Created September 2021 Updated February 2022

This toolkit holds resources to help clinicians limit new opioid prescriptions, optimize nonopioid pain management strategies, implement risk management and harm reduction strategies for patients on chronic opioid therapy (COT), and diagnose and treat patients struggling with OUD.









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Multimodal Analgesia for Pain Control





Behavioral Medicine for PainResources for Clinicians + Patients

Videos

+ Title: American Chronic Pain Association (ACPA)

Description: Four flat tires video

Note: Excellent for watching in the clinic with patients! Source: https://www.youtube.com/watch?v=W_vffF50E3c

+ Title: The Pain Toolkit Videos

Description: Holds about **50 different videos on pain self-management** with separate categories for patients and medical providers.

Note: You can find free and very low-cost downloadables here. Created by a patient peer who is world renowned for developing easy-to-understand patient-centered materials.

Source: https://www.paintoolkit.org/resources/useful-videos

Websites and Online Columns

+ **Title:** American Chronic Pain Association (ACPA)

Description: The ACPA is dedicated to peer support and education for individuals with chronic *pain* and their families so that these individuals may live more fully in spite of their *pain*. Their website includes free pain management tools (print and electronic), local support group information, and a resource guide for chronic pain treatments.

Source: http://theacpa.org

+ **Title:** The Pain Toolkit

Description: The Pain Toolkit website offers a wealth of FREE and LOW-COST pain self-management resources (e.g. \$1-2). Website includes resources for patients and specific resources for medical clinicians.

Source: https://www.paintoolkit.org/

+ **Title:** Psychology Today

Description: Empowered Relief Column by Beth Darnall, PhD. Multiple columns provide public

education on how to use the mind-body connection for pain relief. **Source:** https://www.psychologytoday.com/us/blog/empowered-relief

Free Online Modules for Patients

+ **Title:** Retrain Pain Foundation

Source: https://www.retrainpain.org/





Practical Resources: Relaxation/Mindfulness/Meditation

+ **Title:** Breathe2Relax (from the Department of Defense)

Note: FREE Mobile Relaxation App

Source: http://t2health.dcoe.mil/mediakit/breath2relax-mobile-application

+ **Mindfulness Meditation** is evidence-based treatment for chronic pain. It involves helping calming mind and body and learning to release the mental focus on pain that happens automatically. Research shows that mindfulness and meditation techniques work by changing how your brain responds to pain, thereby reducing pain intensity. Learning mindfulness and meditation can help you reduce your pain. Here are some resources to help you get started:

+ Title: Free 8 Session Self-Paced Online Treatment Based on CBT Principles

PainTrainer: https://www.paintrainer.org/

Title: Free Online Mindfulness-Based Stress Reduction (MBSR)

Note: 8-week course

Source: http://palousemindfulness.com/

+ Title: Free Mindfulness App and Guided Meditations

Source: http://counselingcenter.utah.edu/services/mindfulness.php

Title: Free Guided Meditations (English and Spanish)
 Source: http://marc.ucla.edu/body.cfm?id=22

+ Title: Pain Self-Management Courses

Description: Chronic Disease Self-Management (CDSM) and Chronic Pain Self-Management Program (CPSMP) are 6-week evidence-based group treatments that are led by a therapist or 2 certified peer co-leaders. Courses are not typically covered by insurance but may be embedded into closed-payer networks (e.g., Intermountain Healthcare or the VA Healthcare System). Additionally, many municipalities may offer self-management wellness courses through senior centers or other community services; the courses may be offered free of charge or fees may apply; be sure to check costs (if any). Self-management resources vary by region and community. To determine if self-management courses exist in your area:

- + Check first with your healthcare system or insurance carrier.
- + Google "Chronic Pain Self-Management" and your city to see if courses exist.

Clinical Trainings

+ **Title:** Empowered Relief Single-Session Pain Relief Class (Healthcare Clinician Certification Workshop)

Description: "Empowered Relief" is single-session, 2-hour, evidence-based class that rapidly equips patients with pain relief skills. Attend a 2-day workshop and become certified to deliver the class in your healthcare system. Available in English, French, Spanish, and Dutch.

Source: https://empoweredrelief.com





Patient Books

- + Cognitive-Behavioral Therapy Based
 - + Turk, D., & Winter, F. (2005). The pain survival guide. Washington, DC: American Psychological Association.
 - + Lewandowski, M. (2006). The chronic pain care workbook. Reno, NV: Lucky Bat Books.
 - + Darnall, B. (2014). Less pain, fewer pills: Avoid the dangers of prescription opioids and gain control over chronic pain. Boulder, CO: Bull Publishing Company.
 - + Darnall B. (2016). The opioid-free pain relief kit: 10 simple steps to ease your pain. Boulder, CO: Bull Publishing Company.
 - + Dahl, J., Hayes, S. C., Lundgren, T. (2006). Living beyond your pain: Using acceptance and commitment therapy to ease chronic pain. Oakland, CA: New Harbinger.

Psychologist and Healthcare Clinician Books and Manuals

- + **Title:** Overview of Evidence-Based Behavioral Treatments for Chronic Pain **Source:** Darnall, BD. Psychological Treatment for Patients with Chronic Pain ©2018 (American Psychological Association). Includes clinician and patient free resources.
- Title: Therapist Guide to CBT
 Source: Thorn BE. Cognitive Therapy for Chronic Pain: A Step-by-Step Approach. New York, NY: Guilford; 2004.
- Title: FREE CBT Treatment Manual Source: Murphy JL et al. Cognitive Behavioral Therapy for Chronic Pain. Therapist Manual. 8session treatment guide. https://www.va.gov/PAINMANAGEMENT/docs/CBT- CP Therapist Manual.pdf
- Title: Guide to pain management in low-resource settings

Note: FREE online book

Source: Kopf, A., & Patel, N. B. (Eds.) (2010). *Guide to pain management in low-resource settings*. Seattle, WA: International Association for the Treatment of Pain. Retrieved at https://s3.amazonaws.com/rdcmsiasp/files/production/public/Content/ContentFolders/Public ations2/FreeBooks/Guide_to_Pain_Management_in_Low-Resource_Settings.pdf

Credit: Beth Darnell, PhD ©2020 3

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Developed in collaboration with Stader Opioid Consultants.





Nonopioid Pharmacologic

Treatments

Nonopioid Pharmacologic Treatments

The following section describes a variety of nonopioid pharmacologic treatment options for pain management. The table below summarizes these medications.

Table 1 | Summary of Multimodal Analgesic Agents

Туре	Example
Nonopioid analgesics	APAP, NSAIDs (Cox-1, 2, 3 inhibitors)
Amine reuptake inhibitors	Duloxetine, venlafaxine, amitriptyline, nortriptyline
Antipsychotics	Haloperidol, olanzapine
Gabapentinoids/antiepileptics	Gabapentin, pregabalin, carbamazepine, topiramate
Glucocorticoids	Dexamethasone, prednisone
Local anesthetics/sodium channel blockers	Lidocaine, bupivacaine
Muscle relaxants/antispasmodics	Cyclobenzaprine, tizanidine, methocarbamol, metaxalone, baclofen, dicyclomine
Other topicals	Capsaicin, diclofenac, lidocaine, menthol

APAP

- + **Evidence:** APAP has been shown to significantly reduce pain compared to placebo without increased adverse events. The number needed to treat (NNT) to achieve pain relief is 4.1 Combined treatment with APAP (1000 mg) and ibuprofen (400 mg) appears to be as effective as oral opioid combinations (eg, oxycodone or hydrocodone with APAP) for the treatment of acute extremity pain.²
- + **Mechanism of Action:** While not completely understood, the drug's mechanism of action is theorized to be the activation of descending serotonergic pathways. APAP increases the pain threshold by inhibiting central prostaglandin synthesis (specifically, cyclooxygenase [COX-2]).





- Dosing: APAP is a readily available, inexpensive, effective option for most mild to moderate pain conditions. Doses of 400 to 1000 mg can be given every 4 to 8 hours, not to exceed 4000 mg/day in healthy patients.
- + Contraindications and Cautions: Life-threatening cases of acute hepatic failure that lead to liver transplant or death have been linked to the use of APAP. In most cases of hepatic injury, APAP doses exceeded maximum daily limits and often involved the use of more than one APAP-containing product. Hepatotoxicity has been reported with doses of 4 g or more per day; therefore, a lower maximum dose of 3 g per day in adults with normal liver function is recommended, particularly if the duration of use exceeds 7 days.
- + **Hepatic Dosing:** In patients with cirrhosis and stable liver function tests, a maximum total daily dose of 2 g is recommended.³
- + Monitoring: Check liver function tests, especially if the patient has pre-existing liver disease.
- + **Instructions:** Instruct the patient to avoid other over-the-counter products that contain APAP, and limit the total daily dose to less than 3000 mg.

Amine Reuptake Inhibitors/Antidepressants

- Evidence: Although chronic pain and depression are often comorbid conditions, amine reuptake inhibitors are thought to produce an antihyperalgesic effect (independent of their mood-stabilizing ability) by suppressing the noradrenergic descending inhibitory system.4 Antidepressants have been widely used off-label for the treatment of chronic pain. In particular, venlafaxine (an SNRI) and nortriptyline (a TCA) should be strongly considered for the first-line treatment of neuropathic pain.^{5–10} Low-dose TCAs have an average NNT of 2.6 (range 2.0–5.0) for neuropathic pain.¹¹ In addition to pain relief, TCAs can offer added benefit to patients with depression or whose pain is interfering with sleep. Duloxetine (an SNRI) should also be considered, as it is noninferior to pregabalin for the treatment of pain in patients with diabetic peripheral neuropathy.¹²⁻¹⁴ Duloxetine and TCAs may reduce abdominal pain and increase quality of life in patients with irritable bowel syndrome. 15 Duloxetine should be considered as an adjunct therapy for patients with chronic neuropathic or abdominal pain who are receiving other first-line treatments. Duloxetine has also been shown to be effective for fibromyalgia and chronic musculoskeletal pain and is a first-line agent in patients with chronic pain and depression. 16 A systematic review found that there were no differences between venlafaxine and either gabapentin, pregabalin or duloxetine on average pain scores or the likelihood of achieving significant pain relief.¹⁷
- + Mechanism of Action: Influence on affective components of pain. TCAs and SNRIs increase the concentration of norepinephrine in the spinal cord, a process that inhibits neuropathic pain through a2-adrenergic receptors.
- + **Options:** SNRIs (eg, duloxetine, venlafaxine) and tricyclic antidepressants (TCAs) (eg, amitriptyline, nortriptyline)
- + Dosing: Dosing should be based on effect and tolerability. Duloxetine: Start at 30 mg daily, then increase to 60 mg after 1 week. Venlafaxine: Start at 75 mg daily, then increase by 75 mg every 4 days to 150-225 mg daily. Amitriptyline: Start with 10 mg at bedtime; may titrate up to 50 mg at bedtime. Nortriptyline: 12.5 mg once daily at bedtime; may increase as tolerated up to 35 mg/day. Best used for chronic pain. Do not stop abruptly. May take 1 week or longer to take effect.
- + **Contraindications and cautions:** SNRIs and TCAs may increase the risk of suicide in patients aged 18 to 25 years. Avoid TCAs in the elderly (Beers criteria) due to anticholinergic effects.





- Monitoring: Patients taking SNRIs should be monitored for serotonin syndrome. Monitor the QT interval (at baseline and periodically) of patients taking TCAs.
- + **Instructions:** Close follow up is essential to ensure appropriate titration to target doses. (These medications require time to reach an effective dose, and an adequate duration should be trialed before concluding treatment failure.) Provider oversight is also important to monitor for adverse effects and initiate the safe discontinuation of therapy if deemed necessary.

Antipsychotics

- + Haloperidol
 - **Evidence:** Haloperidol is a first-generation antipsychotic agent that is often used for psychiatric emergencies. It has analgesic and antiemetic properties and shown to be an effective treatment for cyclic vomiting and cannabis hyperemesis syndrome, both of which can be very difficult to treat with physicians resorting unfortunately to opioids for pain control. Rall Haloperidol should be considered a first-line treatment option as part of an opioid-sparing pathway for these conditions. At doses of 2 to 5 mg, the drug is effective for the management of abdominal pain and migraine-associated headaches. Rall Haloperidol shown to reduce pain intensity and nausea scores in patients with suspected gastroparesis. 22
 - + **Mechanism of Action:** Nonselective blockade of postsynaptic dopaminergic D2 receptors. Its mechanism of action for pain reduction is not completely understood. Antiemetic effects are thought to be due to blockade of these receptors in the chemoreceptor trigger zone. It also has weak anticholinergic effects.
 - Dosing: 2-5 mg IM/PO.
 - + **Options:** It can be administered intramuscularly or orally.
 - + **Contraindications and Cautions:** Use caution if treating patients with QT-prolonging conditions, concomitant QT-prolonging drugs and underlying cardiac abnormalities. Use with caution in older adults.
 - + **Monitoring:** Obtain baseline ECG and repeat periodically during therapy.

+ Olanzapine

- + **Evidence:** While a first-line treatment for schizophrenia, there is growing evidence to support the antiemetic properties of olanzapine, particularly in chemotherapy patients.²³ The analgesic properties of olanzapine have also been noted in randomized control trials focused on the treatment of migraine headaches and fibromyalgia.^{24,25} Based on expert opinion and clinical experience, olanzapine is recommended for the management of cyclic vomiting syndromes (particularly cannabis hyperemesis), for which it appears to offer both analgesic and antiemetic benefits.²⁶ The drug may be an effective agent for the treatment of other painful conditions, including headaches and fibromyalgia.
- + **Mechanism of Action:** Olanzapine is a second-generation atypical antipsychotic with high affinity for serotonin and dopamine receptors, as well as antagonist activity at muscarinic receptors. However, its exact mechanism of action for antipsychotic effects is still relatively unknown.²⁷
- + **Dosing:** Recommended initial dose is 2.5-5 mg IM/SL/PO. The 5 mg ODT product may be recommended every 6-8 hours as needed for nausea, vomiting, or abdominal pain.
- Options: Olanzapine can be given intramuscularly, orally, and as an oral disintegrating tablet.





+ Contraindications and Cautions: Somnolence, orthostatic hypotension and cardiac conduction abnormalities have been reported with olanzapine use. Caution should be exercised when prescribing high doses and in patient populations known to metabolize olanzapine more slowly (eg, nonsmokers, women, elderly).

Capsaicin

- + **Evidence:** Capsaicin is the derived active ingredient in chili peppers and is a natural analgesic produced in topical applications including creams, ointments and patches. It acts on nociceptive pain fibers by desensitization, thus inhibiting pain transmission.²⁸ Topical capsaicin has shown benefit in multiple applications including rheumatoid arthritis, osteoarthritis, and postherpetic neuralgia.²⁹ While evidence is of lesser quality, research and experience is mounting for capsaicin being an effective treatment of pain associated with cannabis hyperemesis syndrome. Before higher quality evidence is available (which may be difficult due to the inherent nature of blinding a skin irritant), capsaicin is suggested to be used as an adjunct for cannabis hyperemesis syndrome. This can be particularly helpful as a possible abortive therapy for use at home, as it is also available over the counter and easy to apply. It is used by applying a thin layer over the abdomen. Additionally, capsaicin is considered category B for pregnancy risk factor with no observed adverse events in animal reproduction studies, which may allow more widespread administration as well as prior to pregnancy test results.^{30–32}
- + **Mechanism of Action:** Causes warmth/burning sensation by binding nerve membrane receptors. Initially stimulates then desensitizes and degenerates cutaneous nociceptive neurons; substance P depletion may also reduce pain impulse transmission to the CNS.
- + **Dosing:** Creams and ointments are likely to be the most convenient, and come in forms including from 0.025% to 0.1%. Capsaicin 0.1% cream apply a thin layer to affected area four times daily as needed for pain.
- + Contraindications and Cautions: May cause burning, redness or pain at the site of application. It has a very good safety profile, particularly when compared to other agents used for these common conditions.
- + **Duration of Use:** Burning should reduce with repeated administration. May take 1-4 weeks for maximal pain relief.

Dexamethasone

- + **Evidence:** Glucocorticoids, and predominantly dexamethasone, have been shown to be efficacious in the treatment of acute migraine headache, dental pain, and sore throat, and may be an effective adjunct to other anti-inflammatories. Added to a typical headache regimen, dexamethasone has shown to have a reduction in headache recurrence at 24 and 72 hours in one metaanaylsis.³³ When given for postoperative dental pain, a single dose of dexamethasone has been shown to reduce pain up to seven days postoperatively.³⁴ When combined with gabapentin, increased dexamethasone led to improved analgesia after knee arthroplasty, suggesting a possible role in post-procedural pain control.³⁵
- Mechanism of Action: Glucocorticoids (eg dexamethasone and methylprednisolone) have many actions including analgesic, antiemetic, antipyretic and anti-inflammatory effects.
 Although not completely clear, analgesic effects of dexamethasone are thought to result from the inhibition of phospholipase, leading to a decrease in cyclooxygenase and lipoxygenase production.
- + **Dosing:** Dexamethasone 8-10 mg IM/PO as a single dose. Repeat dosing is rarely required.





+ Contraindications and Cautions: Long term or repetitive use may increase risk of adverse events. Caution in patients at risk for gastric irritation. May lead to transient rise in blood glucose and require more frequent monitoring in diabetics. Repetitive or long term use may increase risk of adrenal suppression, poor wound healing, immunosuppression, myopathy, and psychiatric disturbances.

Dicyclomine

- + **Evidence:** It is effective for treating abdominal pain, particularly caused by cramping, and has been shown to be beneficial in irritable bowel syndrome.^{36–39}
- + **Mechanism of action:** Antispasmodic and anticholinergic effects that alleviate smooth muscle spasm of the GI tract.
- + **Dosing:** Dicyclomine 10-20 mg IM/PO every 6 hours as needed for abdominal cramping.
- + **Options:** Dicyclomine can be administered either orally or intramuscularly. It should NOT be administered intravenously due to risk of thrombosis and thrombophlebitis.
- + **Contraindications and Cautions:** Dicyclomine can be an effective pain reliever in pregnant patients as a category B drug. Avoid use in elderly patients due to anticholinergic effects (Beers criteria) or patients at increased risk for delirium.⁴⁰ May worsen urinary retention or ileus.

Gabapentinoids/Antiepileptics

- + **Evidence:** 4 out of 10 patients with neuropathy will achieve 50% pain relief with gabapentin.⁴¹ Pregabalin has better oral bioavailability and faster onset of action (1 hour vs 3 hours with gabapentin), although it is more costly. Pregabalin alone or combined with ibuprofen has shown efficacy with post-operative pain after third molar extraction.^{42,43} Other antiepileptics (such as carbamazepine, oxcarbazepine, lamotrigine and topiramate) may have potential success at treating chronic neuropathic pain.⁴⁴
- + **Mechanism of Action:** Inhibits alpha 2-delta subunit of voltage-gated calcium channels, believe to decrease conduction of neuropathic pain sensation.
- + **Dosing:** Gabapentin 300-600 mg or pregabalin 75-150 mg. Initiate with low doses and titrate to effective dose based on tolerability. Gabapentin: start at 100-300 mg PO 3x/day, then increase by 100-300 mg/day every 1-7 days as tolerated up to 1200 mg 3x/day. Pregabalin: start at 75 mg PO 2x/day, then increase by 150 mg/day every 3-7 days as tolerated up to 300 mg PO 2x/day.
- + **Renal Dosing:** Adjust dose for renal impairment.
- + Contraindications and Cautions: Avoid use in older adults with a history of falls as it may cause syncope, impaired psychomotor function or ataxia. Caution is advised in patients taking concomitant opioids or CNS depressants, with underlying respiratory diseases such as COPD and in elderly patients due to risk of increased respiratory depression. Avoid abrupt discontinuation.
- + **Monitoring:** Consider checking serum creatinine.
- + Other Considerations: Gabapentinoids have potential for misuse and abuse. Pregabalin is a Schedule V controlled substance. Although it has the lowest potential for abuse relative to other controlled substances, it does require the prescribing provider to have an active DEA number.

Local Anesthetics

- + Local Injection:
 - + **Evidence:** Administration of LAs via subcutaneous infiltration is ideal for minor, localized injuries or procedures such as open wound repair, abscess drainage and foreign body removal. Local anesthetics also appear to have potential analgesic properties for both the treatment of acute and chronic pain when used as an intra-articular injection.





Evidence suggests intra-articular lidocaine provides a similar success rate for shoulder reductions compared to intravenous sedation.⁴⁵ However, intra-articular lidocaine also appears to have fewer complications, shorter length of stay, and lower cost compared to intravenous sedation.^{46,47} Even for the treatment of chronic knee pain, such as that from osteoarthritis, local anesthetics may have potential for pain relief. A double-blind, RCT demonstrated reduction in pain at 3 months after three weekly intra-articular injections of 0.5% lidocaine in those with osteoarthritis.⁴⁸

- Mechanism of Action: Blocks conduction of nerve impulses through inhibition of sodium channels.
- + **Options:** Bupivacaine is a common alternative LAs that may be preferred due to their higher potency and longer duration of action.
- + Cautions: Side effects of these drugs are minimal when used sparingly or in low doses.

