



## Short Report

## Identifying gaps in the implementation of naloxone programs for laypersons in the United States

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## ABSTRACT

**Background:** The opioid epidemic in the United States (US) continues to generate significant increases in morbidity and mortality with no sign of decline. Overdose education and naloxone distribution (OEND) programs are highly effective at preventing opioid overdose mortality. We assessed the geographical distribution of overdose mortality and OEND programs in the US.

**Methods:** We conducted a cross-sectional, ecological study of all 3142 counties in the United States. Our variables of interest included 1) county-level drug overdose mortality rates, and 2) whether the county had an established OEND program. We mapped the drug overdose mortality rates and presence of OEND programs and assessed for differences in OEND program implementation by drug overdose mortality rates with Fisher's exact test.

**Results:** In total, 8% (254) of counties in the US had established OEND programs by 2014, and only 13% of counties with the highest overdose mortality rates (>24 deaths/100,000) had OEND programs operating within them. Counties with the lowest overdose mortality rates were least likely to have OEND programs established ( $p < 0.001$ ).

**Conclusions:** We identified counties experiencing a high prevalence of drug overdose mortality but lacking OEND programs. Improving access to evidence-based approaches like OEND programs is a critical component to address the country's growing overdose epidemic.

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## Background

The opioid epidemic in the United States (US) continues to generate significant increases in morbidity and mortality with no sign of decline. In 2014, the drug overdose mortality rate was 14.7 per 100,000 (Rudd, Aleshire, Zibbell, & Gladden, 2016), and the age-adjusted opioid overdose mortality rate rose nearly 200% from 2000 to 2014 (Rudd, Aleshire et al., 2016). Opioid-involved overdose deaths increased another 16% from 2014 to 2015, fueled by an increase in deaths involving heroin and illicitly-made fentanyl (Rudd, Seth, David, & Scholl, 2016) – a synthetic opioid 25–50 times more potent than heroin (NIDA/NIH/USDHSS, 2016).

Opioid overdoses are safely reversible with naloxone, an opioid antagonist (Sporer & Kral, 2007). Naloxone is highly effective in reversing opioid-involved overdose and serious adverse events are

rare, with most involving physiological responses associated with antagonist-precipitated opioid withdrawal (Sporer & Kral, 2007). Overdose education and naloxone distribution (OEND) programs train laypersons – people who use drugs, family members, peers – as prospective responders in overdose events by providing access to naloxone and directions for drug delivery (Walley, Xuan, & Hackman, 2013). Since implementation of the first OEND programs in the US during the 1990s, the number of programs has been steadily increasing—including a 243% increase from 2010 to 2014 (Wheeler, Jones, Gilbert, & Davidson, 2015). Observational studies have shown that OEND programs are effective at reducing opioid overdose mortality (Walley et al., 2013) and opioid-related emergency department visits (Coffin, Behar, & Rowe, 2016) and have been shown to be cost-effective (Coffin & Sullivan, 2013). However, the opioid overdose epidemic continues to surge throughout the country (Rudd, Seth et al., 2016).

We conducted a cross-sectional, ecological study of the geographical distribution of drug overdose mortality and OEND

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programs in the United States to understand where there is a gap in the implementation of OEND programs.

## Methods

### Study population

Our study population includes all 3142 counties in the 50 United States and District of Columbia in 2014.

### Data sources

We combined two different data sources: (a) drug overdose mortality, as captured in the National Vital Statistics System from the National Center for Health Statistics (NCHS) (Rossen, Bastian, Warner, Khan, & Chong, 2017); and (b) existing OEND programs from a database that was developed to determine the location and effective dates of all programs that distribute naloxone to laypersons in the US (Wheeler et al., 2015).

Publicly available data regarding drug overdose mortality was downloaded from NCHS (Rossen et al., 2017). The International Classification of Diseases, Tenth Revision (ICD-10), was used to classify deaths occurring in the United States in 2014 using the National Vital Statistics System multiple cause-of-death mortality files. The following ICD-10 codes were used to define drug-overdose deaths: X40–X44; X60–X64; X85; or Y10–Y14 (Rudd, Aleshire et al., 2016; Rudd, Seth, David, & Scholl, 2016).

