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Research Paper

Pharmacist dispensed naloxone: Knowledge, availability, participation and cost in selected California counties

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ABSTRACT

Background: In 2014, California signed into law AB1535 permitting pharmacists to dispense naloxone upon request and without physician or midlevel provider prescription.
Objective: We sought to determine pharmacist knowledge of AB1535, participation, availability of naloxone, future plans for participation, and out-of-pocket charges to consumers amongst outpatient pharmacies in selected California counties.
Methods: All pharmacies in Plumas, Lake, Lassen, Humboldt, Shasta, Fresno, and San Diego Counties were identified. Between January 30 and March 30, 2017, pharmacies meeting inclusion criteria were contacted and the pharmacist-on-duty were queried regarding knowledge, participation, availability, and cost of naloxone.
Results: A total of 2296 pharmacies were identified in the 7 counties. Twenty-six were unwilling or unable to participate and an additional 1648 were excluded because of licensing or special pharmacy status. Six-hundred-twenty-two pharmacies completed the survey. There was variation in knowledge of AB1535, participation in, immediate availability of naloxone, charge, and expressed future interest in participation identified. Charge to consumers was similarly variable amongst surveyed pharmacies within counties.
Conclusions: Despite considerable public health and political support, the passage of CA AB1535 has not resulted in broad current, future planned participation, or availability of naloxone in selected counties. Out-of-pocket costs to the consumer remain highly variable.

Background

The United States (US) is facing a serious public health crisis secondary to opioid-related overdoses and fatalities. In 2007, enough opioids were prescribed in the US to provide everyone with a "5 mg dose of Vicodin (hydrocodone 5 mg, acetaminophen 500 mg) every 4 h for 3 weeks" (CDC Grand Rounds: Prescription Drug Overdoses, 2012). According to the US Drug Enforcement Administration (DEA), "Overdose deaths, particularly from prescription drugs have reached epidemic level." (National Drug Threat Assessment Summary, 2015) The Centers for Disease Control (CDC) have declared, "America is awash in opioids; urgent action is critical."(CDC Chief Frieden, 2017) Drug overdose remains the leading cause of death in Americans under the age of 50, and two thirds of these are due to opioids. In fact, drug overdoses kill more Americans than guns (Drug Deaths in America Are Rising Faster than Ever, 2018; Drug overdoses now kill more Americans than guns, 2016).

In response, some have suggested that opioid-related deaths can be reduced by giving opioid drug users/abusers and their families access to naloxone (Opioid Overdose Prevention Programs Providing Naloxone to Laypersons, 2014). Naloxone, a medication available since 1971, reverses the effects of opiates and opioids and "restores breathing within minutes of administration" (Governor Jerry Brown Signs Overdose Law Expanding Naloxone Access in California Pharmacies, 2017). According to published research, providing naloxone to laypersons reduces overdose deaths (Walley, Xuan, & Hackman, 2013), is safe (Doyon, Aks, & Schaeffer, 2014), and is cost effective (Coffin & Sullivan, 2013). Expanding access to naloxone has been identified as a national strategy for preventing death from opioid overdose (US Department of Health & Human Services, 2019). A number of US states have explored options for expanding naloxone access through community pharmacy distribution initiatives (Bachyrycz, Shrestha, Bleske, Tinker, & Bakhireya, 2017; Morton et al., 2003).

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In June 2014, a task force of public health experts met to discuss the "impact of and efforts to address prescription drug misuse, abuse, and overdoses in California (CA)". At that conference, public health experts reviewed available state data, identified, and discussed the dramatic increase from 5,753 cases in 2006 to 11,683 in 2014 (103% increase) in state ED visits for prescription-opioid-related overdoses and other adverse effects. The age-adjusted-opioid-pharmaceutical-related death rates (Deaths/100,000 population) of each CA county were identified. Between 2009 and 2013, Plumas (24.51), Lake (22.50), Lassen (16.78), Humboldt (13.32), and Shasta (11.76) were identified as the counties with the highest average opioid-related death rates in the state (California Department of Public Health, 2016). In September 2014, CA signed into law AB1535, permitting but not mandating pharmacists to furnish naloxone upon request according to standard protocol and without physician (MD/DO) or midlevel provider (PA/NP) prescription. The bill was strongly supported by health and drug treatment organizations (California Legislative Information, 2018). Bill author Richard Bloom stated: "AB1535 will have a real and immediate impact on reducing overdose deaths in California and will empower families throughout the state to access this life-saving drug." (Governor Jerry Brown Signs Overdose Law Expanding Naloxone Access in California Pharmacies, 2017).

