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Co-prescribing naloxone does not increase liability risk

Corey S. Davis, JD, MSPH^a, Scott Burris, JD^b, Leo Beletsky, JD, MPH^{c,d}, and Ingrid Binswanger, MD, MPH, MS^{e,f}

^aNetwork for Public Health Law, Los Angeles, California, USA

^bBeasley School of Law, Temple University, Philadelphia, Pennsylvania, USA

^cSchool of Law, Northeastern University, Boston, Massachusetts, USA

^dBouvé College of Health Sciences, Northeastern University, Boston, Massachusetts, USA

^eInstitute for Health Research, Kaiser Permanente, Denver, Colorado, USA

^fSchool of Medicine, University of Colorado, Aurora, Colorado, USA

Abstract

The opioid overdose epidemic claims the lives of tens of thousands of Americans every year. Opioid overdose is reversible by the administration of naloxone, a pure antagonist now available in formulations specifically designed and labeled for layperson use. Despite broad support for layperson access to naloxone from professional organizations, health officials, and clinical experts, qualitative studies suggest that some providers have concerns about legal risks associated with naloxone prescribing, particularly co-prescribing naloxone to pain patients. Such concerns are unfounded. The legal risk associated with prescribing naloxone is no higher than that associated with any other medication, and is lower than many. Additionally, laws in a majority of states provide explicit legal protections for providers who prescribe naloxone, in many cases extending this protection to prescriptions issued to friends, family members, and others. In this large and increasing number of states, the liability risk of prescribing naloxone in good faith to patient at risk of overdose (or, in states where such prescribing is permitted, to an associate of such a patient) is either extremely low or absent entirely. Where a prescriber determines, in his or her clinical judgment, that a patient is at risk of overdose, co-prescribing naloxone is a reasonable and prudent clinical and legal decision. No clinician should fail or refuse to issue such a prescription based on liability concerns.

Keywords

Naloxone; overdose; liability; opioids

Correspondence should be addressed to Corey Davis, Network for Public Health Law, 3701 Wilshire Blvd #750, Los Angeles, CA 90010. cdavis@networkforphl.org.

AUTHOR CONTRIBUTIONS

Dr. Binswanger conceptualized the article. Mr. Davis conducted research and drafted the text, to which all authors substantially contributed. All authors reviewed and approved the submitted manuscript.

The opioid overdose epidemic continues to claim the lives of tens of thousands of Americans every year – over 28,000 in 2014 alone.¹ Federal and state agencies, nonprofit organizations, and private practitioners have undertaken a number of legal, policy, and clinical interventions to reduce the terrible toll of opioid overdose morbidity and mortality. A key component of this response is increased layperson access to the opioid antagonist naloxone.

First approved by the Food and Drug Administration (FDA) in 1971, naloxone quickly and effectively reverses most opioid overdoses if administered in time.² A prescription medication but not a controlled substance, it is the standard treatment for opioid overdose and is on the World Health Organization's List of Essential Medicines.³ Naloxone has no significant clinical effect if opioids are not present, and severe adverse reactions associated with its administration are rare.⁴

Due to the dramatic increase in opioid overdose fatalities and the demonstrated efficacy and favorable risk profile of naloxone, efforts to increase access to the medication in outpatient settings have rapidly accelerated. The FDA has recently approved two naloxone products specifically intended and labeled for layperson use: Evzio, an auto-injector, and Narcan, an intranasal spray.^{5,6} As of mid-2014 over 150,000 laypeople had received outpatient naloxone for use in an overdose emergency, and naloxone dispensing from retail pharmacies increased 1170% between the fourth quarter of 2013 and the second quarter of 2015.^{7,8}

Guidelines from the Centers for Disease Control and Prevention (CDC) recommend that naloxone be prescribed to any patient at increased risk of overdose, such as those receiving high doses of opioids or opioids in combination with benzodiazepines, as well as patients with a history of overdose or substance use disorder.⁹ Such prescribing is supported by leading professional organizations including the American Medical Association, the American Society of Addiction Medicine, and the American Pharmacists Association.¹⁰

