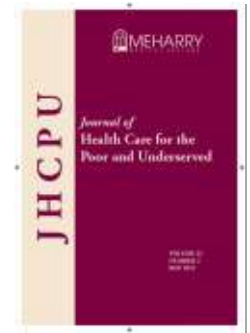




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Insufficient Access: Naloxone Availability to Laypeople in Arizona and Indiana, 2018

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Abstract: Objectives. To understand naloxone availability to laypeople in Arizona (Ariz.) and Indiana (Ind.). **Methods.** Multi-source search conducted from May–December 2018 identified the extent of naloxone availability to laypeople. Internet searches, email follow up, and phone interviews occurred with registered naloxone providers. **Results.** There were 89 naloxone providers in each state. Laypeople were ineligible for access for over half of registered naloxone providers in Ariz. (60.7%) and Ind. (55.1%). Naloxone access was mostly (67.4%) passive in Ariz. but was actively distributed in Ind. (67.4%). Syringe service programs (SSP) were the most frequently identified providers of naloxone to laypeople in Ariz. (20.0%). In Ind., local health departments were most frequently identified as layperson naloxone providers (75.0%). **Conclusions.** Less than half of registered naloxone providers allowed layperson access in Arizona and Indiana. The lack of layperson access highlights the need to review organization practice and state policy to ensure increased layperson access.

Key Words: Naloxone, Narcan, policy, drug users, vulnerable populations.

In 2017 in the U.S., almost 200 people died every day from opioid overdose—a 9.6% increase from 2016.¹ Since the beginning of the COVID-19 pandemic, we have observed an 18% increase in overdoses in the U.S. alone.² Naloxone (Narcan, Evzio) is a highly effective opioid antagonist which is used to reverse the effects of an opioid overdose.³ While approved since 1971 and increasingly used since 1996,^{4,5,6} the extent to which naloxone is available to individuals who might witness an overdose remains unclear. This includes laypeople, defined as people who use drugs (PWUD) as well as their family and friends.⁷ Ensuring layperson access to naloxone is important for two reasons. First, laypeople are usually the first responders by virtue of their proximity;

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over 80% of those who reported administering naloxone were laypeople already present at the time of overdose.^{8,9} Second, increased opioid overdose rates have been associated with the absence of layperson naloxone access programs.¹⁰

Today, naloxone is available to laypeople at U.S. pharmacies in almost every community by prescription or standing order for insurance and/or cash payment.^{11,12} Although pharmacies might appear to be the most efficient access point due to their ubiquity, cost is likely a barrier. In 2018, 30% of naloxone prescriptions dispensed by pharmacies required \$50 or more in out-of-pocket costs.¹³ This is because naloxone is expensive: \$40 for a one-dose intranasal injection, \$150 for a two-dose nasal spray, and up to \$4,500 for an auto-injector two-pack.⁶ A review of naloxone pricing from 2006–2017 found that all but the nasal spray had increased in price, and those formulations that increased did so significantly (from 244%–3797%).¹¹ Insurance coverage varies for naloxone by state, even when covered by Medicaid or Medicare. From 2011 to 2016, Medicare spending on naloxone increased by over 90,000 percent.¹⁴ A study of naloxone dispensing between 2012–2018 found that naloxone was most frequently paid for by commercial insurance, followed by Medicare; 71% of Medicare and 44% of Medicaid subscribers still paid \$10 to \$50 in out-of-pocket costs.¹⁵

In a study of U.S. pharmacy naloxone dispensing from 2012–2018, rural patients were provided naloxone less frequently than urban patients, and overall, naloxone was distributed only once for every 69 high-dose opioid prescriptions dispensed.¹⁵ In contrast, a smaller study of naloxone disbursement by a large pharmacy chain from 2013–2017 in Rhode Island and Massachusetts found that dispensing frequency was higher in more rural areas.¹⁶ Finally, some laypeople who wish to acquire naloxone, especially PWUD, may not be comfortable seeking naloxone at pharmacies due to stigmatizing interactions with pharmacy staff.¹⁷

Federal funding to subsidize naloxone access has made it possible for many organizations to provide naloxone free of charge to particular groups such as schools, first responders, or laypeople. These organizations make naloxone available upon request (passive distribution) or they provide it through community outreach (active distribution). A 2019 study by Townsend et al. found that naloxone distribution to laypeople was cost-effective and extended health benefits.¹⁸ Four years prior, in 2015, the federal government advanced several initiatives to address the dearth of naloxone for laypeople, including prioritizing naloxone for use by the general public and creating state grants for naloxone purchasing programs.¹⁹ By 2017, several states expanded naloxone prescribing and dispensing authority to third-party organizations in addition to pharmacies and first responders.²⁰ One year later, the U.S. Surgeon General recommended that all people have access to naloxone.²¹ Even with federal policy interest, availability of naloxone for laypeople beyond pharmacy dispensing remains unclear.

