Impact of Naloxone Access Laws that Allow Pharmacists to Prescribe Naloxone on Naloxone Dispensing in U.S. Retail Pharmacies

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Abstract

Background: The opioid crisis in the U.S. is a significant public health burden, with 46,802 opioid-related deaths occurring in 2018 alone. To expand access to naloxone, a safe and effective opioid overdose reversal agent approved by FDA, many states have passed naloxone access laws (NALs). These laws vary widely among states. While many include standing orders and similar laws that allow pharmacists to dispense naloxone without a patient-specific prescription, few give pharmacists the authority to independently prescribe (not just dispense) naloxone. Since pharmacists are readily accessible healthcare providers, enhancing their capacity to prescribe and dispense naloxone may increase naloxone access, thus help reduce fatal opioid overdoses.

Purpose: To analyze the impact of state laws that allow pharmacists to prescribe naloxone on naloxone dispensing from retail pharmacies in the U.S.

Methodology: Naloxone dispensing data (2010-2018) from retail pharmacies for all 50 states and the District of Columbia was extracted from Symphony Health PHASTTM Prescription Monthly. Additionally, state laws that allow pharmacists naloxone prescriptive authority were extracted from Lexis Advance® legal database using relevant search terms. A multivariate negative binomial model, adjusted with confounding variables, was used to assess the impact of state pharmacist prescriptive authority NALs on the outcome variable (naloxone dispensed).

Results: As of December 2018, nine states had passed NALs that allow pharmacists independent authority to prescribe naloxone. Results from the multivariate negative binomial model indicate that the presence of pharmacist prescriptive authority NALs was associated with a significant average increase of 331 dispensed naloxone prescriptions per state per quarter (p <0.05), representing a 53% increase from the average number of dispensed naloxone prescriptions (628) per state-quarter.

Conclusion: The results from this study show that state laws that allow pharmacists to prescribe naloxone are associated with increased naloxone dispensing from retail pharmacies. These findings have important implications in policymaking as widespread adoption of these laws may expand naloxone access and reduce opioid related mortality, especially during public health emergencies when overdoses may be on the rise.

Introduction

- Opioid overdose deaths in the U.S. have increased steadily since 1999. In 2018, approximately 46,800 deaths occurred due to opioid overdoses (CDC, 2020).

3 Waves of the Rise in Opioid Overdose Deaths
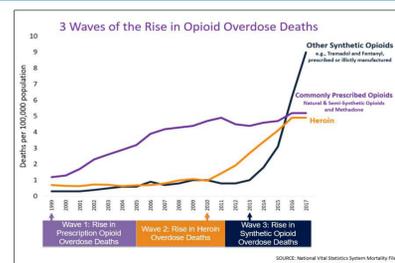
- In 2017, the U.S. Department of Health & Human Services emphasized expanding access to naloxone (an overdose reversing drug) as a key approach to tackle the opioid crisis.

- To expand access to naloxone, states have enacted Naloxone Access Laws (NALs):
  o All 50 states and D.C. had enacted at least one NAL by 2017
  o NALs and their effective dates vary by state

- An increase in naloxone prescriptions dispensed from U.S. retail pharmacies was observed between 2010-2015 (Jones et al., 2016, *Am J Public Health*).

- State NALs such as standing orders and third-party prescribing are associated with an increase in naloxone dispensed from retail pharmacies (Xu et al., 2018, *Drug Alcohol Depend*).

Materials and Methods

- *Extraction of naloxone access laws (NALs):*

  o Lexis Advance® legal database was used to identify relevant NALs using specific search words
  o Cross-reference with laws in Prescription Drug Abuse Policy System (PDAPS) database

Type of NAL	Definition	No. of States
Main Policy Variable:		
Pharmacist Authority to Prescribe (PPA-NAL)	Either provide "pharmacist prescriptive authority" that allows pharmacists to independently prescribe naloxone or "direct legislative authority" which allows licensed pharmacists to sell naloxone.	9
Confounding Policy Variable:		
Standing Orders	Pharmacists can dispense naloxone via a standing order prescription written by a licensed prescriber	45
Third Party Prescribing	Health care providers can issue a naloxone prescription to family members, friends, caregivers etc.	47
Naloxone Co-Prescription	Co-prescribing naloxone in conjunction with an opioid prescription by a medical professional	5

Valid through 12.31.2018.

- *Data analysis:*

Model selection
- Count data model:
  o Negative binomial regression analysis
- A p value <0.05 considered statistically significant
- STATA-MP was used for statistical analysis

Defining outcome variable
- Total naloxone prescriptions dispensed in retail pharmacies, 2010-2018 extracted from Symphony Health PHASTTM Prescription Monthly Database
- State and quarterly level for each year

Controlling confounding factors
- State population
- Number of pharmacists
- Opioid overdose deaths
- Buprenorphine prescriptions
- State and year fixed effects, state-specific linear time trends

Assessing impact of NALs on outcome
- Change in naloxone dispensing **before and after** policy change in states with policy
- Difference in naloxone dispensed between **states with policy vs those without policy**

