Drug and Alcohol Dependence 157 (2015) 112–120

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Full length article

# Legal changes to increase access to naloxone for opioid overdose reversal in the United States

Corey S. Davis[a,*], Derek Carr[b]

[a] Network for Public Health Law, 3701 Wilshire Blvd. #750, Los Angeles, CA 90010, United States
[b] Network for Public Health Law, 101 E. Weaver St. #G-07, Carrboro, NC 27510, United States

ARTICLE INFO

*Article history:*
Received 28 August 2015
Received in revised form 6 October 2015
Accepted 6 October 2015
Available online 22 October 2015

*Keywords:*
Naloxone
Opioids
Overdose
Law
Public health

ABSTRACT

*Background:* Opioid overdose, which has reached epidemic levels in the United States, is reversible by administration of the medication naloxone. Naloxone requires a prescription but is not a controlled substance and has no abuse potential. In the last half-decade, the majority of states have modified their laws to increase layperson access to the medication.
*Methods:* We utilized a structured legal research protocol to systematically identify and review all statutes and regulations related to layperson naloxone access in the United States that had been adopted as of September, 2015. Each law discovered via this process was reviewed and coded by two trained legal researchers.
*Results:* As of September, 2015, 43 states and the District of Columbia have passed laws intended to increase layperson naloxone access. We categorized these laws into three domains: (1) laws intended to increase naloxone prescribing and distribution, (2) laws intended to increase pharmacy naloxone access, and (3) laws intended to encourage overdose witnesses to summon emergency responders. These laws vary greatly across states in such characteristics as the types of individuals who can receive a prescription for naloxone, whether laypeople can dispense the medication, and immunity provided to those who prescribe, dispense and administer naloxone or report an overdose emergency.
*Conclusions:* Most states have now passed laws intended to increase layperson access to naloxone. While these laws will likely reduce overdose morbidity and mortality, the cost of naloxone and its prescription status remain barriers to more widespread access.



## 1. Introduction

### 1.1. The opioid overdose epidemic

Fatal poisonings, most of which are caused by drug overdose, have increased by nearly 600% in the past three decades and are now the leading cause of injury death in the United States (Warner et al., 2011). This rise was initially driven primarily by deaths attributable to opioid painkillers, which nearly quadrupled between 1999 and 2011 and reached over 16,000 in 2013 (Chen et al., 2014; Modarai et al., 2013; Okie, 2010). The country has also seen a dramatic surge in heroin-related deaths, which increased by nearly 400 percent between 2000 and 2013 to over 8,000 per year (Chen et al., 2015; Hedegaard et al., 2015; Jones, 2013; Pollini et al., 2011; Rudd et al., 2014). The vast majority of opioid overdose deaths are preventable.

Opioid overdose occurs when opioids, either alone or in combination with other drugs, cause respiration to slow to the point that insufficient oxygen is available to the brain and other vital organs (Bouillon et al., 2003; Pattinson, 2008; White and Irvine, 1999). This condition, termed hypoxia, can cause irreversible cell death within minutes and can prove fatal if not treated (Michiels, 2004). Regardless of whether it is caused by heroin or prescription painkillers, opioid overdose can be reversed by administration of the medication naloxone (Chamberlain and Klein, 1994). Naloxone, which was first approved by the Food and Drug Administration (FDA) in 1971, is a prescription medication but not a controlled substance (Davis et al., 2013). It rapidly displaces opioids from the brain receptors to which they bind, reversing their effects and restoring normal respiration (Chamberlain and Klein, 1994; Lewanowitsch and Irvine, 2002). It is a pure opioid antagonist that produces no euphoric or analgesic effect and thus has no potential for abuse (Chamberlain and Klein, 1994).

* Corresponding author. Tel.: +1 310 204 6010.
*E-mail addresses:* cdavis@networkforphl.org (C.S. Davis), carr@healthlaw.org (D. Carr).

http://dx.doi.org/10.1016/j.drugalcdep.2015.10.013
0376-8716/

Naloxone is stocked by every medical facility that administers opioids, and is standard equipment on ambulances (Barton et al., 2002; Davis et al., 2014c). Currently, the FDA has approved it only for injection, but an off-label nasally administered version has seen extensive adoption by police officers, emergency medical responders, and laypeople with positive results (Ashton and Hassan, 2006; Davis et al., 2015a, 2014b; Doe-Simkins et al., 2009; Rando et al., 2015; Robertson et al., 2009; Wheeler et al., 2015). An auto-injector specifically labeled for use by laypeople (brand name Evzio) was approved in 2014, and two nasal administration devices are currently under review by the FDA (Enos, 2015; Food and Drug Administration, 2014).

### *1.2. Reducing opioid overdose morbidity and mortality by increasing access to naloxone*

Equipping people who use opioids and the friends and family members of those at risk of opioid overdose with the tools to quickly reverse it can shorten the time to overdose rescue, reducing the probability of overdose death and limiting damage to the brain and other organs (Galea et al., 2006; Walley et al., 2013). Because people who use drugs (PWUD) and their friends and family members are often already "on the scene" of an overdose, experts have suggested equipping them with naloxone since at least the early 1990s, and programs that distribute naloxone to heroin users have operated in Germany, Italy, and the United Kingdom for nearly two decades (Coffin et al., 2003; Simini, 1998; Strang et al., 1996).