This descriptive study examined subsidized opportunities for layperson naloxone access in two U.S. states: Arizona and Indiana. Both states recently enacted policy (whether by statute, regulation, and/or executive order) reflecting the need for layperson naloxone access. In 2015, Arizona passed standing order legislation expanding naloxone availability.²² The standing order authorized Arizona-licensed pharmacists to dispense naloxone to individuals without a prescription. In 2017, Arizona's governor declared an opioid state of emergency following high rates of opioid overdose death,²³ and the

Arizona State Department of Health Services provided free naloxone to first responders who were unable to bill third parties for it.¹⁹ Similarly, Indiana passed a standing order law in 2015 allowing limited naloxone dispensing without a medical exam or prescription.²⁴ In 2016, Indiana amended the standing order so that anyone in the state could access naloxone without a prescription.²⁵ Both states reflect the national trend, as almost all U.S. states have enacted legislation allowing access to naloxone beyond first responders and medical professionals.^{26,27}

Arizona and Indiana are important state examples for this study for several reasons: their opioid overdose death rates exceed the national rate,²⁸ both states have diverse rural and urban populations, and their per capita public health investments are low compared with other states. Arizona invests \$9.00 per capita and is ranked 48th among states; Indiana invests \$13.00 per capita and is ranked 43rd.²⁹ Further, these states are historically similar to others in terms of organizational and programmatic naloxone access: in 2014, Arizona had one naloxone-distributing organization and Indiana had none.⁴ This reflected what was happening across the U.S.: in 2013, 20 states did not have any naloxone-distributing organizations and 29 states reported minimal access to naloxone for laypeople.³⁰

The overall objectives of this study were (1) to describe the type of registered organizations that distribute naloxone in each state, (2) to establish the proportion of registered naloxone distributors that allow layperson access, (3) to determine the percentages of registered organizations actively and/or passively distributing naloxone, and finally (4) to identify cost-related data for naloxone access, both in terms of funding source and financial responsibility of the recipient.

Methods

We used a multi-source (internet, email, phone interview) process to generate a descriptive dataset with focus on the following indicators: 1) eligibility of laypeople to access naloxone from the organization (yes/no), 2) organizational distribution mode (passive and/or active), and 3) source of funding for naloxone dispensing. Study eligibility included organizations registered as naloxone providers with the Arizona or Indiana state health agencies. Pharmacies were excluded because it is already known that naloxone is available for purchase under the standing order in each state with patient insurance or out-of-pocket payment.^{23,31}

Each state established its own processes for agencies to become a registered naloxone entity. In Arizona, registration simply included a written request and proof of naloxone training for the agency to obtain naloxone.³² In Indiana, any entity seeking to “act under the Indiana Statewide Naloxone Standing Order” must register with the state.³⁴ This involved making several agreements with the state related to naloxone education and training, annual reporting, and distributing naloxone that has not expired.³³

First, to identify registered naloxone providers in each state, we searched for online documentation of naloxone dispensing registration data for each state. Then, we followed up via email communications with Arizona and Indiana state health agencies to access their published lists and confirm the list completeness. We then examined the lists for organizational rules governing eligibility for naloxone access. Email and/or phone

communication with listed organizations was used to confirm organizational practice and layperson eligibility for naloxone. The investigative team included representatives of the public health workforce in both states, thereby increasing the likelihood that naloxone-dispensing organizations would respond to requests for information.

In Arizona, the list of organizations registered as naloxone providers was displayed online by a statewide harm reduction organization that coordinated naloxone access information. The online list of naloxone providers was entitled “Find naloxone in Arizona.”³⁴ In Indiana, naloxone providers were identified by the Indiana State Department of Health in an online map format displaying organizations registered in Indiana to distribute or sell naloxone.³⁵ The website map and search engine was labeled “Locate Current Naloxone Entities/Provider Search.” The source list for this map was provided to researchers by the Indiana State Department of Health for closer examination. Frequencies related to key outcome variables of layperson access (yes/no), active distribution (yes/no), and passive distribution (yes/no) were examined as well. The study period was May through December 2018.

