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## Preventing Overdose Through Education and Naloxone Distribution

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APHA Policy Statement LB-11-03 – Reducing Unintentional Prescription Drug Overdoses

Abstract

Opioid overdose deaths represent a public health crisis requiring innovative, evidence-based responses. Community-based overdose education and naloxone distribution programs demonstrate promising approaches with the potential to be scaled up and adapted to a range of settings and populations at risk for overdose from prescription opioid analgesics and heroin. This policy statement calls on federal agencies, elected officials, local and state health departments, and health care professionals to support public education and training, development and dissemination of best practices, and broader implementation of these promising interventions as a core element of a comprehensive approach to opioid overdose.

Problem Statement

The Centers for Disease Control and Prevention (CDC) characterizes prescription drug overdoses as an epidemic.[1] Drug poisoning deaths have become a leading cause of injury death in the United States. Between 1980 and 2008, the annual number of drug poisoning deaths increased from about 6,100 to 36,500. A substantial proportion of this increase is attributable to the dramatic rise in unintentional overdoses involving prescription opioid analgesics (including hydrocodone, oxycodone, and methadone). In 2008, 40% of all drug poisoning deaths involved opioid analgesics, and the number of overdose deaths involving opioid analgesics has more than tripled since 1999 (accounting for 14,800 deaths in 2008). Opioid overdose mortality is not limited to prescription analgesics; heroin was involved in 3,000 overdose deaths in 2008.[2]

A growing body of research demonstrates a strong association between the increase in opioid overdose mortality and the rise over the past two decades in the use and misuse of prescription opioid analgesics.[3] Since 1999, the rate of unintentional drug poisoning deaths has increased among all racial/ethnic groups, with the highest rates observed in non-Hispanic Whites and American Indians/Alaska Natives. Rates of unintentional drug poisoning deaths, particularly deaths involving prescription opioid analgesics, have risen faster in rural areas than in urban settings.[4] Available data suggest that overdose mortality risk is associated with lower socioeconomic status; a study from the state of Washington showed that Medicaid enrollees had a 5.7 greater risk of overdose death than nonenrollees.[5] Higher rates of overdose deaths have also been associated with mental illness as well as polydrug use and other indicators of substance use disorders, including among patients seen in Veterans Health Administration facilities.[6–8]

Prevention of increased poisoning death rates is a Healthy People 2020 objective.[9] In its 2011 Prescription Drug Abuse Prevention Plan, the Office of National Drug Control Policy notes that "[p]rescription drug misuse and abuse is a major public health and public safety crisis."[10] The growing severity of the opioid overdose epidemic warrants urgent attention as a public health crisis requiring a comprehensive, multipronged strategy.

Proposed Recommendations Statement

A growing body of evidence and experience supports innovative community-level approaches to preventing opioid overdose deaths in the broader context of efforts to reduce the risk of overdose through primary prevention of opioid misuse (see alternative strategies below). These community-level strategies draw upon the lessons learned and insights gained from harm reduction programs, including needle exchange programs, with respect to engaging individuals at risk of opioid overdose and their peers as active agents in overdose prevention by providing education and training in responding effectively to opioid overdose. Numerous pilot programs and evaluations have demonstrated the feasibility and viability of providing education and training on overdose risk factors, signs, and symptoms; appropriate responses to an overdose; and emergency administration of an opioid antidote to revive individuals experiencing an overdose. Lessons and best practices from these pilot community programs have broad relevance and likely beneficial applications to the current—and growing—opioid overdose epidemic.

A 2012 survey published in Morbidity and Mortality Weekly Report (MMWR) demonstrated the potential impact of these community-level approaches by assessing 188 opioid overdose prevention programs operating in 15 states and the District of Columbia. The survey documented that an estimated 53,032 people had received training in overdose prevention, including administration of an opioid overdose antidote, through these programs. The programs received more than 10,000 reports of successful overdose reversals through administration of the antidote by individuals who had received training. The opioid overdose antidote distributed through these programs and administered by laypeople was naloxone; this opioid antagonist, approved by the Food and Drug Administration (FDA), reverses the effects of an opioid overdose and rapidly restores breathing to a normal rate. Naloxone has no potential for abuse and causes no adverse effects in a person who has not taken opioids.[11]