Despite broad support for layperson access to the medication from professional organizations and health officials, qualitative studies suggest that some providers have concerns about legal risks associated with naloxone prescribing, particularly regarding the prescription of naloxone to patients to whom they also prescribe opioids.^{11,12} This is not surprising; health care professionals generally over-estimate their liability risk, and many report that liability fears affect their clinical decisions.^{13–15} Additionally, some risk management entities are reportedly advising prescribing clinicians that co-prescribing naloxone to their patients may increase their liability risk, and should therefore be avoided. Such advice ignores the recommendations of public health agencies and clinical experts, and is incorrect as a matter of law.

The legal risk associated with prescribing naloxone is no higher than that associated with any other medication, and is lower than many.^{16,17} In fact, a 2015 expert legal review did not identify a single instance in which prescription or dispensing of naloxone in the outpatient setting was grounds for a lawsuit.¹⁸ Additionally, laws in a majority of states provide additional legal protections for providers who prescribe naloxone – in many cases extending this protection to prescriptions issued to friends, family members, and others.^{19–21} In this

large and increasing number of states, the liability risk of prescribing naloxone in good faith to patient at risk of overdose (or, in states where such prescribing is permitted, to an associate of such a patient) is either extremely low or absent entirely.¹⁹

Under longstanding principles of civil law, medical professionals may not held liable simply because the patient experiences a bad outcome. Rather, for a lawsuit against a health care provider to succeed, the plaintiff must prove that the professional failed to meet the “standard of care” prevailing among practitioners in the same field under the same circumstances, and that that failure caused the harm to the patient.¹⁷ In determining whether the standard of care was met, courts focus on whether the provider’s actions were medically reasonable under the circumstances, including whether the actions conformed to professional and public health recommendations. The plaintiff has the burden of proving that the physician’s actions lacked a reasonable medical basis. In the case of naloxone prescription, the weight of the evidence soundly supports the conclusion that the prescription of naloxone to patients at risk of overdose, if accompanied by any necessary education and counseling, meets the reasonableness standard.

Recently, a related but different concern has emerged: that co-prescribing naloxone could be seen by a court as an admission that the underlying opioid prescription was inappropriate. In other words, the fear is that by attempting to reduce risk to the patient, the prescriber may increase their own risk of legal liability. There is no credible legal basis for such a conclusion.

Prescribing one medication to address potential side effects of another medication is a common and accepted medical practice that does not, in and of itself, provide any information about the appropriateness of the primary treatment. Anti-emetics, for example, are commonly prescribed to counteract the effects of many medications, from HIV and cancer therapy to nonsteroidal anti-inflammatory drugs, and several medications are now marketed specifically to address opioid-induced constipation (OIC). The case for co-prescription of naloxone is much stronger than that for OIC. While constipation can be uncomfortable, it is rarely life-threatening. Opioid-induced respiratory depression (OIRD), conversely, causes tens of thousands of deaths per year.¹

Opioid therapy is appropriate for some patients and indications. However, opioids - even when prescribed as indicated and used as directed – can result in severe negative side effects, up to and including OIRD-associated fatality.²² Nearly all opioid medications are now required to carry a “black box” warning regarding the “serious risks of misuse, abuse, addiction, overdose and death” potentially associated with the medications.²³ It is legally reasonable, and quickly becoming standard medical practice, for prescribers to attempt to mitigate that possible risk by co-prescribing naloxone. In fact, the near unanimity of expert opinion and rapid adoption of naloxone co-prescribing suggest that prescribing the medication where clinically indicated carries lower liability risk than failing to do so.

Evidence from naloxone distribution programs strongly suggests that increased access to naloxone in the outpatient setting can reduce opioid overdose morbidity, mortality, and associated healthcare costs.^{24,25} Where a prescriber determines, in his or her clinical

judgment, that a patient is at risk of overdose, co-prescribing naloxone is a reasonable and prudent clinical and legal decision. No clinician should fail or refuse to issue such a clinically indicated prescription based on liability concerns.

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