+ Topical

- + **Evidence:** Lidocaine is effective in a transdermal (4% or 5%) patch that may be used on intact skin for controlling neuropathic pain, post-herpetic pain, musculoskeletal injuries, and low back pain.^{49,50} Other formulations of lidocaine, including ointment and creams, may be effective during painful procedures such as wound debridement, or for minor acute injuries involving broken skin, such as road rash, abrasions, and burns.⁵¹ Lidocaine 5% patches, topicals or spray can be used for the treatment of a range of painful conditions that are resistant to other treatment modalities.^{52,53} There is some information that over-the-counter lidocaine patches with menthol may actually have superior efficacy for pain management than prescription versions that do not have menthol. These have also been shown useful in decreasing pain to a tolerable level for participation in active therapy.⁵⁴
- + **Mechanism of Action:** Blocks conduction of nerve impulses through inhibition of sodium channels.
- + **Dosing:** Lidocaine 4% or 5% transdermal patch to affected area of intact skin every 24 hours. 55 Up to 3 patches may be applied in a single application. Lidocaine 5% cream apply to affected area up to six times daily. Lidocaine 5% ointment apply up to 5 g to affected area four times daily.
- + **Contraindications and Cautions:** Transdermal patches are only recommended to use on intact skin. Creams or ointments may be used on minor injuries of broken skin.
- + **Discharge:** If 5% prescription concentration is cost prohibitive, can prescribe lidocaine 4% which is over-the-counter.

Menthol Topical

- + **Evidence:** Methyl salicylate and menthol provide significant pain relief of muscle strain compared to placebo.⁵⁶ In a small study, menthol was more effective than ice.⁵⁷
- + **Mechanism of Action:** Stimulates receptors producing cold sensation
- + Contraindications and Cautions: Recommend use only on intact skin.

Muscle Relaxants/Antispasmodics

+ **Evidence:** Cyclobenzaprine reduces low back pain with an NNT of 3.58 It can also reduce pain scores in patients with renal colic who are receiving NSAIDs, though the difference was not statistically significant.59 There are many other types of muscle relaxants and antispasmodic options available, including but not limited to baclofen, tizanidine, dantrolene, carisoprodol,





orphenadrine, metaxalone and methocarbamol, for which there is mixed supporting literature. For most individuals, a short-acting muscle relaxant such as tizanidine or methocarbamol may be more appropriate as a first-line therapy, especially if taken only at night. Carisoprodol, chlorzoxazone and chlormezanone are not indicated due to concerning safety profiles.⁵²

- + **Mechanism of Action:** Cyclobenzaprine: acts in the brainstem and reduces tonic somatic motor activity; structurally similar to TCAs. Tizanidine: alpha-adrenergic agonist. Methocarbamol and metaxalone: depresses CNS activity resulting in musculoskeletal relaxation. Baclofen: inhibits transmission of spinal synaptic reflexes.
- + **Antispasmodic Options:** cyclobenzaprine, tizanidine, methocarbamol, metaxalone. If spasticity (not spasm), consider baclofen.
- + **Dosing:** Start at a low dose and increase to effect while monitoring sedation. Cyclobenzaprine 5-10 mg PO 1-3x/day. Tizanidine 2-4 mg PO 1-2x/day. Methocarbamol 800 mg PO 3-4x/day. Baclofen 5-10 mg PO 3x/day.
- + **Contraindications and Cautions:** Avoid use in elderly patients (Beer's criteria) or patients at increased risk for delirium. 40 All antispasmodics may cause sedation, but anecdotally less sedation is seen with methocarbamol. For tizanidine, may cause bradycardia, hypotension.
- + **Duration of Use:** Use for shortest possible duration due to sedative side effects. Do not abruptly discontinue baclofen.

Non-Steroidal Anti-Inflammatory Agents

- + **Evidence:** When combined with APAP, NSAIDs can reduce acute pain by 50% in 7 out of 10 patients.⁶⁰ Adding an NSAID to a pain regimen containing an opioid may have an opioid-sparing effect of 20% to 35%.⁶¹ For renal colic, both opioids and NSAIDs lead to a clinically relevant reduction in pain scores; however, opioids are associated with higher rates of adverse reactions, particularly vomiting.⁶² While a 2015 Cochrane review found that there was insufficient evidence to either support or refute the use of oral NSAIDs to treat neuropathic pain conditions, the American College of Occupational and Environmental Medicine Practice Guidelines recommend the use of generic ibuprofen, naproxen or other older generation NSAIDs as second-line agents for neuropathic pain, after tricyclic or SNRI antidepressants. They note that side effect profiles may make NSAIDs preferable to antidepressants for some patients.
- + **Mechanism of Action:** Inhibits proinflammatory prostaglandin production via the inhibition of COX-1 and COX-2 enzymes.
- + **Options:** Ibuprofen, naproxen, ketorolac, diclofenac, indomethacin, and selective COX-2 inhibitors (eg, meloxicam, celecoxib)
- + **Different Side Effect Profiles:** In general, COX-2 selective NSAIDs have a lower risk of GI side effects but a higher risk of cardiac side effects. Conversely, nonselective NSAIDs pose a lower risk of cardiac side effects but a higher risk of GI side effects.
- + Contraindications and Cautions: NSAIDs increase the risk of myocardial infarction and stroke. Contraindicated in the setting recent coronary artery bypass graft surgery or myocardial infarction. Can also cause increased risk for GI adverse events including bleeding, ulceration and perforation of the stomach or intestines. Risk is especially increased in elderly (Beer's criteria) and in patients with prior peptic ulcer disease or GI bleeding⁴⁰. Caution should also be used in patients on concomitant anticoagulants or antiplatelet agents. Avoid use in patients with chronic kidney disease, cirrhosis or heart failure. Risk of renal injury is higher in patients who are elderly, dehydrated or with other comorbidities including heart failure, diabetes and cirrhosis.
- + **Special Considerations:** Special caution should be used in patients with renal dysfunction, heart failure, and concern for bleeding.⁶³ For these subpopulations, consider using topical choices





- such as diclofenac gel or patch. Topical options have significantly lower systemic absorption and lower rates of adverse drug events.
- + Monitoring: Check serum creatinine and discuss history of GI ulceration prior to initiation.
- + Recommended Duration of Use: Use the lowest effective dose for the shortest possible duration.

Table 2 | Risk of Gastric Ulcer Bleeding with NSAIDs64

Individual NSAID		Adjusted Conditional RR (95% CI)
	Celecoxib	1.0 (0.4-2.1)
Low	Ibuprofen	4.1 (3.1-5.3)
1	Naproxen	7.3 (4.7-11.4)
High	Indomethacin	9.0 (3.9-20.7)
	Ketorolac	14.4 (5.2-39.9)

Table 3 | GI Risk Factor Assessment and NSAID Therapy

GI Risk Factor Assessment	Treatment	
High Risk + History of previously complicated ulcer, especially recent + OR more than 2 risk factors: + Age >65 years + High-dose NSAID therapy + Previous history of uncomplicated ulcer + Concurrent use of aspirin, corticosteroids, or anticoagulants	Alternative therapy or COX-2 inhibitor + PPI	
Moderate Risk (1-2 risk factors)	NSAID + PPI	
Low Risk (No risk factors)	NSAID alone	

Source: American College of Gastroenterology Guidelines, 200965

Topical NSAIDs

+ **Evidence:** To achieve a 50% reduction in musculoskeletal pain, NNT was 3.7 for topical diclofenac topic solutions which is about the same for oral NSAIDs 60 Only about 5% of topical NSAIDs are systemically absorbed compared to oral NSAIDs but studies show there is local absorption into tissues and synovium. Topical formulations are most effective when the pain is located in a superficial tissue⁵² Topical NSAIDs may be more appropriate for some patients with chronic pain, as there is some evidence that topical NSAIDs are associated with fewer systemic adverse events than oral NSAIDs. These can also be used selectively as a later-line agent for the treatment of neuropathic pain. One randomized controlled trial determined effective





penetration of topical diclofenac sodium 4% spray gel into the synovial tissue and synovial fluid of the knee.⁶⁷ This and several other studies concluded that topical diclofenac presents an effective alternative to systemic NSAID therapy for the treatment of osteoarthritis, soft tissue injury including sprains and strains, and tendon pain particularly in the hands and feet.⁶⁷⁷⁷ Diclofenac is particularly useful in patients at risk for GI side effects or with hepatic or renal disease who cannot tolerate systemic treatment. Topical ketoprofen offers similar benefits but has been studied infrequently.⁶⁹ Topical NSAIDs may be considered in patients who have relative contraindications to oral NSAIDs.

- + **Mechanism of Action:** Inhibits proinflammatory prostaglandin production via inhibition of COX-1 and COX-2 enzymes.
- + **Options:** diclofenac gel, patch and solution.
- + **Contraindications:** Similar side effect profile to oral NSAIDs however a meta-analysis showed systemic adverse events were uncommon and did not differ from placebo⁷⁸
- + Other Considerations: More expensive than oral NSAIDs.

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This material was prepared by the lowa Healthcare Collaborative, the Opioid Prescriber Safety and Support contractor, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS.

Developed in collaboration with Stader Opioid Consultants.





Non-Pharmacologic Treatments

Although nonopioid medications are recommended as first-line *pharmacologic* treatment for pain, non-pharmacological therapy is consistently regarded as the preferred initial modality of treatment. Below are descriptions of some of these therapies and associated supporting evidence.

Lifestyle Modification

Exercise and sleep restoration are both supported in the literature as effective interventions to modify and/or prevent pain. Exercise has specifically been linked to both nociceptive (such as chronic lower back) and central sensitization (such as fibromyalgia) type pain improvement, and is a relatively easy, self-directed therapy to recommend for capable patients. 1,2 Sleep restoration, while straight-forward in some patients, can be more complicated in others. Studies suggest that cognitive behavioral therapy can be an important piece of both improving sleep quality, which in turn is linked to chronic pain development, as well as decreasing pain severity. 3,4

Physiotherapy Options

Active therapies such as physical and occupational therapy, therapeutic exercise, aquatic therapy, self-directed activity, neuromuscular re-education, activities of daily living, and functional activities are widely used and accepted methods of care for a variety of types of pain. There is moderate to strong evidence proving the efficacy of exercise therapy for pain relief and functional improvement in patients with musculoskeletal pain. Massage is the manipulation of soft tissue and may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups, and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioner's hands. There is good evidence that massage therapy in combination with exercise reduces pain and improves function in the short term for patients with subacute low back pain. Here is some evidence that 10 weeks of either relaxation massage or structural massage are more effective than usual care and equally effective in improving functional disability and reducing symptoms of pain in people with chronic low back pain with benefits lasting at least six months. There is also some evidence that in the setting of chronic neck pain four weeks of weekly hour-long massage leads to benefits in both pain and function, and there are incremental benefits from multiple massage sessions per week (up to three sessions) over a single massage session.

Psychotherapeutic Interventions

Psychotherapeutic interventions are recommended as a component of treatment for patients with chronic pain; they may also have utility for some patients with acute pain. Cognitive and behavioral interventions have a neurophysiological basis and are well established as diagnostic and therapeutic modalities. ¹¹⁻¹³ Patients without behavioral health diagnoses may benefit from interventions that aid in developing better strategies to cope with pain or adjust to disability. A psychologist with a PhD, PsyD, or





EdD or psychiatric MD/DO can perform psychosocial treatment through individual or group therapy. For chronic pain, other licensed mental health providers, licensed health care providers with training in CBT or certified CBT therapists who have experience in treating chronic pain disorders in injured workers may perform treatment in consultation with a PhD, PsyD, EdD or psychiatric MD/DO.

Complementary and Alternative Treatments

Manipulation encompasses a variety of modalities including osteopathic manipulative treatment, chiropractic manipulative treatment, manual therapy, manipulation or mobilization. There is good evidence that manipulation can facilitate pain reduction and improved function for both spinal and extremity injuries. 14-18 Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points) and is recommended for subacute or chronic pain (including low back and knee pain) patients who are trying to increase function, decrease medication usage and have an expressed interest in this modality. There is evidence supporting acupuncture use in reduction of disability and pain in chronic low back pain patients and there is some evidence that acupuncture is better than no acupuncture for axial chronic low back pain.¹⁹⁻²² There is also evidence supporting acupuncture for reduction of pain or improvement of function among patients older than 50 years with moderate to severe chronic knee pain from symptoms of osteoarthritis.²³ If not otherwise within their professional scope of practice and licensure, those performing acupuncture should have the appropriate credentials, such as LAC, RAc or DiplAc. Other phyto-chemicals and dietary supplements for various pain conditions that have evidence for short-term use include, but are not limited to, avocado-soybean unsaponifiables²⁴⁻²⁶, collagen hydrolysate²⁷⁻²⁹, passion fruit peel extract³⁰, Curcuma longa extract³¹⁻³⁴, Boswellia serrata extract³⁵⁻³⁷, curcumin³⁸⁻⁴⁰, pycnogenol^{41,42}, L-carnitine^{43,44} undenatured type II collagen⁴⁵, methylsulfonylmethane⁴⁶, diacerein⁴⁷, glucosamine^{46,48,49} chondroitin⁵⁰, capsaicin^{51,52}, alpha-lipoic acid^{53,54}, and theramine⁵⁵.

Procedure-Based Interventions

Trigger point injections involve injection of a corticosteroid/anesthetic/saline combination into a tensed muscle. Indications supported by evidence include a palpable taut band or nodule, reproducible pain with palpation and/or a chronic painful conditions. ⁵⁶⁻⁵⁹ Trigger point injections also have been found to be a successful treatment strategy for migraines. ^{60,61} Trigger point injections of corticosteroids are most effective for adhesive capsulitis, rotator cuff tendinopathy, impingement syndrome and tendon disorders. Trigger point dry needling is a skilled intervention that utilizes a solid filament needle to penetrate the skin and underlying tissues to treat muscular, neural and other connective tissues for the evaluation and management of neuro-musculokeletal conditions, pain, movement impairments and disability. A 2017 systematic review of 15 studies suggests that dry needling is effective in the short term for pain relief, increases range of motion and improves quality of life when compared to no intervention, sham or placebo. ⁶² TENS treats pain by delivering small electrical impulses through electrodes that flood pain receptors in the body, reducing their ability to transmit pain signals to the brain. Some good-quality systematic reviews suggest that TENS is effective for musculoskeletal and postoperative pain. ⁶³⁻⁶⁶





Practical Application

The above interventions can be split into two categories, self-directed after training vs professionally directed:

Self-Directed After Training	Professionally Directed	
Structured exercise	Physical approach	
Mind-body therapies	+ Acupuncture	
+ Biofeedback	+ Assistive devices	
+ Movement meditation	+ Blocks/ablation	
+ Mindfulness	+ Ergonomic modifications	
Relaxation	+ Light therapy	
Music	+ Massage	
Neurostimulators	+ Osteo-manipulation	
Nutritional approach	+ Physical therapy/occupational therapy	
Thermal modalities/balneotherapy	 Regenerative therapies (platelet rich plasma, prolotherapy, stem cells) Stimulators (peripheral, spinal, deep brain) Surgeries Trigger point interventions Ultrasound 	
Sleep hygiene	Psychological approaches/pain behavior	
Spiritual practices	therapies	
Tobacco cessation	+ Acceptance and commitment therapy	
Weight reduction	 + Cognitive behavioral therapy/ behavioral therapies + Pain education 	

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This material was prepared by the lowa Healthcare Collaborative, the Opioid Prescriber Safety and Support contractor, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS.

Developed in collaboration with Stader Opioid Consultants.





Pain Management

Algorithm

Type of Pain

In the past, most chronic non-cancer pain (CNCP) has been thought to be either neuropathic or nociceptive in nature. The proposed cause of this type of pain emanates from the triggering of peripheral pain or sensory nerve pathways. Examples of peripheral neuropathic pain include post-herpetic neuralgia and diabetic neuropathic pain, and examples of peripheral nociceptive pain include rheumatoid and osteoarthritis. As a result, peripherally directed therapies such as injections, surgery, topical treatments, and even sometimes opioids are favored in this pain model. Central pain or central sensitization (CS) is an ever increasingly recognized cause of pain, separate from nociceptive and neuropathic pain, and is not responsive to peripherally directed therapies or opioids. While the quintessential central pain state is fibromyalgia, current research suggests that centralized pain is more accurately described as a spectrum disorder. Common CNCP diagnoses that are linked to CS include chronic headaches, chronic low back pain, and fibromyalgia. The patient examination, labs, and imaging are often inconclusive in centralized pain syndromes, emphasizing the importance of a careful patient history, review of symptoms, and use of validated centralized sensitization screening tools (CSI and PSQ). In addition, the high occurrence of anxiety, depression, PTSD, and substance use disorders in patients with CS make the screening for these disorders critical in the initial assessment. Successful treatment of CS is dependent on behavioral treatment options, sleep and stress management, and dietary intervention; repeated scans, procedures, injections, and opioids are ineffective and may result in unnecessary harm. Pharmacologic options that may garner some success are centrally acting agents, such as tricyclic antidepressants and serotonin-norepinephrine reuptake inhibitors, which target mechanisms that are often dysfunctional in patients having chronic pain and CS.

Chronic pain in general is best described as a bio-psycho-social process, due to the effect of a patient's mental health, trauma history, family, and social situations on the perception of pain. These key behavioral components should be addressed prior to escalation to chronic opioid therapy for management of pain. In fact, cognitive behavioral therapy (CBT) is the gold standard and first-line treatment for all chronic disease states, including and especially chronic pain. If and/or when a patient's pain progresses from acute to chronic, CBT should immediately be employed and maintained as the backbone of their chronic pain management therapy. Studies show that opioids are only moderately successful in relieving acute pain and even less effective for the management of chronic pain; alternatively, sleep restoration, physical exercise, and mindfulness training provide much greater long-term benefit.





Treatment Algorithm

neumem Algomini			
Treatment	Nociceptive Pain	Neuropathic Pain	Mixed Pain
		Nonpharmacological	
	Acute trial of nonsteroidal anti-inflammatory drug/acetaminophen Add topical agent (nonsteroidal anti-inflammatory drug, lidocaine, capsaicin, menthol)		
1st Line			
I - Lille		Gabapentinoids	
		Serotonin-norepinephrine	
		reuptake inhibitor	
		Tricyclic antidepressant	
Ond the a	Serotonin-norepinephrine reuptake inhibitor	Antiepileptics	Gabapentinoids
2 nd Line Intended to be added to	Tricyclic antidepressant		Serotonin-norepinephrine reuptake inhibitor
1 st -line therapy, when appropriate			Tricyclic antidepressant
арргорнате	Condition-specific pharmacologic agents		agents
	Consider referral to specialist		
3 rd Line	Acute add-on muscle relaxer		
Intended to be added to	Interventional therapy		
1 st and 2 nd – line therapy,	Consider short (<7 days) trial of opioid agent* for breakthrough pain		
when appropriate		Referral to specialist	

^{*}Monoproduct opioid agents are preferred (rather than combination agents) so that acetaminophen can continue to be scheduled around the clock. Monoproducts include morphine sulfate IR, oxycodone IR, and tramadol.

Adopted from the West Virginia Safe & Effective Management of Pain (SEMP) Guidelines. www.sempguidelines.org.

Condition-Specific Pharmacologic Agents

- + Bursitis/Joint Pain: steroid injection
- Headache/Migraine Prevention/Treatment: steroid, propranolol, antiepileptic, sumatriptan, caffeine, magnesium supplement, BOTOX injections
- + Abdominal Pain: metoclopramide, prochlorperazine, olanzapine, haloperidol, dicyclomine

Nonpharmacologic Treatments

- + **Lifestyle Modification:** exercise, diet/nutrition, weight management, sleep restoration, mindfulness-based stress reduction
- + Physiotherapy Options: physical therapy, occupational therapy, therapeutic exercise, massage
- + **Procedure-Based Interventions:** trigger point injection, dry needling, nerve block, steroid injection, ablation, TENS, ice, heat, compression, elevation, splinting, orthotics
- + Complementary and Alternative Treatments: Acupuncture, manipulative therapy, herbals, dietary supplements, phyto-chemicals

Behavioral Treatment Options

- + **Psychotherapy:** cognitive behavioral therapy, group therapy, individual counseling, breathing and relaxation exercises, biofeedback therapy, sleep hygiene psychoeducation
- + Substance Use Disorder Treatment: medication assisted treatment referral.
- + Trauma-Related Care: screening for domestic violence, child abuse, PTSD
- + Group-Based Education: shared medical appointments, peer-to-peer meetings, preventive workshops

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Developed in collaboration with Stader Opioid Consultants.



