Naloxone availability and dispensing in Indiana pharmacies 2 years after the implementation of a statewide standing order

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Abstract

Objectives: This study examined changes in rates of pharmacy naloxone stocking and dispensing in Indiana between 2016 and 2018 and explored supplemental variables and factors that may have affected observed differences.

Methods: Researchers used data from 2 existing datasets that were collected from managing pharmacists who responded to statewide pharmacy censuses in 2016 and 2018. After identifying all cases in which a pharmacy’s managing pharmacist responded in both 2016 and 2018 censuses, researchers conducted a nonparametric statistical comparison of naloxone stocking and dispensing rates in 107 Indiana pharmacies. Additional descriptive data regarding naloxone-related pharmacy policies and educational programs during those years were collected in 2019 from pharmacy corporations operating food stores or chain pharmacies in Indiana and from the Indiana Pharmacists Association.

Results: Pharmacy stocking and dispensing in Indiana increased from 2016 to 2018. In 2016, 57% of pharmacies reported stocking naloxone compared with 92.5% in 2018 (P < 0.001). Similarly, 23.4% of pharmacies reported dispensing naloxone in 2016 compared with 76.6% of pharmacies in 2018 (P < 0.001). All responding pharmacy corporations and the state pharmacy association reported offering self-directed volunteer-training programs regarding naloxone since 2016. In addition, they reported that company policy and procedures regarding naloxone were put into place in response to the 2016 statewide standing order.

Conclusion: Pharmacy naloxone stocking and dispensing increased in the 2 years after the statewide standing order was issued. The effect of the order itself was likely moderated and/or mediated by corporate responses to the law. Research examining the impact of naloxone-availability policies on pharmacy practice and patient incomes should longitudinally examine data after policy implementation and with covariates that include type of pharmacy (e.g., chain or independent), location, and opioid overdose–associated mortality rates.

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pharmacies dispense naloxone and educate patients regarding its use. Naloxone is available by prescription, but it neither is regulated as a controlled substance nor does it present a risk of abuse.10 In the wake of the U.S. opioid epidemic, many states have enacted laws to broaden naloxone access through statewide standing orders or third-party prescriber laws.11

Although these laws likely have had an effect on pharmacy stocking and dispensing of naloxone, the association between state policy and pharmacy-practice change is not well understood owing to analytical complexity.11,12 Potential mediators such as pharmacists’ attitudes as well as pharmacy policies and characteristics remain understudied.13

Currently, studies have found differing levels of pharmacists’ knowledge regarding naloxone laws, legal protections, and general comfort dispensing naloxone. Studies conducted in Indiana (2016),13 Kentucky (2015),14 West Virginia (2016),15 North Carolina (2017),16 and Pennsylvania (2017)17 have examined pharmacists’ perception of state laws and pharmacy board policies related to naloxone access, as well as pharmacists’ comfort with dispensing and willingness to dispense naloxone. Findings have been varied. Fifty-four percent of Kentucky pharmacists expressed a willingness to dispense naloxone contingent on a valid prescription.14 In West Virginia, 20.4% of pharmacists expressed a willingness to dispense naloxone over the counter without a prescription.15 In North Carolina, 49.2% of pharmacists reported that they were very comfortable dispensing naloxone on the basis of several scenarios (e.g., “to a patient who is prescribed high-dose opioids”), although results were not disaggregated by scenarios in the study results.16 More than half of Indiana pharmacists (66.5%) believed that a newly enacted, statewide naloxone standing order would increase the likelihood of dispensing naloxone.13 Finally, in Pennsylvania, 64% of pharmacists correctly responded to 2 objective, knowledge-related questions regarding their statewide standing order for naloxone.17

Few studies have assessed pharmacy naloxone stocking and dispensing. Forty-five percent of Pennsylvania pharmacies,17 74.8% of West Virginia pharmacies,15 and 31% of New Jersey pharmacies reported stocking naloxone, although the latter percentage was found to meaningfully vary according to median income and population density.18 In 2016, Indiana’s State Health Commissioner issued a statewide standing order for naloxone, broadening the scope of Indiana’s 2015 provider-based standing order. Several months afterward, statewide managing pharmacists’ reports of naloxone stocking (58.1%) and dispensing (23.6%) remained surprisingly low.13 However, in 2018, a second Indiana study found higher rates.19

Objectives

The objectives of this study were to examine changes in rates of naloxone stocking and dispensing in the state of Indiana between 2016 and 2018 and to explore potential factors of the corporate pharmacy chains that may have influenced any observed changes beyond the standing order. To do so, we first linked and compared responses for the cross section of community pharmacies in which the managing pharmacist responded to an Indiana statewide pharmacy census both in 2016 and 2018 (N = 107). We then conducted interviews with representatives from corporate pharmacy chains within the state to contextualize the findings. To our knowledge, this is the only study with access to state-level pharmacist data on naloxone access collected both several months after the implementation of a statewide standing order (2016) and then 2 years later.

