

Confronting Pain Management and the Opioid Epidemic

Strategies for Federal Agencies

Over the past 25 years, the United States has experienced a dramatic increase in deaths from opioid overdose, opioid use disorder, and other harms related to the prescribing of opioid medications for pain management. Drug overdose—mostly involving opioids—is now the leading cause of unintentional injury death in the United States, an epidemic affecting individuals, families, communities, and society at large.

This opioid crisis lies at the intersection of two substantial public health challenges: containing the rising toll of opioid-related harms, and reducing the burden of suffering for the tens of millions of people suffering from pain. Finding the ideal balance is a challenging task.

A report from the National Academies of Sciences, Engineering, and Medicine outlines strategies for addressing the opioid epidemic, offering a constellation of policies, interventions, and tools to help reduce or contain opioid-related harms while meeting the needs of people with pain.

Facilitate reimbursement for comprehensive pain management.

RECOMMENDATION 5-3

Why?

Meeting the needs of the tens of millions of U.S. residents suffering from pain means access to a broad array of pain management therapies. Current reimbursement systems appear to have misaligned incentives that limit provision of behavioral, mental health, and other nonopioid approaches to pain management. This is despite the fact that a number of nonopioid pharmacologic treatments; nondrug interventions, such as acupuncture, physical therapy and exercise, cognitive behavioral therapy, and mindfulness meditation; and interventional pain management therapies, such as joint injections, nerve blocks, spinal cord stimulation, and other procedures, can be used to manage pain—either alone or in combination with other approaches. Increasing coverage of and access to comprehensive pain management would help balance opioid reduction with such pain management approaches.

How?

Public and private payers should develop reimbursement models that support evidence-based, cost-effective comprehensive pain management encompassing both pharmacologic and nonpharmacologic treatment modalities.

Establish comprehensive pain education materials and curricula for health care providers.

RECOMMENDATION 5-2

Why?

Beyond insurance coverage, any meaningful effort to improve pain management will require a fundamental shift in the nation's approach to mandating pain-related education for all health professionals who provide care to individuals with pain. Current efforts to improve pain education and knowledge about prescription opioid misuse and OUD among prescribers are inadequate.

“The enormity of the opioid crisis requires an immediate, massive expansion of treatment capacity to provide evidence-based treatment and recovery to millions of individuals.”

How?

State medical schools and other health professional schools should coordinate with their state licensing boards for health professionals (e.g., physicians, nurses, dentists, pharmacists), the National Institutes of Health’s (NIH) Pain Consortium, the U.S. Food and Drug Administration (FDA), the U.S. Centers for Disease Control and Prevention (CDC), and the U.S. Drug Enforcement Administration to develop an evidence-based national approach to pain education encompassing pharmacologic and nonpharmacologic treatments and educational materials on opioid prescribing.

Evaluate the impact of patient and public education about opioids on promoting safe and effective pain management.

RECOMMENDATION 5-5

Why?

Changes to payer policy and provider education should be accompanied by a change in patient expectations with respect to the treatment and management of chronic pain. Yet attention is not being paid to educating the general public on the risks and benefits of opioid therapy, or the comparative effectiveness of opioids with nonopioid and nondrug therapies.

How?

The nation’s public health leadership, including the surgeon general, the CDC, and heads of major foundations and professional organizations, should convene a body of experts in communication and in pain and OUD to evaluate the likely impact (and cost) of an education program designed to raise awareness among patients with pain and the general public about the risks and benefits of prescription opioids and to promote safe and effective pain management.

Expand treatment for opioid use disorder.

RECOMMENDATION 5-6

Why?

The enormity of the opioid crisis requires an immediate, massive expansion of treatment capacity to provide evidence-based treatment and recovery to millions of individuals. Aside from its immediate benefits to people with OUD, a strategy of increasing access to and use of treatment for OUD can help lower the number of people misusing opioids and thus lower the risk of public health harms.

How?

States, with assistance from relevant federal agencies, particularly the Substance Abuse and Mental Health Services Administration (SAMHSA), should provide universal access to evidence-based treatment for OUD, including use of medication, in a variety of settings, including hospitals, criminal justice settings, and substance use treatment programs. Efforts to this end should be carried out with particular intensity in communities with a high burden of OUD. State licensing bodies should require training in treatment for OUD for all licensed substance use disorder treatment facilities and providers.

