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Naloxone Saves Lives

Steve Shafer, MD, FASA, Editor-in-Chief

Death from the COVID-19 pandemic was not limited to mortality from respiratory illness. According to the National Institute on Drug Abuse, more than 68,000 died from opioid overdose in 2020, and more than 80,000 died from opioid overdose in 2021 (asamonitor.pub/3mbLWqY). Surging opioid deaths is among the many causes of excess mortality associated with the SARS-CoV-2 pandemic.

Investigators at the University of Wisconsin-Milwaukee used spatiotemporal analysis of opioid overdoses from 2017 through 2020 to causally link the rise in

opioid overdoses to the onset of the pandemic (*J Urban Health* 2022;99:316-27). While all communities experienced an increase in opioid overdoses with the onset of the pandemic, Black and Hispanic communities in poor urban neighborhoods were disproportionately affected compared to affluent suburban White neighborhoods.

The surge in opioid deaths is partly due to the growing street use of synthetic opioids. Two-thirds of overdose deaths in 2022 were from synthetic opioids, including fentanyl and its more lethal cousin carfentanyl (asamonitor.pub/3nYUToj).

Continued on page 4



A Financial Model of the 100% Medicare Practice

Johnathan Pregler, MD, FASA
David S. Larsen, MD, FASA
Elmer Choi, MD, PhD, MBA, FASA
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What are the implications of a single-payer health system in which private insurance would be eliminated and practice finances

would be solely based on Medicare as it exists today. This paradigm would be a unique and especially problematic issue

Continued on page 6

Be the Solution: How Anesthesiologists Can Address Health Equity and Show Leadership to the C-Suite

Sunil Eappen, MD, MBA

Addressing health equity is a top priority for many, if not all, health care systems. Anesthesiologists can have a powerful leadership role in addressing this complex issue. ASA's Be the Solution: Sell Your C-Suite on the Value and Leadership of Anesthesiologists program features guidance and resources on this

critical issue that you can share with your health care executives (asamonitor.pub/3ybWw4A). This involves detailing your leadership throughout the perioperative process, including managing surgical patients with high comorbidities and developing pathways that improve care for all patients.

Continued on page 8



SPECIAL SECTION

Perioperative Waste Is Costing Us

Guest Editor: Lalitha Sundararaman, MBBS, MD

18-26

In the Know: Naloxone Saves Lives*Continued from page 1*

Fentanyl is about 50-fold more potent than heroin (asamonitor.pub/3MqJlud). Carfentanil is 20 times more potent than fentanyl (*Can J Anaesth* 2019;66:414-21). In 2016, the Royal Canadian Mounted Police seized 1 kg of carfentanil in Vancouver, enough drug to kill half the population of Canada (*Can J Anaesth* 2019;66:351-5). The semisynthetic opioids are horrifyingly easy to synthesize for a skilled chemist. I lost a colleague to fentanyl synthesized in the top drawer of his desk.

Naloxone to the rescue

Naloxone, a potent competitive antagonist at the mu opioid receptor, can rapidly reverse respiratory depression in opioid overdose (asamonitor.pub/3K-Dv46d). Naloxone was first synthesized in 1960 and introduced as Narcan® in 1971 (*Camb Q Health Ethics* 2021;30:637-50). Naloxone was the first “pure” mu antagonist after decades of failed efforts to find and synthesize an opioid antagonist devoid of opioid properties (*Camb Q Health Ethics* 2021;30:637-50). In 2014, the CDC estimated that naloxone kits, prepared and

distributed as intravenous injections for use after opioid overdose, had saved more than 26,000 lives (*MMWR Morb Mortal Wkly Rep* 2015;64:631-5).