Methods

2016 Indiana census

A list of Indiana community pharmacies was obtained from Hayes Directories, Inc (Mission Viejo, CA), for 2016 and was matched with a list of managing pharmacists provided by the Indiana Board of Pharmacy (February 2016). A total of 993 community-managing pharmacists were included in the census, with 36.1% responding and 32.9% completing the full survey.20 A post hoc review of pharmacies by a study PI (Beth Meyerson) found that only 850 pharmacies were operating as community pharmacies at the time of the census. After excluding the miscategorized pharmacies (e.g., compounding pharmacies), the fully complete response rate was 33.4% or 284 pharmacies.13 Additional details are available in the cited papers.13,20

2018 Indiana census

A list of Indiana community pharmacies was obtained from Hayes Directories, Inc (Mission Viejo, CA), for 2018, but information on managing pharmacists was not available from the Indiana Board of Pharmacy. A total of 1018 managing pharmacists (self-identified) were included in the census, with 37.6% responding and 31.4% completing the full survey.21 A post hoc review of pharmacies by a study PI (BM) found that only 984 pharmacies were operating as community pharmacies at the time of the census. After excluding the miscategorized pharmacies, the fully complete response rate was 30.8% or 303 pharmacies. Additional details are discussed elsewhere.13,21

Quantitative data analysis

Respondents from 2016 and 2018 were matched by street address, city, county, and name of pharmacy using IBM SPSS 25 syntax (IBM Corp, Armonk, NY) and then by manual review. It was determined that 107 pharmacies had a managing pharmacist who responded to both the 2016 and 2018 surveys. These cases became the analytical sample for this study. Assessment of paired dichotomous stocking and dispensing data for 2016 and 2018 was conducted using McNemar tests.22 Data were then separated into descriptive tables, including the variables found to be statistically significantly in predicting stocking in the 2016 census: number of full-time pharmacists, pharmacy location, continuing pharmacy education (CPE), and the type of pharmacy.

2019 Qualitative data collection and analysis

A list of 9 eligible pharmacy corporations was purposefully constructed23 by identifying the parent organizations of the chain, food store, and mass-merchandiser pharmacies included in the study sample. In addition, the Indiana Pharmacists Association (IPA) was included so as to be inclusive of
independent pharmacies and other statewide pharmacy efforts. The Director of Pharmacy Relations (or equivalent title) at each corporation and IPA were contacted by e-mail and requested to respond to a brief phone or e-mail questionnaire designed to identify corporate policy and sponsored educational programs that were enacted and delivered, respectively, during the 2016-2018 time period. Five organizations responded to the questions (4 by e-mail and 1 by phone). The questionnaire contained 5 items designed by 2 study authors (L.E. and B.M.) and was reviewed by multiple pharmacy-practice researchers for face validity. Given the small number of respondents, responses were not coded but reported in summary. This study was deemed exempt by the Indiana University Institutional Review Board.

Results

Quantitative

In this sample, 61 pharmacies (57.0%) stocked naloxone in 2016, and 99 pharmacies (92.5%) stocked it in 2018, a statistically significant increase ($P < 0.001$). One pharmacy had stocked naloxone in 2016 but stopped by 2018 and 7 did not do so in either year.

Similarly, 25 pharmacies (23.4%) reported dispensing naloxone in 2016, and 82 pharmacies (76.6%) reported dispensing it in 2018, a statistically significant increase ($P < 0.001$). Four pharmacies had dispensed naloxone in 2016 but had not done so in 2018; the remainder of those that did not dispense naloxone ($n = 21$) did not do so in either year (Table 1).