Remove barriers to coverage of approved medications for treatment of opioid use disorder.

RECOMMENDATION 5-8

Why?

Medication-assisted treatment is the standard of care for OUD, including for special populations such as pregnant and postpartum women. Although several medications for treatment of OUD are available, they are underused for a variety of reasons, including insufficient numbers of providers eligible to provide OUD treatment, coverage barriers, and other access limitations.

How?

The U.S. Department of Health and Human Services (HHS) and state health financing agencies should remove impediments to full coverage of medications approved by the FDA for treatment of OUD.

PRESCRIPTION AND ILLICIT OPIOID USE

The prescription and illicit opioid epidemics are intertwined.

One of the consequences of increased prescribing of opioids has been increased use of illicit opioids, such as heroin. In addition to prescription opioids serving as a strong risk factor for heroin use, market forces and efforts designed to reduce prescription opioid-related harms, such as opioids with abuse-deterrent formulations, may be contributing to increased heroin use. The small but growing population of people who use heroin compared to the large population of people who use prescription opioids points to an unprecedented potential market for heroin as well as other illicit opioids.

Consider potential effects on illicit markets of policies and programs for prescription opioids.

RECOMMENDATION 4-1

How?

In designing and implementing policies and programs pertaining to prescribing of, access to, and use of prescription opioids, the FDA, other agencies within HHS, state agencies, and other stakeholders should consider the potential effects of these interventions on illicit markets—including both the diversion of prescription opioids from lawful sources and the effect of increased demand for illegal opioids such as heroin among users of prescription opioids—and take appropriate steps to mitigate those effects.

OPIOIDS AND VULNERABLE POPULATIONS

Three populations are uniquely vulnerable to OUD and its related harms:

PREGNANT WOMEN AND NEWBORNS

The number of U.S. babies born with neonatal abstinence syndrome (NAS) rose significantly along with the increase in opioid use and misuse among pregnant women.

WHAT'S NEEDED: A more comprehensive response to NAS and treatment of OUD in pregnant women would mean a better understanding of the signs and symptoms of NAS for specific prescribed and illicit opioids, better understanding of the effectiveness of various medications and protocols for treatment of NAS, and the development of treatment protocols specifically for pregnant women using fentanyl.

PEOPLE INVOLVED WITH THE CRIMINAL JUSTICE SYSTEM

As the opioid epidemic shifts rapidly from prescription opioids to illicit drugs, more people, many of whom live with OUD, are coming into contact with the criminal justice system.

WHAT'S NEEDED: Improved access to effective treatments and collection of surveillance data with which to track opioid use and associated harms in these settings are necessary. Although there are well-documented social, medical, and economic benefits of providing medication-assisted treatment (MAT) in correctional settings, there has been little to no implementation or routine use of MAT in U.S. jail and prison settings.

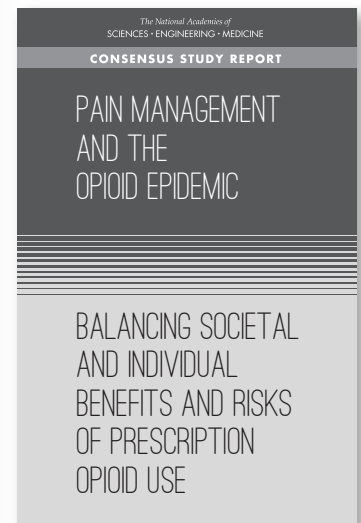
PEOPLE WHO INJECT DRUGS

These users are subject not only to the harms related to the drug itself but also to the harms related to injection.

WHAT'S NEEDED: For new formulations of opioids and other drugs that may be manipulated and injected, it is prudent to anticipate and fully examine the possible harms to health that might occur via injection routes. When harm arises, involving people who inject drugs and their health advocates in interventions that affect them can improve public health outcomes. Harm to this population can be minimized and treatment entry improved through safe access to injection materials.

Conclusion

Years of sustained and coordinated effort by multiple stakeholders and sectors will be required to contain the current opioid epidemic and ameliorate its harmful effects on society while balancing the needs of the millions of individuals suffering from pain. **Several federal agencies and offices within HHS, including CDC, FDA, NIH, and SAMHSA**, have a crucial role to play in these efforts.



