FDA approves nasal spray to treat opioid overdose:

November 20, 2015
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**Article type:** News  
**Topics:** Addiction, Anesthesiology/Pain Medicine, Pharmacology

The Food and Drug Administration (FDA) has approved Narcan nasal spray, which can reverse the effects of an opioid overdose.

A naloxone hydrochloride formulation like the one in the spray previously was approved in injectable forms. The American Medical Association (AMA) Task Force to Reduce Prescription Opioid Abuse, which includes the Academy, and addiction groups have pushed for increased access to naloxone.

Review of Narcan spray was fast-tracked by the FDA.

“We cannot stand by while Americans are dying,” Acting FDA Commissioner Stephen Ostroff, M.D., said in a news release. “While naloxone will not solve the underlying problems of the opioid epidemic, we are speeding to review new formulations that will ultimately save lives that might otherwise be lost to drug addiction and overdose.”

In the U.S., 44 people die from prescription opioid overdoses each day, and people who are addicted to such drugs also are 40 times more likely to develop a heroin addiction, according to the Centers for Disease Control and Prevention (CDC). From 2011-’13, the rate of heroin use among 18- to 25-year-olds doubled compared to the period of 2002-’04.

Narcan nasal spray can be used on adults and children, and medical training is not required to administer the drug, which is distributed by Adapt Pharma Inc. If administered shortly after an opioid overdose, naloxone can reverse the effects in about two minutes, but the person still needs emergency care and also may experience withdrawal symptoms.

“It's not a cure, it's one and done,” said Pamela K. Gonzalez, M.D., M.S., FAAP, a member of the AAP Committee on Substance Abuse. “You give it and be sure you're calling emergency medical services.”

Dr. Gonzalez said pediatricians may want to consider co-prescribing naloxone to children who are prescribed opioids for a chronic illness. She pointed to the AMA task force recommendations (http://bit.ly/1LqsW8p) to consider whether patients are on a high...
opioid dose and their history of substance abuse, mental health conditions and medical conditions that might make them susceptible to respiratory distress or overdose.

It also is important for pediatricians to be aware of their state’s Good Samaritan protections for those assisting someone who has overdosed and naloxone access laws, Dr. Gonzalez said. She stressed the importance of talking to families about opioid addiction and the availability of naloxone, especially since teens tend to start experimenting around age 15 or 16.

Pediatricians should “make ourselves visible and reach out so that any parent knows we know this problem is out there and we’re here to help,” she said. “Come talk to me if you think your kid has got a problem.”

Resources
- AAP News story on opioid prescribing
- AAP policy “Substance Use Screening, Brief Intervention, and Referral to Treatment for Pediatricians”
- Narcan website
- FDA announcement on Narcan nasal spray
- Transcripts and presentations from the FDA’s workshop on naloxone
- CDC statistics on the heroin epidemic
- CDC statistics on prescription opioid overdoses

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