Opioid Risks + Side Effects





Opioid Risks and

Side Effects

Appropriate Opioid Prescribing for Acute Pain: Limiting Use and Duration

In general, opioids should not be considered first line therapy for mild to moderate pain in patients with limited opioid exposure. If other nonpharmacologic and nonopioid pharmacologic options are not effective or appropriate for acute pain, and the provider determines that opioids may be effective, the following recommendations should be considered:

1. Evaluate the patient

- + Identify the type and cause of the acute pain, along with severity
- + Determine likely recovery period and duration of the acute pain
- + Assess age and medical comorbidities that might affect opioid dose or lead to avoidable opioid-related adverse drug events (ORADEs)
- + Assess patient's use of alcohol or sedative medications and prescribe opioids with caution in these patients

2. Maximize other therapies

- + Optimize use of multimodal nonopioid agents, nonpharmacologic agents, and other pain interventions
- + Even when prescribing an opioid, continue other pain interventions thought to be effective

3. Assess the risk of developing opioid use disorder (OUD)

+ Assess the patient for history of substance use disorder

4. Consult the PDMP

- + Review dispensed controlled substance prescription history
- + Take note of concurrent benzodiazepine prescription and any chronic opioid use

5. Educate the patient

- + Counsel patient about pain, expected duration, and course of recovery
- + Goal = improve function + decreased pain + minimize side effects and harms
- + Review the risks and side effects of opioids
- + Provide an opioid safety handout and review with the patient
- + Provide information on safe storage and disposal of opioid medications

6. Choose a type and amount

- + Prescribe the lowest effective dose of short-acting opioids, usually for a duration of < 3 days
- + In cases of more severe acute pain, prescribe < 7-day supply
- + Preferentially use an immediate-release mono-product opioid, such as oxycodone, tramadol, or morphine sulfate
 - Allows for continued utilization of multimodal nonopioid agents such as APAP and NSAIDs

7. Establish a follow-up plan

- + Refer for appropriate intervention (i.e. dental, physical therapy, specialist)
- + Before providing a refill, reassess the patient's pain, level of function, response to treatment, and healing process
 - + Evaluate with a functional pain screening tool (PEG)"





- Evaluate for side effects and risks (i.e., rapid risk assessment for ORADEs and <u>OUD</u> must be documented in EHR)
- + Patients must sign a controlled substance agreement when opioids are first prescribed > 7 days
- 8. Have a plan in place for tapering or discontinuation

Other Recommendations

When deciding whether or not to prescribe an opioid keep in mind the following facts:

- + Opioids are inherently dangerous drugs with numerous side effects, rapid development of tolerance, debilitating withdrawal symptoms, significant potential for misuse and addiction, and lethality in overdose. Clinicians are encouraged to reserve opioids for the treatment of severe pain, pain that has not responded to nonopioid therapy and cases where nonopioid therapy is contraindicated or anticipated to be ineffective.
 - + Opioids are among the three broad categories of medications with potential for misuse, dependence and addiction, the other two being stimulants and CNS depressants. Opioids act by attaching to opioid receptors on nerve cells in the brain, spinal cord, gastrointestinal (GI) tract and other organs, triggering a spike in dopamine that not only reduces the perception of pain but can also produce a powerful sense of well-being and pleasure by affecting the brain's limbic reward system.
 - + When used repeatedly opioids induce tolerance, as higher doses are necessary over time to produce the same effect. This mechanism also contributes to the high risk of overdose following a period of abstinence. Tolerance can be lost in times of abstinence, leading relapsed users to take a previously "safe" dose with tragic results. The effects of opioids are mediated by specific subtype opioid receptors (mu, delta and kappa) that are also activated by endogenous endorphins and enkephalins. The production of endogenous opioids is inhibited by the repeated administration of outside opioids, which accounts for the discomfort that ensues when the drugs are discontinued.
 - + Besides the significant abuse potential, rapidly developing tolerance and agonizing withdrawal symptoms that accompany opioids, patients also experience serious side effects such as nausea, vomiting, constipation, respiratory depression, impaired judgment, sedation and coma (Table 3).^{4,5} These complications, which often necessitate additional medical care, can prevent patients from performing daily tasks and remaining active in the workforce.

Table 1 | Common and Serious Side Effects of Opioids

Table 1 Collinion and Senous side Lifects of Opiolas			
Common Side Effects	Serious Side Effects of Chronic Opioid Use		
+ Nausea/vomiting	 Cardiac abnormalities, including prolonged QTc and torsades de 		
+ Constipation	pointes ⁵⁷		
+ Pruritus	 Sudden cardiac death with the concomitant use of benzodiazepines 		
+ Euphoria	and methadone ⁵⁷		
+ Respiratory	+ Hormonal disruptions, including decreased testosterone in males ⁵⁸		
depression,	 Decreased luteinizing hormone, follicle-stimulating hormone, and fertility 		
particularly with	in women ⁵⁹		
the simultaneous	 Musculoskeletal compromise, including an increased risk of 		
use of alcohol,	osteoporosis ⁶⁰		
benzodiazepines,	+ Immunosuppression ⁶¹		
antihistamines,	 Inhibition of cellular immunity via delta and kappa receptors⁶² 		
muscle relaxants,	 Hyperalgesia (ie, upregulation of receptors and increased tolerance)⁶³ 		
or barbiturates	 Sleep disturbances (eg, shortened deep sleep cycle)⁶⁴ 		





+ Lightheadedness	+ Delayed or inhibited gastric emptying, increased sphincter tone, and
+ Dry mouth	blockade of peristalsis ⁶⁵

Source: Martin PR, Hubbard JR. Substance-related disorders. In: Ebert MH, Loosen PT, Nurcombe B: Current Diagnosis & Treatment in Psychiatry. McGraw Hill; 2000:233-259

- + Opioids are not effective as a long-term option for pain, and lack evidence for many acute pain indications.^{6,7} It is recommended that individual providers and provider groups have a "no" list, i.e. painful conditions lacking evidence of benefit for which they do not routinely prescribe opioids, including but not limited to acute musculoskeletal injuries (including low back pain), neuropathic pain, post traumatic headache, previously reduced fractures or dislocations, dental pain, headache/migraine, and cyclic vomiting.
 - + Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) have been shown to be safer and equally or more effective in managing many types of pain when compared to opioid medications.^{8–12}
 - + Opioids should not be routinely prescribed for uncomplicated low back pain and dental pain.
 - + Many studies have demonstrated the superiority of opioid alternatives, including NSAIDs and acetaminophen, for both dental and uncomplicated back pain. 13,14
 - Opioids are correlated with decreased function at six months and prolonged disability at one year in patients with uncomplicated lower back pain.^{15,16}
 - + Opioids should not be prescribed for migraine headache and post-traumatic headache (headache associated with trauma to the head and/or neck).
 - + Opioids can cause acute migraine medications to be less efficacious. 17,18
 - + Opioids have detrimental effects when used to treat headache, and it is recommended they be avoided. Potential complications include the precipitation of depression, anxiety, disability and medication-overuse headaches.¹⁹
 - Use of opioid analgesia also correlates with the progression of migraine headache from acute to chronic.²⁰
 - + The American Academy of Neurology, American Headache Society and ACEP caution against the use of opioids for headache treatment. These agents are best reserved for extraordinary situations in which all other options fail or are contraindicated.^{21,22}
 - + For patients experiencing cyclic vomiting, continued use of opioid therapy is a poor prognostic indicator that may contribute to disease progression. Dependence and withdrawal are also associated with recurrent episodes.²³
 - + Opioids should not be routinely prescribed for previously reduced dislocations and fractures.
 - + A 2017 study comparing pain levels at two hours for acute extremity pain showed no statistically significant or clinically important differences in pain reduction among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics (oxycodone and acetaminophen, hydrocodone and acetaminophen, codeine and acetaminophen).8
- + Opioid prescribing patterns should be collected and shared with peers or fellow clinicians within a practice.
 - + Opioid prescribing practices vary among clinicians. While little research exists examining provider-level variations in opioid prescribing patterns in primary care practice, some clinicians are minimizing or eliminating use of opioids while others continue to rely heavily on opioid analgesia.^{25–29}
 - + Knowledge of current ordering patterns can be critical for protocol implementation, clinician education and quality improvement.





- Tracking prescribing patterns and providing the comparative data to every clinician within the practice may help reduce discrepancies and identify clinicians who can benefit from further education in multimodal analgesia and opioid stewardship. Clinicians are advised to approach opioid prescribing with the same stewardship they employ when making other medical decisions.
- + Physicians are encouraged to monitor the opioid prescribing patterns of other clinicians providing care under their license, including resident physicians and advanced practice providers.
- Information on prescribing patterns should not be used punitively but rather to help clinicians understand their own treatment habits, facilitate change and improve care. Local sharing has been shown to significantly reduce the number of opioids prescribed at discharge in emergency medicine practice.²⁴
- If and when a decision is made to use an opioid, then the question is which one, as all opioids are not the same.
 - + Each opioid moiety has differential effects on the opioid receptors mu, kappa, delta, and nociceptin. These receptors have differential effects on analgesia and adverse effects³⁰⁻³¹ due to variable affinity, intrinsic activity, and potency, though the mu receptor is generally the most important.
 - + It is useful to consider which opioid worked best in the past; however, a patient's insistence on a particular opioid is very likely to indicate problematic use, if not addiction.
 - + With respect to efficacy and potential adverse effects, genetics at some point in the future may have predictive value, though today that value has not been realized³²⁻³³.
 - + On the other hand, initial opioid selection can be based in part on presence of certain coexisting non-pain medical conditions or concerns (data limited), though relative safety in one domain may be risky in another (Table 2).
 - Opioid selection otherwise is based on more practical considerations: cost, coverage, formulary, prior authorization requirements, and availability.

Table 2 | Opioid Selection Considerations based on Medical Condition

Constipation³⁴⁻³⁷

Worse: Methadone Morphine

Better: Buprenorphine TD Fentanyl TD Oxycodone CR Tapentadol

+ Renal Disease³⁸⁻⁴²

Avoid: Morphine Codeine (also avoid NSAIDs)

Safer: Buprenorphine Methadone Fentanyl

+ Hepatic Disease⁴³⁻⁴⁵

Avoid: Methadone Codeine (also avoid NSAIDs, APAP)

Safer: Fentanyl

- + Serotonin syndrome risk more likely: Tramadol, Tapentadol
- + Depression less likely: Buprenorphine
- + Respiratory depression less significant: Buprenorphine, Tapentadol, Tramadol^{31,46}
- Hypogonadism less likely: Buprenorphine, Tapentadol⁴⁶
- + Addiction liability lower: Buprenorphine, Tapentadol, Tramadol, Methadone, Abuse Deterrent Formulations⁴⁷⁻⁵³





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Developed in collaboration with Stader Opioid Consultants.



Risk Management for COT Patients





Risk Management Steps 1 and 2: Risk Screening + Stratification

Ask

- Personal History of Substance Use Disorder
- + Family History of Substance Use Disorder
- + Personal History of Psychiatric or Mood Issues / Diagnoses PHQ-2 → PHQ-9 if affirmative for depressed mood; GAD-7 if affirmative for anxiety
- Personal History of Trauma: <u>ACE</u> questionnaire
- Risk for future opioid-related aberrancies: <u>SOAPP-R</u> (alternatives: <u>RIOSORD, ORT</u>)
- + Personal History of Addiction-Prone Substance Use: Screening Portion of <u>SBIRT</u> "Do you or have you ever used ______"
 - + Alcohol affirmative → <u>AUDIT</u> screener
 - + Cannabis affirmative → <u>CUDIT-R</u> screener
 - Tobacco affirmative → <u>Fagerström Test</u>
 - + Drug(s) affirmative → <u>DAST-10</u> screener
- + Current opioid amount: Practical Pain Management Opioid MME Calculator

Verify

- + Medical Record review
- + Reports of family, others
- + Online Prescription Database: Specific name varies by state
- Definitive Urine Drug Test: GC/MS or LC/MS-MS
- + If already on opioids:
 - + Oxygenation studies to determine respiratory safety
 - + EKG to determine QTc if methadone is prescribed or considered

Stratify

Estimate risk for controlled substance use based on the screened information

- + LOW risk for controlled substance use
- INTERMEDIATE risk for controlled substance use
- + HIGH risk for controlled substance use

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Risk Management Step 3:

Risk Mitigation

Strategies Limit Future Adverse Outcomes

- + Establish realistic goals: Pain and functional improvement 30%
- + Use of alternatives to opioids caution: they have risks too
- + Consider opioids with lower risk of addiction: buprenorphine, tramadol, tapentadol
- Calculate and address morphine milligram equivalents (MMEs)
- + Prescribe naloxone + provide overdose rescue instructions
- + Avoid co-prescribed respiratory depressants, notably benzodiazepines
- + Provide informed consent: Risks, Benefits, Alternatives
- Provide instructions for secure storage
- Provide instructions for safe disposal
- + Plan for drug testing based on assessed level of controlled substance risk
- + Plan for online prescription database review based on level of controlled substance risk
- + Consider assessment of respiratory status: oxygenation status, underlying conditions

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Risk Management Step 4: Risk Monitoring

At Every Clinical Contact

- + Behavioral Aberrancies
 - + Reported by the patient Clinical Opioid Misuse Measure (COMM) useful
 - + Observed by the medical provider
- + Current opioid amount: Practical Pain Management Opioid MME Calculator

Frequency According to Stratified Level Controlled Substance Use Risk

- + Online prescription database review
- Drug testing typically, urine or oral fluid*
- + Goal attainment
- Remaining product (pills, capsules, tablets, films, patches) count
- + Oxygenation status
- EKG for QTc if methadone is prescribed

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^{*} Drug screening with urine point of care (POC) methodology is fraught with false positives and false negatives. Nonetheless, it is a valuable "conversation starter". Depending on the level of controlled substance risk, clinical impression at the time of the clinical contact, and/or uncertainty about POC validity, submission of the urine for definitive testing (GC/MS or LC/MS-MS methodology) should be done.





Risk Management Step 5: Aberrancy Management

Aberrancy Management

An aberrancy is defined by a violation of the controlled substance agreement. It is a behavior that may reflect or is actual evidence of unsafe controlled substance use.

All aberrancies are not equally worrisome. They can be considered to be low (Table 1), intermediate (Table 2), or high level with respect to level of concern. Each aberrancy should be addressed by a response with the patient and appropriately documented in the chart. The nature of the response includes the following:

- + Coach adherence and increase monitoring
- + Specialist consultation: pain management, addiction, psychiatry, sleep
- + Discontinue opioids and/or other problematic/addition-prone substances
 - + Diversion identified → Abrupt discontinuation
 - + Addiction identified → Abrupt discontinuation + withdrawal meds + referral
 - + Other major concerns → Consider tapering per clinical judgement
 - Invoke when 4 or more lower-level aberrancies have accumulated
- + Discharge from your practice
 - + Last resort
 - + Counsel patient + refer to a responsible prescriber i.e., a therapeutic discharge

Table 1 | Low Level Aberrancies

- + Early refill once
- + Self-directed dose ↑ once
- + Missed / late for appointment
- + Low dose alcohol for special occasion only
- Not informing prescriber of mild adverse reactions
- Non-notification of other opioid prescriber for good reason x1
- Occasional problem-solving phone calls rather than office visits
- + Non-participation in non-medication approaches for noneconomic reasons."





Table 2 | Intermediate Level Aberrancies

- + Early refill >1
- + Consider self-addicted
- + Lost / stolen prescription
- + Unauthorized overuse >1
- + Focused on specific opioid
- + Unauthorized cannabis use
- + Limited interest in non-opioid approaches
- + Multiple phone calls rather than office visits

- Not informing prescriber of significant adverse reactions
- Non-opioid substance addiction slip → return to abstinence
- + Non-participation in non-medication approaches for noneconomic reasons

Table 3 | High Level Aberrancies

- + Forged prescription
- + Cocaine / Stimulant use
- + Involvement in DUI / MVA
- + > 3 lower-level aberrancies
- + Non-pain related opioid use
- Stealing controlled substances
- + IV or IN route of administration
- + Aggressive demands for opioids
- + Active non-opioid substance relapse

- Refusal of non-medication approaches for pain
- Intoxication / Oversedation: Reported or observed
- Multi-sourcing: Other prescribers / street / internet
- Reliance on problem-solving phone calls rather than office visits

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Risk ManagementPutting It All Together

Pain is

"An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"

International Association for the Study of Pain, 2020

The management of pain, particularly that of chronic pain, is highly complex. Medical providers are challenged not only by careful consideration of the risks and benefits of individual medications and non-medication treatments, but also by comparative considerations of the wide range of alternatives primarily considered. For example, it is widely known that opioids have a substantial risk for death, primarily due to respiratory depression in overdose. In studies in which data is stated or from which it can be calculated, 0.02-0.08% of patients prescribed an opioid expire from an opioid-related overdose^{1,2,3,4,5}. Opioids have well-documented additional risks with long term use including osteoporosis, depression, weight gain, pneumonia, and increased pain through opioid-induced hyperalgesia. However, it must be recognized that serious adverse events occur with other medications as well. Non-steroidal anti-inflammatory drugs (NSAIDs), which are often used as first-line agents, have been associated with a gastro-intestinal (GI) bleed death rate of 0.02%⁶ - the same order of magnitude as opioid-related overdose death even when mortality associated with NSAID-related cardiovascular (CV) and renal consequences is not included.

For clinicians - not simply those in pain management - competence is needed in three domains:

- 1. Knowledge
- 2. Application of knowledge
- 3. Documentation

With respect to pain management, these general skill sets are required in two separate but interrelated management tracks: 1) Pain Management and 2) Risk Management.

Pain Management

Pain evaluation and its subsequent management is multifaceted and difficult. In brief, the following elements should be addressed with respect to the patient's history of pain complaints:

- 1. Pain descriptors: intensity, character (nociceptive, centralized, both), location, radiation, aggravating factors, ameliorating factors, red flags, neurologic correlates
- 2. Function descriptors: prior / current status (work, home, school, social), current status with / without current treatment
- 3. Pain onset: gradual / abrupt, injury (describe mechanism)
- 4. Diagnostic studies / results





5. Pain course: overall, diagnoses, efficacy and problems with medications / modalities / procedures / surgeries

Further evaluation, then, encompasses the following:

- 1. Pain-directed physical examination
- 2. Laboratory evaluation
- 3. Imaging
- 4. Neurodiagnostics
- 5. Diagnostic procedures

Outside of the acute / postop pain setting, chronic pain is traditionally defined as pain that persists most days over the previous three months. Defined in that manner 19% or 39.4 million Americans have chronic pain⁷. It is this pain - chronic and intractable - that is relatively resistant to therapies and is particularly challenging to patients and medical providers alike.

In general, preferential treatments are non-opioid options. To begin, there is value to determining the sensory (pain) phenotype as nociceptive, centralized (most commonly neuropathic), or a combination. This aids in treatment decision-making, since centralized pain (burning, lightning, electric, shock-like, dysesthetic) is more likely to respond to non-opioid analgesics⁸. Similarly, inflammatory pain may be better addressed with the use of anti-inflammatories, assuming patients are not at high risk for this class of medication^{9,10}. Medications (viz., substances to solve a problem) which provide analgesia can be categorized based upon their predominant neurophysiologic mechanism (e.g., the primary receptor at which the agent is active) or on the reason for which they were originally used (e.g., antidepressants found later to provide analgesia). The options below are listed primarily by receptor effects when known. Some are available in various delivery options with dermal applications advantageous at times as they may provide fewer adverse reactions though generally with weaker researched support. Options include:

- 1. Anti-inflammatories (often 1st line: corticosteroids [though not for low back pain¹¹], NSAIDs diclofenac > celecoxib)^{11,12,13,14}
- 2. Acetaminophen^{11,13,15} (limited utility^{14,16,17,18,19,20}, complex neuropharmacology^{14,21})
- 3. Selective Serotonin Reuptake Inhibitors (SSRIs)^{22,23,24,25} (minimal benefit¹⁴; not for headache²⁶)
- 4. Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)^{13,22-25} (especially duloxetine^{13414,27,28,29}; milnacipran for fibromyalgia only^{14,30,31}; not for headache¹⁴)
- 5. Tricyclic Antidepressants (TCAs)^{21-24,28} (some utility, more side effects than that for other antidepressants)
- 6. Calcium channel modulators^{14,28,32,33,34,35,36} (gabapentinoids: gabapentin, pregabalin)
- 7. Sodium channel agents (topical lidocaine^{37,38,39,40}, anticonvulsants evidence mixed^{11,41,42})
- 8. N-Methyl-D-aspartic acid or N-Methyl-D-aspartate (NMDA) receptor antagonists (memantine for fibromyalgia¹⁴, methadone⁴³, ketamine^{44,45,46})
- 9. Skeletal muscle relaxants^{11,47,48,49} (limited utility as adjunctive medications)
- 10. Benzodiazepines⁵⁰ (analgesic utility only for burning mouth and stiff person syndromes)
- 11. Stimulants⁵¹ including caffeine⁵² (rare analgesic utility as adjunctive medications)
- 12. Cannabinoids^{53,54,55} (mixed results, adverse reactions of concern⁵⁶)
- 13. Other phyto-chemicals and dietary supplements for various pain conditions for short-term use: avacado-soybean unsoponifiables^{57,58,59}, collagen hydrolysate⁵⁹, passion fruit peel extract⁵⁹, Curcuma longa extract⁵⁹, Boswellia serrata extract⁵⁹, curcumin⁵⁹, pycnogenol⁵⁹, L-carnitine⁵⁹, undenatured type II collagen⁵⁹, methylsulfonylmethane⁵⁹, diacerein⁵⁹, glucosamine⁵⁹, chondroitin⁵⁹, capsaicin⁶⁰, alpha-lipoic acid^{61,62,63}, and theramine⁶⁴.





