Providing Naloxone to Non-Medical Personnel Can Prevent OD Deaths without Increasing Abuse

BY JAMES R. ROBERTS, MD

I t’s certainly no secret that opioid abuse and its associated morbidity and mortality has markedly increased in the United States over the past 10 years. No ED clinician can work a shift without seeing some opioid-related problem, be it an overdose, withdrawal, or a less-than-clandestine attempt by a drug aficionado to obtain more opioids by prescription.

Emergency physicians often get into arguments with patients, and then complaints are registered with the hospital’s PR department and state organizations by the savvy and demanding ones. The frustration of emergency physicians is palpable. Our hospital alone had three visits over the past two years from the State of Pennsylvania, which is charged with investigating all complaints. All three involved the delay of opioid use in the ED or failure to prescribe opioids in sufficient amounts or at all to demanding patients. Patients know their rights, and frequently use multiple resources to further their drug use. Clinicians should consider two opposing, rather inexplicable, mandates: the well-publicized underuse of opioids for pain control versus the gargantuan issue of opioid abuse.

Emergency clinicians are a minor contributor to the opioid epidemic in this country. Physicians’ offices and pain clinics dispense huge doses of opioids to multiple patients, often without a physical examination or verification of a problem, but even these have come under scrutiny by the DEA. Following the crackdown on prescription opioids, opioid abusers have turned to street heroin, which is easier to get and cheaper than oxycodone (OxyContin). Overdoses is easier to get and cheaper than have turned to street heroin, which is prescription opioids, opioid abusers following the crackdown on pre-
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Recently, police have been supplied with nasal naloxone, and use of this antidote by the lay public has also escalated. A single-use auto-injector (Evzio) was approved by the FDA in April via a fast-track effort, and it delivers 0.4 mg of naloxone either intramuscularly or subcutaneously, resulting in drug levels comparable with standard syringe administration. The device is equipped with visual and voice instructions, and is prescribed to family members and caregivers. It’s sort

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of like an epinephrine auto-injector for opioid overdose. Distribution is currently very limited, and Mark Herzog, a vice president for the manufacturer Kaléo, said the wholesale price for two auto-injectors is $575. Out-of-pocket costs for patients are expected to be in the typical co-pay range, and the company has a patient assistance program for those unable to afford the product.

The fear of legal repercussions has always been a barrier to layperson use of naloxone, and many states do not have a Good Samaritan law to protect families and fellow drug users who might intervene. Given the increasing purity of heroin and potent additives such as fentanyl, it is unclear if a single 0.4 mg injection would be adequate for all ODs. Most of the more potent concoctions will be lethal quickly, and would require much more naloxone for reversal.

Overdose Rescue by Trained and Untrained Participants and Change in Opioid Use among Substance Using Participants in Overdose Education and Naloxone Distribution Programs: A Retrospective Cohort Study

Doe-Simkins M, Quinn E, et al

BMC Public Health 2014;14:297

www.biomedcentral.com/1471-2458/14/297

This article coins a new term — Overdose Education and Naloxone Distribution (OEND), which is a program that has been in existence since 2006 and describes the results of the program from 2006 to 2010. OEND programs have been implemented primarily to give naloxone in a rescue kit to substance users who are at high risk for overdose or to those likely to witness another person overdosing. The article states that opinions about the right level of training and the availability of naloxone rescue still exist. Options include giving naloxone to drug users (essentially to those without any medical training) and to giving it only to trained medical personnel.

It is always a concern, of course, to provide drug users with the skills to recognize and respond to an opioid overdose. Many believe that readily available naloxone may increase opioid use or delay entry into an addiction program. This is an intuitive concern; no data from existing OEND programs have yet demonstrated increased drug use by the participants. This report attempted to evaluate the management of opioid overdose by trained and untrained rescuers reporting the use of out-of-hospital naloxone. It also attempted to address how opioid use changed after receiving opioid education and naloxone distribution.

The study evaluated approximately 500 substance abusers who participated in a Massachusetts program. About eight percent of the subjects reported administering naloxone during an overdose rescue. The program provided training sessions to potential bystanders to opioid overdose. The participants received a naloxone rescue kit that contained two pre-filled syringes of naloxone, 2 mg/2 ml, and two mucosal atomization devices. The participants were instructed to deliver 1 ml (1 mg) to each nostril of the overdose victim. The second dose was used if the first one was not effective. A total of 599 overdose rescues occurred, most frequently by friends of the victim. Most of the overdoses occurred in a private setting, and the majority were managed with only one dose of intranasal naloxone. About half of the victims received rescue breathing, rescuers called 911 in a quarter of cases, and most of the rescuers stayed with the victim and turned over care to emergency medical personnel. Overall, there were no statistically significant differences in the overdose treatment by those who were trained and untrained. No clear increase in use of heroin was seen after receiving OEND services. It was not determined whether naloxone rescue kits would meet an over-the-counter standard, and it was concluded that the OEND programs should be expanded because no increased heroin use occurred.