To date, there is limited published literature describing how many CA pharmacies are participating in the program described by AB1535, naloxone availability, or out-of-pocket charge to consumers. We sought to determine knowledge of AB1535, participation, availability of naloxone, future plans for participation, and out-of-pocket charges to consumers amongst outpatient pharmacies in a sample of 7 California counties.

Methods

Setting and design

All pharmacies in Plumas, Lake, Lassen, Humboldt, Shasta, San Diego and Fresno county were identified using the state Department of Consumer Affairs (DCA) "License Search for Pharmacies" website (License Search for Pharmacies, 2018). Inpatient hospital pharmacies, specialty pharmacies (infusion, prison, long-term care, tribal affiliation), and pharmacies with reported limitation (cancelled, restricted, probation, delinquent) in prescribing were excluded.

Plumas, Lake, Lassen, Humboldt, and Shasta counties were chosen for inclusion as they represented the counties with the highest prescription opioid death rates identified by the previously described task force and were therefore thought most likely to implement and benefit from AB1535 (California Department of Public Health, 2016). These counties are sparsely populated, predominantly Caucasian, have slightly higher median age, and are located in the most northern part of the state. As it was logistically impossible to query all state pharmacies in this initial pilot observation study, other counties were added to more closely represent the population demographics and geography of the state. San Diego and Fresno are in the southern and central parts of the state respectively, are more populous, and represent more ethnic diversity (See Table 1). In 2016 (the last year of available data prior to study implementation), Los Angeles was the most populous county in the state but had an opioid pharmaceutical death rate significantly lower than the state as a whole in 2012 (1.59 vs 3.30), 2013 (1.98 vs 3.49), 2014 (1.92 vs 3.52), 2015 (1.85 vs 3.30), and 2016 (2.44 vs 3.43) (California Opioid Overdose Surveillance Dashboard, 2017). The authors felt that it was more appropriate to include counties with the highest opioid pharmaceutical death rates for inclusion as these were thought to be most likely to implement and benefit from AB1535; Los Angeles was therefore not included in the present study.

Data acquisition

Between January 30 and March 30, 2017, pharmacies were contacted using the phone number listed on the DCA website. Interviewers identified themselves as conducting naloxone-related research, university affiliation, voluntary participation, and whether the contacted pharmacist was willing to answer a few questions; the pharmacist-on-duty was asked the following questions: 1) Are you familiar with AB1535 that permits pharmacists to dispense naloxone without a prescription? [Yes/No] 2) Are you or your pharmacy currently participating in the program? [Yes/No] 3) If Yes, do you currently have naloxone on the shelf? [Yes/No] 4) What is the earliest availability of naloxone if not currently available? 5) What is the cheapest available cost? 6) If not currently participating, do you or your pharmacy plan to participate in the next 6 months? [Yes/No].

Three attempts were made over one week to contact the pharmacies that met inclusion criteria during regular business hours for each of the pharmacies. A standard script was utilized by all study authors who participated in data collection to limit variability as a result of how questions were asked. The authors did not specifically ask whether the naloxone product(s) was generic or brand name as it was thought that this would be irrelevant to the consumer. Rather, interviewers asked about the cheapest product available and the charge for same. The recorded values represent either the cheapest product or the charge for whatever product was available at a given pharmacy. Among participating pharmacies in the 5 CA counties previously identified as having the highest prescription-opioid-related death rates, pharmacists were also asked if they had dispensed any naloxone since program implementation.

Analysis

All responses were recorded and tabulated using Microsoft Excel for Mac 2016 (Microsoft Corporation, Redmond WA). Descriptive statistics were calculated.

Results

A total of 2296 pharmacies were identified in the 7 counties using the DCA website. (Fig. 1) Six-hundred-twenty-two pharmacies completed the survey. Study results are presented in Table 2.