Results

At the time of this study, Arizona, and Indiana each had 89 organizations registered as naloxone providers. The Arizona state-level naloxone website identified whether naloxone was available to the general public, patients, first responders, schools, or for internal organizational emergency use. Researchers classified organizations into types shown in Table 1 including: behavioral health, corrections, fire department/EMS, hospital or clinic, housing, individual, local coalition or group, local health department, nonprofit organization, school or university, syringe service program, and tribal government organization. ‘Individual’ refers to people (not organizations) who were permitted to register as naloxone distributors in either state (less than 5% in both cases).

Of the 89 Arizona naloxone providers, the most common organization type was behavioral health (34.8%), followed by corrections (11.2%), hospital or clinic (9.0%), housing organizations (7.9%), and syringe service programs (7.9%). The most frequently listed criteria for naloxone access in Arizona included organizational emergency (31.5% of organizations) followed by layperson access and emergency (28.1%), and emergency and patients of the organization (23.6%). Notably, only 39.3% of registered Arizona organizations made naloxone available to the layperson public (meaning that any layperson could access naloxone without a special organizational relationship, e.g., patient or organizational participant).

Indiana’s naloxone distribution website did not specify organizational rules governing naloxone access. Thus, all listed organizations were contacted by phone; 12.4% did not respond to requests for information. Indiana local health departments were the most frequently listed naloxone provider (75.0%) distantly followed by behavioral health organizations (10.0%). The sole organization classified as “other” was the Indiana Gaming Commission. Of the 89 Indiana entities registered as naloxone providers, 14.6% provided naloxone only to first responders. Fewer than half of Indiana naloxone providers (44.9%) made naloxone available to the layperson public. Eight Indiana

Table 1.**REGISTERED NALOXONE PROVIDERS AND LAYPERSON ELIGIBILITY, ARIZONA AND INDIANA—2018**

Organization Type	Arizona (N=89) (%)	Indiana (N=89) (%)
Behavioral Health	31 (34.8%)	8 (9.0%)
Corrections	10 (11.2%)	5 (5.6%)
Fire Department/EMS	0	3 (3.4%)
Hospital or Clinic	8 (9.0%)	6 (6.7%)
Housing (Shelter or Transitional)	7 (7.9%)	0
Individual	4 (4.5%)	4 (4.5%)
Local Coalition or Group	5 (5.6%)	0
Local Health Department	3 (3.4%)	54 (60.7%)
Nonprofit Organization	5 (5.6%)	3 (3.4%)
Other	0	1 (1.1%) ^a
School or University	3 (3.4%)	3 (3.4%)
Syringe Service Program ^b	7 (7.9%)	2 (2.2%)
Tribal Government Organization	6 (6.7%)	0
Naloxone Access Eligibility		
Laypersons	5 (5.6%)	14 (15.7%)
Laypersons and First Responders	0	17 (19.1%)
Laypersons, Agency Emergency	25 (28.1%)	0
Laypersons, Patients and Agency Emergency	5 (5.6%)	2 (2.2%)
Laypersons, First Responders, Schools	0	7 (7.9%)
Agency Carries for Emergency Only	28 (31.5%)	10 (11.2%)
Patients Only	4 (4.5%)	2 (2.2%)
Patients and Agency Emergency	21 (23.6%)	0
Organization Participants Only	1 (1.1%)	0
First Responders Only	0	13 (14.6%)
First Responders and Schools	0	3 (3.4%)
Individuals who recently overdosed	0	1 (1.1%)
Agency does not have kits	0	8 (9.0%)
No Response	0	11 (12.4%)
Active Distribution of Naloxone (Distributes in community through outreach or events) ^c	11 (12.4%)	60 (67.4%)
Passive Distribution of Naloxone (People must come to the organization for access) ^c	60 (67.4%)	37 (41.6%)
Cost of Naloxone to Individual ^d		
Free	46 (51.7%)	60 (67.4%)
Patient Insurance	27 (30.3%)	1 (1.1%)

(continued on p. 824)

Table 1. (continued)

Organization Type	Arizona (N=89) (%)	Indiana (N=89) (%)
Funding Source for Naloxone ^d		
Organization Underwrites	0	3 (3.4%)
Private Donations	0	2 (2.2%)
Foundation Funding	0	1 (1.1%)
State/Federal Grants	0	58 (65.2%)
State/Federal Medicaid	60 (67.4%)	0

Notes

^aIndiana Gaming Commission was listed as a naloxone provider.

