

Comments to HRSA from NASEMSO Medical Directors Council - Naloxone
January 30, 2015

Question 1) EVZIO® is FDA-approved. However, I am not sure if the intranasal version of naloxone is FDA-approved. The device must be FDA-approved.
Response: We agree that the use of an FDA-approved intranasal atomizer device is a reasonable alternative to the prepackaged intramuscular delivery device. The atomizer itself would be the FDA-approved delivery device while the naloxone (Narcan®) would be the medication to be administered by this FDA-approved device, whether pre-filled or packaged with a vial of naloxone. The intranasal route is a safe and medically effective method of delivery for naloxone that remains currently a very cost effective solution for many services. The intranasal route of administration is particularly important for the EMS providers for whom administration of medications via the intramuscular route lies outside of their state's scope of practice. The reduction or elimination of an accidental needle stick during use of the intranasal route is an occupational health benefit for EMS providers. We agree that this route of administration should be acceptable for this grant.

Question 2) Is the intranasal version technically a device?
Response: The intranasal atomizer itself would be the "device" while the associated naloxone, whether provided in a pre-filled vial or drawn up or packaged in a separate syringe, would be the drug that would be administered by such an approved device.

Question 3) What is the structure of some programs that dispense Narcan®/naloxone? What entities are involved? Who is responsible for purchase and distribution? How is it distributed? Who is it distributed to? (I know that each state has its own laws on this issue)
Response: The answers to these questions are as varied as the individual state laws and regulations that authorize and govern the distribution and use of naloxone. In some states, naloxone is distributed under the authority of a medical director. In others, EMS agencies would be authorized to purchase naloxone and distribute it to their agents. Likewise, there is variance among the states regarding who is authorized to receive and/or administer naloxone. Within the EMS community, some states authorize EMS providers of all licensure levels, including emergency medical responders (EMRs), to obtain and administer naloxone while states limit the authority to emergency medical technicians (EMTs), advanced EMTs (AEMTs), and Paramedics. There are states that have extended the ability to dispense and administer naloxone to pharmacists and first responders such as laypersons and law enforcement personnel. Liability protections vary between states as immunity can be legislatively provided to all or some of the parties authorized to dispense or administer naloxone, including the recipient of the dose of naloxone. In many states, a prescription is the method of obtaining naloxone, while in some; the distribution of naloxone for overdose mitigation programs originates from centralized points of distribution.

***** We agree that, for the purposes of this grant program, naloxone should be provided to the recipients in conjunction with a program which is under the supervision of a qualified medical director. Furthermore, such recipient

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programs should provide a standardized education program which is also approved by the medical director, preferentially a program which is modeled or conforms to educational tools similar to those described in the next sections. Ideally, standardized education programs should be paired with continuing education programs and quality assurance processes approved and supported by the medical director. We would be interested in participating in the compilation and production of naloxone education tools as a part of this grant program (See Separate Naloxone Education Proposal)*****

Question 4) Are there storage concerns? Does it need to be stored at a specific temperature? Are there issues with it being stored in a police vehicle (as an example)? Is there concern about it being stored in a publicly accessible area like an AED? (my thought on this is that there would be no oversight on who uses it and anyone could simply take the device out of the case)

Response: Storage of these medications is typically governed by the pharmacy recommendations regarding temperature extremes and guided by the naloxone manufacturer's recommendations. Security surrounding this medication is typically not a problem as the medication has extremely low abuse potential. As with all medications utilized by EMS, there are challenges with extreme temperatures, especially with vehicles that have less temperature controlling capabilities than ambulances. In an effort to mitigate these potential problems, some naloxone administration programs recommend keeping the naloxone on the individual person to maintain a more reasonably temperature controlled environment. These same programs avoid storage of naloxone in trunks of vehicles and locations susceptible to extreme temperatures. The positioning of naloxone with other public access devices, such as automated external defibrillators (AEDs), to increase the drug's accessibility to laypersons is state-specific in regulation or legislation. Although the abuse potential for the medication is low, the risks for theft of the more expensive naloxone administration devices may be equivalent to that of the AEDs. In the rural settings for which this grant is proposed, storage and availability of naloxone kits should take into consideration local (longer) EMS response times and potential delays in medical care for the time-sensitive nature of opiate-induced respiratory depression or arrest.

