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RESEARCH

Pharmacists' role in opioid overdose: Kentucky pharmacists' willingness to participate in naloxone dispensing

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ABSTRACT

Objectives: To assess pharmacists' willingness to initiate the dispensing of naloxone. As of 2015, Kentucky law permits certified pharmacists to dispense naloxone under a physician-approved protocol.

Design: Electronic survey (e-mail) gauging perception of pharmacists' role in opioid overdose and attitudes toward, and barriers to, naloxone dispensing.

Setting and participants: All Kentucky pharmacists with active licenses in 2015.

Main outcome measures: Ordinal logistic regression was used to estimate the impact of pharmacist characteristics and attitudes on willingness to initiate naloxone dispensing, where the dependent variable was operationalized as a Likert-type question on a scale of 1 (not at all willing) to 6 (very willing).

Results: Of 4699 practicing Kentucky pharmacists, 1282 responded, of which 834 were community practitioners (response rate 27.3%). Pharmacists reported varying willingness to initiate naloxone dispensing, with 37.3% very willing (score 5 or 6) and 27.9% not willing (score 1 or 2). However, a majority of pharmacists reported willingness to dispense naloxone with a valid prescription (54.0%, score 5 or 6). Women pharmacists were 1.3 times more likely than men to be willing to initiate naloxone dispensing (95% confidence interval [CI] 1.0–1.6). Those who reported confidence in identifying individuals at risk for overdose were 1.2 times more likely to initiate dispensing, and those who reported confidence in ability to educate patients about overdose were 1.6 times more likely to express willingness to initiate naloxone dispensing (95% CIs, respectively, 1.0–1.3 and 1.4–1.8). Community pharmacists reported barriers to naloxone access at higher rates than pharmacists from other practice settings.

Conclusion: Kentucky pharmacists are divided in their willingness to initiate naloxone dispensing; however, those who are confident in their ability to identify overdose risks are more willing. Increasing pharmacist confidence through appropriately designed education programs could facilitate pharmacist participation in naloxone dispensing.

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Drug overdose is the leading cause of accidental death in the United States, with the Centers for Disease Control and Prevention (CDC) reporting over 47,000 overdose deaths in 2014. Opioids are the leading contributor to this epidemic,

with 18,893 overdose deaths related to prescription pain relievers and another 10,574 overdose deaths attributed to heroin.¹ Since 1999, the number of deaths associated with accidental opioid overdose has quadrupled in the United States. Prescription opioid overdoses accounted for more than 165,000 deaths from 1999 to 2014 nationally, with the rate of overdose deaths increasing 200% over that time period. Sales of prescription opioids mirrored the trend over the same time period.² Kentucky currently ranks in the top 5 states for drug overdose death rates nationally,³ and the rates continue to increase every year. The 2015 Overdose Fatality Report from the Kentucky Office of Drug Control Policy showed an almost 17% increase in overdose deaths in 2015 compared with 2014,

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Key Points**Background:**

- States have undertaken legislative efforts to expand access to naloxone, with 43 states having passed laws authorizing pharmacists to dispense naloxone via protocol, standing order or collaborative practice agreements.
- In March 2015, Kentucky Senate Bill 192 granted specially certified pharmacists the authority to dispense naloxone via protocol.
- Little is known, however, about pharmacists' willingness to embrace this new role or what barriers to implementation are perceived.

Findings:

- Pharmacists report varying willingness to initiate naloxone dispensing via protocol.
- Women pharmacists and those who report confidence in identifying overdose risk and educating patients about overdose were more likely to express willingness to dispense naloxone under protocol.
- Perceived barriers include time, knowledge of the law and regulations, complications with billing and reimbursement and concerns over the clientele that might frequent the pharmacy if a program were in place.

with 28% of all deaths attributable to heroin and 34% of all deaths attributable to synthetic fentanyl (with or without heroin).⁴

The Trust for America's Health's 2013 report, *Prescription Drug Abuse*, outlined 10 specific strategies that states can use to curb the overdose epidemic, including the creation of state-based prescription drug monitoring programs, introduction of "doctor shopping" laws, strengthening "Good Samaritan" laws (legal protections for reporting drug overdose emergencies), and increased access to the rescue medication naloxone.⁵ Similarly, the Substance Abuse and Mental Health Services Administration's Opioid Overdose Prevention Toolkit, which equips health care providers, communities, and local governments with materials to develop practices and policies to help prevent opioid-related overdoses and deaths, lists ensuring access to naloxone as a specific strategy in opioid overdose prevention.⁶