It was not feasible to conduct multivariate analyses with other covariates because only 8 pharmacies indicated they did not stock naloxone in 2018 and 21 indicated they did not dispense it in 2018. Thus, we report descriptive information for variables that were the significant predictors of naloxone stocking in our 2016 study. In 2016, 8.2% of pharmacies that stocked naloxone and 12% of pharmacies that dispensed naloxone had only 1 full-time licensed pharmacist. In 2018, these percentages were 14.1% and 9.8%, respectively. Rates of participation in CPE that focused on opioid abuse (2016) and opioid use disorder (2018) were different, with 68.2% and 18.7% of managing pharmacists reporting having received CPE on that topic in the past 2 years in 2016 and 2018, respectively. Rates of pharmacists’ participation in naloxone-focused CPE were only measured in 2016, with 57% reporting having received it. Finally, in 2016, 65.6% of pharmacies stocking naloxone and 52% of pharmacies dispensing naloxone were chain pharmacies; in 2018, 42.4% of pharmacies stocking naloxone and 43.9% of pharmacies dispensing naloxone were chain pharmacies (Table 2).

Survey of education and training policies

To thoroughly understand the factors that contributed to the increase in stocking and distribution of naloxone between 2016 and 2018, it was necessary to gain awareness regarding the actions that corporate pharmacy chains executed during this time period. These data provided substantial insight into the potential influences that contributed to the increase in stocking and distribution.

All pharmacy corporations reported efforts to educate pharmacists and pharmacy technicians regarding naloxone since 2016 in a manner that reflected state-by-state policy differences regarding naloxone access. One organization reported directly working with state pharmacy boards to establish policy and procedures surrounding naloxone distribution. Two organizations trained technicians to immediately involve pharmacists when distributing naloxone. One organization’s leadership stated that they began to advertise naloxone in their pharmacies after the Indiana standing order was issued.

All corporate pharmacy organizations reported offering self-directed training programs on naloxone since 2016 and organization-wide training regarding opioid use, abuse, and overdose. In addition, they acknowledged having established policy and procedures within the company, although no corporation was able to share specific policy or procedures for public dissemination.

IPA reported that it had not sponsored any CPE focused on naloxone since 2016 or on opioid abuse or overdose, although it had sponsored awareness campaigns linked to the Surgeon General’s recommendation to stock naloxone and the Indiana standing order for naloxone. However, it believed that the demand for naloxone in pharmacies had not been high since 2016 owing to a perception that naloxone was available to the public and to first responders through other methods.

Discussion

This study found statistically significant and meaningful increases in pharmacy stocking and dispensing of naloxone in Indiana after a statewide standing order in 2016 and 2018. This is something that one might implicitly expect, given the suspected lag time between naloxone-access law enactment and measurable outcomes; however, there is value in knowing that this was actually the case. Although logic suggests that some percentage of the variance in stocking and dispensing rates is because of the statewide standing order, we cannot determine causality. There is a wide variety of other potential mechanisms that may have affected these rates.

Interestingly, we observed lower rates of CPE on opioid use disorder in 2018 than rates of CPE on opioid abuse in 2016. However, both questionnaire items inquired about the past 2 years, and the surveys were administered approximately 2 years apart. Thus, if a managing pharmacist had met his or her

<table>
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<tr>
<th>Year</th>
<th>Naloxone stocking$^a$</th>
<th>2018</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>Yes</td>
<td>60 (56.07%)</td>
<td>1 (0.01%)</td>
<td>61 (57.00%)</td>
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<tr>
<td></td>
<td>No</td>
<td>39 (33.64%)</td>
<td>7 (0.06%)</td>
<td>46 (42.99%)</td>
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</tr>
<tr>
<td></td>
<td>Total</td>
<td>99 (92.52%)</td>
<td>8 (0.07%)</td>
<td>107 (100%)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Naloxone dispensing$^b$</th>
<th>2018</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>Yes</td>
<td>21 (19.63%)</td>
<td>4 (0.37%)</td>
<td>25 (23.36%)</td>
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</tr>
<tr>
<td></td>
<td>No</td>
<td>61 (57.00%)</td>
<td>21 (19.63%)</td>
<td>82 (76.63%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>82 (76.63%)</td>
<td>25 (23.36%)</td>
<td>107 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