Multiple studies have shown that programs that educate laypeople/bystanders on how to recognize the signs and symptoms of overdose and train individuals on how to intervene by using rescue breathing, administering naloxone, and calling emergency personnel result in opioid overdose reversals and save lives.[12–15] A 2008 study concluded that, after basic training, laypeople did just as well as medical professionals in recognizing the symptoms of an overdose and determining when to use the medication.[16] In 2009, the American Journal of Public Health (AJPH) published a study showing that "overdose prevention programs that

include the distribution of intranasal naloxone by non-medical personnel are feasible for city public health departments."[17]

Similarly promising results have been reported from evaluations of projects that adapt community-based opioid overdose prevention strategies to clinical settings, including substance abuse treatment and pain management programs. A Massachusetts study demonstrated the effectiveness of an overdose education and naloxone distribution intervention among individuals primarily recruited from inpatient detoxification units and methadone maintenance treatment programs.[18] Operation OpioidSAFE (Womack Army Medical Center, Fort Bragg, NC) and Project Lazarus (Wilkes County, NC) both work to educate patients and prescribers about recognizing and minimizing the risks associated with prescription opioid analgesics. These efforts include the distribution of naloxone kits and education of caregivers/family members of individuals who take opioids so that they can recognize the signs and symptoms of overdose and intervene should they witness a loved one experiencing an overdose. Between 2009 and 2011, overdose deaths in Wilkes County decreased 69%, while overall prescriptions for opioids generally held steady. Project Lazarus reports that in 2011 "not a single Wilkes County resident died from a prescription opioid from a prescriber within the county, down from 82% in 2008."[19,20]

Despite this established and rapidly growing body of evidence in support of the value of expanding access to and use of naloxone among pain patients and individuals who misuse or abuse opioids, naloxone is currently available to laypeople in only 15 states and the District of Columbia through facilities such as drug treatment programs, community-based organizations, parents' groups, and medical clinics. Notably, community-based overdose education and naloxone distribution programs do not yet exist in many of the states that have the highest rates of opioid use and overdose deaths.[11] The rising overdose mortality rates provide stark testimony to the urgent need to scale up promising approaches to reach individuals at risk of overdose through illicit heroin use and/or nonmedical use of prescription opioids, as well as patients prescribed high doses of opioids (e.g., $\geq$100 mg morphine equivalent dose per day) or receiving opioids from multiple prescribers. According to the FDA, the total number of prescriptions dispensed for all major opioid formulations from US outpatient retail pharmacies in 2009 was 257,706,624.[21] When applied to 2009 US Census Bureau data, this represents an average of 0.84 opioid prescriptions per person in the United States, or 2.27 opioid prescriptions per US household.

A CDC editorial note accompanying the above-mentioned MMWR survey of 188 community-based overdose prevention programs noted that:

"The findings in this report suggest that distribution of naloxone and training in its administration might have prevented numerous deaths from opioid overdoses. Syringe exchange and harm reduction programs for injection drug users were early adopters of opioid overdose prevention interventions, including providing naloxone. More noninjection opioid users might be reached by opioid overdose prevention training and (where feasible) provision of naloxone in jails and prisons, substance abuse treatment programs, parent support groups, and physician offices…. Reaching users of prescription opioid analgesics is important because a large proportion of drug overdose deaths have been associated with these drugs…. To address the substantial increases in opioid-related drug overdose deaths,

public health agencies could consider comprehensive measures that include teaching laypersons how to respond to overdoses and administer naloxone to those in need."[11]

Opposing Arguments/Evidence

A 2009 review published in AJPH considered a series of potential objections to the scale-up of overdose education and naloxone distribution programs and evaluated the evidence supporting these concerns.[22] The potential objections fell within 2 categories: (1) doubts regarding the effectiveness, both pharmacologically and practically, of layperson-administered naloxone and (2) fears that overdose education and naloxone distribution programs would result in increased opioid use.