Knowledge of AB1535

Pharmacist knowledge of AB1535 was generally high with 100% of queried pharmacists being aware of the bill in 4 of the 5 counties identified with the highest prescription-opioid-related death rates (Shasta County 91% (n = 31)). Knowledge of AB1535 was slightly less in Fresno (73%, n = 110) and San Diego Counties (77%, n = 308). Overall, 79% (n = 489) of pharmacists in the present study were aware of AB1535 and the provision for pharmacist dispensed naloxone without a prescription.

Participation and future participation

Despite high rates of knowledge of AB1535, current and future participation was generally low. Thirty-seven percent of pharmacists overall (n = 230) were currently participating while future planned participation was similarly low (21% n = 81). This was especially notable in the counties identified with the highest rates of prescription-opioid related deaths. Only 20% (n = 1) of Plumas, 23% (n = 3) of Lake, 0% of Lassen, 35% (n = 6) of Humboldt, and 29% (n = 10) of Shasta County pharmacists reported current participation. Both Fresno (25% n = 38) and San Diego (43%, n = 172) County pharmacists reported similarly low rates of current participation. Future participation was not planned for the majority of Northern California counties (Lake-

Table 1
Selected California Counties Demographic Characteristics 2017 (California Opioid Overdose Surveillance Dashboard, 2017; United States Census Bureau, 2018).

County	Age adjusted death rate*	Location in State	Population	Population position in state#	Median Income	Median Age	Percentage of Poverty	Percent White	Percent African American	Percent Hispanic	Percent Asian American
Plumas	not reported	Northern	18742	51st	50125	51.7	12.60%	90.80%	1.10%	8.90%	1.10%
Lake	10.61	Northern	64,246	40th	36132	45.8	24.60%	87.40%	2.10%	20.60%	1.40%
Lassen	19.86	Northern	31163	47th	51457	36.4	17.60%	81.40%	8.30%	19.00%	1.60%
Humboldt	16.4	Northern	136754	35th	42,685	37.6	20%	85.30%	1.40%	11.70%	2.90%
Shasta	3.91	Northern	179921	31st	45.582	42.3	17.20%	88.00%	1.10%	10.10%	3.10%
San Diego	4.9	Southern	3337685	2nd	66529	31.6	12.40%	75.60%	5.50%	33.90%	12.50%
Fresno	6.2	Central	989,255	10th	45963	35.3	26%	76.90%	5.80%	53%	11.00%

There are 58 California counties.
* California average 3.43.

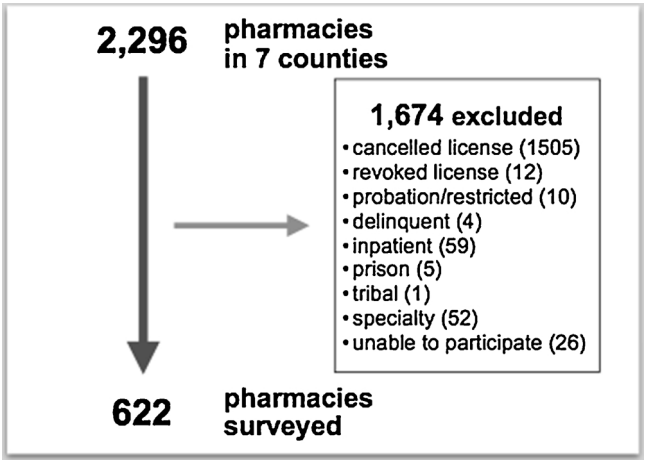

Fig. 1. Study enrollment flowchart.

0%, Lassen-0%, Shasta-0%). Future planned participation in Fresno and San Diego counties were higher (Fresno 19%, n = 21; San Diego 26%, n = 59).

Availability of naloxone

Immediate naloxone was available in all participating pharmacies in Plumas, Lake, Humboldt and Shasta Counties. Same-day naloxone was available at only 24% (n = 9) of participating pharmacies in Fresno County and 78% (n = 135) of participating pharmacies in San Diego County. In San Diego County, 16% (n = 26) of participating pharmacies required more than two days to obtain a naloxone product. Overall, 71% (n = 164) of participating pharmacies reported naloxone in stock and immediately available to a consumer.

