ASRA PAIN MEDICINE

ASRA Pain Medicine Update

A Task Made (Somewhat) Easier: Positive Advances in the Treatment of Opioid Use Disorder

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Positive changes are underway in opioid use disorder (OUD) treatment with the recent removal of the DATA waiver (X-waiver) for buprenorphine prescribing and an FDA advisory committee recommendation for an OTC version of intranasal naloxone. ASRA Pain Medicine has played a crucial part in advocating for these changes, and improved access to these agents will undoubtedly ease the daunting tasks of managing pain and overdoses. In addition, these initiatives will improve the quality of life for those affected by OUD and save countless lives.

OUD has reached staggering proportions in the United States; despite decreased opioid prescribing over the past decade, over 81,000 overdoses occurred between May 2019 and May 2020, fueled partly by illicit opioids.[1] COVID-19-related mental health and substance abuse issues have worsened the situation. While ASRA Pain Medicine maintains that opioids should not be first-line therapy for any pain management, particularly not for non-malignant pain,[1] medication treatment of opioid use disorder (MOUD) with selective opioids is effective and widely used.[2] Buprenorphine, a Schedule III long-acting, mixed opioid agonist and antagonist approved for the treatment of OUD, provides effective pain relief while safeguarding against respiratory depression and decreasing withdrawal symptoms, cravings, and the potential for misuse.[3]

Buprenorphine can provide optimal analgesia in outpatient settings for chronic pain.[2] It need not be discontinued in the perioperative period, thus reducing the risk for relapse and illicit opioid use for patients pre-and post-surgery. However, routine prescribing of buprenorphine has been hindered by the time-consuming process of submitting waivers to the Substance Abuse and Mental Health Services Administration (SAMHSA). On December 29, 2022, the Consolidated Appropriations Act, 2023 ("Omnibus Appropriations Bill") was signed into law, and Section 1262 of the bill removed the federal requirement for practitioners to submit X-waivers.[4] SAMHSA now encourages all practitioners with Schedule III prescriptive privileges to prescribe buprenorphine for OUD in their practice if permitted by applicable state law.

The opioid antagonist naloxone was FDA-approved in 2015 to treat known or suspected opioid overdose. Its prescription-only intranasal formulation is the most commonly sold emergency treatment for that use.[5] As most opioid overdoses occur in the community setting, a readily available OTC naloxone product would be of vital importance in emergent cases. Therefore, on February 15, 2023, a joint FDA advisory committee unanimously recommended that naloxone be switched to OTC status.[5] Every member of the Nonprescription Drugs Advisory Committee (NDAC) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) felt that the benefit-risk profile of intranasal naloxone affirms its use as a nonprescription opioid overdose reversal agent.

The advisory committee met to discuss the New Drug Application for OTC intranasal naloxone submitted by Emergent BioSolutions, Inc., during which a strong case was made for its utility.[5] The proposed agent is identical to the prescription version, its minimal adverse effects of nausea and withdrawal symptoms are manageable, and there is low potential for misuse. In addition, having OTC naloxone readily available for purchase in such places as retail stores, supermarkets, and vending machines would increase access to the everyday consumer and likely help decrease the stigma attached to opioid use.

A simulated human factors validation (HFV) study by Emergent BioSolutions assessing the ease with which consumers could follow package directions in an emergency revealed safe and effective use of the OTC naloxone product, though label clarification may be needed.[5] Although there is no regulatory requirement for nonprescription products, one panelist felt it should be considered. "There's a moral imperative for the FDA to develop a program similar to its [Risk Evaluation and Mitigation Strategies] (REMS)," said Timothy J. Ness, MD, PhD, professor emeritus, Department of Anesthesiology and Perioperative Medicine, University of Alabama at Birmingham. "I would encourage them to do a similar process to help with connection to care," he added. Regardless, a clear pathway to OTC naloxone has been paved.

An August 2021 article published in *Regional Anesthesia & Pain Medicine*, "Buprenorphine management in the perioperative period: educational review and recommendations from a multi-society expert panel," underscored the importance of easily accessible, effective treatments to combat OUD:

> "...the overarching goals of this multi-society working group are to educate anesthesiologists and pain physicians and to encourage the use of evidence-based treatment options for OUD. Understanding the significant morbidity and mortality caused by OUD is critical for both individual patient care and our current public health crisis. This is a prime instance where our specialty can and should make a difference. This multi-society working group encourages physicians to learn more about this safe, efficacious, and underused treatment that can save lives." [3]

ASRA Pain Medicine-affiliated clinicians served as co-authors of the article above, and recommendations made in the report were approved by ASRA Pain Medicine and the other four constituent societies as a whole: the American Society of Anesthesiologists, American Academy of Pain Medicine, American Society of Addiction Medicine, and the American Society of Health System Pharmacists. ASRA Pain Medicine has adopted the recommendations as an official guideline.[6] Likewise, ASRA Pain Medicine's *Statement on the Opioid Crisis* mentions in part that

> "both pain and OUDs should be diagnosed and treated using comprehensive and multidisciplinary approaches and that specialty mental health and addiction resources, including MOUD, should be expanded to meet the growing demand. Anesthesiologists and pain physicians have an opportunity to make a significant impact and save lives. Education, research, and advocacy are critical to accomplishing these goals."[1]

With eased restrictions on buprenorphine prescribing and the imminent OTC approval of naloxone, it appears that ASRA Pain Medicine's advocacy has made a clear, positive difference in access to and destigmatization of these agents, which play a vital role in today's OUD treatment landscape. ASRA Pain Medicine members should be proud of their roles in these initiatives and look forward confidently, trusting that further advances in addiction management lie ahead.

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