Over-the-Counter Naloxone Availability and Its Effect on the Number of Opiate Overdose Deaths

Diana Andres, Karan Nathani & Brianna Roll
University of Nevada School of Medicine – Reno

INTRODUCTION

Opioid overdose is a rising problem in America. According to CDC, opioids are the leading cause of drug overdose deaths in the US. The CDC estimates that opioid overdoses overtook heroin-related deaths in 1999. For many years, opioid overdose has been surpassing MVAs and firearm-related deaths as a cause of death in the US. Naloxone is used to reverse the effects of opioid overdose. It is a prescription drug, meaning it is not currently available as an over-the-counter medication. For it to become available without a prescription, the FDA would need to use the drug's classification status as OTC. Rescheduling naloxone from “prescription only” to “pharmacist only, over the counter” classification presents an opportunity to decrease preventable opioid overdose-related deaths in the US. The topic of rescheduling naloxone is hotly debated because minimal clinical trials have been performed to evaluate the success of increasing naloxone availability to the general public.

LITERATURE SEARCH

Literature search was conducted using the NCBI PubMed database, Google scholar, and government websites such as NIH.gov and CDC.gov. Epidemiological data was obtained using the Dynanbse database. Keywords used in the literature search included: opioid overdose deaths, non-prescription naloxone, naloxone over the counter and community-based naloxone programs. Because of the novelty of naloxone legislation in the USA, there are limited studies available for review. Articles included in this project were surveys, cohort studies, evaluation of community-based programs, and other literature reviews.

STUDY DESIGN


Temporal confounding limiting the number of opioid-positive seizures and liberations after 2011. High-risk status of drug treatment clients following laboratory-validated studies outside of Scotland. Beneficiaries of community-based naloxone kits are usually not the persons for which they are prescribed.

Scottish is the first country to institute a national Naloxone Program (NPP), allowing for nonmedical personnel to administer emergency IV naloxone for life-saving overdoses. NPP is a model program supported by the Scottish prison system at particularly high risk for Opiate Related Overdose (OR) death. Scottish experience indicates that RCT involving former prisoners within four weeks of release, 5 years before and 3 years after naloxone kits were provided as per the NNP.

Randomized Controlled Trial


Study addresses the limitations of small sample size, use of self-reported data, and potential bias with participant selection (ie, patients in opipn may not be a direct translation to US procedures and regulation).

25 patients who had experienced one or more overdoses in their lifetime were recruited for the Overdose Prevention and Reversal Program in NYC. 22 participants had successful follow-up. Program included overdose education and any attempt to administer 2 syringes of naloxone, and 3-month follow-up.

11 participants reported witnessing a total of 26 overdoses during the follow-up period, 15 of 20 participants (75%) said they felt comfortable-very comfortable with naloxone if indicated. 15 of 18 (83%) said they would want to use it if they were overdosing. All instances of naloxone usage identified by clients were accidental overdoses. A significant number of clients reported feeling positive about naloxone and evidence from a pilot study in West Virginia: A Literature Review. American medical journal. 2015;6(1):19-13.

Statements made were specific for statistics and instances in West Virginia. The study also favors a correlation between the surge in opioid addition with the increase in naloxone use as an argument against naloxone OTC legalization. However, it is important to note that there is no alternative explanation of the surge in opioid addition, such as increased availability, lower price, and increased purity of heroin in the US (CDC).

The novelty of naloxone legislation provides minimal resources for review. The amount of controlled research studies is limited, therefore provide little indication for future implications. This study identifies criticism to changing naloxone’s label to OTC that must be addressed for future programs to be successful. Clear and simple label instructions and the information for use must be included to encourage proper administration by someone under the influence. Educational efforts regarding opioid abuse and misuse must be the foundation of naloxone availability. Ongoing research and legislation to further promote decrease in opioid overdose. This review concludes the concern that naloxone OTC availability may result in increased drug use.

RESULTS

Expert review


Study acknowledges that overdose reversals may be under reported. If non-medical personnel were to collect reversal reports, Survey responses are also self-reported and have not been confirmed; some reported provided by the organizations are also based on estimates.

20 community-based programs providing naloxone were surveyed regarding amount of drug distributed and available funds and demands greater than ability of suppliers to fill orders. The article cited the cost and lack of legislation as barriers to providing nonprescription naloxone to reduce the rate of opioid-related drug overdose.

27 Caucasian patients (18 men, 9 women) - the majority of which reported heroin use for greater than 12 months. All 27 patients were interviewed, however, 2 of the interviews was discordant due to one respondent being intoxicated and the other having poor quality recording. The interviews were carried out by an independent research and topic discussed including the following: personal experience with heroin overdose, ability to recognize signs of overdose and subsequent actions taken, and awareness of naloxone and attitudes toward naloxone availability.

This study concluded that there is insufficient evidence to recommend for homeless drug users to have over-the-counter access to naloxone. However, it has been suggested that peer education for naloxone administration can have a positive outcome on homeless populations.

Survey


Self-reported sentiments have potential for bias and additional discrepancies based on individual experiences regarding drug use and familiarity with naloxone. As this study was done in the UK amongst a homeless population, data may not be easily translated to other geographical populations.

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Other references


DISCUSSION

As the death toll from opioid overdose rises, other countries have taken steps to make naloxone more accessible to the public. Unfortunately, despite these efforts, many US physicians are reluctant to write a prescription for naloxone for IV drug users. Sources for these sentiments include lack of training, negative attitudes, toward drug users, doubts about efficacy of interventions, real and perceived legal barriers, and fear of social, professional, and material detriment.

Conclusions

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse encourages widespread access to naloxone, with an increased push towards patient attitudes for high-risk patients. Furthermore, the AMA has advised co-prescribing naloxone to reduce risk of death. Despite these efforts, many US physicians are reluctant to write a prescription for naloxone for IV drug users. Sources for these sentiments include lack of training, negative attitudes, toward drug users, doubts about efficacy of interventions, real and perceived legal barriers, and fear of social, professional, and material detriment.

OTHER REFERENCES


Keywords

Opioid overdose - naloxone - prescription - OTC - availability - public health