Available product and cost

Intranasal (IN) was the most commonly available preparation (204/230). Mean charge for IN naloxone to consumers was $112.62 (standard deviation: 36.54), median $109.99. The lowest charge was $44.99 (Lake County) and highest was $166.25 (Plumas County). The largest range within county was $46.74 to $260 in San Diego County.

Injectable (IV/IM) preparations were less commonly available (32/230) with an even larger variability in charge to consumer identified. Amongst the three out of thirteen participating pharmacies in Lake County, two carried an IV/IM preparation at a cost of $70; none of the remaining five Northern California counties carried injectable naloxone preparations. In San Diego, the charge to consumer ranged from $27 to $4500.

Participation by Type of Pharmacy (Regional/national chain vs independent)

Counties with higher rates of participation were associated with participation by a regional or national pharmacy chain. CVS Pharmacy has made it a point of business practice and culture to dispense naloxone in most communities where able to without a prescription (Save a life with naloxone, 2018). In fact, 123 of the 230 participating pharmacies in the current survey were CVS pharmacies (53.5%). All 10 participating pharmacies in Shasta County were owned by the same parent company and represented a regional pharmacy chain. However, other regional/national chain pharmacies such as RiteAid, Walmart, Walgreen and Costco do not have similar policies and participation by

Table 2
Pharmacy demographics and description of naloxone preparations and costs.

CA County (number of pharmacies)	Plumas n = 5	Lake n = 13	Lassen n = 5	Humboldt n = 17	Shasta n = 34	Fresno n = 150	San Diego n = 398	Total n = 622
Knowledge of bill	5 (100%)	13(100%)	5 (100%)	17 (100%)	31 (91%)	110 (73%)	308 (77%)	489 (79%)
Participation	1 (20%)	3 (23%)	0	6 (35%)	10 (29%)	38 (25%)	172 (43%)	230 (37%)
Naloxone in-stock	1	3	NA	6	10	9	135	164
Naloxone available next-day	NA	NA	NA	NA	NA	29	11	40
Future participation	1/4 (25%)	0/10	0/5	1/11 (9%)	0/24	21/112(19%)	59/226(26%)	81/365(21%)
Intranasal (IN)	1	1	0	6	10	34	152	204
Mean Cost ($, range if applicable)	166.25	44.99	NA	85.83(85-90)	130	77 (44.9-200)	122(46.74-260)	112.62 (44.9-260)
SD	0	0	NA	2	0	45	110	36.54
Median	NA	NA	NA	85	130	57.6	112	109.99
Injectable (IM/IV)	0	2	0	0	0	10	20	32
Mean Cost ($, range if applicable)	NA	70	NA	NA	NA	58.40(29-152.14)	524.10(27-4500)	335.64(27-4500)
SD	NA	0	NA	NA	NA	32	1265	1018.14
Median	NA	NA	NA	NA	NA	53.9	100	51.5

each pharmacy chain was variable both between company and between outlets even within the same county. In the present study, residents of counties with reduced CVS penetrance or regional pharmacy participation experienced decreased availability of naloxone. Larger counties such as Fresno and San Diego County experienced higher rates of participation because these counties had a higher number of CVS pharmacies available to the population while smaller counties often did not have other than independent single outlet pharmacies. Lassen County with 0% current participation and 0% future planned participation had no regional or national pharmacy chain at the time of the study while Lake and Humboldt each had at least one CVS pharmacy outlet.

Dispensed naloxone

No participating pharmacists in Plumas, Lake, Humboldt, Lassen, or Shasta Counties described having dispensed naloxone without a prescription since AB1535 passage in September 2014. No participating pharmacist in Plumas, Lake, Humboldt, Lassen or Shasta Counties similarly described having had a patient who presented with a physician/midlevel provider prescription for naloxone.