The first programs to dispense naloxone to PWUD in the United States were launched in Chicago in 1996 and San Francisco in 2001 (Bigg and Maxwell, 2002; Centers for Disease Control and Prevention, 2012; Seal et al., 2005). By the mid-2000s, community programs in a number of states had begun distributing naloxone and overdose rescue training to PWUD and the friends and family members of people at high risk of overdose (Clark et al., 2014; Doe-Simkins et al., 2009; Galea et al., 2006; Maxwell et al., 2006; Piper et al., 2008). As of 2014, over 150,000 laypeople had received training and naloxone rescue kits, with more than 26,000 overdose reversals reported (Wheeler et al., 2015). Many of these programs initially operated without clear legal authorization, significantly limiting their impact.

Recent evidence from Massachusetts found that communities with higher access to naloxone and overdose training had significantly lower opioid overdose death rates than those that did not (Walley et al., 2013). Access to naloxone does not appear to encourage risky behavior. Researchers examining the naloxone distribution program in Massachusetts found that "training active substance users in overdose management and distributing naloxone rescue kits does not lead opioid users to increase their overall opioid use" (Doe-Simkins et al., 2014). Studies also show that providing naloxone may save resources in addition to lives. In a 2013 analysis, researchers found that providing naloxone kits to heroin users was robustly cost-effective even under extremely conservative assumptions (Coffin and Sullivan, 2013). A separate examination noted that the cost of treating people who had overdosed in Rhode Island hospitals in 2008 could have paid for more than 61,000 naloxone kits at the then-current cost of $15 each (Yokell et al., 2011).

Because naloxone is available only via prescription, it remains out of reach of many people, particularly those who are underserved by the health care system. This situation is made worse by a patchwork of laws and legal considerations. Although it is legal for clinicians to prescribe naloxone to their own patients at risk of overdose, some prescribers have refrained from doing so because of misconceptions about when it is appropriate to prescribe the medication and concerns that doing so might increase their risk of civil liability (Beletsky et al., 2007; Burris et al., 2009). Similarly, state medical practice laws have traditionally prohibited the prescription of medication in the absence of a provider-patient relationship (Davis et al., 2013). Finally, people present at the scene of an overdose often report neglecting or waiting to call 911 because they fear being charged with a crime, particularly where they are using illegal drugs or using prescribed medication other than as prescribed (Enteen et al., 2010; Sherman et al., 2008; Tobin et al., 2005).

Taken together, these barriers often prevent naloxone from being available when and where it is needed. From 2010 to 2015, states have made great strides in changing law, regulation, and policy to increase access to naloxone for patients, first responders, community organizations, and laypeople. This article describes those changes, and offers suggestions for further modifications to improve access to this life-saving medication.

## 2. Material and methods

Using standard public health law research methods, we systematically collected, reviewed, and coded laws relevant to layperson naloxone access in the United States (Davis et al., 2014a; Harvey, 2013). First, we searched the Westlaw legal database for all statutes and regulations (hereafter referred to as "laws") related to such access that had been signed or otherwise become law as of September 15, 2015. This database, which is commonly used by lawyers and legal researchers, contains the text of all state-level laws in the United States. Previous research has reported no differences between the laws available on Westlaw and LexisNexis, another popular legal database (Ibrahim et al., 2011). All laws in the 50 United States and the District of Columbia were searched for the terms "naloxone," "opioid antagonist," "opiate antagonist," and "overdose." Results were cross-referenced with a publicly available compendium of naloxone access laws that is maintained by the authors (Davis, 2015).

Relevant laws identified through this process were first downloaded for review. Each law was then examined for relevance to one or more of three domains: laws that increase access to naloxone among laypeople generally, laws that increase access to naloxone in the pharmacy setting, and laws that encourage laypeople to summon first responders in the event of an overdose. Within these domains, coding categories were created based on the authors' previous research in this area of law as well as a review of the published literature regarding distinguishing characteristics of layperson naloxone access initiatives in the United States, with each category representing a characteristic of each state's law (Bailey and Wermeling, 2014; Banta-Green et al., 2013; Clark et al., 2014; Davis et al., 2013; Green et al., 2015; Haegerich et al., 2014). The research team then collaboratively coded the presence or absence of each categorical characteristic for each state in each of the three domains.

## 3. Results

In 2001, New Mexico became the first state to modify its laws to increase layperson access to naloxone. While there was little movement in this area for nearly a decade, the years between 2010 and 2015 saw a dramatic increase in naloxone access legislative enactments. As of 2010, only four states had amended their laws to improve naloxone access. By September 15, 2015, all but seven states (AZ, IA, KS, MO, MT, SD, WY) had passed legislation designed to improve layperson naloxone access, with most both making it easier for people who might be in a position to assist in an overdose to access the medication and encouraging those individuals to summon emergency responders. The characteristics of these laws vary greatly between states (throughout this section, "states" refers to the 50 United States as well as the District of Columbia).