



Chronic Opioid Use: Comparison of Current Guidelines

INTRODUCTION

Recent controversies about opioid misuse, including misuse among patients with chronic pain treated under Workers' Compensation^{1,2}, have triggered calls for more stringent opioid prescribing guidelines. In particular, over the last decade in the United States, opioid overdoses, both fatal and non-fatal, have increased significantly, and most occur as a result of legal prescriptions, rather than illicit drug use. Indeed, although this epidemic of opioid overdoses has many causes, its epidemiology is still unclear, and may involve small numbers of physicians rather than the physician community as a whole, and may further be related to only a subset of opioid medications, such as sustained release oxycodone and a few others.

A recent study by the California Workers' Compensation Institute (CWCI) made some striking observations about the pattern of opioid prescriptions given to injured workers in California³. According to the CWCI study, only 3% of the roughly 9,000 physicians in the California workers' compensation system are responsible for writing over half (55%) of all prescriptions for strong pain medications. Furthermore, although some injured workers require high doses of opioids, the CWCI found that the length of paid temporary disability was typically 119 days longer than in those taking few or no pain medications.

A recent multi-state comparison of opioid use in Workers' Compensation patients revealed large unexplained variances, up to two-fold, in the rates of opioid prescribing and in the types of opioids prescribed among various states⁴. Furthermore, the study found that "few long term users of narcotics received the monitoring services that medical guidelines recommend."

WOEMA is also aware that California's medical education campaign in the last decade, aimed at encouraging physicians to be more aggressive about controlling both malignant and non-malignant pain, has probably played an important role in increased opioid prescribing over the past decade⁵.

In May, 2011, in response to these controversies, ACOEM decided to release its opioid guidelines at no charge⁶. Other expert groups have updated their own guidelines in the past few years, to take account of newer information about certain clinical approaches useful in managing patients with chronic pain, including the use of screening tools for depression or other psychosocial risk factors, structured informed consent forms for chronic opioid treatment, written patient agreements or patient contracts, timetables for increasing or tapering the dose of opioids, and the use of urine drug screening.

WOEMA believes that, despite this proliferation of opioid guidelines, there is still considerable variance in how opioids are prescribed to injured workers with chronic pain.

SUMMARY of Existing Guidelines on Chronic Opioid Use — "The GRID"

WOEMA has compared seven sets of current opioid guidelines, and has noted some important differences among them, reflecting ongoing uncertainties and controversies in the treatment of chronic pain with opioids.

This summary is not meant to supplant or to preferentially weight any of the current guidelines, although we would note that the ACOEM Guidelines and the Medical Treatment Utilization Schedule appear to be among the best documented with clinical evidence, while other guidelines typically rely on consensus or Delphi methods.

In comparing these guidelines, we have focused on nine basic questions, which we believe the clinician should consider when prescribing opioids for chronic pain, and have listed examples of specific answers as provided in these guidelines. The nine questions are as follows:

1. When to initiate opioids?

Because none of the guidelines recommend the routine use of opioids for treating chronic non-malignant pain, the clinician should consider several factors before starting opioids or before extending opioid prescriptions beyond the acute phase of treatment, including the *diagnosis, likely impact of opioid treatment, whether the patient has failed other therapies, as well as contraindications* to opioid use.

Diagnosis: In general, the patient should have a medical diagnosis that is supported by objective evidence of anatomical or physiologic abnormalities ordinarily associated with pain. Examples include:

- a) Post spinal fusion;
- b) Operative procedures with retained hardware;
- c) Severe DJD in which symptoms are consistent with radiographic findings;
- d) Clearly identifiable neurologic abnormalities that would be expected to affect function (and cause pain with increased use) in a body part that had previously suffered significant trauma (crush injury or burns) or multiple surgical procedures;
- e) Complex regional pain syndrome, corroborated objectively, as required by multiple consensus criteria.

Impact: Does the patient have measurable functional physical or medical limitations that would be expected to improve if pain were reduced?

Failed therapy: Have other approaches already been tried unsuccessfully, including physical restorative approaches, non-opioid analgesics, adjuvants, behavioral interventions, and self-applied modalities?

Contra-indications: Patients with prior psychological disorders, depression, a history of adverse childhood experiences (ACE), a history of substance abuse or dependence, and/or a personality disorder are often at higher risk for a poor outcome, and require more caution and extra clinical steps before being prescribed opioids.

Other clinical considerations include:

Prescribing opioids to high risk patients: Although prescribing opioids to high risk patients should in general be avoided, a risk-benefit decision should be made by the provider for each individual patient. These patients will often require explicit rules of conduct (such as written agreement), careful follow-up, and consultation by a mental health professional prior to, or in conjunction with, the opioid trial.