To read the full report and view related resources, please visit
nationalacademies.org/OpioidStudy

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Report recommendations for the U.S. Food and Drug Administration

RECOMMENDATION 6-1: INCORPORATE PUBLIC HEALTH CONSIDERATIONS INTO OPIOID-RELATED REGULATORY DECISIONS

The U.S. Food and Drug Administration (FDA) should utilize a comprehensive, systems approach for incorporating public health considerations into its current framework for making regulatory decisions regarding opioids. The agency should use this approach, in conjunction with advisory committee input, to evaluate every aspect of its oversight of prescription opioid products in order to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, as actually used, the drugs provide benefits that clearly outweigh their harms. When recommending plans for opioids under investigation; making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids; and monitoring opioids on the U.S. market, the FDA should explicitly consider

- benefits and risks to individual patients, including pain relief, functional improvement, the impact of off-label use, incident opioid use disorder (OUD), respiratory depression, and death;
- benefits and risks to members of a patient's household, as well as community health and welfare, such as effects on family well-being, crime, and unemployment;
- effects on the overall market for legal opioids and, to the extent possible, impacts on illicit opioid markets;
- risks associated with existing and potential levels of diversion of all prescription opioids;
- risks associated with the transition to illicit opioids (e.g., heroin), including unsafe routes of administration, injection-related harms (e.g., HIV and hepatitis C virus), and OUD; and
- specific subpopulations or geographic areas that may present distinct benefit-risk profiles.

RECOMMENDATION 6-2: REQUIRE ADDITIONAL STUDIES AND THE COLLECTION AND ANALYSIS OF DATA NEEDED FOR A THOROUGH ASSESSMENT OF BROAD PUBLIC HEALTH CONSIDERATIONS

To utilize a systems approach that adequately assesses the public health benefits and risks described in Recommendation 6-1, the FDA should continue to require safety and efficacy evidence from well-designed clinical trials while also seeking data from less traditional data sources, including nonhealth data, that pertain to real-world impacts of the availability and use of the approved drug on all relevant outcomes. The FDA should develop guidelines for the collection of these less traditional data sources and their integration in a systems approach.

RECOMMENDATION 6-3: ENSURE THAT PUBLIC HEALTH CONSIDERATIONS ARE ADEQUATELY INCORPORATED INTO CLINICAL DEVELOPMENT

The FDA should create an internal system to scrutinize all Investigational New Drug (IND) applications for opioids. This review should examine whether public health considerations are adequately incorporated into clinical development (e.g., satisfactory trial design; see Recommendation 6-2). In implementing this recommendation, the FDA should rarely, if ever, use expedited development or review pathways or designations for opioid drugs and should review each application in its entirety.

RECOMMENDATION 6-4: INCREASE THE TRANSPARENCY OF REGULATORY DECISIONS FOR OPIOIDS IN LIGHT OF THE COMMITTEE'S PROPOSED SYSTEMS APPROACH (RECOMMENDATION 6-1)

The FDA should commit to increasing the transparency of its regulatory decisions for opioids to better inform manufacturers and the public about optimal incorporation of public health considerations into the clinical development and use of opioid products.

RECOMMENDATION 6-5: STRENGTHEN THE POST-APPROVAL OVERSIGHT OF OPIOIDS

The FDA should take steps to improve post-approval monitoring of opioids and ensure the drugs' favorable benefit-risk ratio on an ongoing basis. Steps to this end should include use of Risk Evaluation and Mitigation Strategies that have been demonstrated to improve prescribing practices, close active surveillance of the use and misuse of approved opioids, periodic formal reevaluation of opioid approval decisions, and aggressive regulation of advertising and promotion to curtail their harmful public health effects.

RECOMMENDATION 6-6: CONDUCT A FULL REVIEW OF CURRENTLY MARKETED/APPROVED OPIOIDS

To consistently carry out its public health mission with respect to opioid approval and monitoring, the FDA should develop a process for reviewing, and complete a review of, the safety and effectiveness of all approved opioids, utilizing the systems approach described in Recommendation 6-1.

RECOMMENDATION 6-7: APPLY PUBLIC HEALTH CONSIDERATIONS TO OPIOID SCHEDULING DECISIONS

To ensure appropriate management of approved opioids, the FDA and the U.S. Drug Enforcement Administration should apply the same public health considerations outlined in Recommendation 6-1 for approval decisions to scheduling and rescheduling decisions, and study empirically the outcomes of scheduling determinations at the patient and population health levels.