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California Pharmacists Association
Pharmacists’ Response to the Opioid Crisis: A California Naloxone Survey

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Background
The opioid crisis continues to worsen in the U.S., with increased fatal opioid overdoses increasing during the COVID-19 pandemic. The Centers for Disease Control and Prevention National Center for Health Statistics reported an estimated 100,306 drug overdose deaths over one year (April 2020 to April 2021). This was an increase of 28.5% from 78,056 deaths the year before. Over the past decade, deaths from opioid-related overdoses have almost tripled in the U.S., increasing from approximately 17,500 in 2006 to 42,200 in 2016. Along with the public health advisory on naloxone and opioid overdose released by the surgeon general, the Department of Human and Health Services declared the opioid crisis a national public health emergency. There were 70,237 overdose deaths reported in 2017, with more deaths associated with fentanyl. Moreover, the top three California counties by number of opioid overdose deaths in 2017 included Los Angeles, San Diego and Orange. Opioids can be lethal, especially when taken at high doses and combined with alcohol and/or other central nervous system (CNS) depressant medications (i.e., benzodiazepines or hypnotics). Pharmacists have an opportunity to reduce opioid overdoses and mortality, especially through the provision of naloxone and education to patients and consumers at risk of an overdose. Naloxone is a competitive opioid receptor antagonist that reverses the respiratory neuroinhibitory effects, resulting in temporarily stopping opioid overdose-induced respiratory depression that may progress to apnea. There are studies reporting favorable results of naloxone used among laypersons, police and emergency medical first responders in reducing deaths associated with opioid overdoses. Furthermore, there is growing public concern and awareness of the negative and fatal consequences associated with opioid misuse and overdose, but there is not much reported about the community pharmacists’ response and attitudes toward dispensing naloxone in California. As a result, we performed a larger study as a follow-up to our pilot study that evaluated the prevalence of naloxone dispensing without a prescription in Orange County with 38 pharmacists. The questionnaire contained 28 multiple-choice and Likert-type questions that took approximately five minutes to complete. The questionnaire items included questions about the pharmacists’ demographics and length of practice, whether they have received requests for naloxone and treatments for OUD and pain in the past three months, pharmacists’ attitudes about providing naloxone education and using the Controlled Substance Utilization Review and Evaluation System (CURES) as a prescription drug monitoring program and existence of a pharmacy policy for naloxone dispensing information. Additionally, we investigated the number of naloxone units dispensed across California counties. Completion of the questionnaire was voluntary and anonymous. Our study was approved by our university’s Institutional Review Board (IRB #18-95). The questionnaire was conducted between March and September in 2018.

Objective
This study aimed to assess pharmacists’ response to the current opioid crisis in California, particularly regarding the prevalence of naloxone furnishing (or dispensing without a prescription) and prescriptions for medication-assisted treatment (MAT) drugs for opioid use disorder (OUD) to patients and consumers.

Methods

Study Design
This was a descriptive study of California licensed community pharmacists working in chain and independent pharmacies. A questionnaire was developed to evaluate pharmacists’ response to patients and consumers requesting naloxone. Content validity and comprehension of the questionnaire were tested in our previous pilot study conducted in Orange County with 38 pharmacists. The questionnaire contained 28 multiple-choice and Likert-type questions that took approximately five minutes to complete. The questionnaire items included questions about the pharmacists’ demographics and length of practice, whether they have received requests for naloxone and treatments for OUD and pain in the past three months, pharmacists’ attitudes about providing naloxone education and using the Controlled Substance Utilization Review and Evaluation System (CURES) as a prescription drug monitoring program and existence of a pharmacy policy for naloxone dispensing information. Additionally, we investigated the number of naloxone units dispensed across California counties. Completion of the questionnaire was voluntary and anonymous. Our study was approved by our university’s Institutional Review Board (IRB #18-95). The questionnaire was conducted between March and September in 2018.

Participants
Eligible participants included being a California licensed pharmacist working in a community pharmacy setting and a member of the California Pharmacists Association (CPhA). With the assistance of CPhA, the community pharmacist members were sent an email with the questionnaire link. There were two email attempts made to CPhA pharmacist members to complete the questionnaire within the study time frame. A second email was deployed three months after deployment of the first one.