Discussion

In the present study, we sought to characterize the nature and characteristics of outpatient pharmacist dispensing of naloxone to laypersons as a result of state bill AB1535. While knowledge of AB1535 by pharmacists was high participation was generally low with similarly low interest in future participation. Many non-participating pharmacists freely expressed a lack of interest because, "no one has asked for it" or "opioids are not a problem in my area" despite the evidence to the contrary identified by the number of prescription-opioid-related deaths per year in their areas by the previously described state task force (California Department of Public Health, 2016). This is consistent with other published descriptions of reasons for lack of participation including "low public awareness, heavy workloads, fear that they won't be adequately paid, and reluctance to treat drug-addicted people." (Pharmacists Slow to Dispense Lifesaving Overdose Drug, 2018) Other sources have described ethical concerns related to the role of the pharmacist and whether dispensing naloxone could somehow condone continued drug abuse/misuse (Bailey & Wermeling, 2014). This previously published literature and the current study suggest that other factors are involved in a reluctance of pharmacies to participate. Reasons for current or future planned participation were not examined in the present study and represent a potential future topic for research.

Even amongst participating pharmacies in the 5 Northern California counties with the highest prescription-opioid related death rates, expressed public interest in pharmacist-dispensed naloxone is quite low. In fact, no surveyed participating pharmacist in Plumas, Lake, Lassen, Humboldt, or Shasta Counties reported having dispensed naloxone by prescription or under the auspices of AB1535. However, the costs associated with these products may be prohibitive, a lack of public awareness of naloxone and its benefit may exist, as well as a myriad of other factors not examined in the present study. In 2014, New Mexico (NM) initiated a similar program for pharmacist dispensed naloxone without provider prescription. In 2016, 28% of outpatient pharmacies in NM were dispensing naloxone. This is consistent with overall rates of participation found in the present study in CA. The top 3 perceived barriers to implementation in NM included pharmacy reimbursement challenges, affordability, and lack of patient interest. Many of these same issues are identified in the present study, suggesting that these issues and concerns are more global and not state specific (Morton et al., 2003).

There was wide variability in out of pocket charge for naloxone between pharmacies in the same geographical region. It is notable that the previously cited research involving cost effectiveness and safety of distribution of naloxone to opioid users/abusers and family did not require purchase or charge to those receiving the naloxone (Morton et al., 2003; Walley et al., 2013). We are unable to find research that adequately describes the impact of charge to the end-user on naloxone effectiveness or on willingness to purchase. Similarly, the wide variability in cost within the same county but at different pharmacies may limit effectiveness due to limited access because of charge.

One unforeseen observation from the current study was the influence of type of pharmacy on program participation. Specifically, the influence of the number of CVS pharmacies overall and within a specific county on program participation in the present study was seen. Counties with more CVS pharmacies were most likely to have at least one participating pharmacy and counties with more CVS pharmacies were more likely to have higher rates of participation. Higher penetrance of other national pharmacy chains (i.e. Walgreen, RiteAid, Costco, etc.) was not associated with higher participation; it was observed that even within the same county, participation was highly variable amongst different outlets of the same national chain. This may represent an incidental finding resulting from the specific counties queried rather than a more global association for the state of California as a whole. However, this also represents a potential area for further research and targeted intervention.

Limitations

This is an observational survey study limited to the responses received by pharmacists at the time of call. There was no way to validate responses made or information received. A standard script was utilized by all study authors who participated in data collection to limit variability as a result of how questions were asked. The results are also limited to the counties queried and may not be generalizable to other California counties or other states with similar programs. It was not logistically feasible in this initial pilot study to query all California pharmacies and this represents a significant limitation. However, the authors feel that the information obtained is particularly useful to discussions of policy and policy-making: namely limited participation, limited interest on the part of pharmacies and pharmacists, and wide variability in out-of-pocket charges to consumers. The authors similarly did not specifically ask about charges related to insurance coverage. Other external factors such as naloxone distribution programs or naloxone being carried by first responders (Law Enforcement, EMS, etc.) were not evaluated in the present study. The authors acknowledge that the availability of free naloxone through county or other public health programs may have an undetermined influence on pharmacist participation or pharmacy availability.

Conclusions

Despite considerable public health and political support, the passage of CA AB1535 has not resulted in broad current or future planned participation, or immediate availability of naloxone in all parts of California. No surveyed pharmacist in the 5 counties with the highest rates of opioid related deaths reported dispensing naloxone under the auspices of AB1535. Out-of-pocket charges to consumers are highly variable between pharmacies within the same county. Future studies should be aimed at examining the reasons for low participation by pharmacists and the public and potential areas for intervention to increase availability of naloxone and state-wide implementation of AB1535.

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Conflict of interest

None of the authors have any conflicts of interest to declare.

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