chains ($n=63$) were found to be more likely to have naloxone in stock than private pharmacies ($n=75$) (95% vs 82%, $p=0.03$).

Table 1. Pharmacy Responses by Category

Category and response	Metric and %	Metric and %	Metric and %	p-value	Total, % (n=146)
Category A	Rural (n=38)	Suburban (n=68)	Urban (n=40)		
Pharmacies aware of the law	100%	87%	100%	n.s.	96%
Pharmacies that dispensed naloxone without a prescription	68%	63%	63%	n.s.	65%
Pharmacies that regularly stock naloxone	92%	88%	78%	n.s.	86%
Category B	High overdose rate (n=48)	Medium overdose rate (n=59)	Low overdose rate (n=39)		
Pharmacies aware of the law	98%	92%	92%	n.s.	94%
Pharmacies that dispensed naloxone without a prescription	65%	68%	59%	n.s.	64%
Pharmacies that regularly stock naloxone	96%	80%	85%	n.s.	87%
Category C	High prescription rate (n=42)	Medium prescription rate (n=57)	Low prescription rate (n=47)		
Pharmacies aware of the law	93%	93%	96%	n.s.	94%
Pharmacies that dispensed naloxone without a prescription	71%	63%	60%	n.s.	65%
Pharmacies that regularly stock naloxone	88%	82%	89%	n.s.	86%

Note: Chi-square tests were performed for each category grouping: A, rural/suburban/urban; B, high/medium/low overdose rate; and C, high/medium/low prescription rate. Values were not statistically significant ($p>0.05$; n.s.). n.s., not significant.

In addition, we recorded explanations that pharmacists provided for not dispensing naloxone, and these are shown in Table 3. The explanations fell into 3 major categories—policy/procedure, training, and need—and included explanations such as “It takes too much time to develop policy and procedures” and “You must go through a course before being able to dispense.”

DISCUSSION

As of August 2021, nearly all surveyed California pharmacies (94%) were aware of CA AB1535, most (86%) kept naloxone in stock, and a majority of pharmacies (64%) dispensed naloxone without a physician's prescription. These findings indicate improvements from a 2018 study showing that only 23.5% of pharmacies dispensed naloxone without a prescription and that

only 50.6% kept nasal naloxone in stock¹⁰ as well as improvement from a 2020 study that found that 42.4% of pharmacies dispensed naloxone without a prescription and that 81.9% kept nasal naloxone in stock.¹¹ These are promising findings because they suggest that more California pharmacies are utilizing the 2016 law. However, despite those successes, deaths from opioid overdoses have not decreased since the passage of CA AB1535. In fact, the number of opioid overdoses has continued to rise since 2016, and the COVID-19 pandemic complicated the matter by decreasing access to medical care,¹⁴ creating social isolation,¹⁵ and exacerbating comorbid mental health conditions.¹⁶ Furthermore, there are still many pharmacies that do not dispense naloxone without a physician's prescription, despite near ubiquitous knowledge of the current legal framework.

Table 2. Comparison of Responses From Pharmaceutical Chains and Private Pharmacies

Category	Pharmaceutical chains (n=63)	Private pharmacies (n=75)	p-value	Total (n=138)
Pharmacies aware of the law	97%	91%	n.s.	93%
Pharmacies that dispensed naloxone without a prescription	82%	55%	0.03	68%
Pharmacies that regularly stock naloxone	95%	82%	n.s.	88%

Note: Chi-square tests were performed between categories; $p<0.05$ was considered significant. n.s., not significant.

Table 3. Explanations Given for not Dispensing Naloxone Without a Prescription

County type	Pharmacy types	Theme	Explanations
Suburban	Chain and private	Policy and procedures	It takes too much time to develop policy and procedures.
			Company policy.
			You need to have a protocol or an advanced practice pharmacist.
Suburban	Private	Training	You must go through a course before being able to dispense.
			You would need to complete state required training. Also need a protocol created.
			Haven't gone through the process to get certified, it takes approximately 1–2 months.
Rural	Private	Need	Normally doctors prescribe naloxone so it is covered by insurance.
			Most doctors here always prescribe naloxone with opioids, so we never have to dispense without a prescription.
			Nobody has ever asked for naloxone without a prescription.

Our study first sought to examine whether there were any differences in the awareness of CA AB1535, dispensing naloxone without a prescription, or stocking naloxone in pharmacies between rural, suburban, and urban counties. There were no statistically significant differences between rural, suburban, and urban counties in any of these parameters (Table 1). This may have been because the vast majority of pharmacies were aware of the 2016 law (94%) regardless of county. Of the pharmacies that did not dispense naloxone without a prescription, many cited a lack of policies and procedures, the need for training, or the absence of need in their patient population (Table 3). One pharmacist's explanation for not dispensing naloxone was, "our demographic does not experience opioid addiction." Another stated, "Nobody has ever asked for naloxone without a prescription." Others cited systems in place that create barriers to dispensing naloxone without a prescription. Notable barriers included the need to develop policies and procedures to adopt CA AB1535 and the training required to be able to dispense naloxone without a prescription.¹⁷ Finally, several pharmacies were already associated with clinics or physicians who prescribed naloxone.