^bIn 2018, Indiana local health departments operated seven of eight state-authorized SSPs. It is likely that naloxone distribution was also through the syringe service programs of these local health departments. Source: Indiana State Department of Health. <https://www.in.gov/isdh/files/SSP%20Map%20-%20July%202018-EC.pdf>

^cDoes not add to 100%, as some organizations did not distribute at all; others provided both active and passive options for access.

^dSub-categories do not add to 100% (N=89).

organizations (9.0%) indicated that they did not have naloxone kits at all, despite being registered naloxone providers.

Over half of Arizona and Indiana organizations (51.7% and 67.4%, respectively) provided naloxone for free to individuals. Funding sources for these organization efforts in Arizona included Medicaid (67.4%) and patient insurance reimbursement (30.3%); in Indiana 65.2% of naloxone from the identified organizations was underwritten by state and federal grants.

Over half of Arizona entities (67.4%) made naloxone available by passive distribution. This means that naloxone was accessible only if the organization was contacted or approached for naloxone. In contrast, active distribution refers to naloxone distribution through organizational outreach or community events. Active distribution was reported by only 12.4% of listed Arizona naloxone providers. Among the 11 Arizona organizations actively distributing naloxone through outreach, seven were syringe service programs (SSP).

In Arizona, the most frequently listed entity allowing layperson naloxone access was SSP (20.0%), followed by hospitals/clinics (17.1%), and individuals and behavioral health (11.4% each). See Table 2.

In Indiana, local health departments (LHD) were the most frequently identified organizational type allowing layperson naloxone access (75.0%), and this was just over half of all Indiana LHDs registered as naloxone providers. Seven of the Indiana LHDs permitting layperson naloxone access had state-authorized syringe service programs. Eight behavioral health organizations were registered as naloxone providers in Indiana but only four permitted layperson access. Most of Indiana’s naloxone

Table 2.**LAYPERSON NALOXONE ELIGIBILITY BY ORGANIZATION TYPE, ARIZONA AND INDIANA 2018**

Organization Type	Arizona		Indiana	
	Layperson Eligible # (%)	Layperson Not Eligible # (%)	Layperson Eligible # (%)	Layperson Not Eligible # (%)
Behavioral Health	4 (11.4%)	27 (50.0%)	4 (10.0%)	4 (8.2%)
Corrections	1 (2.9%)	9 (16.7%)	—	5 (10.2%)
Fire Department/EMS	—	—	—	3 (6.1%)
Hospital or Clinic	6 (17.1%)	2 (3.7%)	2 (5.0%)	4 (8.2%)
Housing (Shelter or Transitional)	2 (5.7%)	5 (9.3%)	—	—
Individual	4 (11.4%)	—	—	4 (8.2%)
Local Coalition or Group	3 (8.6%)	2 (3.7%)	—	—
Local Health Department	3 (8.6%)	—	30 (75.0%)	24 (49.0%)
Nonprofit Organization	3 (8.6%)	2 (3.7%)	2 (5.0%)	2 (4.1%)
Other	—	—	—	1 (2.0%) ^a
School or University	—	3 (5.6%)	—	2 (4.1%)
Syringe Service Program	7 (20.0%)	—	2 (5.0%)	—
Tribal Government Organization	2 (5.7%)	4 (7.4%)	—	—
Total	35 (100%)	54 (100%)	40 (100%) ^b	49 (100%)

Notes^aIndiana Gaming Commission.^bSeven of the eight Indiana local health departments operating syringe service programs reported layperson eligibility for naloxone. They are included under the local health department category.

providers actively distributed it through trainings or outreach events (67.4%), even if laypeople were barred from access. Passive distribution was offered by 42.0% of Indiana naloxone providers.

Discussion

Despite state-level policy expanding public access to naloxone in Arizona and Indiana, far fewer than half of registered naloxone distributors allowed layperson access. In one respect, this is a matter of concern given the fairly strong evidence that naloxone in the hands of laypeople can help to reduce overdose deaths.⁸⁻¹⁰ However, this does not suggest failure in state efforts to support naloxone access in view of the likely importance of allowing various groups access to subsidized naloxon. At the same time, layperson access, including to PWUD, is an important component of the overall national response to the opioid overdose crisis.²² Thus, it is important to understand that, at least as of 2018, extant efforts were probably necessary but not sufficient to facilitate broad access to naloxone by laypeople in these two states.