Comment: Deaths in towns that had the OEND programs were reduced 27 to 40 percent. The authors noted that no statistical difference was seen in trained versus untrained participants in their attempts to seek help, the institution of rescue breathing, staying with the victim, or success in naloxone administration. Interestingly, no increase in the use of opioids or other drugs of abuse was found following resuscitation. One of the theoretical objections to such programs is that naloxone distribution would increase opioid use by giving recipients a sense of security, enabling risky behavior, but two studies evaluating such criticisms found a decrease in drug use following naloxone distribution. (J Urban Health 2005;82[2]:303; Int J Drug Policy 2010;21[3]:186.) Many positive points support expanding the distribution of naloxone to laypeople, and opinions abound on the rationale for such an intervention. The decreased death rate with no abuse

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Timely Article on Hydrocodone

Dr. Roberts: Thank you for the interesting and timely article. (EMN 2014;36[5]:8; http://bit.ly/1OoaxCR.) I would like to have had more information about the FDA proposal to change hydrocodone mixtures to Schedule II, which could have a huge impact on emergency medicine. I wonder if the FDA understands the potential firestorm of complaints from our 25,000 emergency physicians and their patients if we all become shackled by Schedule II red tape. It seems to me more sensible to address hydrocodone overuse by limiting pills per prescription (15-20?), phone prescriptions (none), and refills per prescription (none, except maybe from pain doctors). — David Hoyer, MD, Houston

Dr. Roberts responds: Cogent thoughts, Dr. Hoyer. Unfortunately, the FDA works on its own agenda, but many physicians and groups are for and against the change. The constraints on medication are fixed by the FDA schedule, so I don’t think it will be possible to have different regulations for different medications. Limiting the number of pills has its own drawbacks when patients truly need analgesics, and making it more difficult to prescribe spaws its own problems. Heroin use skyrocketed in the United States, for example, when attempts to limit physician prescriptions of oxycodone are successful. Now heroin is easier to score than oxycodone. The problem of drug abuse is a gargantuan one. If only there were an easy answer. Simply trying to limit ED prescriptions of opiates is controversial. Of course, some people would rather be high than not, and the drugs are very addicting. Never underestimate drug abusers’ to get and worldwide drug makers’ ability to produce new drugs and other stimulants and hallucinogens. We have essentially given up trying to regulate marijuana.
Potential and the rare adverse reactions to naloxone are all positive. The studies have demonstrated that no significant training is required, and overdose prevention can be undertaken by the vast majority of drug addicts and their friends. The precipitation of withdrawal was not addressed, but no significant interactions occurred where naloxone administration kept victims from receiving EMS/hospital care. Overall, only limited negative social consequences were seen for providing naloxone for out-of-hospital opioid overdose.

California recently passed a bill that allows health care providers to prescribe, dispense, and issue standing orders for an opioid antagonist to those at risk for an overdose, their family members, and their associates who are in a position to assist patients at risk. Such individuals would not be liable under civil or criminal statutes if they acted with reasonable care. The American College of Medical Toxicology has submitted a proposal to members advocating wide use of education, legal protection, and naloxone distribution to try to halt the burgeoning increase in opioid deaths. This concept will likely garner significant interest, and have advocates as well as detractors. Simply stated, opioid use is a chronic illness with usually no cure, similar to diabetes and hypertension. One wonders if ED clinicians will be soon be expected to prescribe naloxone to those resuscitated by the ED.

Whether this concept garners praise or criticism, one thing is certain: Opioid use is largely a medical illness, like alcoholism, but this understanding is still overshadowed by misconceptions that drug use is a moral weakness or entirely a willful choice. (JAMA 2014;311[14]:1393.) Methadone and buprenorphine programs have been successful in extending the life of many opioid users, and many official organizations support medication-assisted treatment.

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Dr. Roberts is a professor of emergency medicine and toxicology at the Drexel University College of Medicine in Philadelphia. Read the Procedural Pause, a blog by Dr. Roberts and his daughter, Martha Roberts, ACNP, CEN, at http://bit.ly/ProceduralPause, and read his past columns at http://bit.ly/RobertsInFocus.

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Learning Objectives for This Month’s CME Activity: After participating in this CME activity, readers should be better able to identify the benefits and pitfalls of prescribing naloxone to drug addicts and those who might assist them in overdose situations.

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