The review authors evaluated the first potential objection, finding that a preponderance of evidence weighed against it. The concern about pharmacological efficacy relates to the relatively short half-life of naloxone, leading to fear that once administered its opioid antagonist effects may wear off while recipients still have opioids in their system, thus potentially resulting in a recurrence of overdose. The authors cited data on the experience of both community-based overdose prevention programs and medical settings supporting the effectiveness of a single dose of naloxone, noting that many community-based programs provide trained laypeople with 2 doses in the event that a single dose is ineffective. They also considered the possibility that these programs may inadvertently discourage other appropriate responses, including calling 911 for the assistance of trained paramedics. However, the authors found that structural barriers, including fears of law enforcement involvement in responding to 911 calls for assistance at the scene of an overdose, result in delays and low rates of use of emergency services, particularly among peers of opioid misusers most likely to witness an overdose. The authors concluded that "[i]n all cases of opioid overdose, it makes intuitive sense to reduce the time it takes to administer naloxone by getting it into the hands of those best positioned to respond rapidly…. The logic and support for placing time-critical medications in the hands of nonmedical persons is not new. Epinephrine injections are made available as a life-saving measure for people at risk for suffering anaphylaxis, and glucagon injections are provided to diabetes patients in case of severe insulin reactions."[22]

The review also addressed the potential objection that "naloxone availability may encourage more frequent or higher-volume drug use by acting as a safety net." The authors judged this outcome to be highly unlikely and unsupported by available evidence, noting that "studies suggest that increasing health awareness through training programs that accompany naloxone distribution actually reduces the use of opioids and increases users' desire to seek addiction treatment."[22] Extensive discussion at an FDA workshop on expanding access to naloxone overwhelmingly supported this conclusion.[23] As noted in the FDA's postmeeting summary:

"Speakers commented on the concern that increasing the overall availability of naloxone might lead to increased drug use by giving a false sense of security, and suggested this was not a likely concern. An overview of research related to attitudes and behaviors related to [sexually transmitted diseases,] and in particular to [human papillomavirus] vaccination (Gardasil), presented at the meeting reported no association with an increase in unprotected sex among sexually active women. Similarly, no evidence for greater risk-taking has been seen in the area of protective equipment to prevent childhood injuries (such as bike helmets). One speaker said that such interventions do not necessarily lead to more risky behaviors. Instead, the results are dependent on the prevention strategy, the target of the strategy, individual characteristics and the larger social context."[24]

In summary, the AJPH review evaluated and ultimately provided compelling and persuasive counterarguments to potential objections to expanding overdose prevention and naloxone distribution programs, finding strong support for increasing these initiatives through both community programs and physician prescription in the context of broader "appropriate illicit opioid supply and demand reduction measures." The authors concluded:

"Naloxone is an eminently safe and nonabusable substance that has 1 pharmacological function: to reverse the effects of opioids on the brain and respiratory system in order to prevent the ultimate adverse event, death. Indeed, one can purchase dozens of more dangerous and abusable substances over the counter at a local drug store. Current medico-legal biases and regulations have nonetheless unduly restricted the availability of naloxone for those who need it most. It is

local drug store. Current medico-legal biases and regulations have nonetheless unduly restricted the availability of naloxone for those who need it most. It is understandable that regulators did not foresee the utility of naloxone as a public health intervention carried out by people who are not medical professionals. In the midst of our current epidemic of accidental deaths related to illicit and prescription opioids, however, these restrictions are untenable. The status quo must be challenged by a public health ethic that seeks to ‘advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.’”[22]

Alternative Strategies

A range of alternative strategies to address the prescription opioid overdose epidemic have been proposed by various federal agencies, public health officials, and policymakers. These strategies include implementation of prescription drug monitoring programs, voluntary or mandated prescriber education, proper medication disposal, development of abuse-deterrent formulations of prescription opioid analgesics, substance abuse screening and access to treatment, and law enforcement efforts targeting prescription opioid misuse and diversion.[10,25,26]

These alternative strategies offer a potential range of complementary approaches to overdose education and naloxone distribution programs, but they are not sufficient in and of themselves to address fully the urgencies of opioid overdose as a public health crisis. These strategies aim only secondarily to reduce opioid overdose as a byproduct of their primary goals of reducing the supply and preventing the misuse of prescription opioids. Although these goals reflect important components of a comprehensive, public health–based approach, they cannot fully substitute for the need for strategies that intervene at the point of overdose itself. Moreover, the evidence base for the effectiveness and impact of many of these strategies is incomplete and still evolving.[27]

An additional limitation of these alternative strategies—with the exception of substance abuse treatment—is their focus on prescription opioid analgesics. As the prescription opioid epidemic evolves, increasing evidence indicates a concurrent rise in heroin use, potentially associated with the implementation of strategies to reduce availability, diversion, and misuse of prescription opioid analgesics.[28] Community-level overdose education and naloxone distribution programs have been piloted and field tested among heroin users, with ample evidence supporting their feasibility and acceptability in this population.