When possible and efficacious, non-medication approaches are often preferable as they may afford analgesic and functional benefit without as high a risk of adverse outcomes (not always) as medications:

Self-Directed after Training

- 1. Structured exercise
- Mind-Body Therapies: Biofeedback, Movement meditation, Mindfulness, Relaxation
- 3. Music
- 4. Neurostimulators
- 5. Nutritional approaches
- Professionally Directed
 - 1. Physical Approaches
 - a. Acupuncture
 - b. Assistive devices
 - c. Blocks / Ablation
 - d. Ergonomic modifications
 - e. Light therapies
 - f. Massage
 - g. Osteo-manipulation
 - Physical therapy / Occupational therapy
 - Regenerative therapies: platelet rich plasma, prolotherapy, stem cells
 - j. Stimulators: peripheral, spinal, deep brain
 - k. Surgeries
 - I. Trigger point interventions
 - m. Ultrasound

- 6. Thermal modalities / Balneotherapy (spa)
- 7. Sleep hygiene
- 8. Spray and stretch
- Spiritual practices
- 10. Tobacco cessation
- 11. Weight reduction
- Psychological Approaches / Pain Behavior Therapies
 - a. Acceptance and Commitment Therapy
 - b. Cognitive Behavioral Therapy
 - c. Behavioral therapies
 - d. Pain education
- Treatment of certain underlying medical conditions
 - a. Acute pain conditions
 - b. Diabetes
 - c. Gastrointestinal conditions
 - d. Psychological conditions
 - e. Rheumatologic conditions
 - f. Sleep-related conditions
 - g. Strategic deprescribing

Opioids

The judicious use of opioids may provide functional (the primary goal) and analgesic (the intermediate goal) advantage to patients. Benefit in both ways is well-established for short-term acute, including postoperative, pain^{65,66,67}. In acute contexts, though, non-opioids may perform as well as or better than opioids^{68,69}. Even when the condition in which opioids are used is reasonable, the amounts prescribed are often far greater than is necessary and should be limited⁷⁰. Prescribers are well advised to keep abreast of the researched recommendations relevant to the pain conditions they treat.

Far more controversial - appropriately so - is the use of opioids long-term for chronic pain conditions. While it is true that there are no prospective, placebo-controlled studies involving opioids for a year or more, it is also true these studies will never be performed to answer the controversy definitively because it is unethical to allow patients to remain on a placebo for a long duration of time while experiencing disabling pain. There are, however, open-labeled studies that suggest that some patients may have long-term benefit^{71,72,73,74}, though the methodology of the research can be called into question.





If and when a decision is made to use an opioid, then the question is which one, as all opioids are not the same. Each opioid moiety has differential effects on the opioid receptors mu, kappa, delta, and nociceptin. These receptors have differential effects on analgesia and adverse effects^{75,76} due to variable affinity, intrinsic activity, and potency, though the mu receptor is generally the most important. It is useful to consider which opioid worked best in the past; however, a patient's insistence on a particular opioid is very likely to indicate problematic use, if not addiction. With respect to efficacy and potential adverse effects, genetics at some point in the future may have predictive value, though today that value has not been realized^{77,78}. On the other hand, initial opioid selection can be based in part on presence of certain co-existing non-pain medical conditions or concerns (data limited), though relative safety in one domain may be risky in another (Table 1). Opioid selection otherwise is based on more practical considerations: cost, coverage, formulary, prior authorization requirements, and availability.

Table 1

Opioid Selection Considerations based on Medical Condition

+ Constipation 79,80,81,82

Worse: Methadone Morphine

Better: Buprenorphine TD Fentanyl TD Oxycodone CR Tapentadol

+ Renal Disease 83,84,85,86,87

Avoid: Morphine Codeine (also avoid NSAIDs)

Safer: Buprenorphine Methadone Fentanyl

+ Hepatic Disease 87,88,89,90

Avoid: Methadone Codeine (also avoid NSAIDs, APAP)

Safer: Fentanyl

- + Serotonin syndrome risk more likely: Tramadol, Tapentadol
- + Depression less likely: Buprenorphine
- + Respiratory depression less significant: Buprenorphine, Tapentadol, Tramadol 80,89,91
- + Hypogonadism less likely: Buprenorphine, Tapentadol 80,91
- + Addiction liability lower: Buprenorphine, Tapentadol, Tramadol, Methadone, Abuse Deterrent Formulations 92,93,94,95,96,97,98

On follow-up, in general the goal is to achieve a 30% improvement in both pain⁹⁹ and function¹⁰⁰. This should be assessed on each patient encounter to ensure durability of benefit over time. If efficacy is not found or if gains are lost over time, a change in therapy is indicated. The presence (or not) of adverse reactions should be elicited – first in an open-ended fashion, then direct inquiry about constipation (the most common side effect at $40\%^{101}$), nausea \pm vomiting (experienced by $30\%^{71}$ yet usually resolves spontaneously), dyscognition, sedation, psychomotor impairment, respiratory function, mood decrements (PHQ-2 \rightarrow PHQ-9 for depression, GAD-7 for anxiety) – all of which should be specifically listed in the Review of Systems if not already documented in the History of Present Illness section.

If side effects are present, they should be addressed. Dose reduction can be considered but unlikely to help constipation for which other options are available 102,103. End-of-dose failure (increased pain before the next scheduled dose) can be managed by decreasing the interval between dosages, since in research or by clinical experience individuals may experience limited duration of action for various opioids: oxycodone short-acting (2 hours), oxycodone controlled release (6 hours), morphine extended release (6 hours), hydromorphone (2 hours), methadone (6 hours), fentanyl transdermal (48 hours), and buprenorphine weekly patch (6 days) 104,105,106. Breakthrough pain - separately defined 107 - may be incident (environmentally prompted) or spontaneous (no obvious trigger) in type and can be addressed with short-acting opioids 108,109,110 (no more than 8 per month recommended) and better yet non-opioid





options¹¹¹. Opioid inadequacy can also be addressed by switching (rotation) to a different opioid, which can be successful in half or more of patients in research primarily involving single rotations^{112,113,114,115,116,117,118,119}. Research on multiple sequential switches was found in only one poorly designed study¹²⁰ and should be reserved to prescribers highly experienced.

Continued opioid therapy, however, is not always appropriate. Opioid use in some patients can become a source of pain due to central hypersensitization (opioid-induced hyperalgesia)^{121,122}. This paradoxical response was first suggested by Lord Albutt in 1870: "Does morphia encourage the very pain it pretends to relieve?" ¹²³ However, the phenomenon is still poorly understood, is caused by multiple neuropharmacologic mechanisms, and should be suspected when opioid efficacy declines when the underlying pain condition has not progressed. Management primarily involves opioid tapering as opposed to that for opioid tolerance which responds favorably to opioid dose increases ^{124,125,126}.

In fact, because it is difficult to discern evolving loss of benefit and/or advancing adverse reactions (e.g., subtle dyscognition), it is prudent to offer opioid tapering to all persons on long-term opioids. Such an offer does not mean forced reductions¹²⁷, however, unless clear-cut respiratory compromise is identified. Indeed, voluntary tapering can be very successful and often result in improvements in pain and function^{128,129}. Even if complete discontinuation is not achieved, the least necessary dose can be established, providing a better safety profile for the patient. In the absence of severe opioid side effects like respiratory compromise, there is plenty of time to taper. Because ultimate success is more important than rapid failure, initiating the taper by a small amount (e.g., by 5 mg of hydrocodone) is preferred for a few reasons. Patients are concerned prescribers will "throw them under the bus" with brisk dose decrements, and maintaining a therapeutic alliance is enhanced by a slower trajectory. Patients need to know the medical provider is "all in" on addressing their pain, so sequential trials of non-opioid approaches simultaneously are important. Small initial reductions can be adjusted up or down according to the individual's response. Here, patients should lead the shared decision-making because it is their expertise – their lived experience – which is most relevant in the tapering progression.

Some circumstances call for abrupt discontinuation rather than tapering, though. Identification of major opioid-related aberrancies - for example, a forged prescription, obvious impairment, or diversion - necessitates this. It is also quite unlikely that individuals with Opioid Use Disorder (OUD) will be able to taper due to the craving they experience. Depending on the circumstances, discontinuation should be paired with the use of withdrawal medications, such as outlined in Table 2.

Table 2
Withdrawal Medications: Basic Recommendations

Pain	<u>Naproxen</u>	220 mg	РО	qid prn	#20
Back Spasm	<u>Cyclobenzaprine</u>	10 mg	PO	qid prn	#20
Abdominal Cramps	<u>Hyoscyamine</u>	0.125 mg SL	SL	qid prn	#20
Shakes, Sweats	Clonidine ⁵⁻⁸	0.1 mg	РО	qid prn	#20
	Lofexidine 9,10	0.1 mg	PO	2 tid	#36 or #96

Risk Management

The recommendations above assume that patients use these agents safely, which is not the case for a significant proportion of those exposed to opioids. Central to this concern is the nonmedical use and OUD. Studies vary widely^{130,131,132,133}, but in a systematic review, Vowles *et al* found the prevalence of opioid addiction in pain populations prescribed opioids to be 8-12%¹³⁴. Identification of and managing this is critical in and of itself, but also because opioid addiction characteristics have been seen in 80-95%





of those who die of an opioid-related overdose^{135,136}. Consequently, clinicians should carefully attend to risk management as well as pain management. The following steps are recommended^{137,138}:

- 1. Risk Screening (Table 4)
- 2. Risk Stratification (Table 4)
- 3. Risk Mitigation (Table 5)
- 4. Risk Monitoring (Table 6)
- 5. Aberrancy Management (Table 7)

Risk Screening and Risk Stratification

Risk Screening ideally should begin prior to the first office visit contact with a new patient through the review of the patient's medical records. Among the risk factors that predict poorer outcomes (Table 3), eliciting responses to the following are especially important: 1) Personal and family history of Substance Use Disorder (SUD), 2) Personal history of psychiatric or mood problems, and 3) Personal history of trauma.

Table 3

Factors Associated with Opioid Nonmedical Use, OUD, Opioid-Related Overdose

- 1. Personal / Family history of Substance Use Disorder especially OUD135,139,140,141,142,143,144,145,146
- 2. Personal history of psychiatric or mood problems^{144,145,147,148,149}
- 3. Personal history of trauma^{150,151,152}
- 4. Male gender^{143,153,154}
- 5. Younger age^{143,147,155}
- 6. Legal problems¹⁴²
- 7. Specific opioid prescribed: fentanyl, morphine, methadone¹⁴⁵
- 8. High dose opioid prescribing 142,144,147,156,157,158
- 9. History of medication-related aberrancies^{141,159,160}
- 10. Multiple prescribers or pharmacies^{161,162}
- 11. Respiratory / pulmonary disease, including COVID145,149,163,164,165,166,167
- 12. Co-prescribed respiratory depressants, notably benzodiazepines 145,149,168,169,170,171,172,173
- 13. Cardiac disease¹⁴⁹
- 14. Certain circumstances with cancer¹
- 15. Impaired renal or hepatic function^{145,146}
- 16. Certain infectious diseases, e.g., HIV, hepatitis^{174,175,176}
- 17. Lower educational achievement 177
- 18. Not married, divorced^{175,178}

There is a range of approaches that are effective in determining and managing safe controlled substance prescribing, which are best employed in a multi-faceted manner^{179,180}. To being with, all patients – not just those for whom controlled medications are or might be prescribed – should be screened for the use of addiction-prone substances through the use of the screening portion of Screening, Brief Intervention, and Referral to Treatment (SBIRT) ^{181,182,183,184,185}. This is no more complicated than to ask, "Do you currently or have you ever used [tobacco, alcohol, cannabis, illicits; stimulants, benzodiazepines, opioid for reasons other than prescribed]?" A "yes" answer to any one specific substance should be secondarily screened for problems with tobacco (Fagerström Test¹⁸⁶), alcohol (Alcohol Use Disorder Identification Test [AUDIT]¹⁸⁷), cannabis (Cannabis Use Disorder Identification Test [CUDIT-R]¹⁸⁸), illicit drug use (Drug Abuse Screening Test [DAST-10]¹⁸⁹). If problematic use is identified through these screeners, the presence (or not) of addiction should be determined and addressed accordingly. If prior but not current use is found, inquiry as to why a substance was discontinued is





important as the person may have discontinued use due to difficulties or addiction, which are still risks even when problems are remote.

"Trust, but Verify"

Because some individuals may not be honest about addiction-prone substance $use^{190,191}$, additional approaches are indicated. When available, information provided by family and others associated with the patient can be useful. Though imperfect^{192,193}, review of the online prescription database (specific name varies by state) can determine 1) Which controlled prescriptions were filled, 2) How many prescribers prescribed them, and 3) How many pharmacies dispensed them^{194,195}. Enhancements within these databases differ by state, but can be helpful in determining other worrisome circumstances, such as high daily morphine milligram equivalents (\underline{MME} s) of opioids received. Risky prescribing/dispensing has been associated with opioid-related overdose¹⁹⁶, and use of the online prescription database can limit inappropriate prescribing^{197,198,199,200,201}, as well as opioid-related overdose deaths²⁰². It is recommended that review of prescription databases be performed prior to any controlled substance prescribing – *i.e.*, for both acute and chronic pain.

When considering opioid prescribing for chronic pain or for acute pain when concerned, drug testing should be performed for additional verification (or not) of reported substance use^{203,204,205,206}. In-office point-of-care urine drug screening has advantages in that it is inexpensive and results are immediate but is fraught with false positives and false negatives^{206,207,208}. Such immunoassays are good "conversation starters" but should not be relied upon for major clinical decisions²⁰⁶. Definitive - also termed confirmatory or quantitative - testing, on the other hand, will identify those substances to which a patient has been exposed with certainty, using Gas Chromatography with Mass Spectrometry (GC-MS) or High Performance Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS) techniques²⁰³⁻²⁰⁸. Definite identification, however, does not clearly indicate the reason for the presence of a particular substance. For example, a "morphine" result may be due to morphine per se (prescribed or not), codeine (prescribed or not), poppy seeds (variable individual results), or heroin^{209,210}. Validity testing by various means is important as well in order to determine if the patient has attempted to adulterate, dilute, or substitute the sample provided for analysis²⁰⁶.

A valid definitive test that shows only the prescribed agents is termed "expected". The presence of non-prescribed substances or the absence of prescribed medications are "unexpected" or "potentially inappropriate" and necessitates a discussion with the patient, and possibly a change in plan²⁰⁶. Research demonstrates this process of initial as well as follow-up drug testing using either urine or oral fluid matrices improves identification of inappropriate substance use^{201,212,213} and improves the safe use of prescribed medications by patients²¹⁴. Skill in the interpretation of drug testing is best accomplished through establishing a basic knowledge, selecting a testing vendor²¹⁵ with whose laboratory scientist can provide guidance, and experience over time.

Opioid-related overdose is primarily related to respiratory compromise 145,149,163-167. Of particular concern are those to whom other respiratory depressants – especially benzodiazepines – are currently prescribed or being considered 145,149,168-173. The STOP-BANG questionnaire is useful in identifying those at risk for obstructive sleep apnea 216. Those on opioids or might be and have pulmonary conditions can be evaluated by screening with overnight nocturnal oximetry and/or testing with formal sleep studies 217,218. Though less prominent lately, methadone is over-represented among opioid-related overdose deaths 219 not only because of its effect on respiration, but also because it can cause QT prolongation that can result in *torsades de pointes*, a life-threatening arrhythmia 220. For that reason, baseline and periodic EKGs are indicated when methadone is prescribed 221.





When opioid prescribing is considered, determining the risk for unsafe use in the future is helpful. Many screeners have been developed, though many have limited validation. Among these, perhaps the best validated as predictive is the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) now available in a shorter 12-item form^{222,223,224}, rising above other screeners in comparative studies²²⁵. More recently developed, the Risk Index for Overdose or Serious prescription Opioid-induced Respiratory Depression (RIOSORD), unlike many other screeners includes elements regarding clinical conditions and the opioids themselves (e.g., MMEs, methadone). It has been validated in veterans and commercial populations^{226,227,228} and could be used on follow-up if changes in the measured elements occur. The Opioid Risk Tool (ORT) has been used widely but has limited validation²²⁹.

Although the above description is complex, Risk Screening is outlined more succinctly in Table 4. It is medical judgement then applied to screening data that stratifies an individual patient's risk as low, intermediate, or high^{230,231,232}. For those at high risk, non-opioid options are clearly preferred. The estimated level of risk helps determine the kind and frequency of risk monitoring on follow-up.

Table 4

Risk Screening and Stratification

ASK

- Personal History of Substance Use Disorder
- + Family History of Substance Use Disorder
- Personal History of Psychiatric or Mood Issues / Diagnoses
 PHQ-2 → PHQ-9 if affirmative for depressed mood; GAD-7 if affirmative for anxiety
- Personal History of Trauma: ACE questionnaire
- + Risk for future opioid-related aberrancies: SOAPP-R (alternatives: RIOSORD, ORT)
- + Personal History of Addiction-Prone Substance Use: Screening Portion of <u>SBIRT</u>
 Do you or have you ever used ______
 - + Alcohol affirmative → <u>AUDIT</u> screener
 - + Cannabis affirmative → <u>CUDIT-R</u> screener
 - + Tobacco affirmative → Fagerström Test
 - + Drug affirmative → <u>DAST-10</u> screener
- + Current opioid amount: Practical Pain Management Opioid MME Calculator

VERIFY

- + Medical Record review
- + Reports of family, others
- + Online Prescription Database: Specific name varies by state
- + Definitive Urine Drug Test: GC/MS or LC/MS-MS
- + If already on opioids:
 - + Oxygenation studies to determine respiratory safety
 - + EKG to determine QTc if methadone is prescribed or considered

STRATIFY

Estimate risk for controlled substance use based on the screened information

- + LOW risk for controlled substance use
- + INTERMEDIATE risk for controlled substance use
- + HIGH risk for controlled substance use





Risk Mitigation

Mitigation, as used here, means those strategies that are employed to limit future risks with opioid prescribing and should be initiated prior to prescribing. The focus is safety and that concern should be clearly communicated to patients. The approaches are listed in Table 5.

Table 5

Risk Mitigation

- + Establish realistic goals: Pain and Functional improvement 30% 99,100
- + Use of alternatives to opioids caution: they have risks too 11-64
- + Consider opioids with lower risk of addiction: buprenorphine, tramadol, tapentadol 80,89,91
- + Calculate and address morphine milligram equivalents (MMEs) 142,144,147,156-158
- + Prescribe naloxone + provide overdose rescue instructions 233,234,235
- Avoid co-prescribed respiratory depressants, notably benzodiazepines 145,149,168-173
- + Provide informed consent: Risks, Benefits, Alternatives 236,237,238,239,240,241,242,243,244,245
- + Provide, explain, and have the patient sign a Controlled Substance Agreement (CSA) 242,243,244,246,247,248,249,250,251,252,253
- Provide instructions for secure storage and safe disposal ^{254,255,256}
- + Plan for drug testing and online prescription database review based on assessed level of controlled substance risk 192-210
- + Assessment of respiratory status: oxygenation status, underlying conditions 257,258,259,260

Managing expectations through setting realistic goals is important. Pain improvement by 30% means that a typical patient with 7/10 pain severity can expect to achieve a reduction to 4/10 making it possible to also achieve functional goals s/he establishes and not press for higher opioid dosages to try and move to zero pain which is more unsafe. Keeping tabs on the total MMEs is important in this context as well. Prescribing naloxone to all patients on opioids regardless of dose and providing rescue instructions to their significant others can be life-saving²³³⁻²³⁵. Plans for monitoring by means of prescription database review, drug testing, and evaluation of oxygenation status as discussed above should be done.

Patient education and discussions begins with the first visit and continues at subsequent clinical contacts. Fundamentally, informed consent is not a document to be signed but a process of communication about the risks, benefits, and alternatives of and to opioid use as well as how to use these medications properly and safely. It is central to medical practice that shared decision-making involve engaging patients about the uncertainties of specific therapeutic interventions to optimize outcomes²³⁶⁻²⁴⁴. With the initial prescription, verbal delivery of information, responding to questions and concerns, and directing patients to obtain the Medication Guide - the plain language section of the Prescribing Information - from their pharmacist. On follow-up, specific topics should be addressed more in depth and then documented: "Informed consent given with emphasis on ".

Although informed consent information may be included in the CSA.²⁴⁴, the latter differs from the former. The term "agreement" is used rather than "contract" since a contract implies a definite consequence to a violation and agreement makes room for flexibility, an important and practical approach in clinical medicine. Found effective²⁴⁶⁻²⁵⁰, this document describes in plain language²⁵¹ expected and prohibited behavior; patient authorization for consults, prescription database reviews, drug testing; and potential responses to medication-related aberrancies^{252,253}. Specifically, the use of alcohol and illicits should be prohibited. Prescribers have to decide if cannabinoids might be allowed under certain conditions (not recreational) and for certain patients but only if those prescribers have adequate knowledge base about cannabinoids⁵³⁻⁵⁵. Clear instructions on secure storage – a safe (combination preferred) *not* in the bathroom – and safe disposal through reverse distributors²⁵⁴⁻²⁵⁶.





It is recommended that the written CSA be provided at the first patient encounter and that the patient have an opportunity to review at their leisure between visits with the expectation of addressing questions and obtaining the patient's signature at the second clinical contact. In that way, the patient should be truly informed about its contents before agreeing to them.

Risk Monitoring

If and when the opioids are prescribed, ongoing monitoring (Table 6) is critical to help ensure continued safe use. Behavioral aberrancies are actions by patients which place them at risk, both those that may be reported by patients and those that might be observed by the practitioner at the time of clinical contact. Inquiry about and observation of specific items should be done with every clinical encounter, including those listed in the following documentation example for someone who is adherent in this case:

Subjective section of the note for the patient encounter – i.e., reported by the patient: "The patient reports taking opioids on a regular basis as directed, source here only, securely stored, and not ending up in other persons' hands. S/he reports not using alcohol, cannabis, or illicit substances."