Statistical Analyses
Our sample of 77 pharmacists for degrees of freedom up to 12 can detect a large effect size (w = 0.5) with 0.05 significance at a power of 0.85. We used Fisher’s exact test if the number of samples in each category was less than five; otherwise, an χ² test was used. The most conservative multiple testing adjustment, Bonferroni correction, was applied to minimize false positive or type I error when evaluating variables associated with naloxone dispensing. Spearman’s
A correlation test was used for checking association. All statistical analyses assumed a significance level of \( \alpha = 0.05 \).

### Results

Of the 1,612 California pharmacist recipients of the emailed questionnaire, 118 (7.32%) partially responded and 79 (4.90%) completed the questionnaire. Two of the 79 pharmacists were excluded because they were not practicing in a community pharmacy at the time of the study, resulting in 77 (4.78%) pharmacists included in the study.

#### Demographics of Pharmacist Participants, Pharmacy Settings, and Counties

Among the 77 pharmacists who completed the questionnaire, 33 were female (42.9%) and 44 were male (57.1%). Forty-six pharmacists (59.7%) worked in independent pharmacies, 14 (18.2%) in chain pharmacies and 17 (22.1%) in other pharmacy settings, which included ambulatory care. The counties with the higher number of pharmacists completing the questionnaire included Los Angeles (n = 12), Orange (n = 6), Sacramento (n = 5), and San Diego (n = 5) (Table 1).

#### Naloxone Dispensed and Policy To Dispense Without a Prescription

Most pharmacists (97.4%) were already aware of the California AB 1535 legislation, which allows pharmacists to furnish or dispense naloxone without a prescription.\(^\text{15}\) Fifty-three pharmacists (68.8%) stocked naloxone in their pharmacies. However, only 11 pharmacists (14.3%) had furnished naloxone in the past three months. Twenty pharmacists (26.0%) responded that their patients requested the price of naloxone (intranasal or intramuscular formulation) and 17 pharmacists (22.1%) reported that some patients declined to purchase naloxone because it “was too expensive”. Similarly, 33 pharmacists (42.9%) reported having a policy in place for naloxone education when naloxone is dispensed: 19 (24.7%) reported having a policy to dispense naloxone to patients who were prescribed a daily dose of \( \geq 90 \) morphine milligram equivalents (MME) and for more than 90 days; and 12 (15.6%) had a policy to dispense naloxone to patients who were prescribed both opioid and benzodiazepine prescriptions.

Despite being among the top three counties in California by number of opioid-related deaths, the six pharmacists from Orange County had not dispensed naloxone in the past three months. Only two pharmacists from San Diego and Sonoma counties reported dispensing more than five units of naloxone in the past three months. Four out of 12 pharmacists from Los Angeles County and 3 out of 5 pharmacists from San Diego had dispensed at least one naloxone unit in the past three months (Figure 1). These findings highlighted the discrepancy between opioid overdose deaths and naloxone dispensing when compared to the 2017 California opioid use data that showed a significant correlation between the number of opioid prescriptions dispensed and opioid overdose death.\(^\text{7}\)

**Figure 1.** Bar graph of the self-reported number naloxone units dispensed across California counties as indicated by participating pharmacists (n=77). Pink bars indicate pharmacies reportedly dispensing 1-5 naloxone units while light blue bar indicate dispensing more than 5 naloxone units dispense within the last three months prior to survey completion.
Amount of Naloxone Dispensed Versus Buprenorphine/Naloxone and Buprenorphine

Forty-six pharmacists dispensed at least one of these medications: naloxone, buprenorphine/naloxone and buprenorphine. However, only 43 pharmacists reported the number of units dispensed. Because of the large variation in the number of units dispensed (0 to 200), we categorized the reported dispense of these units into three categories: less than three, between three and 30, and greater than 30 in the past three months. Most prescriptions contained naloxone alone or in combination with buprenorphine (Table 2). The total naloxone units dispensed (n = 396) were lower compared to dispensed MAT drugs for OUD, such as buprenorphine/ naloxone (n = 1,116) and buprenorphine (n = 508). This finding indicated the overall dispensing of naloxone was low. Only 33 pharmacists (42.9%) dispensed naloxone, and most with a prescription (31 or 40.3%). Interestingly, there were 31 pharmacists (40.3%) who did not dispense any of the three medications: naloxone, buprenorphine/naloxone, or buprenorphine.

