



December 2019

## Framing Opioid Prescribing Guidelines for Acute Pain: Developing the Evidence

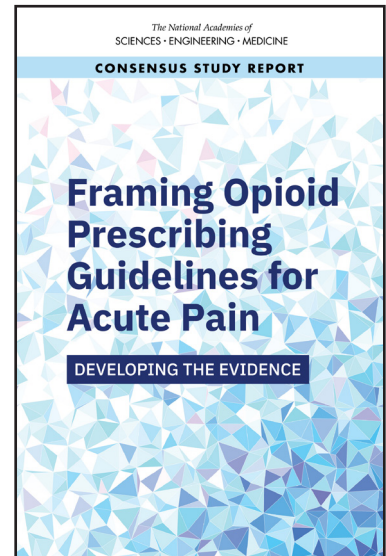
Despite widespread efforts over the past decade to reduce opioid prescribing, opioids are still commonly overprescribed for acute pain—meaning pain that is sudden and may last up to 90 days. In addition, the amount of opioids prescribed for acute pain varies by clinician, hospital, and geographical region, and by the surgical procedure or medical condition causing the pain.

The epidemic of opioid misuse and overdose, combined with the need to reduce the burden of acute pain, poses a significant public health challenge. To address how evidence-based clinical practice guidelines (CPGs) for prescribing opioids for acute pain might help meet this challenge, the U.S. Food and Drug Administration (FDA) asked the National Academies of Sciences, Engineering and Medicine (National Academies) to develop a framework to evaluate CPGs, recommend indications for which new evidence-based guidelines should be developed, and recommend a future research agenda to inform and enable the development and dissemination of evidence-based CPGs.

The resulting report, *Framing Opioid Prescribing Guidelines for Acute Pain: Developing the Evidence*, recommends two frameworks—an analytic framework and an evidence evaluation framework—that medical professional societies, health care organizations, and state, national, and local agencies could use to develop CPGs for prescribing opioids to manage acute pain.

### IDENTIFYING PRIORITIES FOR OPIOID PRESCRIBING

Excessive opioid prescribing not only puts patients at risk for opioid addiction and overdose; leftover prescription opioids may also be misused by family members. After surgery, patients consume on average only half of the opioids prescribed. Between 6 and 14 percent of opioid-naïve patients—meaning patients who do not take these medications on a regular basis—who receive opioid prescriptions after surgery or in the emergency department continue to use them 6 to 12 months



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later, increasing their risk of misuse. The report identifies priority surgical procedures and medical conditions for which evidence-based CPGs for opioid prescribing would be desirable. These indications were selected based on their prevalence or frequency and evidence of variation in prescribing opioids for them.

High-priority surgical procedures include cesarean delivery (C-section), total knee replacement, and wisdom tooth removal; and medical indications include low-back pain, sickle cell disease, migraines, and kidney stones. For example, childbirth is the most common reason for hospital admission and C-section is the most common surgical procedure in the United States, but there are no evidence-based guidelines for opioid prescribing after cesarean or vaginal delivery. In other common conditions, like low back pain, there is a lack of evidence that opioids are more effective for acute pain than nonopioid alternatives such as over-the-counter medications or physical therapy. In these situations, a trustworthy CPG

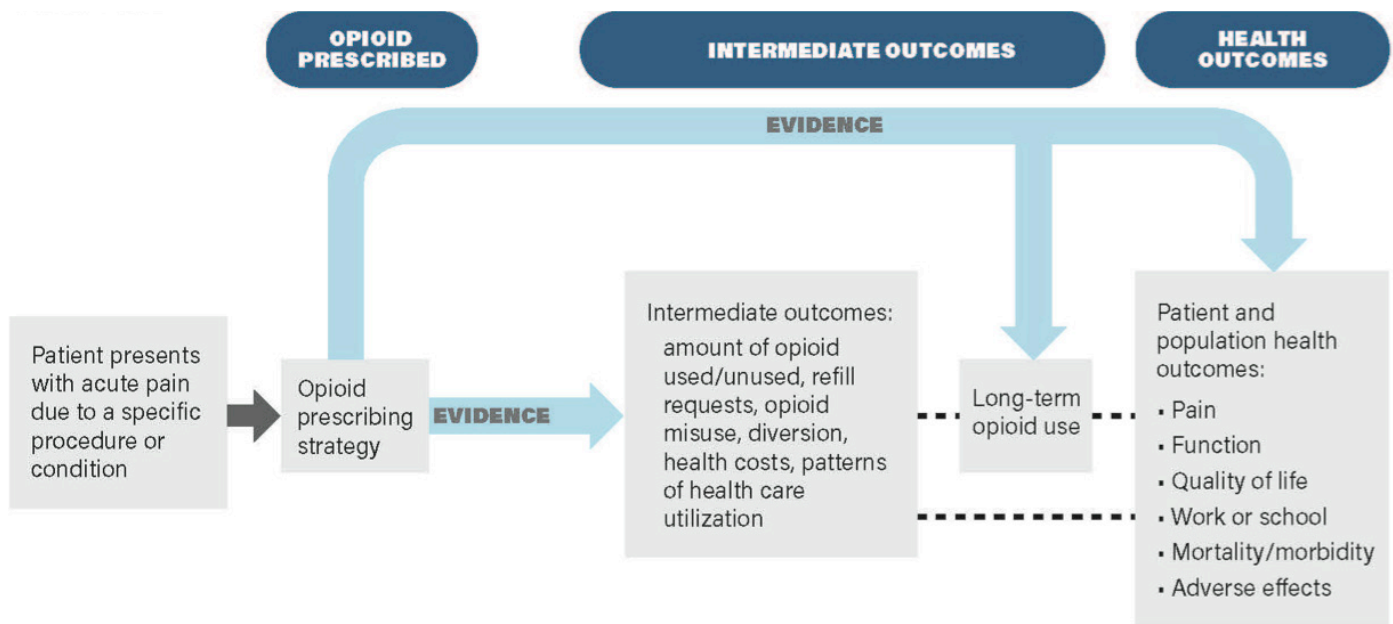
can help clinicians relieve acute pain and reduce the risks of excessive prescribing of opioids, the report says.