Which medication to choose at initiation: Based on the literature, the combination medication 37.5mg tramadol/325mg acetaminophen has the best safety profile, although addiction and withdrawal are possible, and caution is needed in patients taking SSRI's or other serotonergic neuroleptics because of possible serotonin syndrome. Initial dose is 1 tablet up to 4 times a day with possible titration up to 8 tablets a day. If tramadol is contraindicated or ineffective, other short-acting opioids such as 5mg oxycodone or 5mg hydrocodone every 4 to 6 hours may be used. These shorter acting opioids may also be used occasionally during active functional and physical restoration of the deconditioned patient to mitigate pain increases during activity. However, these patients should be followed-up frequently, and expected to improve their function within a few days. High-dose opioids (such as morphine or oxycodone) should generally be avoided at the start, as these agents have higher adverse effect profiles.

What dosing schedule to use at initiation: Most patients initially should be started on low-dose PRN short-acting opioids, since monitoring pain frequency can help determine whether they need continued opioids after their physical limitations have been addressed. For many patients, PRN usage can increase pain behavior, pain complaints, and dysfunction, and for these patients a long-acting opioid taken round-the-clock would be a consideration.

Whether to allow refills on an initial opioid prescription: During the acute phase of treatment, if the patient is expected to improve over a few weeks, it may be appropriate to write for no refills on an initial opioid prescription, with the expectation that a patient's later request for an opioid refill would trigger a conversation about risk factors and treatment goals.

2. What are the treatment goals?

Treatment efficacy should be measured not solely against pain reduction, but also against other functional domains such as improvement in work capacity, interpersonal relationships, use of health care services, biological markers, coping with activities of daily living, and the family's rating of global improvement. Improvement across several of these domains would be a reasonable treatment goal, to set in advance of an opioid trial.

3. When and how to screen for possible risk of addiction or opioid abuse?

Patients at higher risk of opioid abuse or other adverse effects can often be identified through relatively simple screening questions, or the use of short questionnaires, which are readily available. Screening for such risk factors should be done early, and should address the following:

- a) Prior history of narcotic and/or substance abuse;
- b) Psychiatric conditions, including depression and personality disorders;
- c) History of prolonged disability (greater than six months off work);
- d) Difficulty with opioids in the past.

Several of the pain guidelines suggest screening with specific questionnaire tools, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP) and the Opioid Risk Tool (ORT), which are validated, self-administered questionnaires. Use of a

questionnaire does not replace the need for a formal professional assessment in high risk patients considered for maintenance therapy.

4. When to increase or decrease the dose of opioids?

Adjustment of other medications such as NSAIDs, acetaminophen, adjuvants, and weaker opioids, alone and in combination (including an opioid with an NSAID) should be considered prior to initiation of higher dose therapy.

If the patient fails to demonstrate any improvement, or is noncompliant with other treatments aside from opioids, the clinician should consider prompt discontinuation of opioids. In rare situations, the physician may decide to continue the trial for an additional two weeks and even increase the opioid dose slightly, but if the patient shows no objective evidence of improvement by four weeks, the clinician should consider stopping the opioid trial. Statements about pain relief in the absence of any evidence of functional improvement would not be grounds for opioid continuation.

If the patient has improved on opioids, but still states that his or her activities are limited by pain, a judicious increase in opioid dose can be considered but must be followed by evidence of appropriate pain reduction and/or increased function.

Once a patient has demonstrated both improved function and decreased pain, the clinician should consider decreasing the opioid dose. Tapering of opioids should be done slowly, while monitoring the patient's clinical and functional status, with the goal of weaning entirely from opioids after several months. If attempts at weaning are accompanied by increased pain and worse function, the medication dose can be reinstated, and weaning may be attempted again after the patient has stabilized. If weaning continues to be difficult, consideration can be given to long-term opioid use. High-dose opioids are essentially never indicated in patients without clear anatomic explanations for their pain. Sustained release formulations may be appropriate for patients who have more than 12 hours of pain a day on a daily basis. Methadone can be used successfully for chronic pain treatment, although its use is somewhat controversial, and may be responsible for a significant proportion of overdoses.

5. When to initiate opioid contracts or Pain Agreements?

Some guidelines recommend establishing a Pain Agreement on all patients prescribed chronic opioids. Other guidelines recommend such agreements only for patients at high risk for abuse. Still other guidelines recommend only that the clinician "consider" such contracts in specific patients whose management has become difficult.