Objective section of the note for the patient encounter – i.e., observed by the clinician: "Normal level of consciousness and orientation. No observed impairment, confusion, imbalance, slurred speech, track marks, alcohol or cannabis odor. Observed pain behavior is consistent with patient report."

The validated Current Opioid Misuse Measure^{261,262} (<u>COMM</u>) is a questionnaire that may be used to elicit behavioral aberrancies as well. Every office visit should also track and address goal attainment and the opioid daily <u>MME</u>. MME calculators vary widely^{263,264} and the <u>Practical Pain Management Opioid MME</u> <u>Calculator</u> is recommended, as it is based on the best available research.

Other monitoring should be done periodically based on stratified level of controlled substance risk and concerns identified at the time of clinical contact. Clinical experience suggests drug testing and prescription database review should be performed at a minimum of the following according to level of risk: low level (1-2 times per year), intermediate level (3-4 times a year), and high risk (5-6 times a year). Periodic random drug testing is useful^{213,265,266} but a sample is not truly random if ordered on the basis of intuition and is probably better termed "surprise" testing. The inexpensive immunoassay is sufficient to begin a conversation about substance exposure, but the more-expensive definitive testing should be done at times unexpected by the patient even when there is no concern and, in addition, anytime misrepresentation is suspected²⁰³⁻²¹⁰.

The patient's clinical status may prompt other types of monitoring. Depending on clinical circumstances, re-evaluating oxygenation status can be considered when daily <u>MME</u> advances or there is new evidence of a developing respiratory problem²⁵⁷⁻²⁶⁰. An EKG should be obtained for QTc measurement annually or upon methadone dosage increase^{220,221}. EKGs are also important when other medications that affect the QT are added or increased²⁶⁷. Counts of remaining product (pills, capsules, tablets, films, patches) can identify any mismatch with time dispensed and may have some utility²⁶⁸. Some prescribers will do this at every clinical encounter or periodically according to level of risk. Because of practical challenges, counts may be more useful when circumstances suggest problems or aberrancies. Patients have gamed this, however, by presenting look-alike pills (avoid by employing pill identification) or rent-back product previously diverted or overused^{269,270}. In part, this can be obviated by requiring an on-demand count of a texted picture of the remaining prescribed product provided in real time by the patient.





Table 6 Risk Monitoring

At Every Clinical Contact

- + Behavioral Aberrancies
 - + Reported by the patient Clinical Opioid Misuse Measure (COMM) useful
 - Observed by the medical provider
- + Goal attainment
- + Current opioid amount: Practical Pain Management Opioid MME Calculator recommended

Frequency According to Stratified Level Controlled Substance Use Risk

- Online prescription database review
- + Drug testing with urine or oral fluid
- + Counts of remaining product (pills, capsules, tablets, films, patches)
- + Oxygenation status
- + EKG for QTc if methadone is prescribed

Aberrancy Management

Aberrancies can be defined as violations of the CSA or somewhat more broadly as any activity by the patient that indicates unsafe or nonmedical use. Not all aberrancies are alike, and although not described in the literature, clinical experience suggests they can be ranked as low (Table 7), intermediate (Table 8), or high (Table 9) in terms of severity or concern. Research shows that 40-80% patients will exhibit opioid-related aberrancies, results varying by population studied, aberrancies measured, and duration of observation^{213,266,271,272,273}. In one study 10% of low risk and 90% of high risk patients were aberrant²²⁹. Not all of these are of great concern. Lost or stolen prescriptions do occur, and patients might take an extra dose for severe pain (viz., a medical aberrancy). These are problematic and not welcome, but do not necessarily forebode future aberrancies, addiction, and overdose death. Still, each must be addressed and documented along with the clinician's response. The clinician has the following options when faced an aberrancy or aberrancies:

- 1. Coach adherence / behavioral intervention + increased monitoring 274
- 2. Specialist referral: Pain management, Addiction, Psychiatry 275
- 3. Discontinue opioids and other addiction-prone prescriptions 274
- 4. Discharge from the clinician's practice last resort ²⁷⁵

For low and intermediate level aberrancies, adherence coaching (warning, brief behavioral intervention) along with increased monitoring is often successful²⁷⁴. Recurrence may warrant exploration of the issues by specialty consultation²⁷⁵. "One strike and you're out" for lower level aberrancies is generally contraindicated as many patients may end up subsequently resorting to injudicious prescribers or street sources out of desperation. Even "three strikes and you're out", while catchy, is not evidence-based. Investigation on this issue is very sparse, and only two studies by the same research group were identified from 2007 and 2008. In that work, OUD was associated with one aberrancy involving cocaine but four or more of other types of aberrancies^{276,277}.

Pending other data, it may be reasonable to warn, monitor, and refer those presenting with up to three aberrancies, but just one in the case of stimulants. At that point, discontinuation of opioids (and other addiction-prone medications if relevant) rather than discharge from the practice is far preferable²⁷⁵. Just as in other areas of medical practice, ascertaining a new diagnosis does not mean release from care has to occur. The impetus to dismiss patients often has to do with their dishonesty: a violation of trust. Lying, however, is a symptom of the disease of addiction of patients trying keep the substances they





desperately crave available. These patients do not deserve to be shamed, but rather should receive evidence-based treatment, such as with Medication for Opioid Use Disorder (MOUD), formerly termed Medication Assisted Treatment (MAT).

On occasion, discharge from the clinician's practice is indicated, for example when forgery is identified, threatening behavior occurs, or non-compliance consistently recurs. However, it should be a last resort and done "therapeutically", i.e., by reviewing why the aberrancies are problematic with the patient along with a referral to a known responsible prescriber who respectfully manages challenging situations. In doing so, it is important to follow the rules and guidance provided by the medical board in respective states to avoid abandoning the patient – typically, a registered letter indicating that the clinician will no longer be available to care for the patient after 30 days. Excepting for benzodiazepines whose discontinuation could result in life-threatening seizures^{278,279,280}, the clinician is not obligated to continue the same, reduced, or any opioids, though there is a responsibility of appropriate withdrawal management if opioids are tapered or discontinued altogether.

Table 7

Low Level Aberrancies

- + Early refill x1
- + Missed or late for appointment
- Self-directed dose increase x1
- Non-notification of mild adverse reaction(s)
- + Low dose alcohol for a special occasion only
- + Non-notification of other prescriber for a good reason x1
- + Occasional problem-solving phone calls in lieu of clinical encounter (office or virtual)
- + Non-participation in recommended non-opioid pain treatments for valid economic reasons

Table 8

Intermediate Level Aberrancies

- + Early refill >1
- + Lost / stolen prescription
- + Unauthorized overuse >1
- Focus on specific opioid
- + Unauthorized cannabis use
- + Considers one's self to be addicted
- + Limited interest in non-opioid approaches
- + Not informing prescriber of significant adverse reaction(s)
- + Non-opioid substance addiction slip, followed by return to abstinence
- + Multiple problem-solving phone calls in lieu of clinical encounter (office or virtual)
- + Non-participation in recommended non-opioid approaches for noneconomic reasons

Table 9

High Level Aberrancies

- + Forged prescription
- + Cocaine / Stimulant use
- Involvement in DUI / MVA
- + > 3 lower level aberrancies
- + Non-pain related opioid use
- Stealing controlled substances
- + IV or IN route of administration





- + Aggressive demands for opioids
- + Active non-opioid substance relapse
- + Refusal of non-medication approaches for pain
- + Intoxication / Oversedation: Reported or observed
- + Multi-sourcing: non-allowed prescribers / street / internet
- + Reliance on problem-solving phone calls in lieu of clinical encounter (office or virtual)

Putting It All Together: Pain Management + Risk Management

Managing pain in clinical practice means managing the associated risks as well, particularly with opioid prescribing. As challenging as it is, this review attempts to adhere to Einstein's dictum to "make things as simple as possible...but not simpler" – see also Table 10. Each medical provider should become aware of one's biases – we all have them. Does one tend to over-trust or under-trust? Does one tend to over-prescribe or under-prescribe?

Table 10

Recommended Screening Tools for Pain and Opioid Risk Management

- + Acute Pain (short-term use): Initial Visit
 - + PEG-3 (Pain, Enjoyment, General Function)
 - + Interview questions: personal and family history of substance use disorders
 - + Screening Portion of Screening, Brief Intervention, and Referral to Treatment
 - + Online Prescription Database (aka Prescription Drug Monitoring Program varies by state)
- + Chronic Pain (long-term use): Initial Visit(s)
 - + PEG-3 (Pain, Enjoyment, General Function)
 - + Screening Portion of <u>Screening</u>, <u>Brief Intervention</u>, <u>and Referral to Treatment</u>
 - + Tobacco \rightarrow <u>Fagerström Test</u> Alcohol \rightarrow <u>AUDIT</u> Cannabis \rightarrow <u>CUDIT-R</u> Drugs \rightarrow <u>DAST-10</u>
 - + Interview questions:
 - + Personal and family history of substance use disorders
 - + Personal history of psychiatric or mood problems
 - + Adverse Childhood Experience questionnaire (ACE) for trauma
 - + PHQ-2 \rightarrow PHQ-9 if affirmative for depressed mood; GAD-7 if affirmative for anxiety
 - + <u>STOP-BANG</u> for obstructive sleep apnea risk
 - + Online Prescription Database (aka Prescription Drug Monitoring Program varies by state)
 - + Drug testing by definitive method: GC/MS or LC/MS-MS
 - + Screener and Opioid Assessment for Patients with Pain Revised (SOAPP-R)
 - Alternatives: Risk Index for Overdose or Serious prescription Opioid-induced Respiratory Depression (RIOSORD), Opioid Risk Tool (ORT)
- + Chronic Pain (long-term use): Follow-up Visits
 - + Five A's: Activities (function), Analgesia, Affect (mood), Adverse Effects, Aberrancies
 - + PEG-3 (Pain, Enjoyment, General Function)
 - + Current Opioid Misuse Measure (COMM)
 - + $\underline{PHQ-2} \rightarrow \underline{PHQ-9}$ if affirmative for depressed mood; $\underline{GAD-7}$ if affirmative for anxiety
 - + Online Prescription Database (aka Prescription Drug Monitoring Program varies by state)
 - + Drug screening by immunoassay, testing by definitive method: GC/MS or LC/MS-MS
- For Other Conditions Suggested by History





- + Post-Traumatic Stress Disorder: PTSD Check List (PCL-C)
- + Bipolar Disease: Mood Disorder Questionnaire (MDQ)
- + Attention Deficit Hyperactivity Disorder: Adult ADHD Self-Report Scale (ASRS)
- Psychosis: Psychosis Screener (PS)
- + Insomnia: Sleep Condition Indicator (SCI)
- + Suicidality: Patient Safety Screener (PSS-3)

It is incumbent upon the pain provider to acquire and update one's knowledge, recognize her or his limitations, and access specialty consultation in those matters beyond one's ability or capacity, as well as when there is significant uncertainty as to diagnosis and treatment approach. It is not enough to have the knowledge: it needs to be applied. A thorough understanding of drug testing is pointless, for example, if it is not ordered.

All this should be reflected in the chart, including concerns that might not be communicated directly to the patient at any one time – a surprise urine drug test, for instance. Language that describes both actual pain management and risk management activities, discussions, and considerations should be recorded consistently in each SOAP section (or equivalent): subjective, objective, assessments, and plans for both of those domains. Guidelines are just that: guidelines, not rules, not laws – although clinicians are governed by those as well. They are typically reflective of best practices but also include the minimal standard of care elements that must be performed. Indeed, there are occasions when off-guideline prescribing is the best approach for the patient, and in that case the medical record should clearly state the rationale: "off-guideline prescribing because..." Doing so serves as a prompt for the practitioner to take a second look at the intervention(s) prescribed to make sure medical decision-making is sound as well.

This review, too, reflects best practice recommendations and is not meant to supplant sound clinical judgment for the individuals served - individuals whose conditions and treatment responses vary widely. These are persons, not cases, who deserve our attention to their lived experiences and struggles. Naomi Wolfe expresses well the challenge so many patients face with their medical providers:

"Pain is real
when you get other people to believe in it.

If no one believes in it,
pain is madness or hysteria."

Listen

Steven Wright, MD Stader Opioid Consulting July 27, 2021

Family Medicine Addiction Medicine Medical Pain Management





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Developed in collaboration with Stader Opioid Consultants.





Recommended Screening Tools for Pain + Opioid Risk Management

Acute Pain (Short-Term Use): Initial Visit

- + PEG-3 (Pain, Enjoyment, General Function)
- + Interview questions: personal and family history of substance use disorders
- + Screening Portion of <u>Screening</u>, <u>Brief Intervention</u>, <u>and Referral to Treatment</u>
- + Online Prescription Database (aka Prescription Drug Monitoring Program varies by state)

Chronic Pain (Long-Term Use): Initial Visit(s)

- + <u>PEG-3</u> (Pain, Enjoyment, General Function)
- + Screening Portion of <u>Screening</u>, <u>Brief Intervention</u>, <u>and Referral to Treatment</u>
- + Tobacco → <u>Fagerström Test</u> Alcohol → <u>AUDIT</u> Cannabis → <u>CUDIT-R</u> Drugs → <u>DAST-10</u>

Interview Questions:

- + Personal and family history of substance use disorders
- Personal history of psychiatric or mood problems
- + Adverse Childhood Experience questionnaire (ACE) for trauma
- + PHQ-2 → PHQ-9 if affirmative for depressed mood; GAD-7 if affirmative for anxiety
- + <u>STOP-BANG</u> for obstructive sleep apnea risk
- Online Prescription Database (aka Prescription Drug Monitoring Program varies by state)
- Drug testing by definitive method: GC/MS or LC/MS-MS
- + Screener and Opioid Assessment for Patients with Pain Revised (SOAPP-R)
 - + Alternatives: Risk Index for Overdose or Serious prescription Opioid-induced Respiratory Depression (RIOSORD), Opioid Risk Tool (ORT)

Chronic Pain (Long-Term Use): Follow-Up Visits

- + Five A's: Activities (function), Analgesia, Affect (mood), Adverse Effects, Aberrancies
- + PEG-3 (Pain, Enjoyment, General Function)
- Current Opioid Misuse Measure (COMM)





- + $PHQ-2 \rightarrow PHQ-9$ if affirmative for depressed mood; GAD-7 if affirmative for anxiety
- + Online Prescription Database (aka Prescription Drug Monitoring Program varies by state)
- + Drug screening by immunoassay, testing by definitive method: GC/MS or LC/MS-MS

For Other Conditions When Suggested by History

- + Post-Traumatic Stress Disorder: PTSD Check List (PCL-C)
- + Bipolar Disease: Mood Disorder Questionnaire (MDQ)
- + Attention Deficit Hyperactivity Disorder: Adult ADHD Self-Report Scale (ASRS)
- + Psychosis: Psychosis Screener (PS)
- + Insomnia: Sleep Condition Indicator (SCI)
- + Suicidality: Patient Safety Screener (PSS-3)

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Opioid Benzodiazepine Tapering





Opioid + Benzodiazepine

Tapering

General Approach to Tapering

There are many approaches to opioid tapering. Figure out the best method for you, your patient and your practice. Here are a few recommended structured approaches:

- + BRAVO: A Collaborative Approach to Opioid Tapering
- + HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term
 Opioid Analgesics

How To Get Your Patient on Board with Opioid Tapering and Be Successful¹

- Explain patients need to understand individualized reasons for tapering (intrinsic motivation), beyond general, population-level concerns like addiction potential or regulatory/prescribing guidelines (extrinsic motivation)
- Negotiate Share decision making and allow patients to have input (e.g. rate of tapering, which
 opioid to taper first if on multiple opioids)
- + **Manage difficult conversations** When patients and providers do not reach a shared understanding, difficulties and misunderstandings arise and therapeutic alliance breaks down
- + **Pledge your support** Patients need to know that their providers won't abandon them during the tapering process. Commit to more scheduled office visits, more time spent during appts, or more frequent phone call check ins between office visits

Checklist Throughout Tapering Phases

Before Taper

- + Identify appropriate candidates
 - Resolution of pain, No meaningful improvement in pain/function, Adverse effects, Risk of harm outweighs potential benefits, Aberrant behavior
- + Engage patients in discussion of opioid benefit/risk and tapering
- + Assess readiness to taper
 - + If not ready, re-visit periodically
 - + Assess for substance abuse disorder
 - + Provide naloxone prescription
- Implement pharmacologic and non-pharmacologic strategies to manage pain/function and establish behavioral support
- + Obtain patient buy-in and share decision making





- + Agree upon which opioid to taper first, duration of taper and contingency plan to manage pain and/or withdrawal while tapering
- + Set date to initiate taper and approximate completion date
- Confirm patient has Naloxone at home

Initiation of Opioid Taper

- + Opioid <u>calculations</u> and conversion steps
 - + Total daily dose of current opioid: _____ mg
 - + Convert to Morphine Equivalent Daily Dose (MEDD): _____ mg
 - + MEDD = Total daily dose of current opioid x Conversion factor

Opioid	Conversion Factor		
Codeine	0.15		
Hydrocodone	1		
Hydromorphone	4		
Morphine	1		
Oxycodone	1.5		
Oxymorphone	3		
Tapentadol	0.4		
Tramadol	0.1		

- + If rotating opioid/formulation to use for taper
 - Calculate new opioid total daily dose: _____ mg
 - + Develop new prescription
 - + Consider decreasing dose of new opioid prescription due to <u>incomplete</u> <u>cross-tolerance</u>
- + Calculate taper dose
 - + Calculate 5% of tapering opioid dose: _____ mg
 - + Calculate 10% of tapering opioid dose: _____ mg
- + Individualize taper
 - + Slow taper:
 - + Decrease total daily MEDD by 5–10% every 2-4 weeks, as tolerated
 - + Patient Candidates:
 - Most patients (unless the need to taper quickly due to imminent safety risk)
 - + Preferred for long-acting opioids





- + Rapid taper:
 - + Decrease total daily MEDD by 5-15% per week, as tolerated
 - + Patient Candidates:
 - + Imminent safety concern (e.g. recent overdose, respiratory depression)
 - + Preferred for shorter-acting opioids
 - + Buprenorphine (Micro)induction
 - Introduce small doses of buprenorphine (0.25-2mg/day) to existing full opioid agonist regimen. Gradually increase buprenorphine dose and frequency until therapeutic dose is reached (16-24mg/day), then discontinue (or quickly taper) full opioid agonists. For optimal analgesic effect, split total daily buprenorphine dose into BID-TID dosing.
 - + Patient Candidates:
 - + OUD, Prior failed tapering attempt, Opioid-induced hyperalgesia, Fearful of withdrawal during taper
- + Taper involving a transdermal fentanyl patch
 - + Transition to long-acting oral opiate, then initiate taper
 - + Ex: transdermal fentanyl patch q3d → oral morphine ER q12h
 - + Remove fentanyl patch → wait 12 hrs → Take ≤ 50% of new calculated morphine dose → wait 12 hrs (total 24 hrs since patch removed) → Take 100% of new calculated morphine dose
 - During this transition, consider providing a 2 3-day supply of IR oxycodone prn breakthrough pain
- + Educate patient how to manage withdrawal symptoms
 - + Teach patient how to use SOWS or COWS
 - + Consider prescribing PRN medications for symptom relief

During Opioid Taper

- + Commit your support
 - Duration and Frequency
 - + Schedule increased office visits (every 1-4 weeks)
 - + Increase time spent with patient at office visits
 - + Phone/email check in weekly
 - + Evaluate patient at each dose reduction:
 - Review patient's goals, reinforce benefits of tapering, assess risks/harms of tapering
- + Individualize taper based on response and tolerance
 - + Evaluate pain, function and withdrawal symptoms periodically
 - + Treat pain/function with non-opioids
 - + Treat withdrawal symptoms as needed
 - + If intolerable, slow or pause taper. Do NOT increase dose.
 - + Once lowest effective dose reached, extend interval between doses





+ Stop opioids if taken less frequently than once a day

Withdrawal Symptoms and Management

	Clonidine* 0.1mg PO QID
Autonomic symptoms (sweating,	Gabapentin 100-300mg PO BID-TID
myoclonus, tachycardia)	Tizanidine 4mg PO TID
	Lofexidine 0.1mg 2 tabs PO TID
Anxiety, dysphoria, lacrimation,	Hydroxyzine 25-50mg PO TID prn
rhinorrhea	Diphenhydramine 25mg PO q6hr prn
Myalgias	Naproxen* 220mg PO BID QID prn
	APAP 650mg PO q6h prn
Mydigids	Topicals (menthol/methylsalicylate cream, lidocaine
	cream/ointment)
Sleep disturbance Trazodone 25-300mg PO qhs	
	Prochlorperazine 5-10mg PO q6hr prn
	Promethazine 25mg PO or PR q6h prn
Nausea/Vomiting	Ondansetron* 4mg PO q6h prn
	Haloperidol 0.5-1mg PO q12hr prn
	Metoclopramide 10mg PO q4-6hr prn
Abdominal Crampina	Dicyclomine 20mg PO q6-8hr
Abdominal Cramping	Hyoscyamine 0.125mg PO QID prn
Diarrhea Loperamide* 4mg PO x 1, then 2mg with each loose stoch 16mg/day)	

^{*}Consider providing initial prescription when initiating opioid taper





Opioid Taper

Template

Current Dose:	_
Target Dose:	
Timeline to Reach Taper "Target Dose":	

	Date	# weeks	Dose 1	Dose 2	Dose 3	Total Daily Dose	Total MME
0							
1							
2							
3							
4							
5							
6							
7							
8							
9							
10					_		
11							
12							

Example Taper Using Oxycodone IR

Week	Dose 1	Dose 2	Dose 3	Total Daily Dose	Total MME
0	40mg	40mg	40mg	120mg	180mg
1-2	40mg	35mg	40mg	115mg	172.5mg
3-4	40mg	35mg	35mg	110mg	165mg
5-6	35mg	35mg	35mg	105mg	157.5mg
7-8	35mg	30mg	35mg	100mg	150mg
9-10	35mg	30mg	30mg	95mg	142.5mg
11-12	30mg	30mg	30mg	90mg	135mg

Other examples: <u>Example 1</u>, <u>Example 2</u>, <u>Example 3</u>

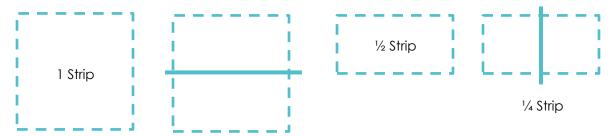




Transition to Buprenorphine and Microinduction:

- + General Concept²
 - + Precipitated withdrawal during buprenorphine induction is a common concern, especially if preceded by recent exposure to full opioid agonists. Therefore, traditional recommendations are to initiate buprenorphine once the patient is already showing signs of withdrawal.
 - + To facilitate the transition from full opioid agonists to buprenorphine, consider introducing buprenorphine in a microinduction approach.
 - + By utilizing buprenorphine's dose-dependent effects of mu-opioid receptor resensitization and upregulation, opioid tone is maintained while allowing a faster taper of full opioid agonists and posing minimal risk of precipitated withdrawal.
- + Buprenorphine Microinduction
 - + Introduce small doses of buprenorphine (0.25-2mg/day SL bup) and gradually increase the dose and frequency while co-administering full opioid agonists until a therapeutic dose of buprenorphine is reached.
 - + Once therapeutic doses of buprenorphine are achieved, the full opioid agonist therapy can be discontinued or more quickly tapered than traditionally tolerated (5-10 days).
- + Candidates
 - OUD, Previously failed attempts at opioid tapering, Suspected opioid-associated hyperalgesia, Needed quick taper (e.g. recent overdose), Patients fearful of withdrawing during taper
- + Buprenorphine Microinduction Patient/Clinical Tool

2 - 0.5mg Suboxone Film



The first strip will be cut into 2 pieces

Half of it is then cut into 2 pieces (1/4 of a strip).