We next investigated whether differences were present in pharmacies categorized by overdose rates. Perhaps surprisingly, there was no significant difference found between counties with a high-, medium-, or low-overdose rate in awareness of CA AB1535, dispensing naloxone without a prescription, or stocking of naloxone. Although the law did increase the number of pharmacies that dispense naloxone, there was no relationship found between availability of naloxone without a prescription and opioid overdose incidences. We also investigated whether differences were present in pharmacies categorized by prescription rates. There was again no significant difference found between counties with high, medium, or low prescription rates in awareness of CA

AB1535, dispensing naloxone without a prescription, or stocking naloxone. Although beyond the scope of the current manuscript, together, these data suggest that complementary strategies, such as increased access to medication-assisted treatment for individuals stopping opioid use,¹⁸ provision of naloxone to released incarcerated individuals,^{19–21} and access to fentanyl testing kits,²² may be needed to continue to address the opioid epidemic. Additional work is needed to examine the interplay between the strategies mentioned earlier and the impact of the COVID-19 pandemic on the response to the opioid crisis.

Finally, our study examined potential differences between pharmaceutical chains and private pharmacies (Table 2). Chain pharmacies were more likely to dispense naloxone without a physician's prescription than their privately owned counterparts. Notably, there was no significant difference in awareness of CA AB1535, and the vast majority (93%) of all chain and private pharmacies had knowledge of the law. These results suggest a correlation between increased corporate oversight and adherence to current laws and guidelines because most pharmaceutical chains likely have more standardized guidelines, whereas privately owned pharmacies are more likely to have individualized policies. Furthermore, the chain pharmacies that provided explanations as to why they did not dispense naloxone focused on a lack of established policies and procedures (Table 3). The privately owned pharmacies also cited policy and procedures for reasons why they did not dispense naloxone. However, they also mentioned factors such as the training time required to become certified and the lack of demand for pharmacist-provided naloxone. Overall, more work is needed to better understand the different barriers to dispensing naloxone encountered by the various types of pharmacies in California.

Limitations

One of the main limitations of this study is the sample size. Although the survey conducted included a wide variety of pharmacies throughout California, only 146 of the 6,243 pharmacies in the state¹³ took part in the study. Many pharmacies that were called did not participate owing to time constraints or lack of interest. Furthermore, although we aimed to determine the ability of a given pharmacy to dispense naloxone without a prescription, we were unable to quantify the actual amount of naloxone that was dispensed. Hence, this study did not determine how the volume of naloxone distributed by pharmacies compares with that of needle exchange programs or other harm reduction centers, where naloxone is available for free at dozens of locations in many counties in California.²³ More work is needed to understand where people using opioids obtain naloxone despite its availability in pharmacies. In addition, our survey did not examine the types of naloxone formulations that were available at California pharmacies. This will be important to address in a follow-up study.

CONCLUSIONS

Despite legislative efforts to make naloxone more accessible, insufficient attention and resources limit its full potential as a life-saving tool in the fight against the opioid epidemic in California and the U.S. Our study showed that since the passage of CA AB1535 in 2016, more and more pharmacies are dispensing naloxone without a physician prescription. However, opioid overdose death rates in California have continued to rise since CA AB1535 went into effect, and more work needs to be done to further increase naloxone access. For example, jails and prisons could dispense naloxone when releasing inmates because formerly incarcerated individuals have a much higher probability of overdosing on opioids than the general population.^{19–21} Prison-based take-home naloxone programs implemented in other states and countries have been shown to reduce opioid overdose death rates in individuals with a history of injection drug use who were recently released from prison.²⁴ In addition, first responders could be allowed to dispense naloxone because they are regularly in contact with people at high risk for opioid overdose, and enabling first responders to administer naloxone has been shown to decrease opioid overdose deaths in studies conducted in multiple other states.^{25,26}

Importantly, despite its effectiveness as an opioid antagonist, naloxone cannot treat or prevent opioid use disorder.⁴ As vital as naloxone may be to decreasing harm from opioid use and deaths due to opioid overdoses, it is not the only tool to save lives. Other possible

strategies include widespread access to drug testing kits that screen for fentanyl,²² creating policies that allow opioid-dependent people leaving jail or prison to enter medication-assisted treatment centers,²⁷ increasing the number of supervised injection clinics to mitigate the risk of opioid overdose,²⁸ and making medication-assisted treatment more accessible.²⁹ Our study suggests that the number of California pharmacies dispensing naloxone without a physician's prescription has continued to increase since the implementation of CA AB1535 in 2016. However, opioid overdose rates have continued to rise despite increased access to naloxone at pharmacies, and a multifaceted harm reduction approach is needed.

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CREDIT AUTHOR STATEMENT

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.focus.2023.100112](https://doi.org/10.1016/j.focus.2023.100112).

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