Opioid contracts might initially be reviewed and updated monthly, then approximately every three months in patients who have been stable on treatment for at least six months, and then every six months if the treatment plan remains stable. The contract should include a discussion of how refills will be handled, the frequency of urine drug screening, if any, as well as conditions for tapering or discontinuing opioids. (See the References for sample contracts / agreements included in several of the guidelines.)

6. When to perform Urine Drug Screening?

Current pain guidelines differ significantly in their recommendations about whether and how often to perform urine drug screening. Some guidelines recommend screening before starting opioids, in order to detect other drugs which would signal a higher risk for adverse effects, including benzodiazepines and illicit drugs. Other guidelines recommend urine drug screening at a frequency ranging from annually to up to four times a year, or more often if the provider suspects misuse, because of observed sedation or intoxication, a history of an accident or DUI, or drug-seeking behavior.

The Washington Guideline — the only one of the guidelines with specific recommendations on the type of urine testing to be done — recommends that urine drug screening should first be done using a less expensive immunoassay. If the results are non-conclusive, or require confirmation for other reasons, then the physician would proceed to order a more expensive confirmatory test (GC/MS or other).

7. How to follow a patient on chronic opioids?

Follow-up visits might be scheduled as soon as two to three days after initiating opioid therapy, and certainly within two weeks. The patient should be asked to describe specific improvements in their daily activities as a result of opioid use. After one or two weeks of treatment, the patient should report verifiable improvements in daily functional activity (preferably work-related), improvement in one or more of the objective functional criteria described above, and increased participation in social activities.

Some guidelines recommend that patients on chronic opioids be given a structured questionnaire, such as the Current Opioid Misuse Measure (COMM), at follow-up visits. Other guidelines recommend that clinicians routinely consult their state's Prescription Drug Monitoring Program (PDMP), to see if the patient is obtaining opioids from other prescribers.

Unsuccessful attempts at return to purposeful activity should be discussed in depth; and, in general, patients should be informed that opioids are usually continued only if the patient demonstrates progress toward functional goals. If the clinician has difficulty eliciting concrete examples of functional improvement, consideration should be given to referring the patient to a physical or occupational therapist to assist in the development of a therapeutic strategy combining graded exercise (predominantly home based) and other activities to improve physical conditioning, and to reduce activity-avoidance fears or "catastrophizing." Worsening psychiatric conditions may require consultation with a mental health professional.

A discussion of weaning off opioids should occur periodically. Some guidelines suggest such a discussion be held with the patient at least annually.

8. How to approach the patient who is already using opioids?

If a clinician begins caring for a patient who is already on opioids, the clinician may sometimes judge that the patient's drugs were not appropriately prescribed, or that the doses are excessive. A trial of weaning from opioids, in conjunction with initiation of other treatments aimed at functional restoration, is then recommended, although the likelihood of success can depend on the clinical presentation.

9. When to request a psychiatric or pain management consultation?

Current guidelines differ in their advice about when a primary care physician should obtain consultation. Some guidelines contemplate that the primary care physician will be able to manage most patients on chronic stable opioids without specialty consultation, and suggest consultation only for high risk patients. Other, including MTUS and the Washington guidelines, recommend such consultation on high risk patients, and for patients on other psychiatric medications, especially benzodiazepines and other sedatives.

Many of the guidelines recommend that nearly all patients being weaned from opioids should be referred to a mental health professional with experience in substance abuse or opioid management, specifically for treatment of anxiety and other withdrawal symptoms that can complicate the weaning process.

Source References for Specific Guidelines On Chronic Opioid Use

ACOEM GUIDELINES

The American College of Occupational and Environmental Medicine (ACOEM) — Guidelines for the Chronic Use of Opioids (2008). Available at: http://www.acoem.org/Guidelines_Opioids.aspx⁶.

The ACOEM Guidelines advise that chronic opioids are indicated in certain patients, but caution against “routine” use in non-cancer pain. At the initiation of opioid treatment, the document recommends a screening history, and suggests but does not mandate the use of a formal screening instrument (such as the SOAPP instrument) to document risk factors for misuse and dependency. The document recommends opioid contracts in all patients on chronic opioids, although it says that the current evidence base is “insufficient” to establish the effectiveness of such contracts. The document recommends urine drug screens on all patients, whether high risk or low risk, at a frequency of 2 to 4 times a year.

AMERICAN PAIN SOCIETY GUIDELINES

American Pain Society and American Academy of Pain Medicine - Opioids Guidelines Panel⁷. Opioid Treatment Guidelines: Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. (2009). Published in *The Journal of Pain*, Vol 10, No 2 (February, 2009): pp 113-130.