The OEND database was developed and maintained by the Harm Reduction Coalition (HRC), a national advocacy and capacity-building organization. A detailed description of the data-collection procedures can be found elsewhere (Wheeler et al., 2015). Since 2008, HRC has managed a list of OEND programs. Using this list, HRC conducted an online survey in 2014 of all the known programs in the US, including public health departments, pharmacies, community-based organizations providing services to people who use drugs, health care facilities, and substance use treatment facilities. Emergency medical services, law enforcement organizations and other professional first responders were not included in the survey since they do not train and provide naloxone to laypeople. Survey questions included, among other items, the year the program began and the counties where each program operated. Managers from 136 (97%) programs responded to the survey.

### Data measures

The two variables of interest included a) county-level, age-adjusted drug overdose mortality rates (per 100,000 people) in 2014, and 2) whether the county had a OEND program operating within it (yes/no) during 2014. Detailed methods for obtaining smoothed age-adjusted death rates are described elsewhere. Bayes estimates of county-level, age-adjusted drug overdose mortality rates were generated from two-stage hierarchical models (Rossen, Khan, & Warner, 2014). To generate more stable estimates of mortality rates in counties with small population sizes or a small number of events, county-level estimates of mortality 'borrow strength' across other counties. To achieve this, as part of small area estimation techniques, mixed effects models use data from nearby counties to create stable estimates when the population size or number of drug overdose deaths is small in a county (Rossen et al., 2014). This technique shrinks extreme and unstable values (Rossen et al., 2014). To understand whether naloxone programs were established in counties that had the greatest need (i.e., higher levels of drug overdose mortality), we categorized drug overdose mortality into 5 groups based on equivalent increments across the distribution:  $0 \leq 6$  deaths per 100,000;  $>6 \leq 12$  deaths per

100,000;  $>12 \leq 18$  deaths per 100,000;  $>18 \leq 24$  deaths per 100,000; and  $>24$  deaths per 100,000. We chose these groups to have a consistent range of overdose mortality rates, facilitating interpretation of the results. Rather than opioid overdose mortality, we utilized drug overdose mortality as it is a more comparable indicator across geographic areas in the United States (Slavova, O'Brien, & Creppage, 2015).

### Data analysis

Using ArcGIS (Redlands, CA), we mapped drug overdose mortality rates and presence of OEND programs in counties throughout the US. Using Stata v14.1 (College Station, Texas), descriptive statistics of the proportion of counties with OEND programs were generated, and Fisher's exact test was used to assess for differences in OEND program implementation by drug overdose mortality rates.

## Results

In total, 8% (254) of counties in the US had established OEND programs by the time of the HRC survey in 2014, and counties with the highest overdose mortality rates had very low implementation of OEND programs – 12% of counties with  $>18 \leq 24$  deaths per 100,000, and 13% of counties with  $>24$  deaths per 100,000 had established OEND programs [Fig. 1]. The counties with the lowest overdose mortality rates were least likely to have OEND programs established –  $<1\%$  of counties with  $\leq 6$  deaths per 100,000, 7% of counties with  $>6 \leq 12$  deaths per 100,000, and 8% of counties with  $>12 \leq 18$  deaths per 100,000 had established OEND programs ( $p < 0.001$ ).

## Discussion

Given the scope of the opioid epidemic in the United States, we observed strikingly low levels of OEND programs established throughout the country. While counties experiencing the highest rate of drug overdose mortality ( $>24/100,000$ ) did have the highest percentage of OEND programs in our analysis, these programs were operating in only 13% of these high burden counties. The relatively low volume of OEND coverage throughout the United States highlights a critical implementation gap in the delivery of OEND programs, even in areas with the highest rates of overdose deaths.

In addition, regional variation with regards to OEND implementation existed. One possible reason that some counties with higher levels of overdose mortality had OEND programs implemented within them could be related to whether, and how long ago, the state in which they are located had enacted a law that created an enabling environment for the establishment of OEND programs. In 2001, states began passing laws that addressed the barriers of naloxone's status as a prescription medication (PDAPS, 2017). For example, New Mexico – a state in which many of its counties had a need for and supply of OEND programs – passed a law in 2001 that facilitated the development of naloxone programs (PDAPS, 2017). On the other hand, other states in which their counties had a high burden of overdose mortality but with fewer OEND programs had not passed such laws until 2013 (Kentucky) or 2014 (Tennessee, West Virginia and Nevada) (PDAPS, 2017). Future research should assess the impact of these naloxone laws and their provisions on OEND program implementation. However, even when a law is present, research has identified other barriers to OEND implementation, such as provider-level stigma, cost of naloxone and staff time (Winstanley, Clark, Feinberg, & Wilder, 2016). Implementation science initiatives should focus on

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