Following years of ad hoc intranasal administration for opioid overdose (*Am J Health Syst Pharm* 2014;71:2129-35), in 2015 the FDA approved intranasal Narcan® (asamonitor.pub/3KIP2Rv; asamonitor.pub/3ZTldh3; asamonitor.pub/3zZfZWJ). A high-dose (8 mg) intranasal naloxone preparation, Kloxxado, was approved in April 2021 (asamonitor.pub/3zEzR0Y). Zihmi®, a single-use naloxone syringe for intramuscular or subcutaneous administration, was approved by the FDA in 2021 (asamonitor.pub/43f17kc). As noted in the *New York Times*, the FDA legalized over-the-counter naloxone on March 29, 2023, the day I’m writing this column. However, it may remain unavailable because insurance companies will not pay for it (asamonitor.pub/3KHdU7G). Intranasal naloxone works. Emergency department data suggests that intranasal naloxone is more than 90% effective at reversing opioid overdose (*Prehosp Emerg Care* 2017;21:322-26). In 2021, the *New England Journal of Medicine* published a video and “how to” arti-

cle on the administration of intranasal naloxone to patients following opioid overdose (*N Engl J Med* 2021;384:e44).

Naloxone intranasal pharmacokinetics

Naloxone concentrations rise rapidly following intramuscular and intranasal injection, with intramuscular administration peaking sooner (4 minutes vs. 20 minutes) (*Addiction* 2019;114:859-67). Although intramuscular injection peaks more quickly, the simplicity of intranasal injection makes it the preferred route for administration by bystanders and non-health care providers.

An Australian study found that those who received intranasal naloxone were more likely to require additional doses than those who received intramuscular naloxone, likely due to decreased bioavailability (*JAMA Netw Open* 2019;2:e1914977). The expected duration of reversal is 30-60 minutes, so additional naloxone doses may be required depending on the opioid taken.

A recent expert review emphasized that if ventilatory depression is not rapidly reversed, a second dose of naloxone should be given within two minutes (*Expert Opin Drug Metab Toxicol* 2022;18:203-17). The review also emphasized that the goal of naloxone reversal is ventilation, not the return of full consciousness. If the patient is breathing satisfactorily, additional doses may result in acute opioid withdrawal and should be avoided.

Over-the-counter naloxone

In 2022, the FDA stated, “It is our preliminary opinion at this time that naloxone nasal spray up to 4 mg, and naloxone autoinjector for intramuscular or subcutaneous use up to 2 mg, have the potential to be safe and effective for use as directed in nonprescription drug labeling without the supervision of a health care practitioner. We believe the prescription requirement for these naloxone products might not be necessary for the protection of the public health” (asamonitor.pub/3UitXMs).

At the FDA’s Joint Meeting of the Nonprescription Drugs Advisory Committee and the Anesthetics and

Analgesic Drug Products Advisory Committee on February 15, 2023, ASA member and cardiac anesthesiologist Bonnie Milas, MD, offered powerful testimony for the approval of naloxone as a nonprescription countermeasure for opioid overdose (asamonitor.pub/3Uh-Qh8S). In her testimony (which begins at approximately the 4:40:00 mark of the video), Dr. Milas described tragically losing both of her sons to accidental fentanyl overdoses. Having personally administered the naloxone nasal spray to her sons in her own household, Dr. Milas’ testimony was utterly compelling.

Dr. Milas advocates for over-the-counter naloxone because “only naloxone gave them (her sons) a chance at recovery.” She added that “nasal naloxone spray was a blessing because that meant my nonmedical husband and father-in-law could rescue our sons.... Each rescue of our sons with naloxone was yet another chance to live with additional recovery care – it was a chance to live a full life.”

ASA’s position on over-the-counter naloxone

In a letter to the FDA, the ASA conveyed their strong support for the approval of nonprescription status for naloxone hydrochloride nasal spray products. As stated by ASA President Michael W. Champeau, MD, FAAP, FASA, “Improving community access to naloxone nasal spray through over-the-counter use and implementing equitable access solutions are critical components of addressing the opioid epidemic.... Increasing the availability of naloxone nasal spray, especially in communities across the country most impacted by drug overdoses, is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment of opioid use disorder, to ending the opioid epidemic.”

At the conclusion of the February 2023 FDA joint advisory panel meeting, panel members voted unanimously to recommend nonprescription availability for naloxone. That approval was granted on the day I wrote this column. ■



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