Question 5) What type of training should be required? (should it include training on the use the device, recognizing signs of opioid overdose, training on what to expect after administration of the drug)

Response: Naloxone should be administered by individuals who have first completed training in cardiopulmonary resuscitation (CPR) followed by the completion of a standardized training program for naloxone. The standardized training program for naloxone should include the recognition of signs and symptoms of an opiate overdose, the identification of the appropriate patient who will benefit from receiving naloxone, the signs and symptoms of opiate withdrawal, and the psychomotor skills required to administer the appropriate dose of naloxone to a patient. Naloxone administration can be associated with potential side effects due to opiate withdrawal (e.g., nausea, vomiting, aspiration, agitation), risks secondary to the half-life of naloxone (e.g. recurrent

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decreased mental status and/or respiratory depression), and administrative challenges (e.g. refusal of other emergent medical care or refusal of transport). Failure to appropriately assess and address a need for airway management or chest compressions can lead to adverse patient outcomes. In collaboration with other appropriate stakeholders, e.g. the American Heart Association and the American Red Cross, we would be interested in creating a naloxone educational tool under this grant.

Question 6) What is the role of EMS in this type of program?

Response: The activation of the emergency response system should always be the first step prior to the administration of naloxone by laypersons and non-medical personnel. As such, EMS retains the essential primary role in the initial definitive care of a person with a suspected or confirmed opioid overdose. In areas where laypersons or first responders may be the initial provider of care to person with an opioid overdose, activation of the emergency response systems and integration with the local EMS system is essential. Patients who appear to be suffering from an opioid overdose may, in fact, be suffering from other unrelated medical emergencies or have additional emergent medical needs. Early assessment by trained medical professionals remains an important link in the chain of survival.

Question 7) What is a reasonable funding amount for the grant?

Response: Funding for such a grant should also support medical oversight, associated educational tools and training, continuing education, and quality assurance measures to support and protect patient safety. **In the interest of maximizing patient safety and the utility of the available funding, we strongly recommend that the grant eligibility requirements for all applicants include formal engagement and coordination of the naloxone administration program with the state EMS office and prior successful completion of CPR training approved by the qualified medical director or state EMS office by the participants in the program.**

Naloxone Education Proposal

- 1) Programs involving distribution, education, and administration of naloxone should be conducted in coordination with a qualified medical director.
- 2) Education programs should include
 - a) Activation of the emergency response system (911 if available) and/or local EMS
 - b) Cardiopulmonary resuscitation (CPR) training
 - c) Scene and personal safety, including personal protective equipment (PPE)
 - d) Identification of signs and symptoms of opiate overdose
 - e) Identification of the appropriate patient who may benefit from naloxone administration
 - f) Identification of the signs and symptoms of opiate withdrawal
 - g) Risks related to the half-life of naloxone and administrative challenges related to patient disposition
 - h) Expected results of naloxone administration
 - i) Training on naloxone administration by intranasal and intramuscular (including auto-injector) routes
 - j) Awareness of individualized state, regional, or local laws and/or regulations
- 3) Separate education tools could include:
 - a) Educational flier with simple mnemonic and references to additional resources (e.g., CABIN, Can-Breathe)
 - b) Standardized electronic emergency medical dispatch scripts, to be used in conjunction with previously established respiratory and circulatory assessment scripts, to guide layperson or non-medical first responders through the patient assessment and appropriate administration of naloxone when a naloxone administration device is available.
 - c) Education for laypersons with limited protective equipment and limited patient assessment skills (coordinate with established community CPR course materials)
 - d) Education for non-medical first responders or other medical persons tailored to their respective Basic Life Support (CPR and AED) skills sets.
 - e) Consideration of data collection to include, but not limited to, short and long-term patient outcomes, community engagement, adverse events and incidents.
 - f) Possible coordination with the local health departments, hospital associations, drug rehabilitation centers, prescribers of naloxone for layperson use, and pharmacists for tracking and trending.
- 4) Some Links to example educational materials from programs and states
 - a) http://www.ct.gov/dph/lib/dph/ems/pdf/training/ct_ems_naloxone_bls_training_27_may2014.ppt
 - b) http://www.ems.ohio.gov/ems_naloxone_education.stm
 - c) <http://www.nmhr.org/retreat/2014/6-245p-m.pdf>