Overdose Prevention Education and Naloxone Prescription

Background Paper

According to the Centers for Disease Control and Prevention, prescription drug overdoses are a U.S. epidemic. Drug overdose deaths are now the leading cause of injury death in the United States. More specifically, in 2012, there were approximately 16,000 prescription drug overdose deaths involving opioid analgesics in this country. In 2013, over 1,900 Floridians died with at least one prescription drug listed as a cause of death, and many involved an opioid. In addition, Florida experienced a nearly 80% increase in heroin caused deaths in 2013 compared with 2012.

Overdose victim epidemiology covers a broad demography of our population and affects every socio-economic strata. Overdose occurs from therapeutic and completely licit use of prescription medication, as adverse events or accidents, to the non-medical use of prescription medicines and heroin. Data indicate the main U.S. populations at risk for prescription drug overdose are the approximately five (5) million people reporting current, nonmedical use of prescription drugs and the approximately nine (9) million people reporting long-term medical use of opioids, in particular those patients who are high-dosage medical users. Other populations at higher risk include those completing mandatory opioid detoxification or abstinence programs, those taking prescription opioids for pain relief with concurrent substance use disorders, and those taking extended release/long-acting opioid preparations.

In response to our national opioid overdose problem, various national organizations (including the American Medical Association, the American Society of Addiction Medicine) have taken action to address the issue.
and the American Association of Poison Control Centers\textsuperscript{11}) as well as federal government agencies (including the Office of National Drug Control Policy\textsuperscript{12} and the Substance Abuse and Mental Health Administration\textsuperscript{13}), have adopted policy positions that support greater access to naloxone.

Naloxone is the standard treatment of known or suspected opioid overdose. It has been a federal Food and Drug Administration approved medication since 1971. Naloxone is a pure opioid antagonist with no potential for abuse. It is a prescription drug, but is not a DEA controlled substance. The medication is virtually inert to patients without opioids in their systems. However, administration of naloxone to patients intoxicated by opioids can reverse such effect and can result in patients regaining consciousness and spontaneous respiration.

Traditionally, naloxone has been used in post-operative recovery and in emergency rooms and by emergency medical services to reverse the effects of opioid central nervous, cardiovascular and respiratory system depression. Time is of the essence in this emergency setting since hypoxia, similar to hypoxia from drowning, results in brain damage and death. There is an evolving medical practice to provide first responders (including, close family contacts, police officers, and firemen) to a suspected opioid overdose scene with instructions supporting the patient until professional emergency medical care arrives. The training involves recognizing opioid overdose, calling 911, administering naloxone, rescue breathing for apneic patients, putting patients on their side in the rescue position if breathing, and staying with the patient until EMS arrival.

Naloxone is currently available for intravenous, intramuscular or subcutaneous injection. Most naloxone injection is (1) a multi-source generic medication and (2) relatively inexpensive. A new naloxone auto-injector product has been recently approved by the FDA and is specifically designed to be given by family members or caregivers.\textsuperscript{14}


In addition, medical directors of EMS and physicians in other disciplines have recognized that nasal delivery of the injection naloxone product also reverses opioid overdose. Although the administration of an injection naloxone product intranasally, using a mucosal atomizer device, represents an off-label route of administration, it has been shown to be effective in reversing an opioid overdose\(^1\) and is being co-prescribed to patients in the United States on a take-home basis.\(^6\) Such off-label prescribing is considered permissible under the general premise that such utilization falls squarely within a physician’s broad discretion to prescribe drugs, off-label, as part of routine medical practice.\(^7\) In fact, some major city EMS services now utilize the nasal route of administration for naloxone as the first route of administration.

According to a 2012 report published by the CDC, forty-eight (48) programs known to distribute naloxone in the United States responded to a 2010 survey conducted by the Harm Reduction Coalition.\(^8\) Those respondent programs represented 188 local naloxone distribution sites in 15 states and the District of Columbia as of 2010.\(^9\) According to the 2012 CDC report, since the first program began distributing naloxone to laypersons in 1996, over 50,000 individuals have been trained in naloxone use, primarily drug users and their friends and family, with over 10,000 overdose reversals reported between 1996 and 2010.\(^10\) According to the 2010 survey, forty-two of the 48 programs reported provided only injectable naloxone, four programs provided only intranasal naloxone, and four provided both injectable and intranasal naloxone.\(^11\) In a more recent study of the Massachusetts naloxone distribution program, communities with high implementation of overdose education and naloxone distribution had a nearly 50% lower opioid overdose mortality rate compared to communities that did not implement overdose education and naloxone distribution, over the course of the same time period and accounting for community differences.\(^12\) In addition, preliminary results of a 2014 survey show that the practice of providing take-home naloxone to patients prescribed opioids exists at some level in at least 16

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\(^{1}\) Walley Alexander Y, Xuan Ziming, Hackman H Holly, Quinn Emily, Doe-Simkins Maya, Sorensen-Alawad Amy et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis *BMJ* 2013;346:f174


\(^{18}\) CDC. Community-Based Opioid Overdose Prevention Programs Providing Naloxone - United States, 2010.. MMWR 2012; 61:101-105.

\(^{19}\) Id.

\(^{20}\) Id.

\(^{21}\) Id.

states, and the U.S. Department of Veterans Affairs has widely implemented such co-prescribing practice.\textsuperscript{23}

Here, in Florida, however, take-home naloxone is largely underutilized in the prevention and treatment of opioid overdose. From a legal perspective, naloxone should be viewed no differently than the prescribing of other legend drugs.\textsuperscript{24} Naloxone is indicated for patients who, upon evaluation, are at risk of experiencing an opioid overdose and who could benefit from naloxone administration by a third party. As a result, it should be within a physician’s professional scope of practice to prescribe naloxone, even while recognizing someone else will need to administer the drug. In fact, Florida physicians routinely prescribe other non-oral medications that may require the assistance of third parties, as may be the case in which the patient is a minor, elderly or disabled. Florida medical practices prescribing opioids, regardless of reason, could offer their patients access to the antidote for at home use to increase chances of survival.