The document emphasizes the role of the primary care physician's judgment and the importance of continuity of primary care, and has soft recommendations about the use of several tools to assess the risk of adverse outcomes at the beginning of care, including SOAPP and ORT, and during follow-up care, including PADT and COMM. The document has no recommendation regarding opioid contracts, although it contains a sample agreement in its appendices. Urine drug screening is recommended routinely in patients at high risk for drug abuse, and should be “considered” in lower risk patients.

CANADIAN PAIN GUIDELINE

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain, April 30, 2010 (available at: <http://national-paincentre.mcmaster.ca/opioid/>)⁸.

The Canadian Guideline emphasizes clinical assessment through taking an appropriate verbal history at each visit, to assure that the patient's opioid dose is optimal, that the patient is aware of the risks of drowsiness that can occur if the dose changes, and that the patient does not exhibit aberrant behavior suggestive of opioid abuse. There is no routine recommendation for use of opioid contracts or urine drug screening. Recommendations for clinical consultation with pain management specialists are at the discretion of the primary care physician.

At the initiation of opioid therapy, the clinician is encouraged to document a comprehensive understanding of the patient's pain history, and the use of an instrument such as SOAPP or the Opioid Risk Tool (ORT) is suggested.

COLORADO PAIN GUIDELINES

Colorado Division of Workers' Compensation: Guidelines for prescribing controlled substances. (Revised Nov 18, 2004).

Colorado's Guidelines are very stringent, requiring all patients placed on chronic opioids to undergo a formal psychosocial and physical evaluation by two separate specialists (pain management or physical medicine), and requiring a written informed consent and an opioid contract in all patients. No specific risk screening tools are listed, but the clear intent is that opioids are to be used only after other treatments have failed, and almost never if the patient is at high risk. Urine drug screening is strongly encouraged in all patients on opioids.

The Colorado Guidelines' intent is further clarified by an accompanying document that allows the clinician to bill extra for certain services if provided in accordance with the Guidelines, and if appropriately documented. The following excerpt from the Colorado workers' compensation medical fee schedule spells out these additional payment rules (Rule 18, January 1, 2010). Available at: <http://www.colorado.gov/cs/Satellite?c=Page&childpagename=CDLE-WorkComp%2FCDLELayout&cid=1251568485616&pagename=CDLEWrapper>

Chronic Opioid Management Report -

- a) When the authorized treating physician prescribes long-term opioid treatment, s/he shall use the Division of Workers' Compensation Chronic Pain Disorder Medical Treatment Guidelines and also review the Colorado State Board of Medical Examiners' Policy # 10-14, "Guidelines for the Use of Controlled Substances for the Treatment of Pain." Urine drug tests for chronic opioid management shall employ testing methodologies that meet or exceed industry standards for sensitivity, specificity and accuracy. The test methodology must be capable of identifying and quantifying the parent compound and relevant metabolites of the opioid prescribed. In-office screening tests designed to screen for drugs of abuse are not appropriate for chronic opioid compliance monitoring.
 - (1) Drug testing shall be done prior to the initial long-term drug prescription being implemented and randomly repeated at least annually.
 - (2) When drug screen tests are ordered, the authorized treating physician shall utilize the Colorado Prescription Drug Monitoring Program (PDMP).
 - (3) While the injured worker is receiving chronic opioid management, additional drug screens with documented justification may be conducted. Examples of documented justification include the following:
 - (i) Concern regarding the functional status of the patient
 - (ii) Abnormal results on previous testing
 - (iii) Change in management of dosage or pain
 - (iv) Chronic daily opioid dosage above 150 mg of morphine or equivalent
 - (4) The opioids prescribed for long-term treatment shall be provided through a pharmacy.
 - (5) The prescribing authorized treating physician shall review and integrate the screening results, PDMP, and the injured worker's past and current functional status on the prescribed levels of medications. A written report will document the treating physician's assessment of the patient's past and current functional status of work, leisure activities and activities of daily living competencies.
- b) Codes and maximum fees for the authorized treating physician for a written report with all the following review services completed and documented:
 - (1) Ordering and reviewing drug tests
 - (2) Ordering and reviewing PDMP results
 - (3) Reviewing the medical records
 - (4) Reviewing the injured worker's current functional status
 - (5) Determining what actions, if any, need to be taken
 - (6) APPROPRIATE CHRONIC PAIN DIAGNOSTIC CODE (ICD).

Bill using code DoWC Z765

\$75.00 per 15 minutes – maximum of 30 minutes per Report.