Naloxone is an opioid antagonist that can be administered to an opioid overdose victim parenterally or by nasal spray and can reverse opioid overdose partially or completely.⁷ It is fast-acting and counteracts the opioid-induced depression of the respiratory system, thereby allowing the overdose victim to breathe normally. Response time to naloxone varies based on route of administration; when given intravenously it can be effective within 1 to 2 minutes, with slightly slower onset observed when administered via intramuscular or subcutaneous routes. Intranasal administration allows naloxone to be quickly transported across the capillary network and delivered to the systemic circulation with an onset of action

of 2 to 3 minutes and has been shown to be effective when administered in pre-emergency room settings.⁸ Naloxone has no effect if opioids are absent, and has no potential for abuse.

Despite the absence of abuse potential, naloxone access historically has been limited to practice models of administering medical emergency personnel. The public health practice model distributes naloxone as part of a larger preventive health mission similarly to other population health-driven harm reduction strategies related to opioid use disorder, such as needle exchange programs.⁹ Recent legislative efforts have promoted increased access to naloxone as rescue therapy for opioid overdose by capitalizing on the accessibility of community pharmacists, with 43 states having passed laws authorizing pharmacists to dispense naloxone via protocol, standing order, or collaborative practice agreements.¹⁰ Patient access to naloxone, especially in rural areas, however, depends on the willingness of community pharmacists to participate in such programs, which may rely, in part, on the strength of the legal protections that cover those practitioners.¹¹

In March 2015, Kentucky Senate Bill 192 (SB 192) was passed, granting pharmacists the authority to dispense naloxone via a physician-approved protocol.¹² Pharmacist certification for naloxone dispensing is issued by the Kentucky Board of Pharmacy (BOP), which requires that certified pharmacists be trained in naloxone administration and opioid overdose before establishing a protocol agreement. SB 192, commonly known as the "heroin bill," also included provisions to legalize needle exchange programs and to expand the existing "Good Samaritan" law provision that outlines liability protections for third-party individuals who carry and administer naloxone in cases of suspected overdose. Although SB 192 provides licensed health care providers who prescribe and dispense naloxone to a third-party protections from disciplinary action from professional licensing agencies, the law does not provide full or partial civil immunity for health care professionals who prescribe and dispense naloxone, which is common in other states.¹³

It is unclear whether pharmacists in Kentucky are aware of changes in the law related to naloxone dispensing or how pharmacists view their role in opioid overdose prevention. Therefore, the objectives of the present study were to: 1) provide an understanding of the baseline experience and attitudes of pharmacists toward naloxone dispensing before the statewide law implementation; 2) assess pharmacists' willingness to initiate the dispensing of naloxone; and 3) identify self-perceived barriers to implementing SB 192.

Methods

A team of practicing pharmacists and health policy researchers developed a survey instrument to assess pharmacists' experience with naloxone and their attitudes toward naloxone dispensing (via prescription and protocol) and other relevant risk prevention strategies. The instrument was intended to capture information about pharmacists' practice settings as well as their opinions and perceptions about their role in opioid overdose prevention. The University of Kentucky Institutional Review Board approved the survey protocol.

The request for study participation, explanation of the study, electronic survey link, and a cover letter from the Kentucky Board of Pharmacy (BOP) were e-mailed to all licensed Kentucky pharmacists on June 23, 2015. A reminder was sent 1 week after the initial e-mail invitation, and a final reminder was sent 2 weeks after the initial e-mail. Once a respondent clicked on the survey link, they were redirected to a screening question, which they were required to answer before proceeding to the survey: “Do you currently practice pharmacy in the Commonwealth of Kentucky?” If the screening question was left unanswered or received a response of “no,” then the respondent was exited from the survey. Any survey containing at least 1 response beyond the screening question was captured within a Web-based application called Research Electronic Data Capture (REDCap)¹⁴ and was included in analysis. Responses entered into REDCap were not linked back to respondent e-mails and did not contain identifying information. The survey link was deactivated 2 weeks after the final reminder e-mail.

Variables

Pharmacists rated willingness to dispense naloxone via a physician protocol agreement on the survey on a scale of 1 through 6, where 1 represented “not at all willing” and 6 represented “very much willing.” Pharmacists’ willingness to dispense was selected as the dependent variable for the multivariate analysis, where willingness to initiate naloxone dispensing was operationalized as the numeric score selected by the respondent.