Take Suboxone According to the Table Below

Day 1: Begin to cut down your opioid use

Day 2 - 6: Continue to cut down on opioid use and utilize comfort medications

Day 7: Aim to stop other opioid use by this day

		AM		PM	Date (write in)
1	⅓ film	63	-		
2	⅓ film	<u>[1]</u>	⅓ film	E]	
3	⅓ film		½ film		
4	1 film		1 film		
5	1 ½ film		1 ½ film		
6	2 films		2 films		
7	2 – 3 films		2 - 3 films		

Time Point	Standardized Buprenorphine Microinduction Recommendation				
	Bup-nal Recommendation	Full Opioid Agonist Recommendation			
Day 1 (Initial Appt)	0.5mg-0.125mg (¼ strip) SL daily	Continue current dose/use			
Day 2	0.5mg-0.125mg (1/4 strip) SL BID	Continue current dose/use			
Day 3	1mg-0.25mg (½ strip) SL BID	Continue current dose/use			
Day 4	2mg-0.5mg (1 strip) SL BID	Reduce dose/use by 25%			
Day 5	3mg-0.75mg (1 ½ strip) SL BID	Reduce dose/use by 25%			
Day 6	4mg-1mg (2 strips) SL BID	Reduce dose/use by 25%			
Day 7 (Follow-Up Appt)	6mg-1.5mg (3 strips) SL BID	Reduce dose/use by 50%			
Day 8	Based on craving/pain response: 16mg-4mg to 24mg-6mg once to four times daily	Reduce dose/use by 50%			
Days 9-11	Based on craving/pain response: 16mg-4mg to 24mg-6mg once to four times daily	Reduce dose/use by 50-75%			
Days 12-13	Based on craving/pain response: 16mg-4mg to 24mg-6mg once to four times daily	Reduce dose/use by 75%			





Time Point	Standardized Buprenorphine Microinduction Recommendation		
Day 14 (Follow-Up Appt)	Based on craving/pain response: 16mg-4mg to 24mg-6mg once to four times daily	STOP or continue as needed dosing for additional pain relief	
Days 15 – Beyond	Based on craving/pain response: 16mg-4mg to 24mg-6mg once to four times daily	STOP or continue as needed dosing for additional pain relief	

- + Other Tools:
 - + <u>Case Series</u> (2020)
 - + Bernese Method (2016)

Deprescribing

Consider Opioid Deprescribing When

- + Loss of efficacy
 - + Function > report
- + Evidence of harm
 - + Hyperalgesia
 - + Adverse effects falls, sedation, pneumonia, depression
- + Anticipate risk-benefit change
 - + Co-occurring health conditions (COPD, Kidney/Liver failure)
 - + PK/PD changes with age
- Medication combination is a clear danger
 - + High MME
 - + Concurrent sedatives
- + Substance use disorder

Deprescribing and Documentation

- + Standardize and incorporate a Benefit-Risk Framework Analysis
 - + Rationale for opioid tapering
 - + Opioid-related benefit (pain, function, QOL)
 - + Observed opioid-related harm
 - + No mention vs mentions harm (OUD, AE)
 - + Potential for opioid-related harm
 - + No mention vs mention of potential harm (underlying risk factor, concerning patient behavior, polypharmacy)





Co-prescribing Opioids and Benzodiazepines

- + Discuss the harms > benefits of using both opioids and benzos and the need to taper BOTH
- + Taper opioids to goal dose first, then taper off benzos
- + Use the Generic Deprescribing Logic Model (below) or other validated tool

Generic Deprescribing Logic Model³

Patients' Perspective Patients' perceptions, concerns about medication use and deprescribing Shared decision-making Cost (financial, other) People at Risk Deprescribe **Short Term Outcomes Short Term Outcomes** Does reducing the Elderly (over Evidence for benefit Quality of life dose/or stopping this age 65); of deprescribing Self-reported health drug (class) do more differentiate Evidence for safety of good than harm? robust vs frail? Reduced morbidity deprescribing Subquestion for which Reduced mortality Evidence for harm of we use existina deprescribing materials: What evidence is there for effectiveness or harm in continuina the drug/drug class? Balance benefits vs. harm model

Patient Important Outcomes (examples provided; content and relevance to be determined):

Critical: Fractures related to falls mortality, admission to long-term care

Important: Emergency room visits, falls

Possibly Important: Creatinine, blood pressure, orthostatic hypertension, blood sugar, general practitioner visits, number of medications taken, symptom control, reduced risk of drug interactions, increased chance of adherence, decreased cost, care giver stress, dizziness and confusion

Other Examples:

- Deprescribing.org
 - + Benzodiazepine deprescribing algorithm





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Opioid Tapering

The Risks and Benefits

On August 3rd, 2021 JAMA published, <u>Association of Dose Tapering with Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids</u>. The study reflects a trend also documented in a 2020 <u>BMJ article of the VA system</u> showing increased risk of overdose and mental health crisis in patients tapered or stopped on their opioids. These studies highlight the importance of tapering the right way, and with sensitivity to patient needs and priorities. In digesting these studies, one might think of a chapter of a favorite book, the Tao Te Ching. The chapter, as translated by Stephen Mitchell:

Chapter 13

"Success is as dangerous as failure. Hope is as hollow as fear.

What does it mean that success is as dangerous as failure? Whether you go up the ladder or down it, your position is shaky.
When you stand with your two feet on the ground, you will always keep your balance.

What does it mean that hope is as hollow as fear? Hope and fear are both phantoms that arise from thinking of the self. When we don't see the self as self, what do we have to fear?

See the world as yourself. Have faith in the way things are. Love the world as yourself; then you can care for all things."

The takeaways from this exploration between philosophy and medicine are as follows:

- 1. Going up or down the opioid ladder is a time of risk we should always be aware and conscious of these risks and how to mitigate them.
- 2. How do we keep our two feet on the ground? By rooting ourselves in the driving principles of nonmaleficence (do no harm) and beneficence (do good). When treatment with opioids is starting to cause harm or become unsafe, it is time to go down the ladder. When patients might benefit from opioids being decreased or stopped, it is time to go down the ladder. There are significant benefits to tapering patients off opioids, in terms of reduced pain, improved testosterone/estrogen levels, reduced overdose risk, reduced fall and infection risk, and improved function. Always evaluate and





emphasize the positive aspects when tapering, as patients are more driven by positive anticipated results than negative consequences or warnings.

- 3. Rushing patients on a taper, just as rushing down a ladder, incurs more risk. Whenever possible, taper slowly and respect how powerful the effects of opioids are on the brains' neurochemistry; in particular, the endogenous dopaminergic and endorphin systems that regulate mood and motivation. The findings of the JAMA and BMJ studies are not surprising when thinking of the underlying neurochemistry. Depression, suicidality and mental health crises become more common when the brain is transitioning from exogenous supply to endogenous production of the aforementioned neurotransmitters especially when changes are abrupt or drastic. Another finding, not highlighted by the authors of the JAMA study, but apparent in the data, is that slow tapering has low risk, pretty much the same as no tapering.
- 4. When going down a ladder, it's important to have someone holding the bottom. That means involving family and friends, and increasing your own monitoring and involvement with patients. Check in more frequently with patients you are tapering, increase your communication. Adapt the taper speed to assure success and provide patients as much self agency as possible. In a voluntary, non-emergent taper, patients can often guide you on how quickly they can and should come down. In the case that you identify your patient has opioid use disorder, abrupt discontinuation is much riskier than rotating the patient on to buprenorphine or methadone. It is recommended to change the treatment the patient is on, rather than throwing them off the ladder.
- 5. Knowing the science, your practice, and all the tools available to you will allow you, as the Tao says, to "care for all things". Patients with chronic pain, opioid use disorder, or both are challenging to many clinicians. But once you find your footing, establish good protocols, and learn to effectively communicate with these patients this becomes enjoyable and very meaningful medicine.

Unilateral or forced tapers, just for the sake of reaching a "safer" MME/day or meeting a metric, is an overwhelmingly dangerous practice. <u>Is Nonconsensual Tapering of High-Dose Opioid Therapy Justifiable?</u> reviews some of the dynamics surrounding legacy patients and the issues facing providers managing these relatively high-risk patients.

The Compass Opioid Stewardship Certificate Program offers additional tapering resources and Subject Matter Experts to discuss the studies mentioned, pearls and pitfalls of tapering, how to taper more effectively, how to mitigate risk in patients not tapering, and the benefits often seen in patients who taper.

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Developed in collaboration with Stader Opioid Consultants.



Tapering Examples:
Cross Taper to Buprenorphine | Short-Acting Opioid





Immediate Release Opioid to Buprenorphine

How to Cross Taper from Your Short-Acting Opioid to Buprenorphine

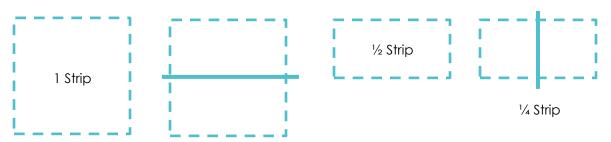
Are you taking one of the following opioid medications?

- + Norco (hydrocodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily
- + Morphine sulfate immediate release (MSIR) 15-30 mg: 1 tab by mouth 3-4x daily

If you are taking one of these medications, or something similar, you may be appropriate to switch to a safer, more effective pain management medication called **Suboxone**, or **buprenorphine** (+/- naloxone). You can be transitioned from your opioid to buprenorphine slowly over two weeks, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- 1. You will be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- Learn how to use the Suboxone medication. The table below shows a visual of how to use the suboxone 2 mg – 0.5 mg SL films each day during week 1 of the cross taper:

2 – 0.5mg Suboxone Film



The first strip will be cut into 2 pieces

Half of it is then cut into 2 pieces (1/4 of a strip).





		AM		PM	Date (write in)
1	1/4 film	63]	-		
2	⅓ film	E.]	⅓ film	[5]	
3	½ film		½ film	\blacksquare	
4	1 film		1 film		
5	1 ½ film		1 ½ film		
6	2 films		2 films		
7	2 – 3 films		2 – 3 films		

3. Plan out a reasonable **cross taper schedule**. The table below shows how to increase Suboxone and decrease the short-acting (i.e., immediate release [IR]) opioid over two weeks. The titration of the Suboxone during the second week and beyond will be very patient-dependent, and your provider will work closely with you to find the best regimen.

Time Point	Buprenorphine Microinduction Recommendation			
	Suboxone Rec	Opioid IR Rec		
Day 1 (Initial Apt)	(1/4) film SL Daily	100% of usual dose 3-4x daily		
Day 2	(1/4) film SL 2x daily	Continue		
Day 3	(1/2) film SL 2x daily	Continue		
Day 4	1 film SL 2x daily	75% of usual dose 3-4x daily		
Day 5	1.5 film SL 2x daily	Continue		
Day 6	2* films SL 2x daily	Continue		
Day 7 (F/U Apt)	2-3* films SL 2x daily	50% of usual dose 3-4x daily		
Day 8	2-4* films SL 2-3x daily	Continue		
Day 9-11		25% of usual dose 3-4x daily		
Days 12-13	Based on craving/pain response: up to	25% of usual dose 2x daily		
Day 14 (F/U Apt)	16mg-4mg to 24mg-6mg/day split 3-4x daily	Stop or use needed dosing for		
Days 15-Beyond		additional pain relief		

^{*}Based on pain response; may not need to increase Suboxone dose any higher than 2 films per dose at this point, vs. increasing frequency to 3 or 4x daily. For best pain relief, 3 or 4x daily dosing is recommended. Rarely will a patient on these opioid doses need Suboxone doses of 3 or 4 films SL at a time.





Dosing Help

For oxycodone- or hydrocodone-containing IR 10 mg products 4x daily:

75% of the dose (7.5 mg) = 1.5×5 mg tabs 50% of the dose (5 mg) = 0.5×10 mg tab OR 1 x 5 mg tab 25% of the dose (2.5 mg) = 0.5×5 mg tab

For MSIR 30 mg 4x daily:

75% of the dose (22.5 mg) = 1.5×15 mg tabs 50% of the dose (15 mg) = 0.5×30 mg tabs OR 1 x 15 mg tab 25% of the dose (7.5 mg) = 0.5×15 mg tab

For MSIR 15 mg 4x daily:

75% of the dose (aprx 10 mg) = 5 mL of the 10 mg/5 mL solution 50% of the dose = 0.5×15 mg tab 25% of the dose = (aprx 5 mg) = 2.5 mL of the 10 mg/5 mL solution

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Tapering Examples:
Cross Taper to Buprenorphine | Long-Acting Opioid





Fentanyl 50 mcg TD + IR Opioid to Buprenorphine

How to Cross Taper from Your Fentanyl 50 mcg Transdermal Patch +/- Short-Acting Opioid to **Buprenorphine**

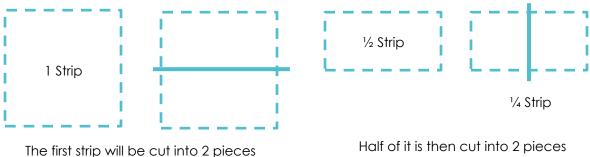
Are you taking Fentanyl 50 mcg transdermal every 72 hours plus one of the following opioid medications?

- + Norco (hydrocodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily

If you are using fentanyl patches and taking one of these medications, or something similar, you may be appropriate to switch to a safer, more effective pain management medication called **Suboxone**, or **buprenorphine** (+/- naloxone). You can be transitioned from your opioid to buprenorphine slowly over two weeks, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- You will be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- Learn how to use the Suboxone medication. The table below shows a visual of how to use the suboxone 2 mg – 0.5 mg SL films each day during week 1 of the cross taper:

2 – 0.5mg Suboxone Film



(1/4 of a strip).





		AM		PM	Date (write in)
1	⅓ film	61	-		
2	⅓ film	<u> </u>	⅓ film	6	
3	½ film		½ film		
4	1 film		1 film		
5	1 ½ film		1 ½ film		
6	2 films		2 films		
7	2 – 3 films		2 -3	films	

3. Plan out a reasonable **cross taper schedule**. The table below shows how to increase Suboxone and decrease the fentanyl transdermal over the first week, followed by decreasing the short-acting oral opioid over the second week. For representation purposes, the table will assume the patient is taking a concomitant oral opioid at 10 mg (+/- APAP) per dose 3-4x daily. The titration of the Suboxone during the second week and beyond will be very patient-dependent, and your provider will work closely with you to find the best regimen.

Time Point	Bupre	norphine Microinduction Recommendation
	Suboxone Rec	Fentanyl TD + Oral IR Opioid Rec
Day 1 (Initial Ap)	(1/4 film) SL daily	Place new fentanyl 50 mcg patch;
		Continue oral IR opioid 10 mg tab: 1 tab 3-4x daily
Day 2	(1/4 film) SL 2x daily	Continue
Day 3	(1/2 film) SL 2x daily	Continue
Day 4	1 film SL 2x daily	Remove fentanyl 50 mcg patch – place new fentanyl 25
		mcg patch;
		Continue oral IR opioid 10 mg tab: 1 tab 3-4x daily
Day 5	1.5 film SL 2x daily	Continue
Day 6	2 films* SL 2x daily	Continue
Day 7 (F/up apt)	2-3 films* SL 2x daily	Remove fentanyl 25 mcg patch – stop use;
		Continue oral IR opioid 10 mg: 1 tab 3-4x daily
Day 8	2-4 films* SL 2-3x daily	Reduce to IR opioid 5 mg tab**: 1.5 tabs 3-4x daily
Days 9-11	Based on craving/pain	Reduce to IR opioid 5 mg tab: 1 tab 3-4x daily
Days 12-13	response: up to 16mg-	Reduce to IR opioid 5 mg tab: 0.5 tab 3-4x daily
Day 14 (F/up apt)	4mg to 24mg-6mg/day	STOP oral IR opioid or continue as needed dosing for
Days 15 – beyond	split 3-4x daily	additional pain relief

^{*}Based on pain response; may not need to increase Suboxone dose any higher than 2 films per dose at this point, vs. increasing frequency to 3 or 4x daily. For best pain relief, 3 or 4x daily dosing is recommended. Some patients on these opioid doses may need Suboxone doses of 3 or 4 films SL at a time, though your provider will likely change the Suboxone film strength if higher doses are needed.

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^{**}Take careful note of IR opioid tablet strength 10 mg vs 5 mg.





Oxycontin 20 mg + IR Opioid to Buprenorphine

How to Cross Taper from Your Oxycontin 20 mg Tablets +/- Short-Acting Opioid to Buprenorphine

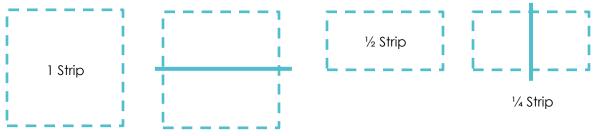
Are you taking Oxycontin 20 mg tablets by mouth twice daily, plus one of the following opioid medications?

- + Norco (hydrocodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily

If you are using Oxycontin and taking one of these medications, or something similar, you may be appropriate to switch to a safer, more effective pain management medication called **Suboxone**, or **buprenorphine** (+/-naloxone). You can be transitioned from your opioid to buprenorphine slowly over two weeks, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- 1. You will be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- 2. Learn how to use the Suboxone medication. The table below shows a visual of how to use the suboxone 2 mg 0.5 mg SL films each day during week 1 of the cross taper:

2 – 0.5mg Suboxone Film



The first strip will be cut into 2 pieces

Half of it is then cut into 2 pieces (1/4 of a strip).





		AM		PM	Date (write in)
1	¼ film	61	-		
2	¼ film	61]	¼ film	[6]	
3	½ film		½ film		
4	1 film		1 film		
5	1 ½ film		1 ½ film		
6	2 films		2 films		
7	2 - 3 films		2 - 3 films		

3. Plan out a reasonable **cross taper schedule**. The table below shows how to increase Suboxone and decrease the Oxycontin over the first week, followed by decreasing the short-acting (ie immediate release [IR]) opioid over the second week. For representation purposes, the table will assume the patient is taking a concomitant oral opioid IR at 10 mg (+/- APAP) per dose 3-4x daily. The titration of the Suboxone during the second week and beyond will be very patient-dependent, and your provider will work closely with you to find the best regimen.

