

Medical direction issues related to non-medical provider naloxone (Narcan) use:

There is increasing interest in making naloxone, an opioid reversal agent, available to non-medical providers for administration in case of opioid overdose. Traditionally, this agent has been given intravenously or intramuscularly and thus has been limited to use by advanced life support providers (such as paramedics), but more recently, it has been shown to be effective when given by the intranasal route. Because of this, there is potential that it could be given by basic trained EMS providers (i.e. emergency medical technician or emergency medical responder) or even by lay persons.

Opioid overdose causes sedation, respiratory depression, and potentially respiratory arrest (not breathing), which can then lead to cardiac arrest. Naloxone is a reversal agent. From a medical standpoint, naloxone can reverse respiratory depression in the case of an acute overdose of opioid, for example, someone who took a handful of pain medication such as oxycodone, in a suicide gesture, or has injected a particularly strong dose of heroin intravenously. For short-acting opioids such as regular oxycodone and illicit intravenous opioids such as heroin, this may be a useful intervention by reversing the respiratory depression. Unfortunately, when rapidly given intravenously, it often also results in a fairly combative patient and risks the safety of the individual providing the naloxone. Intranasal administration has somewhat slower absorption so is likely safer for the individual administering it. It is very important to note that there is a large population of chronic opioid users, for example those on long-acting oxycodone (Oxycontin), or methadone, who have a more complex response to naloxone's opioid reversal. In these individuals, naloxone may precipitate acute withdrawal symptoms, including severe abdominal pain and vomiting, profuse sweating, fast heart rate, and elevated blood pressure. These withdrawal symptoms are much more concerning in this population and cannot be treated adequately due to the way that naloxone works. This is a profoundly unpleasant and potentially dangerous experience for the patient. While less invasive, the intranasal administration method that would be used by basic or lay responders does not allow dose adjustment or titration to effect (increasing respiratory rate), while limiting patient discomfort (withdrawal symptoms). The intranasal route only allows for an all or none dosing option.

An alternative to deployment of naloxone may be a much simpler, less expensive, and less potentially dangerous intervention for the patient and provider. Since the major concern in opioid overdose is respiratory depression which may then lead to cardiac arrest, it would be equally effective to train interested individuals to provide "rescue breaths" using a bag and mask, and administer CPR if needed until EMS arrives. This eliminates the potential problems with widespread naloxone deployment, and has the additional positive effect of increasing the population trained to provide bystander CPR for any patient in cardiac arrest, which has been shown to be one of the strongest predictors of positive outcomes. Because of the nature of medical practice and evolution of standard of care as well as additional medication options, placing specific medical therapies or medication in statute is likely not the best option from the standpoint of assuring the most current and best possible care options being available to patients.

Specific issues:

1. For basic EMS providers to be able to administer this medication, statute and regulation would require change.
 - a. there would need to be education on medication administration via the intranasal route, which is not part of current EMT education

2. For non-medical providers to be able to administer this medication would require physician oversight, assurance that there are protocols to determine appropriate individuals to administer medication to, education to assure that providers can recognize these individuals and appropriately administer the medication, assure documentation of administration, and have monitoring of individual cases for appropriateness of use. In Kansas, there is currently no regulatory oversight over this mechanism by any agency, and thus the physician would be solely responsible for such a program.
3. Logistics:
 - a. Prescription: there must be physician authorization for a “prescription” to allow the agency to order the medication. There have been chronic shortages of generic medications such as naloxone in recent years, for a number of reasons including a very small number of generic manufacturers. Because of this, there are significant cost and availability concerns, particularly if demand for this medication increases by orders of magnitude as it would if much more widely deployed.
 - b. Deployment: a needs assessment should be done in any area contemplating deployment of this intervention to determine whether there is even enough potential demand to warrant the effort needed to provide this service, and if the planned providers of this medication can realistically arrive significantly faster than EMS to provide the intervention. Medication expires and would need to be monitored for expiration and stock rotated. It also should be maintained in a moderately stable temperature environment to be effective when needed, so storage in vehicles that are outdoors subject to the elements consistently can cause significant degradation of medication effect over time. Given recent FDA approval of a naloxone autoinjector device, encouraging utilization of this device by family members of at-risk individuals may be more useful and timely for the patient.
 - c. Pharmacy regulations: there may be issues with pharmacy regulations as well regarding some of the logistics, storage, dispensing, etc, that would need to be assessed to allow this prescription medication to be provided without an individual patient prescription outside an established healthcare setting (such as EMS, clinic, hospital).

Resources:

[September 2012 FDA meeting on Naloxone](#)

[ACEP 2013 Resolutions \(pages 158-161\) proposed resolution on over the counter naloxone with background information](#)

[FDA approval of naloxone autoinjector](#)