Note: $^a$Exact significance (2-sided) < 0.001

Implementation of a statewide standing order

Table 1

Indiana pharmacy naloxone stocking and dispensing in years 2016 and 2018 ($N = 107$)
CPE needs before the 2016 survey, he or she may have seemed to lack CPE in 2018. For this reason, we encourage caution when interpreting this result. In addition, in 2016, a multivariable regression model found that being a chain pharmacy was the independent factor most strongly associated with stocking naloxone. In the present study, we observed decreases in the percentages of chain pharmacies compared with all other types of pharmacies reporting stocking (65.6% vs. 42.4%) and dispensing naloxone (52.0% vs. 43.9%) from 2016 to 2018. This information supports our previous supposition that chain pharmacies were perhaps better poised to quickly respond to the standing order compared with other pharmacy types, given that pharmacies were perhaps better poised to quickly respond to the standing order compared with other pharmacy types, given their ready access to resources.

In addition, pharmacies’ roles within the health care system have become increasingly visible and valued in recent years. Especially given the importance of using an opioid receptor antagonist (naloxone) in response to an overdose, pharmacies are essential components of the response to the opioid epidemic because they serve as primary agencies responsible for the distribution of naloxone. Although, in theory, naloxone must be dispensed only to people to whom it is prescribed, states have rapidly been changing laws to broaden access, typically through a standing order for naloxone or through third-party prescriber laws. The nature of these laws and policies is varied: 29 states provide civil, criminal, and disciplinary immunities; 16 states provide some level of immunity (across at least 1 category but fewer than 3 categories); and 6 states provide no immunity.

Contemporaneously with the advent of state standing orders and third-party prescriber provisions, pharmacy dispensing of naloxone has increased. At the same time, the association between policy implementation and practice change is not well understood, partly because evaluation of state-level policies in response to the opioid epidemic is complex. Furthermore, the potential mediators of such an association, including individual pharmacists’ and pharmacies’ characteristics that may affect both stocking and dispensing of naloxone, remain understudied. Pharmacists’ ability to provide direct intervention through naloxone dispensing is of great importance to generate a coordinated response to the opioid crisis and necessitates continued research into this paradigm, which includes pharmacists’ knowledge regarding naloxone laws, legal protections, and general comfort with dispensing naloxone.

Our qualitative investigation suggests that corporate education efforts have the potential to have an impact on naloxone stocking and dispensing. We found that corporate entities overseeing pharmacies in the state implemented a variety of practice changes after the statewide standing order, most directly in response to the order. It is plausible that similar training, advertising, and procedural modifications occurred in at least some independent pharmacies, although we do not know this for certain. Many of these activities have face validity in terms of their ability to influence stocking and dispensing rates or, at the very least, to address anticipated deficits in pharmacy practices related to naloxone, such as naloxone education. At the same time, considering the extent to which the activities were prompted by the standing order, they may more appropriately be understood as mediating factors rather than as independent causal variables. In addition, IPA raised the important confounding factor of demand affecting dispensing—that is, regardless of the availability and willingness to dispense naloxone, there must be a patient for there to be a transaction.

**Limitations**

There are several limitations to this study. First, the response rates to both censuses were lower than the preferred ones (33.4% and 30.8% for fully complete instruments). At the same time, the Pew Research Center identified few statistically significant differences between a standard response rate (25%) and a rigorous response rate (50%) in a national survey, either for substantive content or for representativeness. Second, the data used in this study are self-reported and thus are subject to biases common to those types of data. However, this study assessed change over time, and thus, any bias would be similarly reflected in both 2016 and 2018, meaning that the
change value itself is less likely to be subject to those biases. This study has limited generalizability within the United States as a whole because it was conducted only among Indiana pharmacies. At the same time, this is the only extant study to provide this type of sequenced naloxone stocking and dispensing data relative to a statewide standing order, so it may serve as a starting point for a broader national investigation on this topic.

Conclusion

Despite concerns regarding the low rates of pharmacy naloxone stocking and dispensing soon after Indiana’s standing order was issued in 2016, both rates substantially increased by 2018. Furthermore, corporate entities that oversee pharmacies in Indiana and the United States reported undertaking a variety of activities in response to Indiana’s standing order. Research examining the impact of naloxone-availability policies on pharmacy practice and patient incomes should include data for several years—at least after the law’s implementation to accurately measure outcomes. Some variables closely associated with naloxone stocking soon after a statewide standing order (e.g., chain pharmacy status) may regress to the mean over time.

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References


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