Time Point	Buprenorphine Microinduction Recommendation		
	Suboxone Rec	Oxycontin + Opioid IR Rec	
Day 1 (Initial Ap)	(1/4 film) SL daily	Oxycontin 20 mg 2x daily;	
		Continue opioid IR 10 mg tab: 1 tab 3-4x daily	
Day 2	(1/4 film) SL 2x daily	Continue	
Day 3	(1/2 film) SL 2x daily	Continue	
Day 4	1 film SL 2x daily	Oxycontin 20 mg 1x daily;	
		Continue opioid IR 10 mg tab: 1 tab 3-4x daily	
Day 5	1.5 film SL 2x daily	Continue	
Day 6	2 films* SL 2x daily	Continue	
Day 7 (F/up apt)	2 -3 films* SL 2x daily	Stop use of Oxycontin;	
		Continue opioid IR 10 mg tab: 1 tab 3-4x daily	
Day 8	2-4 films* SL 2-3x daily	Reduce to opioid IR 5 mg tab**: 1.5 tabs 3-4x daily	
Days 9-11	Based on craving/pain	Reduce to opioid IR 5 mg tab: 1 tab 3-4x daily	
Days 12-13	response: up to 16mg-	Reduce to opioid IR 5 mg tab: 0.5 tab 3-4x daily	
Day 14 (F/up apt)	4mg to 24mg-6mg/day	STOP oral opioid or continue as needed dosing for additional	
Days 15 – beyond	split 3-4x daily	pain relief	

^{*}Based on pain response; may not need to increase Suboxone dose any higher than 2 films per dose at this point, vs. increasing frequency to 3 or 4x daily. For best pain relief, 3 or 4x daily dosing is recommended. Some (though rarely) patients on these opioid doses may need Suboxone doses of 3 or 4 films SL at a time, though your provider will likely change the Suboxone film strength if higher doses are needed.

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^{**}Take careful note of IR opioid tablet strength 10 mg vs 5 mg.





MS Contin 30 mg + IR Opioid to Buprenorphine

How to Cross Taper from Your MS Contin 30 mg Tablets +/- Short-Acting Opioid to Buprenorphine

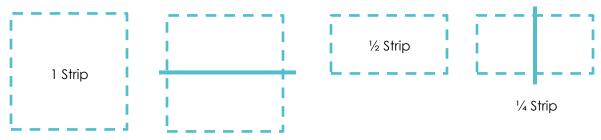
Are you taking MS Contin 30 mg tablets by mouth twice daily, plus one of the following opioid medications?

- + Norco (hydrocodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily

If you are using MS Contin and taking one of these medications, or something similar, you may be appropriate to switch to a safer, more effective pain management medication called **Suboxone**, or **buprenorphine** (+/- naloxone). You can be transitioned from your opioid to buprenorphine slowly over two weeks, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- 1. You will be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- 2. Learn how to use the Suboxone medication. The table below shows a visual of how to use the suboxone 2 mg 0.5 mg SL films each day during week 1 of the cross taper:

2 - 0.5mg Suboxone Film



The first strip will be cut into 2 pieces

Half of it is then cut into 2 pieces (1/4 of a strip).





		AM		PM	Date (write in)
1	¼ film	61	-		
2	¼ film	61]	¼ film	[6]	
3	½ film		½ film		
4	1 film		1 film		
5	1 ½ film		1 ½ film		
6	2 films		2 films		
7	2 - 3 films		2 - 3 films		

3. Plan out a reasonable **cross taper schedule**. The table below shows how to increase Suboxone and decrease the MS Contin over the first week, followed by decreasing the short-acting (ie immediate release [IR]) opioid over the second week. For representation purposes, the table will assume the patient is taking a concomitant oral opioid IR at 10 mg (+/- APAP) per dose 3-4x daily. The titration of the Suboxone during the second week and beyond will be very patient-dependent, and your provider will work closely with you to find the best regimen.

Time Point	Buprenorphine Microinduction Recommendation			
	Suboxone Rec	MS Contin + Opioid IR Rec		
Day 1 (Initial Ap)	(1/4 film) SL daily	MS Contin 30 mg 2x daily; Continue opioid IR 10 mg tab: 1 tab 3-4x daily		
Day 2	(1/4 film) SL 2x daily	Continue		
Day 3	(1/2 film) SL 2x daily	Continue		
Day 4	1 film SL 2x daily	MS Contin 30 mg 1x daily; Continue opioid IR 10 mg tab: 1 tab 3-4x daily		
Day 5	1.5 film SL 2x daily	Continue		
Day 6	2 films* SL 2x daily	Continue		
Day 7 (F/up apt)	2 -3 films* SL 2x daily	Stop use of MS Contin; Continue opioid IR 10 mg tab: 1 tab 3-4x daily		
Day 8	2-4 films* SL 2-3x daily	Reduce to opioid IR 5 mg tab**: 1.5 tabs 3-4x daily		
Days 9-11	Based on craving/pain response: up to 16mg-4mg to 24mg-6mg/day split 3-4x daily	Reduce to opioid IR 5 mg tab: 1 tab 3-4x daily		
Days 12-13		Reduce to opioid IR 5 mg tab: 0.5 tab 3-4x daily		
Day 14 (F/up apt)		STOP oral opioid or continue as needed dosing for		
Days 15 – beyond		additional pain relief		

^{*}Based on pain response; may not need to increase Suboxone dose any higher than 2 films per dose at this point, vs. increasing frequency to 3 or 4x daily. For best pain relief, 3 or 4x daily dosing is recommended. Rarely will a patient on these opioid doses need Suboxone doses of 3 or 4 films SL at a time.

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^{**}Take careful note of IR opioid tablet strength 10 mg vs 5 mg.



Tapering Examples:
Tapering Off Opioid | Short-Acting Opioid





Morphine Sulfate IR

Taper

How to Taper Your Immediate-Release Morphine 30 mg Medication

Are you taking the following opioid medication?

+ Morphine sulfate immediate release (MSIR) 30 mg by mouth 3-4x daily

If you are taking this medication, or something similar, you may be appropriate to taper to a safer dosage or off altogether. You can be tapered down or off your morphine slowly, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- 1. You will be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- 2. Talk to your provider about other nonopioid medications and nonpharmacologic treatments that can help augment pain and mitigate withdrawal.
- Use a chart, calendar, and/or medication box to help keep you on track with the correct dosage each week.
- 4. Plan out a reasonable **taper schedule**. The table below shows how to decrease MSIR over a 1+ year period. This schedule can be accelerated based on individual response and conversations with your doctor. The goal is to get you to the finish line safely, not how quickly you get there!

Week	Dose 1	Dose 2	Dose 3	Dose 4	Total MME
0	30 mg	30 mg	30 mg	30 mg	120
1-4	30 mg	22.5 mg	22.5 mg	30 mg	105
5-8	22.5 mg	22.5 mg	22.5 mg	22.5 mg	90
9-12	22.5 mg	15 mg	15 mg	22.5 mg	75
15-16	15 mg	15 mg	15 mg	15 mg	60
17-20	10 mg	10 mg	10 mg	15 mg	45
21-24	7.5 mg	7.5 mg	7.5 mg	7.5 mg	30*
25-28	7.5 mg	5 mg	7.5 mg	5 mg	27.5
29-32	7.5 mg	5 mg	5 mg	7.5 mg	25
33-36	5 mg	5 mg	5 mg	7.5 g	22.5
37-40	5 mg	5 mg	5 mg	5 mg	20
41-44	5 mg	2.5 mg	5 mg	5 mg	17.5
45-48	5 mg	2.5 mg	2.5 mg	5 mg	15
49-52	2.5 mg	2.5 mg	2.5 mg	5 mg	12.5
53-56	2.5 mg	2.5 mg	2.5 mg	2.5 mg	10
57-60	2.5 mg	2.5 mg		2.5 mg	7.5
61-62	2.5 mg		2.5 mg		5

^{*}Taper slows once reaching ~20% of total starting dose.





Dosing Help

22.5 mg dose = 1.5 of the 15 mg tabs 10 mg dose = 5 mL of the 10 mg/5 mL solution 7.5 mg dose = 0.5 of the 15 mg tabs 5 mg dose = 2.5 mL of the 10 mg/5 mL solution 2.5 mg dose = 1.25 mL of the 10 mg/5 mL solution

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Oxycodone IR

Taper

How to Taper Your Immediate-Release Oxycodone Medication

Are you taking the following opioid medication?

- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1-2 tab(s) by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1-2 tab(s) by mouth 3-4x daily

If you are taking one of these medications, or something similar, you may be appropriate to taper to a safer dosage or off altogether. You can be tapered down or off your oxycodone slowly, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- You will be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use
 of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from
 taking too many opioids. This is a key safety measure.
- 2. Talk to your provider about other nonopioid medications and nonpharmacologic treatments that can help augment pain and mitigate withdrawal.
- 3. Use a chart, calendar, and/or medication box to help keep you on track with the correct dosage each week.
- 4. Plan out a reasonable **taper schedule**. The table below shows how to decrease your IR oxycodone product over a 1+ year period. This schedule can be accelerated based on individual response and conversations with your doctor. The goal is to get you to the finish line safely, not how quickly you get there!

	Oxycodone IR Product Taper Recommendation						
Week	Dose 1	Dose 2	Dose 3	Dose 4	Total MME		
0	20 mg	20 mg	20 mg	20 mg	120		
1-4	20 mg	15 mg	15 mg	20 mg	105		
5-8	15 mg	15 mg	15 mg	15 mg	90		
9-12	15 mg	10 mg	10 mg	15 mg	75		
15-16	10 mg	10 mg	10 mg	10 mg	60		
17-20	7.5 mg	7.5 mg	7.5 mg	7.5 mg	45		
21-24	5 mg	5 mg	5 mg	5 mg	30*		
25-30	5 mg	2.5 mg	5 mg	5 mg	26.25		
31-36	5 mg	2.5 mg	2.5 mg	5 mg	22.5		
37-42	2.5 mg	2.5 mg	2.5 mg	5 mg	18.75		
43-48	2.5 mg	2.5 mg	2.5 mg	2.5 mg	15		
49-54	2.5 mg	2.5	mg 2.5 mg		11.25		
54-60	2.5	mg	2.	7.5			
61-62 2.5 mg					3.75		

^{*}Taper slows once reaching ~20% of total starting dose.





Dosing Help

20 mg dose = 2 of the 10 mg tabs 15 mg dose = 1.5 of the 10 mg tabs 7.5 mg dose = 1.5 of the 5 mg tabs 2.5 mg dose = 0.5 of the 5 mg tabs

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Tapering Examples:
Tapering Off Opioid | Long-Acting Opioid





Fentanyl 50 mcg Transdermal

Taper

How to Taper Your Fentanyl 50 mcg Transdermal +/- Short-Acting Opioid Agent

Are you taking Fentanyl 50 mcg transdermal every 72 hours plus one of the following opioid medications?

- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily

If you are using fentanyl patches and taking one of these medications, or something similar, you may be appropriate to taper off your fentanyl transdermal patch. You can be transitioned slowly off of your fentanyl, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- You will also be prescribed NALOXONE. You and your support member/s will be counseled on appropriate
 use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death
 from taking too many opioids. This is a key safety measure.
- 2. Talk to your provider about other nonopioid medications and nonpharmacologic treatments that can help augment pain and mitigate withdrawal.
- Use a chart, calendar, and/or medication box to help keep you on track with the correct oral opioid dosage each week.
- 4. Plan out a reasonable **taper schedule**. The table below shows how to decrease the fentanyl transdermal, along with increased immediate-release (IR) oxycodone product, whenever the fentanyl dose drops. For representation purposes, the table will assume the patient is taking a concomitant IR oxycodone product at 10 mg (+/- APAP) per dose 4x daily.
 - + Whenever the fentanyl TD dose is dropped, it takes at least 24-48 hours for the body to eliminate the old dose and equilibrate to the new dose; that is why it's important to follow the IR oxycodone dosing instructions carefully:
 - + Increase the IR 10 mg oxycodone tab to 1.5 tab/dose (ie 15 mg) at the 18 hour mark and then continue per the table.
 - + Once you are off the fentanyl TD completely, your IR oxycodone can also be further tapered if desired or necessary.
 - + This schedule can be slowed or accelerated based on individual response and conversations with your doctor. The goal is to get you to the finish line safely, not how quickly you get there!





Time Point	Fentanyl TD Taper Recommendation					MME
	Fentanyl TD Rec	IR Oxycodone Rec			180	
Day 1 (Initial	Decrease to Fentanyl 37 mcg/hr	10 mg	10 mg	15 mg	15 mg	180
Appointment)	TD Q 72 hrs					
Day 2	Continue	15 mg	15 mg	15 mg	15 mg	180
Day 7	Continue	15 mg	15 mg	10 mg	15 mg	172.5
Day 14	Continue	15 mg	10 mg	10 mg	15 mg	165
Day 21	Continue	10 mg	10 mg	10 mg	15 mg	157.5
Day 30 (Apt)	Decrease to Fentanyl 25 mcg/hr	10 mg	10 mg	15 mg	15 mg	150
	TD Q 72 hrs					
Day 31	Continue	15 mg	15 mg	15 mg	15 mg	150
Day 37	Continue	15 mg	15 mg	10 mg	15 mg	142.5
Day 44	Continue	15 mg	10 mg	10 mg	15 mg	135
Day 51	Continue	10 mg	10 mg	10 mg	15 mg	127.5
Day 60 (Apt)	Decrease to Fentanyl 12 mcg/hr	10 mg	10 mg	15 mg	15 mg	120
	TD Q 72 hrs					
Day 61	Continue	15 mg	15 mg	15 mg	15 mg	120
Day 75	Continue	15 mg	15 mg	10 mg	15 mg	112.5
Day 90 (Apt)	Continue	15 mg	10 mg	10 mg	15 mg	105
Day 105	Continue	10 mg	10 mg	10 mg	15 mg	97.5
Day 120 (Apt)	Fentanyl patch OFF	10 mg	10 mg	15 mg	15 mg	90
Day 121 +	Fentanyl patch OFF	15 mg	15 mg	15 mg	15 mg	90
		\	\	\downarrow	\	\downarrow
		10 mg	10 mg	10 mg	10 mg	60*

^{*}Length of time to taper to oxycodone IR 10 mg 4x daily (or lower) will vary by patient; target an additional 10% decrease of MME/day monthly until reach goal dose.

Dosing Help

 $15 \text{ mg dose} = 1.5 \times 10 \text{ mg tab}$

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OxyContin 20 mg Taper

How to Taper Your Oxycontin 20 mg +/- Short-Acting Opioid Agent

Are you taking OxyContin 20 mg tablets twice daily plus one of the following opioid medications?

- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily

If you are using OxyContin and taking one of these medications, or something similar, you may be appropriate to taper off your OxyContin. You can be transitioned slowly off of your OxyContin, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- 1. You will also be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- 2. Talk to your provider about other nonopioid medications and nonpharmacologic treatments that can help augment pain and mitigate withdrawal.
- 3. Use a chart, calendar, and/or medication box to help keep you on track with the correct dosage each week.
- 4. Plan out a reasonable **taper schedule**. The table below shows how decrease the OxyContin dose, along with increased immediate-release (IR) oxycodone, whenever the OxyContin dose drops. For representation purposes, the table will assume the patient is taking a concomitant IR oxycodone product at 10 mg (+/- APAP) per dose 4x daily.
 - + Whenever the OxyContin dose is dropped, it takes at least 24 hours for the body to eliminate the old dose and equilibrate to the new dose; that is why it's important to follow the IR oxycodone dosing instructions carefully:
 - + On Day 1 when the OxyContin dose drops, increase the IR 10 mg oxycodone tab to 1.5 tab/dose (ie 15 mg) at the 12-18 hour mark and then continue per the table.
 - + On Day 120 when the OxyContin dose drops in frequency, take the IR 5 mg oxycodone 1.5 tab/dose (ie 7.5 mg) for the first two concomitant doses, then increase to 10 mg/dose at the 18 hour mark and then continue per the table.
 - Once you are off the Oxycontin completely, your IR oxycodone can also be further tapered if desired or necessary.
 - + This schedule can be accelerated based on individual response and conversations with your doctor. The goal is to get you to the finish line safely, not how quickly you get there!





Time Point	Taper Recommendation					MME
	OxyContin Rec	IR Oxycodone Rec				120
Day 1 (Initial	to OxyContin 10 mg	10 mg	10 mg	15 mg	15 mg	120
Appointment)	2x daily					
Day 2	Continue	15 mg	15 mg	15 mg	15 mg	120
Day 7	Continue	10 mg	15 mg	15 mg	15 mg	112.5
Day 30 (Apt)	Continue	10 mg	15 mg	10 mg	15 mg	105
Day 44	Continue	10 mg	10 mg	10 mg	15 mg	97.5
Day 60 (Apt)	Continue	10 mg	10 mg	10 mg	10 mg	90
Day 74	Continue	7.5 mg	10 mg	10 mg	10 mg	86.25
Day 90 (Apt)	Continue	7.5 mg	10 mg	7.5 mg	10 mg	82.5
Day 104	Continue	7.5 mg	7.5 mg	7.5 mg	10 mg	78.75
Day 120 (Apt)	↓ to Oxycontin 10 mg 1x daily	7.5 mg	7.5 mg	10 mg	10 mg	75
Day 121	Continue	10 mg	10 mg	10 mg	10 mg	75
Day 134	Continue	7.5 mg	10 mg	10 mg	10 mg	71.25
Day 150 (Apt)	Continue	7.5 mg	7.5 mg	10 mg	10 mg	67.5
Day 164	Continue	7.5 mg	7.5 mg	7.5 mg	10 mg	63.75
Day 180 (Apt)	Stop Oxycontin	10 mg	10 mg	10 mg	10 mg	60

Dosing Help

15 mg dose = 1.5 x 10 mg tab 7.5 mg dose = 1.5 x 5 mg tab

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MS Contin 30 mg

Taper

How to Taper Your MS Contin 30 mg +/- Short-Acting Opioid Agent

Are you taking MS Contin 30 mg tablets twice daily plus one of the following opioid medications?

- + Percocet (oxycodone/acetaminophen) 10/325 mg tabs: 1 tab by mouth 3-4x daily
- + Oxycodone IR 10 mg tabs: 1 tab by mouth 3-4x daily

If you are using MS Contin and taking one of these medications, or something similar, you may be appropriate to taper off your MS Contin. You can be transitioned slowly off of your MS Contin, working with your provider to make sure your pain is controlled while avoiding significant withdrawal.

- 1. You will also be prescribed NALOXONE. You and your support member/s will be counseled on appropriate use of the naloxone prior to beginning the taper. Naloxone is a medication that reduces the risk of death from taking too many opioids. This is a key safety measure.
- 2. Talk to your provider about other nonopioid medications and nonpharmacologic treatments that can help augment pain and mitigate withdrawal.
- Use a chart, calendar, and/or medication box to help keep you on track with the correct opioid dosage each week.
- 4. Plan out a reasonable **taper schedule**. The table below shows how decrease the MS Contin dose, along with increased immediate-release (IR) oxycodone product, whenever the fentanyl dose drops. For representation purposes, the table will assume the patient is taking a concomitant IR oxycodone product at 10 mg (+/- APAP) per dose 4x daily.
 - + Whenever the MS Contin dose is dropped, it takes at least 24 hours for the body to eliminate the old dose and equilibrate to the new dose; that is why it's important to follow the IR opioid dosing instructions carefully:
 - + On Day 1 when the MS Contin dose drops, increase the IR 10 mg oxycodone tab to 1.5 tab/dose (i.e. 15 mg) at the 12-18 hour mark and then continue per the table.
 - + On Day 120 when the MS Contin dose drops in frequency, take the IR 5 mg oxycodone 1.5 tab/dose (i.e. 7.5 mg) for the first two concomitant doses, then increase to 10 mg/dose at the 18 hour mark and then continue per the table.
 - + Once you are off the MS Contin completely, your IR oxycodone can also be further tapered if desired or necessary.
 - + This schedule can be accelerated based on individual response and conversations with your doctor. The goal is to get you to the finish line safely, not how quickly you get there!





Time Point	MS Contin Taper Recommendation				MME	
	MS Contin Rec	IR Oxycodone Rec			120	
Day 1 (Initial Appointment)	↓ to MS Contin 15 mg 2x daily	10 mg	10 mg	15 mg	15 mg	120
Day 2	Continue	15 mg	15 mg	15 mg	15 mg	120
Day 7	Continue	15 mg	15 mg	10 mg	15 mg	112.5
Day 30 (Apt)	Continue	10 mg	15 mg	10 mg	15 mg	105
Day 44	Continue	10 mg	10 mg	10 mg	15 mg	97.5
Day 60 (Apt)	Continue	10 mg	10 mg	10 mg	10 mg	90
Day 74	Continue	7.5 mg	10 mg	10 mg	10 mg	86.25
Day 90 (Apt)	Continue	7.5 mg	10 mg	7.5 mg	10 mg	82.5
Day 104	Continue	7.5 mg	7.5 mg	7.5 mg	10 mg	78.75
Day 120 (Apt)	↓ to MS Contin 15 mg 1x daily	7.5 mg	7.5 mg	10 mg	10 mg	75
Day 121	Continue	10 mg	10 mg	10 mg	10 mg	75
Day 134	Continue	7.5 mg	10 mg	10 mg	10 mg	71.25
Day 150 (Apt)	Continue	7.5 mg	7.5 mg	10 mg	10 mg	67.5
Day 164	Continue	7.5 mg	7.5 mg	7.5 mg	10 mg	63.75
Day 180 (Apt)	Stop MS Contin	10 mg	10 mg	10 mg	10 mg	60

Dosing Help

15 mg dose = 1.5×10 mg tab 7.5 mg dose = 1.5×5 mg tab

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Naloxone + Overdose Prevention





Naloxone, Overdose Prevention + Harm Reduction

Naloxone, the lifesaving antidote to an opioid overdose, is recommended for patients at risk for opioid overdose by the CDC, SAMHSA, World Health Organization, American Medical Association, FDA and many other health authorities. Many states have passed laws mandating naloxone co-prescribing for highrisk patients or allow patients to fill naloxone without a prescription. The evidence behind naloxone as a tool to decrease overdose deaths is robust. For clinicians who prescribe opioids or care for patients with OUD the prescription of naloxone is rapidly becoming the standard of care.