Variables Associated With Naloxone Dispensing Without Prescription

Within the completed responses, we investigated the association of 12 variables with naloxone furnishing using Fisher’s exact test or χ² test (Table 3). After Bonferroni correction of the P values for multiple testing, only three variables were found to be statistically significant: units of naloxone sold in the previous 3 months (P<.001, Fisher’s Exact Test [FET]); whether pharmacists were asked for the naloxone price (P<.001, FET); and whether patients declined to purchase naloxone because of its cost (P<.001, FET) (Table 3). The results for two questions — whether pharmacists were asked for the price of naloxone and whether patients declined to purchase naloxone — were highly correlated (Spearman correlation 0.994, P<.001).

Pharmacists’ comfort in Providing Naloxone Education

Sixty-nine pharmacists (89.6%) felt very comfortable or comfortable educating patients about naloxone use. However, only two pharmacists (2.60%) felt uncomfortable in educating patients about naloxone. Forty-seven pharmacists (61.0 %) received a minimum one-hour CE about naloxone. Pearson’s χ² test did not show a significant relationship between how comfortable pharmacists were about educating patients regarding naloxone use and receiving a minimum one-hour CE course. Pharmacists who received more than one hour of CE reported feeling more comfortable regarding naloxone patient education, but the difference was not significant (P = .060). However, a significant relationship existed between how comfortable pharmacists felt about naloxone education and the number of practicing years (P = .003). In terms of the format of naloxone training and education, most pharmacists preferred an online course (67.6%), followed by attending live workshops (48.1%).

Patient Counseling About Opioid Dependence and Overdose Potential

When dispensing new opioid prescriptions, most pharmacists reported counseling patients always (45.5%) or sometimes (29.9%) about the dependence potential and the risk of accidental opioid overdose. However, five pharmacists (6.49%) did not counsel patients when dispensing new opioid prescriptions, and nine pharmacists (11.7%) did not counsel patients when dispensing recurring opioid prescriptions. Fourteen pharmacists (18.2%) had not dispensed opioid prescriptions in the past three months.

Pharmacists’ Attitudes About Using CURES and Prescribers’ Usage of CURES

Seventy-two pharmacists (93.5%) believed checking CURES is effective in preventing opioid abuse. However, 22 (28.6%) strongly disagreed or disagreed that they have enough time to check CURES every time they filled an opioid prescription. Most pharmacists strongly agreed or agreed that prescribers should check CURES every time an opioid is prescribed for new patients (96.1%), acute pain (93.5%), chronic pain (92.2%), and concurrent opioid with benzodiazepine prescriptions (92.2%) (Table 4).

Discussion

In response to the opioid crisis, many states have expanded the pharmacists’ legal functions to dispense naloxone without a prescription, with a standing order or under protocol as naloxone providers and first responders. Our study findings showed that there were significantly more prescriptions dispensed for MAT drugs (buprenorphine/naloxone and buprenorphine) than for naloxone. One possible reason for this could be that prescribers may be selecting alternatives to opioids to treat their patients’ pain and attempt to reduce the risks associated with opioid dependence, addiction or a precipitated opioid withdrawal. In spite of naloxone being safe and effective as a rescue medication for opioid overdoses, precipitated or an acute opioid withdrawal syndrome could occur in individuals who are opioid dependent. These individuals could experience agitation, sweating, pain, vomiting and flu-like symptoms after receiving naloxone. On another note, a previous survey found that only 23.5% of the California community pharmacies were dispensing naloxone to patients without a prescription. However, the study did not evaluate whether the pharmacies were dispensing prescriptions of MAT for OUD in place of naloxone as our study has done. In any case, both studies found a very low rate of dispensing naloxone without a prescription by community pharmacists. Despite the rising opioid-related mortality in the U.S., the annual number of naloxone prescriptions modestly increased from 2.8 million to 3.2 million between 2009 and 2015. Furthermore, the CDC reports that prescriptions for naloxone and buprenorphine have increased only marginally in the past three years. Since 2016, the California State Board of Pharmacy has provided naloxone training to over 700 pharmacists as part of the implementation process of AB 1535. However, the rate of naloxone dispensing with or without a prescription appeared to be low among community pharmacists. Some potential reasons for the low dispensing rate could include the pharmacies’ decision not to stock naloxone, lack of time to educate patients about naloxone and stigma associated with patients or consumers requesting naloxone. Another possible reason for the low dispensing rate could be that some pharmacists have not completed the required one-
hour CE naloxone education. More recently, California AB 2760 was enacted in January 2019 and requires co-prescribing naloxone for high-risk patient groups (i.e., those receiving a daily prescription dosage of ≥ 90 MME of an opioid medication or concurrent prescriptions for other CNS depressants, having a history of opioid-related ED visit or prior overdose and having a personal or family history of substance use disorder). Further studies could evaluate if the number of naloxone prescriptions will increase as a result of this new legislation.