A study limitation is that we did not collect data concerning why organizations disallowed layperson access to naloxone. Understanding this discrepancy is likely to be important given the national goal of universal layperson access to naloxone.²² There may be several reasons that layperson access was lower than anticipated. First, perhaps by their very nature, many registered organizations are focused internally,³⁶ seeking to prevent overdoses among their patients and/or clients. This is entirely rational and important, but it serves as a reminder that simply increasing the number of organizations eligible to distribute subsidized naloxone may not improve access throughout a community. A second explanation may be that the evidence regarding the importance of layperson access to naloxone has not been sufficiently disseminated outside of academia and harm reduction organizations. Without this information, it stands to reason that organizations would not necessarily prioritize layperson access. Third, it may reflect a policy delay whereby layperson access was encouraged nationally, but uptake was not reflected by the year of this study. We found such a policy delay in Indiana with pharmacy naloxone stocking and dispensing following the passage of state law permitting naloxone access via statewide standing order.³⁷ Finally, layperson naloxone access might not have been a consideration at the time the online databases were constructed. It may be that the original thought in their design was to provide naloxone to the public through prescription only and focusing on dispensing to first responders and organizations thought likely to be in close proximity to a person overdosing (behavioral health, syringe service programs).

Furthermore, it is important to ensure that websites are clear and correct. In Arizona, for example, the online list of naloxone distributors is entitled “Find naloxone in Arizona.” In Indiana, the website map and search engine are labeled “Locate Current Naloxone Entities/Provider Search.” One would reasonably assume that the audience of such searches includes laypeople. An information gap was apparent in Indiana because the online map did not indicate naloxone access criteria. It is necessary that there be a future exploratory study of naloxone distribution organizations across states identifying rationales for prohibiting layperson access.

Beyond clarifying which organizations provide naloxone for the general public, a greater concern is the fact that the majority of registered naloxone distributors in Arizona and Indiana do not allow layperson access. To our knowledge, there is no effort to articulate a policy requiring organizations receiving subsidized naloxone to make it available to laypeople. Given federal and state recognition that layperson naloxone access is important, including a formal statement by the U.S. Surgeon General,²² such a requirement would be entirely consistent with the current evidence for naloxone efficacy. Moreover, the types of organizations accepting publicly subsidized naloxone (e.g., hospitals/clinics and behavioral health organizations) may have the ability to bill third party payors for remaining expenses, but this is only relevant in cases of individuals who have insurance. A review of such organizations is likely warranted, especially if the naloxone subsidies or kits are limited within states.

While naloxone is available over the counter at pharmacies, one can assume that this is more likely to benefit laypeople who can afford the unsubsidized cost. While no studies have examined the proportion of laypeople who have attempted to access nal-

oxone unsuccessfully due to cost prohibitions, the need might be grossly approximated by the percentages of pharmacy customers who ask about inexpensive naloxone. Our 2019 statewide survey of Indiana managing pharmacists in community pharmacies found that 36.1% were asked how to get free or subsidized naloxone by their patients in the past two years, and 73.8% had been asked whether insurance covers naloxone.³⁸ The outcomes of these informational requests, whether individuals purchased naloxone through insurance or used some form of subsidy of which we are unaware, are unclear. These results do, however, indicate public interest in naloxone acquisition, and concern about prices.

In addition to layperson interest in subsidized pricing, we assume they are interested in having naloxone available and easily accessible in communities. Our finding that only 12.4% of Arizona organizations actively distributed naloxone compared with 67.4% of organizations in Indiana makes clear the potential for broad differences in distribution approaches among states. An additional study limitation is that ours included only two states and therefore cannot make implications relevant for the nation as a whole. Future studies should investigate the existence and effects of active and passive naloxone distribution on reported use for overdose reversal among a large sample of states. One might hypothesize that active naloxone distribution is critical in ensuring that those in close proximity to someone overdosing (most often drug users themselves or other laypeople) have naloxone in hand.

In conclusion, less than half of registered naloxone distributors in two states allowed layperson access. The low frequency of organizations reporting active distribution, versus passive, was also observed. These findings suggest a necessary realignment with national goals to improve layperson naloxone access.

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