Pharmacist characteristics, as covariates, included degree type, gender, years in practice, and whether the pharmacist practiced in a community pharmacy or other practice setting (e.g., hospital). Other covariates and predictor variables included whether the pharmacist had ever dispensed naloxone to prevent overdose (“yes,” “no”) or ever administered naloxone to a person experiencing respiratory depression (“yes,” “no”). Responses regarding pharmacist confidence also were included as predictor variables. These questions included confidence in ability to identify individuals at risk for opioid overdose, ability to educate patients to recognize opioid overdose and administer naloxone, and ability to identify the signs and symptoms of opioid overdose. Similarly to the willingness questions, confidence questions were measured with the use of Likert-type items where respondents could choose on a scale of 1 to 6, where 1 was “not at all confident” and 6 was “extremely confident.” Responses of “don’t know” were not included in multivariate analysis.

Finally, pharmacists were asked to select from a list of possible perceived barriers to implementing a naloxone dispensing program in their pharmacies. Pharmacists could provide a qualitative text answer for “other barriers” that were not included in the list of possible selections on the survey instrument. Barriers to naloxone dispensing implementation were not included in the multivariate analysis but were instead subject to an independent analysis as described below.

Statistical analysis

Question response frequencies were compiled and descriptive statistics calculated. A multivariable regression

Table 1

Kentucky pharmacists’ characteristics in 2015 survey (n = 1282)

Characteristic	n (%)
Terminal degree	
BSP Pharm	511 (39.9%)
PharmD	745 (58.1%)
Other (PhD, others)	22 (1.7%)
No response	4 (0.3%)
Years in practice	
0 to 2	145 (11.3%)
3 to 5	163 (12.7%)
6 to 10	188 (14.7%)
11 to 20	228 (17.8%)
>20	552 (43.1%)
No response	6 (0.5%)
Gender	
Female	675 (52.7%)
Male	578 (45.1%)
Prefer not to answer	29 (2.3%)
Pharmacy practice setting	
Community pharmacy	843 (65.8%)
Other practice setting (e.g., hospital)	431 (33.6%)
No response	8 (0.6%)
Experience with naloxone	
Ever administered naloxone	77 (6.0%)
Ever dispensed naloxone for prevention	78 (6.1%)

model was constructed with the use of a forward selection strategy, where each survey item (demographic characteristics, pharmacist practice characteristics, and pharmacist attitudes and experiences related to naloxone) was added to the model until the model fit no longer improved according to McFadden *R*-square. Ordinal logistic regression was used to estimate the impact of pharmacist characteristics and attitudes on willingness to initiate naloxone dispensing via a physician protocol agreement, where attitudes operationalized as described in the preceding section acted as the dependent variable. Ordinal regression was selected as the method of choice owing to the ranked discrete nature of the dependent variable as a value from 1 to 6. Multicollinearity in the independent variables and covariates were explored via pairwise correlation testing, with no result precluding multicollinearity problems in the final multivariate model.

The community pharmacists who selected any perceived barrier to implementing a naloxone dispensing program in their pharmacies were compared via Pearson chi-square testing with the pharmacists in other practice settings (e.g., hospitals) who selected the same barriers. All statistical analyses were conducted in the Stata v13.0 program.¹⁵

Results

E-mails were sent from BOP to 5154 Kentucky pharmacists, and of those, 455 were either returned as undeliverable or were respondents who replied to the screening question in the negative, indicating they currently did not practice pharmacy in Kentucky. Of the remaining 4699 potential respondents, 104 replied but left the screening question blank or did not respond to the remaining questions. A total of 1282 respondents completed the survey after identifying as a currently licensed and practicing pharmacist (response rate 27.3%). A summary of responding pharmacist characteristics is

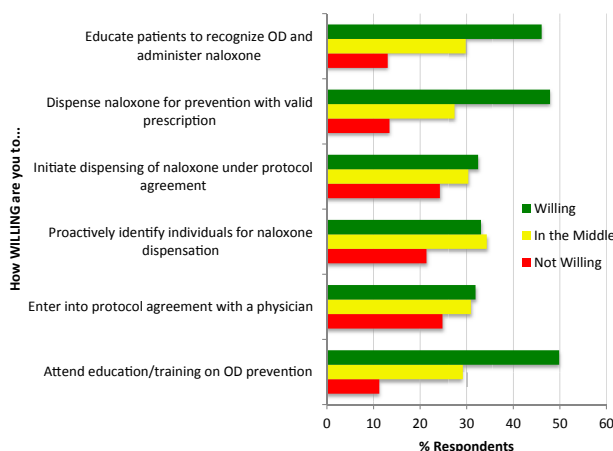


Figure 1. Kentucky pharmacists' willingness to participate in opioid overdose risk prevention strategies. Willingness scores were collapsed for clarity (1 and 2 = Not Willing, 3 and 4 = In the Middle, 5 and 6 = Willing). Responses of "Don't Know" are not included on the figure.

provided in Table 1. More than one-half of the respondents had PharmD degrees and had been in practice more than 10 years. Nearly two-thirds of respondents were community pharmacists, and respondents from hospital practice settings were the second most represented group (hospitalists; $n = 285$). The pharmacists reported little experience with either administering or dispensing naloxone for opioid overdose prevention.