Finally, community-level overdose education and naloxone distribution programs represent both a significant harm reduction innovation and a uniquely public health–grounded contribution to the overdose epidemic, bringing an important and otherwise absent perspective to bear on proposed solutions to the overdose epidemic.

Action Steps

Given the growing incidence of opioid fatalities, coupled with the serious, myriad adverse consequences associated with use, misuse, and abuse of opioids in the United States, the American Public Health Association should undertake a renewed effort to reduce and prevent the adverse public health consequences of opioid use, abuse, and misuse; increase awareness among the public and health professionals of the risks associated with opioid use and misuse; improve recognition of the signs and symptoms of overdose and educate the public and health professionals regarding what to do if someone experiences an overdose; improve access to treatment and recovery services; support public, private, and community-based efforts, including data collection and research, to understand and tackle the myriad factors contributing to the rise in opioid use, misuse, and abuse; and advance policies and programs that increase access to evidence-based interventions that reduce fatalities from opioid overdose.

Therefore,

• The federal government should undertake a coordinated national effort focused on the prevention of overdose fatalities, with a particular emphasis on education and awareness efforts targeting patients, health professionals, and the public that are centered on the effectiveness of naloxone as a potentially life-saving opioid antagonist.

• Federal, state, and local elected officials and agency staff should ensure that efforts designed to reduce and prevent opioid misuse do not have a chilling effect on effective pain management for people in need and do not unintentionally create a situation in which individuals are driven to misuse other drugs instead of securing treatment and support for recovery from drug use.

• All federal agencies involved in research, policies, regulation, and programs related to opioid misuse should coordinate efforts and develop and disseminate information to health professionals, individuals, families, and communities to increase awareness of the signs and symptoms of overdose, improve awareness of and facilitate access to naloxone as a life-saving intervention for opioid overdose, and support entry into treatment and recovery for those individuals seeking such services.

• The US Department of Health and Human Services and its agencies (including the National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, Agency for Healthcare Research and Quality, and Health Resources and Services Administration) and the Department of Veterans Affairs should provide funding for research, identification, and dissemination of best practices for reducing and preventing opioid misuse, abuse, and overdose.

• Congress and the administration should increase and improve federal surveillance efforts and data collection regarding opioid use, misuse, and deaths to ensure that policies and programs are designed to target the actual causes of opioid misuse and death and to monitor the impact of any new efforts on access to pain management, the incidence and prevalence of opioid misuse, and overdose deaths from opioids.

• Congress should support best practices by providing resources to federal agencies for technical assistance and toolkits to community programs and health professionals who wish to distribute naloxone.

• Federal, state, and local elected officials and agency staff should support increased access to—and funding of—drug treatment and recovery.

• Local and state health departments should increase awareness among the public and health professionals of the signs and symptoms of overdose, improve awareness of and facilitate access to naloxone, and support entry into treatment and recovery for those individuals seeking such services.

• Local and state health departments should develop and disseminate evidence-based, comprehensive toolkits that provide resources to assist communities in

• Local and state health departments should develop and disseminate evidence-based, comprehensive toolkits that provide resources to assist communities in responding to opioid and heroin outbreaks.

• The medical community, pharmaceutical companies, the FDA, and other entities involved in the dissemination of information regarding opioids should develop educational materials aimed at health professionals and patients (including family members) that specifically address the risks associated with prescription opioids and include information regarding signs and symptoms of overdose and the role that naloxone can play in reversing an overdose from opioids.

• Professional preparation schools and programs for health care providers and public health, allied health, health education, and health communication professionals should strengthen their professional preparation and training with respect to the risks associated with prescription opioids, signs and symptoms of overdose, and how to work with patients and their families in an effort to prevent and reduce misuse and overdose. Training should address safe storage of prescription drugs, access to naloxone, what to do in response to an overdose, and how to support entry into treatment and recovery services.

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