

Wisconsin Opioid Prescribing Guideline Draft

Scope and purpose of the guideline: To help providers make informed decisions about acute and chronic pain treatment -pain lasting longer than three months or past the time of normal tissue healing. The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. Although not specifically designed for pediatric pain, many of the principals upon which they are based could be applied there, as well.

Opioids pose a potential risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1) Identify and treat the cause of the pain, use non-opioid therapies

Use non-pharmacologic therapies (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) and non-opioid pharmacologic therapies (such as acetaminophen and anti-inflammatories) for acute and chronic pain. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

2) Start low and go slow

When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

3) Close follow-up

Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or discontinue opioids, if needed.

What's included in the guideline?

The guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, treating the cause of the pain, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the guideline include:

1) Determining when to initiate or continue opioids

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

2) Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

3) Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder

Prescription Opioid Guideline

1. Pain is a subjective experience and at present, physicians lack options to objectively quantify pain severity other than by patient reported measures including pain intensity. While accepting the patient's report of pain, the clinician must simultaneously decide if the magnitude of the pain complaint is commensurate with causative factors and if these have been adequately evaluated and addressed with non-opioid therapy.

2. In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 5 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults. When prescribing opioids, physicians should consider writing two separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Most patients do not fill the second prescription, thus limiting opioid excess in a patient's home and potential misuse.

3. A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.

- a. Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.
- b. Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.
- c. Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.

4. Opioids should not necessarily be the first choice in treating acute or chronic pain.

- a. Acute pain: Evidence for opioids is weak. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments should be attempted prior to initiating opioid therapy. Although opioids could be simultaneously prescribed if it is apparent from the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.
- b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (tricyclic antidepressant, serotonin/norepinephrine re-uptake inhibitor, anticonvulsant, etc.) should be attempted.
- c. Chronic pain: Evidence for opioids is poor. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) should be utilized. Multiple meta-analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. Note: There is no high-quality evidence to support opioid therapy longer than 6 months in

duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior.

- d. Patients unwilling to accept non-pharmacological and/or nonnarcotic treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

5. Patients should not receive opioid prescriptions from multiple physicians. There should be a dedicated provider such as a primary care or pain specialist to provide all opioids used in treating any patient's chronic pain, with existing pain contracts being honored. Physicians should avoid prescribing controlled substances for patients who have run out of previously prescribed medication or have had previous prescriptions lost or stolen.

6. Physicians should avoid using intravenous or intramuscular opioid injections for patients with exacerbations of chronic non-cancer pain in the emergency department or urgent care setting.

7. Physicians are encouraged to review the patient's history of controlled substance prescriptions using the Wisconsin Prescription Drug Monitoring Program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three-day supply.

8. Pain from acute trauma or chronic degenerative diseases can oftentimes be managed without opioids prior to surgery. Surgical patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.

9. Prescribing of opioids is not encouraged in patients concurrently taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already high increases in annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.

10. The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse.

11. Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:

- a. Medical history and physical examination targeted to the pain condition
- b. Nature and intensity of the pain
- c. Current and past treatments, with response to each treatment
- d. Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal disease, sleep apnea, COPD, etc.)
- e. Effect of pain on physical and psychological functioning
- f. Personal and family history of substance abuse
- g. History of psychiatric disorders associated with opioid abuse (bipolar, ADD/ADHD, sociopathic, borderline, untreated/severe depression)
- h. Medical indication(s) for use of opioids.

12. Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be weaned or discontinued.

13. Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating chronic opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

- a. Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).
- b. Components of ongoing assessment of risk include:
 - i. Review of the Prescription Drug Monitoring Program (PDMP) information
 - ii. Periodic urine drug testing (including chromatography)– at least yearly in low risk cases, more frequently with evidence of increased risk
 - iii. Periodic pill counts – at least yearly in low risk cases, more frequently if evidence of increased risk
 - iiii. Violations of the opioid agreement

14. All patients on chronic opioid therapy should have informed consent consisting of:

- a. Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death
- b. Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects

15. Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long-acting agents for a majority of the daily dose.

16. Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented (see #13.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and appropriate documentation to support such dosing should be present on the chart.

17. The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. Finally, methadone can have a potent effect on prolonging the QTc, predisposing susceptible patients to potentially fatal arrhythmias.

18. Prescribing of opioids is strongly discouraged for patients abusing illicit drugs. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.

19. During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks. During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.

20. Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:

- a. History of overdose (a relative contraindication to chronic opioid therapy)
- b. Opioid doses over 50 MMEs/day
- c. Clinical depression
- d. Evidence of increased risk by other measures (behaviors, family history, PDMP, UDS, risk questionnaires, etc.)

The recommended dose is 0.4 mg for IM or intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives. Family members can be prescribed naloxone for use with the patient.

21. All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner should be able to assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an addiction treatment center which is willing to accept the patient. Simply discharging a patient from the provider's practice after prescribing the medication that led to the complication of opioid use disorder is not considered acceptable.

22. Discontinuing Opioid Therapy

A. If lack of efficacy of opioid therapy is determined discontinuation of therapy should be performed.

1. Opioid weaning can be performed by reducing the MED by 10% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued
2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

B. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered.

1. Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued
2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.
3. Physicians can consider weekly or bi-monthly follow-up during the weaning process

C. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be immediately discontinued and the patient should be treated for withdrawal, if needed.

1. Exceptions to abrupt opioid discontinuation include patients with unstable angina and pregnant patients. These patients should be weaned from the opioid medications in a gradual manner with close follow-up

Resources

CDC Guideline for Prescribing Opioids for Chronic Pain--United States 2016. Dowell D1, Haegerich TM1, Chou R1., JAMA. 2016 Apr 19;315(15):1624-45. doi: 10.1001/jama.2016.1464.

Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care. <https://dwd.wisconsin.gov/wc/medical/pdf/CHRONIC%20OPIOID%20CLINICAL%20MANAGEMENT%20GUIDELINES%20.pdf>

Within-subject comparison of the psychopharmacological profiles of oral oxycodone and oral morphine in non-drug-abusing volunteers. Zacny, James, & Lichtor, Stephanie. Psychopharmacology (2008) 196:105-116

Subjective, Psychomotor, and Physiological Effects Profile of Hydrocodone/Acetaminophen and Oxycodone/Acetaminophen Combination Products. Zachny, James, & Gutierrez, Sandra. Pain Medicine (2008) Vol 9, No 4: 433-443

Positive and Negative Subjective Effects of Extended-Release Oxymorphone versus Controlled-Release Oxycodone in Recreational Opioid Users. Schoedel, Kerri et. al. Journal of Opioid Management 7:3 May/June 2011. 179-192

Tapentadol Abuse Potential: A Postmarketing Evaluation Using a Sample of Individuals Evaluated for Substance Abuse Treatment. Stephen F. Butler, PhD et. al., Pain Medicine 2015; 16: 119–130

Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in collaboration with the Heart Rhythm Society. Chou R1, et. al., J Pain. 2014 Apr;15(4):321-37

Emerging Issues in the Use of Methadone. SAMHSA Substance Abuse Treatment Advisory, Spring 2009, Volume 8, Issue 1, available at <http://store.samhsa.gov/shin/content//SMA09-4368/SMA09-4368.pdf>

Opioid Use, Misuse, and Abuse in Orthopaedic Practice. American Academy of Orthopedic Surgeons, Information Statement 1045, October, 2015, available at <http://www.aaos.org/PositionStatements/Statement1045/?ssopc=1>

Wisconsin Medical Society Opioid Prescribing Principals. <https://www.wisconsinmedicalsociety.org/advocacy/boards-councils/society-initiatives/opioid-task-force/opioid-prescribing-principles/>.