Similarly, the high price of naloxone could reduce the affordability to many patients and consumers who pay out-of-pocket for naloxone. The generic naloxone injectable or intranasal vial (2 mg/2 mL), which could be used with the mucosal atomizer device, is approximately $40.

Regarding the pharmacists’ knowledge and comfort level of training and educating patients about naloxone, those who have been practicing for more than 10 years expressed feeling comfortable in providing naloxone education and training to patients. In contrast, pharmacists who practiced for less than 10 years expressed feeling less comfortable about providing patient education about naloxone. There is clearly an educational need to provide further naloxone training opportunities for pharmacists to ensure that they feel adequately trained.

The majority of pharmacists felt that checking CURES was important for both pharmacists and prescribers in their effort to monitor opioid overprescribing, dispensing and improving clinical decision-making when prescribing opioid prescriptions for their patients. However, the pharmacists expressed concerns about the extra time needed to check CURES while trying to avoid long waiting times for patients because of their busy work schedules. The findings of this study suggest the need for expanding the pharmacists’ counseling to include patients on new and recurring opioid prescriptions at daily doses ≥ 90 MME. Further studies could assess why these patients refuse counseling or other reasons for the low reported counseling rates.

With the continued opioid crisis occurring nationally, we should expect more demand of naloxone within our communities. A recent publication projected that 700,400 individuals will die from an opioid overdose between 2016 to 2025, with 80% of those deaths attributable to illicit opioids, such as heroin and synthetic fentanyl. With more restrictions and scrutiny on opioid prescriptions, the number of individuals who will be using illicit opioids is projected to increase by 61%, or from 0.93 million in 2015 to 1.5 million individuals by 2025. Current interventions aimed at lowering the incidence of prescription opioid misuse (i.e., prescription drug monitoring programs, substance use education and prevention, alternative pain management and harm reduction) may have some effect, however, the opioid crisis is predicted to worsen in the next decade. The reality is that more people are starting with illicit opioids than with prescription opioids. Moreover, infiltration of the heroin supply with highly potent synthetic opioid fentanyl and carfentanil is increasing the lethality of illicit opioids. As a result, promoting broader awareness and easier access to naloxone within our communities as well as expanding the role of the pharmacist are key to preventing opioid overdose deaths.

Limitations

There were some limitations to this study. Owing to the low response rate of the survey, the questionnaire results assessed from the cohort of pharmacist participants may not be generalizable to the community pharmacists in California. We note that the descriptive statistical analyses are based on complete responses rather than total survey distribution. Also, the study sample was comprised mostly of community pharmacists. However, there could be pharmacists in other settings who may also dispense naloxone in other settings (e.g., emergency department). Therefore, study selection bias may not capture the true variability regarding naloxone dispensing in the pharmacist population. Of note, pharmacists may not have naloxone in their pharmacies or use the same protocol for calculating MME to be able to identify high-risk patients and the opportunity to dispense naloxone. Finally, the validity of the study results may be affected by self-report, recall and perception-based bias. Thus, further research is needed to assess and validate these results in a larger pharmacist population.

Conclusion

The provision of naloxone in California community pharmacies continues to remain low since the approval of AB 1535 that authorizes pharmacists to dispense naloxone without a prescription. As the opioid epidemic continues to devastate our communities, there is an urgent need to expand the availability and affordability of naloxone in our communities. A multipronged and multilayered approach and commitment from various key stakeholders need to happen to reduce naloxone access barriers for patients and consumers. For instance, more education and training programs about naloxone should be offered in high schools, universities, and health professional schools to broaden the public’s awareness about naloxone’s life-saving potential. Policymakers, drug manufacturers and third-party insurers should make naloxone available as an over-the-counter medication and more affordable to increase its access to patients and consumers. More importantly, future harm reduction programs should be developed to address the availability and affordability of naloxone and implement opioid overdose education and naloxone distribution training programs to consumers and health care providers in California.

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