Figure 1 contains the distribution of responses for the pharmacists' willingness to participate in several naloxone-related opioid overdose risk prevention strategies, where all questions were asked as "willingness on a scale of 1 to 6, with 1 being 'not at all willing' and 6 being 'very much willing.'" In accordance with SB 192 allowing pharmacists to initiate naloxone dispensing, pharmacists reported varying willingness to do so, with 37.3% very willing (score 5 or 6) and 27.9% not willing (score 1 or 2) to initiate naloxone dispensing under a protocol. However, a majority of pharmacists reported willingness to dispense naloxone with a valid prescription (54.0%, score 5 or 6), which has always been permitted by law, as with any other prescription medication. About one-half of the responding pharmacists reported willingness to attend education and training on opioid overdose prevention (49.9%, score 5 or 6), but only one-third indicated willingness to proactively identify individuals meeting the criteria for naloxone dispensation under a protocol (33.1%, score 5). When asked about plans to apply to BOP for certification to dispense naloxone via protocol, fewer than one-fourth (24.4%) indicated plans to do so.

Table 2 contains multivariate analysis results. In relation to their male pharmacist counterparts, women pharmacists were 1.3 times more likely to express willingness to initiate naloxone dispensing (95% confidence interval [CI] 1.0–1.6). An increase of 1 unit in reported confidence in identifying individuals at risk for overdose was associated with a 1.2-fold increase in willingness to initiate naloxone dispensing (95% CI 1.0–1.3). Similarly, a single-unit increase in reported confidence in ability to educate patients about overdose was associated with a 1.6-fold increase in willingness to initiate

Table 2

Kentucky pharmacists' willingness to initiate naloxone dispensing in 2015, multivariate model results ($n = 1037$)

Factor	OR	95% CI
Terminal degree		
BSP Pharm	Ref.	
PharmD	1.13	0.81-1.59
Other (PhD, others)		
Years in practice		
0 to 2	Ref.	
3 to 5	0.90	0.59-1.38
6 to 10	0.79	0.52-1.19
11 to 20	0.94	0.63-1.41
>20	1.05	0.68-1.61
Gender		
Female	1.26*	1.01-1.59
Male	Ref.	
Pharmacy practice setting		
Community pharmacy	1.15	0.89-1.49
Other practice setting (e.g., hospital)	Ref.	
Experience with naloxone		
Ever administered naloxone	1.32	0.82-2.13
Ever dispensed naloxone for prevention	1.41	0.88-2.24
Pharmacist confidence^a		
Ability to identify signs of overdose	1.10	0.96-1.26
Ability to identify individuals at risk	1.17*	1.03-1.34
Ability to educate patients about naloxone	1.56*	1.38-1.78

Abbreviations used: OR, odds ratio; CI, confidence interval.

*Statistical significance.

^a Confidence questions were structured as "How confident are you in your ability to ...," where respondents could select a response on a scale of 1 (not at all confident) to 6 (extremely confident). Responses of "don't know" were not included in regression analysis.

naloxone dispensing (95% CI 1.4–1.8). Pharmacist practice setting and previous experience with naloxone dispensing were not significant predictors of willingness to initiate naloxone dispensing.

When asked about perceived barriers to implementing a naloxone access program, both community pharmacists and pharmacists in other practice settings were foremost concerned about the time to develop and implement the program (59.9% community pharmacists, 43.2% other pharmacists; Table 3), although community pharmacists selected this as a barrier more often than other pharmacists ($P = 0.002$). Interestingly, a larger proportion of community pharmacists appeared to consider nearly every barrier more significant compared with pharmacists in other practice settings. In particular, concerns over clientele that might frequent the pharmacy was considered to be a barrier to implementation by more than twice the proportion of community pharmacists compared with those in other practice settings (48.4% vs. 21.4%; $P < 0.001$). Few pharmacists considered supply chain issues, such as packaging or stocking naloxone products, to be a barrier to naloxone access program implementation, although, again, a greater proportion of community pharmacists than other pharmacists considered this to be a barrier (18.4% vs. 11.6%; $P = 0.007$). Knowledge regarding the law was also a major barrier reported by community pharmacists (48.2%), but less so for pharmacists in other practice settings (31.6%; $P < 0.001$).