Results and Discussion

Figure 1. Pharmacist Authority to Prescribe NALs by State and D.C.
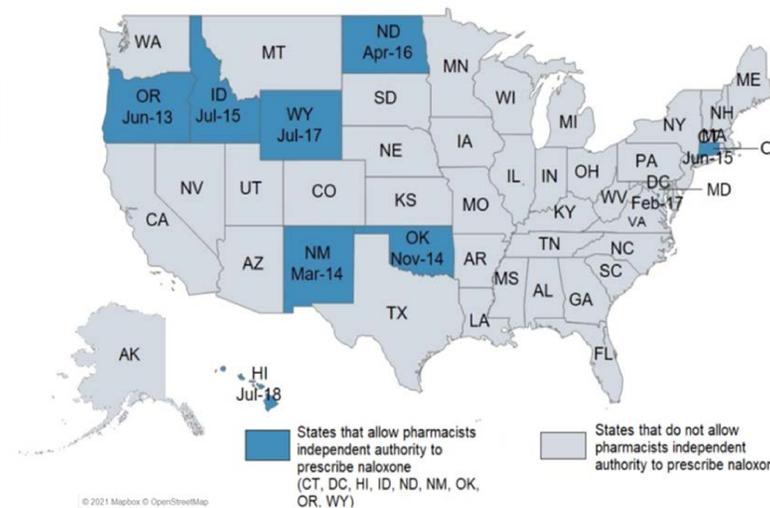
Nine states have enacted PPA-NALs. Effective dates for the nine states are also indicated in the figure. Valid through 9.9.2019.

Table 1. General Characteristics of Dispensed Naloxone Prescriptions in Retail Pharmacies, 2010-2018

Characteristics	2010-2018	2010	2018
	No. (%)	No. (%)	No. (%)
Gender			
Female	635,575 (55.11)	1,609 (49.45)	367,177 (56.55)
Male	498,871 (43.25)	1,450 (44.56)	274,394 (42.26)
Unknown	18,937 (1.64)	195 (5.99)	7,680 (1.18)
Payment Type			
Cash	50,663 (4.39)	1,450 (44.56)	17,497 (2.69)
Medicaid	140,530 (12.18)	172 (5.29)	72,545 (11.17)
Total third party	962, 190 (83.42)	1,632 (50.15)	559,209 (86.13)
Patient age group			
Ages 1-10	2,454 (0.21)	124 (3.81)	709 (0.11)
Ages 11-20	10,870 (0.94)	74 (2.27)	5,016 (0.77)
Ages 21-30	98,174 (8.51)	105 (3.23)	49,023 (7.55)
Ages 31-40	159,549 (13.83)	220 (6.76)	87,160 (13.42)
Ages 41-50	196,358 (17.02)	406 (12.58)	107,940 (16.63)
Ages 51-60	293,356 (25.43)	704 (21.63)	167,287 (25.77)
Ages 61-70	210,917 (18.29)	660 (20.28)	131,552 (20.26)
Ages 71+	101,475 (8.8)	539 (16.56)	68,769 (10.59)
Unknown Ages	80,230 (6.96)	422 (12.97)	31,795 (4.9)
Brand Product			
Yes	1,004,820 (87.12)	7 (0.22)	609,229 (93.84)
No	148,563 (12.88)	3,247 (99.78)	40,022 (6.16)
Product			
Evzio; Kaleo Inc.	150,011 (13.01)	N/A	20,363 (3.14)
Naloxone HCl	148,563 (12.88)	3,247 (99.78)	40,022 (6.16)
Narcan	854,809 (74.11)	7 (0.22)	588,866 (90.7)

Data extracted in February 2020.

Table 2. Estimated Impact of Pharmacist Direct Prescribing Authority on Naloxone Dispensing, 2010- 2018

Naloxone Access Laws (NALs)	Multivariate Negative Binomial Estimator		
	Average Marginal Increase in Naloxone Dispensing per State-Quarter	p-value	95% Confidence Interval
Main policy variable:			
Pharmacist Authority to Prescribe Naloxone (PPA-NAL)	331	0.024	43.56 – 618.49
Key confounding policy variables included in the model:			
Standing Orders	255	<0.001	121.17 – 389.30
Third Party Prescribing	283	<0.001	140.66 – 425.81
Naloxone Co-Prescription	443	0.030	41.96 – 845.14

Conclusion

- To our knowledge, our study is the first to observe a statistically significant association between naloxone dispensing in retail pharmacies and NALs providing prescribing authority to pharmacists:
  - PPA- NALs are associated with an increase of 331 (p-value<0.005) dispensed naloxone prescriptions per state per quarter.
  - This represents an average 53% in naloxone dispensing compared to states without pharmacist authority to prescribe naloxone.

- Many states have adopted these laws in recent years (Figure 1). Thus, the full effects of these laws may not yet be realized.

- Our findings suggest that pharmacists may play an important role in dispensing naloxone which may be because:
  - Pharmacists are readily accessible healthcare providers and can identify those at risk of opioid-use disorders as they have access to patient medication records.
  - They can provide education to patients and laypersons about opioid overdose and naloxone use.

- Continued efforts are needed to improve access to naloxone. This study provides evidence for state and local policy makers to consider whether to enact and/or refine such pharmacist-focused policies.