NOTE: THIS CODE IS NOT TO BE USED FOR ACUTE OR SUBACUTE PAIN MANAGEMENT.

CALIFORNIA MTUS (MEDICAL TREATMENT UTILIZATION SCHEDULE)

The California Division of Workers' Compensation has promulgated enforceable treatment guidelines — the Medical Treatment Utilization Schedule (MTUS) — for the care of patients with chronic pain, under the California Workers' Compensation system¹¹.

Workers' compensation final regulations: Medical treatment utilization schedule regulations / Chronic Pain Medical Treatment Guidelines Title 8, California Code of Regulations Sections 9792.20 - 9792.26 (Effective July 18, 2009).

The regulations for chronic pain are available at:

http://www.dir.ca.gov/dwc/DWCPropRegs/MTUS_Regulations/MTUS_ChronicPainMedicalTreatmentGuidelines.pdf

MTUS contains a detailed alphabetic listing of possible options for the treatment of chronic pain, with a specific discussion of opioid use (pages 80 – 96). Before starting opioids, the physician should document both psychosocial risk factors and functional status, using a validated instrument, although no specific tool is required. MTUS gives considerable flexibility to the physician's judgment, and suggests, but does not mandate, such steps as opioid contracts, psychiatric consultation, or urine drug screening. Follow-up office visits are recommended at intervals of 2 weeks to 6 months, depending on clinical stability.

NEW YORK PAIN GUIDELINES

New York State Department of Health (April, 2008): Medical Conduct Program / Pain Management — A Guide for Physicians.

Available at: <http://www.health.state.ny.us/publications/4179/>

The New York State Guidelines listed above are very general, and do not contain specific recommendations for such items as psychosocial screening, use of opioid contracts, or urine drug screening¹².

WASHINGTON STATE PAIN GUIDELINES

Washington State Agency Medical Directors Group (2010): Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain¹³.

Available at: <http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf>

The Washington State Guidelines place strong emphasis on the Morphine Equivalent Dose (MED), noting that the risk of opioid overdoses in patients with legal opioid prescriptions increases markedly with MED levels above 100 mg / day. Accordingly, these Guidelines are the only ones to recommend specific clinical steps when the MED exceeds 100 mg /day. In such cases, the physician must either document functional improvement or obtain a consult with a pain specialist.

The Washington State Guidelines are also quite prescriptive in requiring several other clinical steps, including the use of a screening questionnaire before starting chronic opioids, an opioid contract, and periodic urine drug screening.

REFERENCES

- 1 Okie S. A Flood of Opioids, a Rising Tide of Deaths. *N Engl J Med* (2010) 363:1981-1985.
- 2 See www.whitehousedrugpolicy.gov, specifically <http://www.whitehousedrugpolicy.gov/news/press11/022311.html>
- 3 California Workers' Compensation Institute (2009). CWCI Research Spotlight Report. Schedule II Prescription & Payment Distribution in California Workers' Compensation: 2005, 2008.
- 4 Wang D., Mueller K., Hashimoto D., (2011). Interstate variations in use of narcotics. Workers Compensation Research Institute (WCRI) paper WC-11-01, Cambridge, MA
- 5 Swedlow A, Ireland J, Johnson G. (2011). Prescribing patterns of schedule II opioids in California workers' compensation. CWCI Update. California Workers' Compensation Institute. Oakland, CA.
- 6 ACOEM. Chronic Pain Guidelines (2008). Available at: <http://www.acoem.org/chronicpain.aspx>
- 7 Chou R, et al, for the American Pain Society, and American Academy of Pain Medicine, Opioids Guidelines Panel (2009). *The Journal of Pain*.10:113-130.
- 8 Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain, April 30, 2010 (available at: <http://nationalpaincentre.mcmaster.ca/opioid/>)
- 9 Colorado Division of Workers' Compensation: Guidelines for prescribing controlled substances. (Revised Nov 18, 2004).
- 10 http://www.colorado.gov/cs/Satellite?c=Document_C&childpagename=CDLE-WorkComp%2FDocument_C%2FCDLEAddLink&cid=1250162692799&pagename=CDLEWrapper.
- 11 Workers' compensation final regulations: Medical treatment utilization schedule regulations / Chronic Pain Medical Treatment Guidelines Title 8, California Code of Regulations Sections 9792.20 - 9792.26 (Effective July 18, 2009).
- 12 New York State Department of Health (April, 2008): Medical Conduct Program / Pain Management — A Guide for Physicians.
- 13 Washington State Agency Medical Directors Group (2010): Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain.

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