



## Patient safety

The current opioid crisis calls on health care providers to embrace a cautious new approach to opioid prescribing that emphasizes safety. The following recommendations address key safety concerns that are relevant to all pain phases.

## Clinical recommendations

1. Check the Prescription Monitoring Program (PMP) whenever prescribing an opioid for acute pain, prior to each refill during the post-acute pain period, prior to initiating and routinely during chronic opioid analgesic therapy (COAT).
2. Avoid providing concurrent prescriptions of opioids and benzodiazepines or other sedative-hypnotic medications. Use extreme caution when prescribing opioids to patients using benzodiazepines or other sedative-hypnotic medications on an on-going basis. Advise patients intermittently using benzodiazepines to stop use while taking opioids for acute pain. Frankly discuss the risks of concomitant use with the patient and conduct close follow-up during the period in which opioids are used.
3. Address concomitant use of benzodiazepines and other sedative hypnotics for patients receiving COAT. Patients receiving potentially dangerous drug combinations require care coordination and medication management. Obtain a patient release of information and contact the relevant prescribers. Consider prescribing naloxone to patients with concomitant use.
4. Avoid prescribing opioids for 1) fibromyalgia, 2) headache, including migraine, 3) self-limited illness, e.g. sore throat, 4) uncomplicated, acute neck and back pain and 5) uncomplicated, acute musculoskeletal pain. Complicated, acute back, neck or musculoskeletal pain is objectively verifiable and includes pain accompanied by severe or rapidly progressive neurological deficit, evidence of infection, new cancer diagnosis or metastasis or fracture. Provide appropriate non-opioid alternative pain management for conditions not indicated for opioid analgesic therapy.
5. Use extreme caution when prescribing opioids to patients with comorbid conditions that may increase risk of adverse outcomes. Comorbid conditions associated with elevated risk include Chronic Obstructive Pulmonary Disease, Congestive Heart Failure, obstructive sleep apnea, history of alcohol or substance use disorder, advanced age, or renal or hepatic dysfunction.
6. Assess pregnancy risk in all women of childbearing age ([/dhs/opip/opioid-guidelines/factors-in-treatment/childbearing-age-women.jsp](https://dhs.opip/opioid-guidelines/factors-in-treatment/childbearing-age-women.jsp)) prior to prescribing an opioid.
7. Avoid prescribing opioids to pregnant women. Educate pregnant women about the known risks of opioids to both the mother and the fetus.
8. Provide patient education about opioid use and pain management beginning with the first opioid prescription. Engage the patient in shared decision-making. Carefully describe the risks and benefits associated with opioid analgesic use and repeat patient education on an ongoing basis.

9. Provide safety information about safe use, safe storage and disposal with every opioid prescription. Provide information, both oral and written, to patient, family members and caregivers, if appropriate.
10. Educate patients receiving opioids that the medications **impact their ability to safely operate motor vehicles**. Advise patients who are initiating opioid therapy or who just had a dose increase not to operate heavy machinery, including driving a car, or participate in activities at home that may be adversely effected by the sedating effect of opioids.

In Minnesota, it is illegal to operate a motor vehicle when the person is under the influence of alcohol, under the influence of a controlled substance, or the person's body contains any amount of a controlled substance listed in Schedule I, II or its metabolite, other than marijuana or tetrahydrocannabinols.

See the [Joint Statement on the Impact of Health Conditions and Medication Use on the Operation of Vehicles](https://mn.gov/boards/assets/Joint%20Statement%20NTSB%20with%20APA_tcm21-116260.pdf) ([https://mn.gov/boards/assets/Joint%20Statement%20NTSB%20with%20APA\\_tcm21-116260.pdf](https://mn.gov/boards/assets/Joint%20Statement%20NTSB%20with%20APA_tcm21-116260.pdf)).

11. Advise patients, family members and caregivers to dispose of opioids not used for a period of two weeks after discontinuation of therapy. [Acute Pain; Post-Acute Pain]
12. **Monitor patients for opioid-related adverse outcomes**, especially when opioid use continues for more than a couple of days. Adverse outcomes associated with longer term use include central sleep apnea, endocrine dysfunction, opioid-induced hyperalgesia, opioid use disorder and signs of acute toxicity.
13. Naloxone (<https://www.health.state.mn.us/communities/opioids/mnresponse/naloxoneaccess.html>) is a pure opioid antagonist that reverses opioid overdose when administered correctly. Consider co-prescribing naloxone to patients at elevated risk for overdose who receive opioid analgesia.

## Discussion\_

### Prescription Drug Monitoring Program (PMP) use

Empirical research examining the effect of PMPs on opioid prescribing behavior is growing; however to date the evidence remains mixed. Among states that have implemented mandatory registration and use laws among providers, reductions in opioid prescribing is demonstrated (*Bao, 2015; Wen, 2017*). However, evidence from states where use is voluntary suggests a more limited impact of PMPs on prescribing behavior (*Finley, 2017*). Based both on the growing body of evidence that supports the effectiveness of PMPs in states where use is mandatory and on expert consensus, the PMP is an effective patient safety tool for providers and should be used whenever opioid therapy is considered. \_

### Concomitant prescribing of opioid analgesics and benzodiazepines

Concomitant use of benzodiazepines and opioid analgesics creates significant risk for opioid-related harm and overdose deaths. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31 to 61 percent of decedents (*Gomes, 2011; Dasgupta, 2015; Nuckols, 2014*). In addition, emergency visits and substance abuse treatment admissions involving the combined use of these two drug classes are also increasing (*Jones, 2015*).