**TWO FRAMEWORKS FOR DEVELOPING CPGS**

The committee’s CPG development approach provides a stepped process that begins with establishing the CPG development group and determining the scope of the CPG, and moves on to the analytic framework (see Figure 1) that is used to identify what evidence will be assessed and what outcomes will be considered.

The analytic framework depicts the evidence that needs to be assessed before making an opioid prescribing recommendation; the intermediate outcomes of different prescribing strategies (such as refill requests, unused pills, misuse, or diversion); and health outcomes (such as pain relief, improved quality of life, adverse effects, morbidity, and mortality). The framework can also highlight gaps in the body of evidence that new studies might fill.

**FIGURE 1. ANALYTIC FRAMEWORK FOR PRESCRIBING OPIOIDS FOR ACUTE PAIN**



*This figure shows the evidence linkages that are necessary to support the development of a CPG for opioid prescribing. The framework begins with a determination of the patient population that is presenting with acute pain (e.g., opioid-naïve patients vs. opioid exposed). The wide arrow indicates evidence evaluating the effects of an opioid prescribing strategy on a health or intermediate outcome. The dotted lines indicate linkages between different outcomes (e.g., the association between a lesser amount of opioid used and risk of long-term use or quality of life), not between an intervention and an outcome (or, in the case of intermediate outcomes and long-term opioid use, between one intermediate and another intermediate outcome). Short- and long-term health outcomes, both beneficial and harmful, may be seen at the patient and community or population levels.*

**“Health care providers, patients, caregivers, and communities all have an interest in optimal prescribing of opioids, not only to manage patients’ acute pain, but also to reduce the risk of opioids harming them and others.”**

## **CONCLUSION**

Acute pain causes physical and emotional distress, affecting a person’s quality of life, sleep, physical functioning, mental health, and ability to meet family, job, school, and other responsibilities. Suboptimal pain management can increase morbidity, slow recovery, prolong analgesic use during and after hospitalization, and increase the cost of care. However, the number of deaths from opioid overdoses, which began to increase noticeably in 1999, has continued to rise, resulting in the ongoing opioid overdose epidemic.

Health care providers, patients, caregivers, and communities all have an interest in optimal prescribing of opioids, not only to manage patients’ acute pain, but also to reduce the risk of opioids harming them and others. A standardized process for developing CPGs would provide trustworthy evidence-based criteria for prescribing opioids, help clinicians assess the potential risks and benefits of prescribing opioids, and identify areas where more evidence and research is needed.

Next, clinicians and developers of CPGs should use the evidence evaluation framework to grade the quality of existing evidence and the strength of recommendations they make—and in doing so can use a number of formal methods to evaluate the quality of evidence. For example, they might consider whether the prescribing strategy—e.g., the dosage, duration, and type of opioid prescribed—was linked to pain reduction, opioid-related adverse effects, or mortality. Sources of evidence may include randomized controlled trials, observational studies, and quality improvement initiatives.

In applying its analytic framework to several surgical procedures and medical conditions, the committee found that there were considerable variations in opioid prescribing for those indications, and in some cases, opioids were not the preferred first-line treatment. Available guidelines for those indications did not always discuss optimal opioid prescribing or indicate when opioids should not be used.

## **ADDRESSING GAPS IN RESEARCH**

Rigorous evidence—and CPGs based on that evidence—help clinicians make the best possible decisions about patient care. The report identified important gaps in current CPGs for opioid prescribing in acute pain and recommended more research to address those gaps, including:

- how nonopioid interventions affect the need for opioids and the outcomes of patients who have been prescribed opioids;
- the outcomes of opioid prescribing strategies in different patient populations, such as children and the elderly;
- the impact of clinical setting on opioid prescribing strategies (for example, emergency departments, primary care clinics, or ambulatory surgical facilities); and
- how the amount of opioids prescribed and the amount leftover affect health outcomes, particularly long-term health outcomes.

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To read the full report, please visit  
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