Discussion

This study surveyed Kentucky pharmacists soon after passage of a law expanding pharmacy practice to permit greater

Table 3

Perceived barriers to implementing a naloxone access program in 2015, community pharmacists (n = 843) versus pharmacists in other practice settings (n = 431)

Barrier ^a	Community pharmacists, n (%)	Pharmacists in other practice settings, n (%)	P value
Time to develop and implement program	505 (59.9%)	186 (43.2%)	0.002
Support from manager or administration for program	229 (27.2%)	94 (21.8%)	0.106
Knowledge regarding the law and regulations authorizing naloxone access programs	406 (48.2%)	136 (31.6%)	<0.001
Complications with billing and reimbursement	419 (49.7%)	168 (39.0%)	0.025
Moral or ethical concerns associated with drug abuse and overdose	214 (25.4%)	48 (11.1%)	<0.001
Concerns over clientele that might frequent the pharmacy if a program were in place	408 (48.4%)	92 (21.4%)	<0.001
Packaging or stocking the various forms of naloxone	155 (18.4%)	50 (11.6%)	0.007
Community opposition to a local naloxone access program	143 (17.0%)	29 (6.7%)	<0.001
Other barriers	45 (5.3%)	79 (18.3%)	<0.001
None of these are barriers	25 (3%)	58 (13.5%)	<0.001

^a Respondents could select more than 1 barrier.

naloxone access, to provide an understanding of the baseline practices, attitudes, and barriers before statewide law implementation. Almost one-half of responding pharmacists expressed willingness to receive education on opioid overdose risks and willingness to educate their patients on how to administer naloxone, but fewer than one-third were willing to take the steps necessary to proactively identify those patients in need of naloxone. This implies that pharmacists agree that they have a role to play in opioid overdose prevention but disagree on the nature of that role.

Kentucky pharmacists are also divided in their willingness to initiate naloxone dispensing under physician protocol, but those who expressed confidence in their ability to identify overdose risks were more likely to express willingness to initiate dispensing. These findings suggest that pharmacy school-based efforts and pharmacist continuing education initiatives, including training in how to use naloxone and identify those who may benefit from naloxone, could increase pharmacist confidence, and thereby participation, in naloxone dispensing.¹⁶ The regulations promulgated by BOP outline the pharmacist education and training required to apply for certification to dispense naloxone via physician protocol. The components of education include risk factors for opioid overdose, how to recognize and respond to an opioid overdose, overdose prevention strategies, and detailed education on the use of naloxone for rescue therapy.¹⁷ The development of training and education programs that meet the BOP requirements will hopefully be sufficient to increase pharmacists' confidence in these areas.

Implementing wide-scale pharmacy practice change is not without real and perceived barriers. Those identified by pharmacists related to the time needed to implement naloxone programs and complications with billing could potentially be addressed by providing community pharmacies with resources to help them to streamline the administrative hurdles to implementation and to clarify billing and reimbursement issues. Resources such as those of prescribetoavoid.org, guidelines from state and national pharmacy associations, and practice improvement newsletters and support tools are needed to assist pharmacists in Kentucky and elsewhere with program development and implementation. Pharmacists who perceive knowledge regarding the law as a barrier would also benefit from a well designed education and training program. Attitudinal barriers, such as those associated with concerns over clientele that might frequent the pharmacy if a naloxone access

program were in place, may prove to be more difficult to address.

Limitations

This study has several limitations. First, even though the entirety of the Kentucky pharmacist population was given the opportunity to participate in the study, it is possible that those who responded are different in some way than those who did not participate, which would contribute to nonresponse bias. Additionally, the response rate was low compared with traditional mail surveys, although it was within the expected range for electronically solicited Web-based surveys and surveys of health professionals.¹⁸

Conclusion

Pharmacists, particularly community pharmacists, are well positioned to provide preventive services to mitigate opioid overdose risks. Training community members in overdose recognition and naloxone administration has shown promise in preparing communities to respond to and prevent overdose mortality,¹⁹ and Kentucky pharmacists have expressed a willingness to participate in such educational efforts with their patients. Training and other logistical supports are indicated to improve confidence in naloxone provision in the pharmacy and expand access to this life-saving medication for all patients.

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