Nearly all recent opioid prescribing guidelines recommend against the concomitant use or prescribing of opioids and benzodiazepines, yet concomitancy remains common. A recent study of concomitant use found that the proportion of opioid users who were co-prescribed benzodiazepines nearly doubled from 9 percent in 2001 to 17 percent in 2013 (*Sun, 2017*). Clinicians should be extremely cautious about concomitant prescribing and use among their patients. Check with the PMP for current benzodiazepine use frequently and inquire about intermittent use when prescribing opioid analgesic therapy. \_

## Conditions not indicated for opioid therapy

There are a number of conditions associated with significant opioid use for which the evidence strongly discourages opioid therapy. These conditions include: fibromyalgia; headache, including migraine; self-limited illness, e.g. sore throat; and uncomplicated, acute neck, back and musculoskeletal pain. Two longitudinal studies found that outcomes in fibromyalgia in opioid-treated participants were worse than those treated with non-opioid drugs (*Fitzcharles, 2013; Peng, 2015*). There is no evidence from randomized controlled trials to support the use of opioids for fibromyalgia. Systematic reviews of opioid efficacy for low back pain demonstrate modest improvements in pain, but little improvement in function and no evidence that pain relief will be sustained (*Chou, 2007; Chaparro, 2014*). Evidence from a population-based, prospective study of a low back pain cohort in Washington State's workers compensation program supports non-opioid therapy for acute pain. The study found that even minimal use of opioids in the first six weeks following an acute low back injury was associated with doubling the risk of disability one year later (*Franklin, 2008*). The American Academy of Neurology recommends against the use of opioids for conditions such as headache, fibromyalgia and chronic low back pain, given that the risk of death, overdose, opioid use disorder or serious side effects outweighs any benefit (*Franklin, 2014*). \_

## Conditions that elevate the risk of opioid-related adverse effects

Certain medical conditions significantly increase the risk of opioid related harm for patients on long-term opioid therapy. Two large observational studies of patients with a history of chronic obstructive pulmonary disease (COPD) and sleep apnea who were prescribed opioids showed a weak, but positive association with opioid-related toxicity/overdose and overdose-related death (*Zedler, 2015; Bohnert, 2011*). Zedler et al, found that sleep apnea and chronic pulmonary disease as well as renal disease, moderate or severe liver disease and age > 55 years were associated with increased risk for life-threatening respiratory central nervous system depression or overdose. Reduced renal and/or hepatic function results in decreased ability to process and excrete drugs, which can result in greater peak effect and longer duration of action. Although the evidence primarily examines the effect of long-term opioid use, clinicians should consider these comorbidities in the risk-benefit analysis anytime opioids are considered for pain management.\_

## Patient education about pain management and opioid use

Address the following at each visit:

- Pain following an injury or surgery does not represent harm
- Expected duration and severity of pain
- Warning signs that require immediate medical attention
- When to resume normal activities and return to work, if applicable
- How to prevent future episodes of pain, especially for patients with back pain

- The importance of pain self-management and active participation in pain control
- The patient's questions, especially those related to concerns about the severity of pain.

Shared decision-making about opioid therapy for pain management should begin with the first opioid prescription. Carefully describe the risks and benefits of opioid use to every patient, regardless of their perceived risk profile or the intended duration of opioid therapy. Explain the harms associated with opioids in an objective, non-judgmental manner and repeat patient education often. Clinics and health systems should have a variety of patient education materials—written materials, references to online content, suggested videos on platforms such as YouTube—available to patients beginning with the first opioid prescription. \_

## Safe use, storage and disposal

Address the following safety considerations with the patient at every visit when opioid therapy is initiated or continued (*SAMHSA, 2016*):

- Take prescription medicine only if it has been prescribed to you by your doctor
- Do not take more medicine or take it more often than instructed
- Call your doctor if your pain gets worse
- Never mix pain medicine with alcohol, sleeping pills, or any illicit drug
- Do not operate heavy machinery, including vehicles, when initiating opioid therapy or increasing dosage
- Store prescription opioids in a locked container, whenever possible, and in a place where children and pets cannot access them
- Dispose of unused opioids appropriately. \_

## Naloxone

Co-prescribing naloxone with opioid analgesia and providing the necessary information about naloxone administration are important risk mitigation strategies to prevent opioid overdose-related death. A systematic review of 22 observational studies provided moderate-quality evidence that take home naloxone programs are effective in improving overdose survival and decreasing mortality, with a low rate of adverse events (*McDonald, 2016*). Prescription of naloxone kits and accompanying education have also been found to reduce opioid-related emergency department visits (*Coffin, 2016*).

Clinicians should ask their patients whether they have received a previous prescription for naloxone and whether it was filled. Educate patients that naloxone is not a self-administered drug. Review the following with the patient and a family member, friend or caregiver prior to prescribing naloxone: 1) how to identify an overdose; 2) how to properly use naloxone; and 3) safe storage. Educational resources are available on the Minnesota Department of Health's [Expanding Access to Naloxone and Preventing Opioid Overdose](https://www.health.state.mn.us/communities/opioids/mnresponse/naloxoneaccess.html) (<https://www.health.state.mn.us/communities/opioids/mnresponse/naloxoneaccess.html>) web site.

Consider prescribing naloxone to the following populations at high-risk of opioid overdose:

- Individuals with substance use disorder
- Individuals concomitantly using benzodiazepines
- Individuals on COAT with an acute injury
- Individuals with a past overdose
- Individuals with respiratory insufficiency, especially sleep apnea

- Individuals who were recently incarcerated with a history of substance abuse.

Other patient populations who are at elevated risk of opioid-related harm, especially when prescribed long-term opioid therapy, include:

- Pediatric patients
- Geriatric patients
- Individuals referred to addiction specialists, pain medicine specialists or mental health providers. These patients may be at risk for overdose during care transitions
- All patients receiving COAT.

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