The provision of a naloxone prescription can help facilitate a discussion between clinicians and patients about the risks of overdose, the importance of compliance with medical regiments and counseling on behaviors that may increase the risk of an overdose. Naloxone is an efficient, low barrier way for clinicians to demonstrate good opioid stewardship principles and improve patient safety. The following is recommended for patients on chronic opioid therapy.

Compass Opioid Stewardship Program Recommends the Following to Clinicians

- + Education on opioid overdose, use of naloxone, and safe storage and disposal of medication should be provided to all patients on chronic opioid therapy.
- + Naloxone should be prescribed to all patients on chronic opioid therapy.
- + In patients at high risk of overdose, clinicians should verify that a naloxone prescription is filled. This can easily be done by asking patients to bring their naloxone with them to their office visit.
- + Patients with children, pets or family members should be counseled on the risks of diversion and accidental overdose. Naloxone can improve safety for all members and guests of a household where opioids are present.

The tools below are meant to help educate clinicians and to be used to educate patients on the importance of naloxone.

Patient Education Materials

- + Preventing opioid overdose death: A guide to naloxone for patients on chronic opioid therapy
- + Narcan Training Video #1
- + Narcan Training Video #2
- Safe storage and disposal of prescription medications

Clinician Materials and Recommendations

+ <u>Brief analysis on naloxone for patients on chronic opioid therapy: Naloxone is effective, well-received and underutilized</u>

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Brief Analysis on Naloxone for Patients on Chronic Opioid Therapy.

Naloxone is Effective, Well-Received and Underutilized.

Don Stader MD FACEP; Nate Novotny Stader Opioid Consultants

Introduction

The life-saving opioid-reversal drug Naloxone is safe and efficacious for lay-person administration¹ and for patients taking opioids for chronic pain²⁻⁴. The CDC guideline for prescribing opioids for chronic pain advocates for co-prescribing Naloxone in a variety of cases (history of substance use disorder, high dose opioids, concomitant benzodiazepine prescription)⁵. This has resulted in a substantial increase in Naloxone dispensing rates nationally from 2012-2018; however, Naloxone dispensing rates to patients receiving high-dose opioid therapy remains low. In 2018, of the estimated 9 million patients who received high-dose opioid prescriptions only 406,203 of them were prescribed Naloxone—only 1 Naloxone prescription was given for every 69 high-dose opioid prescriptions⁶. Given that just over 1 in 3 overdose deaths involves a prescription opioid⁷, there is a significant treatment gap that exists in providing naloxone to patients at risk for overdose on chronic opioid therapy.

Naloxone is Effective for Patients in Chronic Pain

A common misconception held by clinicians is that naloxone is only for patients who misuse opioids or have opioid use disorders. One survey of physicians found that there was a general lack of consensus about which patients should be receiving Naloxone, as it is generally thought of as an antidote for heroin overdose⁸, but considered less in cases of prescription drug overdose. As previously stated, data from the CDC show as much as 36% of opioid-associated overdose deaths involve a prescription opioid as recently as 2017⁶. Other retrospective data from 2001-2007 indicate that over 60% of Americans who succumbed to opioid-involved overdoses were being treated for chronic pain. What's more, 49% of those people received a prescription for an opioid the same month they died⁹. In the same survey, several physicians felt that withholding the opioid prescription from at-risk patients was the superior option due to misconceptions that Naloxone gives patients a false sense of security and the belief that opioids are not effective for chronic pain⁸.

While opioid prescribing has significantly decreased since peaking in 2012^{10,11}, opioids remain a frequently utilized medication for chronic pain, and patients on chronic opioid therapy warrant protection with naloxone. The benefits of providing naloxone to patients is significant. One study found that when Naloxone was integrated as part of physicians' routine care for patients at risk of an opioid





overdose, it resulted in a 50% decrease in opioid-associated deaths in a single year³. In another multicenter primary care study patients who received a naloxone prescription had 63% fewer opioid related ED visits after 1 year compared with patients who did not receive naloxone¹⁷. It is not only feasible to dispense Naloxone and educate chronic pain patients (and their families) on how to use it, it is efficacious and beneficial¹².

Naloxone Prescription are Well-Received by Patients and Do Not Increase Medical Legal Risk

A prominent theme amongst clinicians beginning to prescribe naloxone is the fear of offending patients, essentially conveying the message that they cannot be trusted with medication. One study showed that clinicians were concerned about stigmatizing their patients and it resulting in lower satisfaction ratings⁸. These concerns are not without merit¹³, but virtually all studies on this topic show that dispensing Naloxone to at-risk patients and providing patient counseling is well received and a feasible strategy to destigmatize Naloxone and increasing access to it^{14,15}. Furthermore, one qualitative study of Naloxone consumers, including chronic pain patients, found that stigma from healthcare providers actually contributed to fear of requesting naloxone¹⁶. The risk of offending a patient is presented in a non judgemental manner and less consequential than the risk of sending a patient home on a high-dose opioid without Naloxone. Mitigating the risk of developing a negative rapport with patients can be achieved with adequate counseling and framing of the situation as 'high risk medication' rather than 'a high risk patient'.

There have been concerns in the past that naloxone prescribing may increase medical legal risk if a patient has an adverse reaction to naloxone, if it is given to a patient using heroin or naloxone is misused. These risks of naloxone co-prescribing have been studied and do not increase medical liability¹⁸. Conversely, it is the opinion of several experts that with published recommendations from the CDC, FDA, AMA and WHO (to name a few organizations), that failure to prescribe or discuss naloxone with patients at risk of overdose may increase medical legal risk.

Compass Opioid Stewardship Program Recommends the Following to Clinicians:

- + Overdose education, safe storage and safe disposal should be provided to all patients on chronic opioid therapy
- + Naloxone should be prescribed to all patients on chronic opioid therapy.
- + In patients at high risk of overdose, clinicians should verify that a prescription is filled. This can easily be done by asking patients to bring their naloxone with them to their office visit.
- + Patients with children, pets or family members should be counseled on the risks of diversion and accidental overdose. Naloxone can improve safety for all members and guests of a household where opioids are present.

Conclusion

Dispensing rates of Naloxone have increased, but still remain low in patients who receive high-dose opioids for chronic pain. Naloxone is not exclusively for people who use opioids illicitly. Either through prescription or take-home Naloxone programs, it is medically appropriate and recommended to supply patients on opioid-therapy for chronic pain with Naloxone due to the risk of overdose and death. Through proper counseling, Naloxone is well-received by chronic pain patients and their families and can be life saving in the event of an accidental overdose.





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Patient Education Materials





Preventing Opioid Overdose Death

A Guide to Naloxone for Patients with Chronic Pain

What is Chronic Pain?

Chronic pain is pain that lasts for more than 3 months. While *acute* pain can be caused by injuries, *chronic* pain is most often caused by changes in the nervous system, which remains sensitive to pain even after an injury has healed. Chronic pain is a common condition that affects approximately 50 million Americans, or 20% of the United States population. After careful consideration, your physician may prescribe an opioid. While these medications can help reduce your symptoms, they also carry serious risks — including the risk of an accidental, fatal overdose.

What Are Opioids?

Opioids include prescription pain medications like oxycodone (OxyContin, Percocet), hydrocodone (Vicodin, Lorcet/Lortab), fentanyl, hydromorphone (Dilaudid), and morphine (MS Contin). Buprenorphine (Suboxone) and methadone are used for the treatment of OUD. While some opioids can be injected and others are taken in pill form, they all act on the brain in the same way. Although opioids are good medications for some types of pain, their use may result in physical dependence and, in some cases, addiction.

What is an Opioid Overdose?

Most opioid overdoses are accidental. Because these medications interfere with breathing and brain functioning, people who overdose become sleepy or comatose, and breathing slows or eventually stops completely. When the brain and body can't get enough oxygen, injury and death follow. An overdose can happen minutes or hours after using opioids. Although it is impossible to predict who will overdose, taking opioids — even in low doses — can put a person at risk.

Can You Overdose if You're Taking Prescription Opioids for Chronic Pain?

Yes. Even people on stable doses of opioids are at risk of an overdose. Changes in how your lungs, kidneys, liver, and heart are working can dangerously elevate the amount of the drug in your blood. Infections can also alter how your body processes drugs. Changes in your other medications can also increase the level of opioids in your system. Drinking alcohol or taking benzodiazepines or other sedating medications further increases the risk of an overdose. As with other unlikely emergencies, it's best to be prepared. It is important to understand that most overdoses happen at home; 20% of these events lead to death simply because they aren't recognized as overdoses.





What Factors Increase the Risk of an Opioid Overdose?

- Taking any dose or formulation of opioid for any reason
- + Using opioid pain medications more often or at a higher dose than prescribed
- + Mixing opioids with benzodiazepines, alcohol, or illicit drugs
- Taking extended-release/long-acting preparations of opioids such as OxyContin, fentanyl patches, methadone, or MSContin
- + History of **overdose or emergency department visits** for opioid-related problems
- Using someone else's opioid pain medications
- + Using opioids **alone** (you are more likely to die if no one is there to help)
- + Serious **medical illnesses**, such as COPD or another lung disorder; kidney, liver, or heart disease; and HIV/AIDS
- + Using **after a period of abstinence** from opioids (for example, after a period of hospitalization, incarceration, or "detox")

What are the Signs of an Overdose?

People with opioid poisoning may look as if they're sleeping.

REMEMBER: IT IS NEVER SAFE TO LET A PERSON WHO MIGHT BE OVERDOSING "SLEEP IT OFF."

Signs of Overdose Include:

- + Unresponsive to shouting or shaking, or difficult to wake up
- + Absent or shallow breathing, sometimes with gurgling or deep snoring sounds
- + Pale or grayish skin
- + Blue lips or fingertips
- + A slow or undetectable pulse

What is Naloxone and Who Should Have It?

Naloxone, also known by the brand name Narcan, is the antidote for an opioid overdose. The drug temporarily reverses the effects of opioids on the brain. **Giving naloxone to someone who has overdosed can be lifesaving.** The antidote can restore a person's ability to breath and restore their level of consciousness. Naloxone is a safe, nonaddictive medication that has been used for decades to reverse overdose.

Anyone who is at risk of overdose, or knows someone who is, should carry naloxone — and this includes patients undergoing opioid therapy for chronic pain. If given to a patient with opioid dependence, naloxone can cause opioid withdrawal. Although these effects can be unpleasant and may cause agitation, naloxone will not cause harm.

Store naloxone at room temperature (never in a hot or freezing car), and **let your family and friends know where the medication is kept**. Replace your naloxone every 2 years.





Can My Friends and Family Members Get Naloxone, too?

Yes! Naloxone is available without a prescription at many pharmacies. Narcan nasal spray is the easiest naloxone formulation to use. **Medicaid, Medicare, and most private insurers cover the full cost of naloxone or charge only a small copay.** If you care about someone who is at risk of overdose, remind them that it is easy to get naloxone.

What Should I do if I Think Someone is Overdosing?

1. If you have naloxone, give it!

Try to wake the victim by shouting their name and shaking them. If someone is with you, they can call 911 while you prepare to administer naloxone. Naloxone is only effective for reversing opioid overdoses. However, if you are unsure of the substance(s) or illness involved, it's still wise to give naloxone. Many overdoses involve multiple drugs. Naloxone will not cause any harm in the case of a nonopioid overdose or other medical problem. If the first dose of naloxone doesn't bring back breathing and alertness within a few minutes, give a second dose. For videos on how to give naloxone, visit ERnaloxone.org.

2. Call 911

Call 911, even if the patient begins to wake up, and follow the operator's instructions. You may be instructed to perform CPR or rescue breathing if the victim remains unconscious.

3. Stay with the patient

The victim should be placed in the recovery position once they have begun breathing on their own. Even after waking up, some patients may not realize that they have overdosed. It is important to calmly explain what happened and stay with the victim until emergency medical help arrives. When revived, some victims may be agitated and suffering from withdrawal symptoms. It is important to know that naloxone wears off within 30 to 90 minutes, and victims can slip back into overdose. Always seek help in the emergency department, even if the patient appears to be feeling better.

For More Information About Naloxone and Opioid Overdose

If you would like more information about naloxone and opioid safety, please visit **Ernaloxone.org**. In addition, **OpiRescue** is a free smartphone application that can direct you to nearby pharmacies that stock naloxone; it can also guide you through a naloxone rescue in the event of an overdose.

For Help Finding Treatment

If you or someone you care about would like help for OUD, we encourage you to call the Substance Abuse and Mental Health Services Administration (SAMHSA) national helpline **1-800-662-HELP (4357)**. This free, confidential service provides 24-hour-a-day, 365-day-a-year support for individuals and families struggling with substance use disorders.





Signs of Overdosing



Breathing will be slow or gone





Lips and nails are blue



Person is not moving



Person may be choking



You can hear gurgling sounds or snoring



Can't be woken up



Skin feels cold and clammy



Pupils are tiny





Recovery Position Steps



1



2

Lay the victim on his back, placing the right hand next to the head.

Place the left hand on the right cheek.



3



4

Hold the left shoulder and left leg, and pull the victim's body toward you, rolling him onto his side.

Rest the victim as show and move the head backward slightly.

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Naloxone Training Videos

Naloxone Training Video 1: How to Use Narcan Nasal Spray

This training video provides instructions on how to use Narcan Nasal Spray to reverse an opioid overdose and save a life.

Link to video: https://www.youtube.com/watch?v=ObiTTBBXbKM&t=3s

Naloxone Training Video 2: Instructions for Administration of NARCAN® Nasal Spray 4mg

This training video highlights how to administer NARCAN® Nasal Spray in the event of an opioid overdose emergency.

Link to video: https://www.youtube.com/watch?v=tGdUFMrCRh4

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Safe Storage + Disposal of

Medications

Why is it Important to Securely Store My Prescription Medicines?

Every year, 2 million Americans end up in the hospital due to drug-related injuries, including medication errors, adverse drug reactions, allergic reactions, and overdoses. Safe and secure storage of your prescription medicine can make a big difference when it comes to avoiding accidental injuries.

How Can I Store My Prescription Medicine Safely?

- + First, get organized. Check to see if any of your prescription medicines are expired; old medication may no longer be safe or effective. Make sure your prescription medicine is stored in its original packaging with the safety lock tightened and secured.
- + Second, secure your medicine. The safe storage of controlled medications is especially important, as they can be dangerous if taken when not prescribed. Make sure your medications are in a locked location, unable to be accessed by others.

How Can I Dispose of My Prescription Medicine Safely?

You should dispose of any unused or expired prescription medicine as soon as possible. Timely disposal of prescription medicine can reduce the risk of others taking the medication accidentally or misusing the medication intentionally.

The best and most environmentally friendly way to dispose of your prescription medicine is through a drug take-back program. The U.S. Drug Enforcement Administration (DEA) periodically provides drug disposal sites in communities across the nation. The DEA also has permanent drug disposal sites in certain pharmacies or hospitals.

Get more information about drug disposal and a disposal site locator at takebackday.dea.gov.

What if There Are No Drug Disposal Sites in My Area?

If there are no disposal sites in your area, there are ways to safely dispose of your medication at home.

- + First, read the packaging label on your medication. Controlled substances and other medicines can be harmful if ingested by others, so the label might have special disposal instructions that you should follow.
- + If there are no special disposal instructions, see if your medication is on the FDA's "flush" list: https://www.fda.gov/media/109643/download If permitted, immediately flush your medicine down the toilet, and scratch out all personal information on the prescription bottle and recycle/throw away.
- + If your medication is NOT on the FDA flush list, you can safely dispose of it in your household trash by following these four steps:





- + Mix your medicine with an inedible substance like dirt, cat litter, or used coffee grounds.
- + Put the mixture in a container, such as a sealed plastic bag.
- + Throw the container in your household trash.
- + Scratch out all the personal information on the prescription label of your empty medication bottle to make it unreadable. Then dispose or recycle the empty medication bottle.

Adopted from www.cdc.gov/wtc/prescriptionsafety.html

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Opioid Use Disorder + Buprenorphine





Opioid Use Disorder

Diagnosis + Treatment

The medical profession now recognizes that OUD is a chronic, relapsing medical illness. Like patients with other chronic illnesses, patients diagnosed with OUD need evidence-based, ongoing care. The gold standard for treatment of OUD employs one of three FDA-approved medications: methadone, buprenorphine or naltrexone. Overwhelming evidence shows that patients receiving MAT have higher treatment retention rates, lower rates of both opioid-related and non opioid-related hospital admissions, and lower morbidity and mortality. While a patient receiving MAT with methadone or buprenorphine will be physiologically dependent, it is important to recognize that opioid dependence and opioid addiction are different entities; patients may be physically dependent on methadone or buprenorphine, but when maintained on these medications the behaviors and risks seen in addiction are avoided. Patients receiving MAT can lead productive, fulfilling lives while maintained on treatment. In stark contrast, abstinence-oriented treatments have relapse rates of greater than 80% and are ineffective for the treatment of OUD. It is crucial that clinicians refer their patients with OUD to evidence-based care that is effective and safe.

Compass Opioid Stewardship Program Recommends the Following to Clinicians

Screen All Patients for Substance Use Disorders

- + An empathic, non-stigmatizing, medically accurate approach to the patient interview is most effective in eliciting an accurate substance use history. The stigma surrounding OUD and other SUDs prevents many patients from providing a full history.
 - + While some patients present with a clear diagnosis of OUD, many patients with OUD will conceal their disease. Between 8% and 29% of hospitalized patients are estimated to have a non-alcohol SUD, but only 64% of these patients are identified as having SUD by their hospital treatment teams.³
 - + The principles and techniques of motivational interviewing can be powerful tools when engaging with patients with SUD. More information about motivational interviewing can be accessed at https://www.integration.samhsa.gov/clinical-practice/motivational-interviewing.
- + Providers should consider using the Screening, Brief Intervention, and Referral to Treatment (SBIRT) protocol to identify and address risk for substance misuse and SUD in all patients when prescribing opioids.





- + The screening component of an SBIRT protocol can be any validated screening instrument.
- + When OUD is suspected, use of an opioid-specific screening tool like the Rapid Opioid Dependence Screen (RODS) should be considered to further evaluate patients for OUD. The RODS can be administered and scored in two to three minutes.
- + Clinicians should document the results of a validated SUD screening instrument before prescribing any scheduled substance.
- + Laboratory data, medical records and the PDMP are not reliable screening instruments for OUD.
 - + Some opioids will not be detected on routine urine toxicology. Urine screening can detect metabolites of morphine and heroin within three days of last use and sometimes longer in chronic users. Not all opioids are detected on routine urine screening with immunoassays. Use of synthetic opioids (oxycodone, hydrocodone, hydromorphone, fentanyl, tramadol) may result in a false negative result; these substances require specific screening. False positive tests can be seen in patients ingesting poppy seeds or taking medications such as quinolones and rifampin.
 - + PDMP monitoring should be routinely performed, although many patients with OUD will not be flagged by the PDMP. Among non-medical users of opioids, over 70% acquire opioids from friends or family or illicit purchase.4

Clinicians Should Be Well Versed in Recognizing and Diagnosing OUD.

- + OUD and SUD more generally are poorly understood by many medical professionals. The gap in knowledge begins in medical school, where SUD is insufficiently addressed. Despite the fact that overdose is the leading cause of death in Americans under the age of 50, as of 2018 fewer than 10% of medical schools had a formal addiction curriculum.⁵
- + OUD as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), replaces "opioid addiction" and "opioid dependence" as a diagnostic entity. The DSM-5 defines <u>OUD using 11 criteria</u>; in order to be diagnosed with OUD, a patient must meet two of the 11 criteria within a 12-month period.
 - + Two to three criteria indicates mild OUD, 4-5 criteria indicates moderate OUD and 6-7 indicates severe OUD.
 - + Of note, physiologic dependence represents only two of the 11 criteria used to diagnose OUD. Patients receiving COT for chronic pain often exhibit pharmacological dependence but would not necessarily be considered to have OUD.
- + Many medical professionals fail to recognize the distinction between dependence and addiction. Addiction includes both physiologic dependence on a substance and the behaviors that surround the use of that substance. These behaviors include the 4 C's of addiction: loss of Control, use despite negative Consequences, Compulsive use and Cravings.





MAT with Buprenorphine, Methadone or Naltrexone Is the Evidence-Based Treatment for OUD. Clinicians Should Be Familiar with the Basic Principles of Addiction Treatment with Those Medications.

- + Most patients with OUD are not adequately treated. Estimates from 2019 data show less than 35% of all Americans living with OUD underwent treatment in the past year. 4 Additionally, there is no existing data on how many of those individuals are receiving one of the three FDA approved drugs for OUD. 2
- Like many medical conditions, OUD is a chronic, relapsing disease. Clinicians should provide patient education about OUD and its treatment in an accurate and compassionate manner.
 - + Patients with OUD benefit from learning that OUD is a chronic disease in which the brain is changed.
 - + Analogies with other chronic diseases like diabetes may help providers communicate the idea that OUD is a chronic disease in which biochemical derangements, behavior and medications contribute to disease management and recovery.
 - Patients and clinicians alike should be educated that relapse in patients with OUD receiving MAT is common, manageable and not a contraindication to future trials of treatment.
- + MAT using buprenorphine, methadone or naltrexone is the cornerstone of the treatment of OUD. A Cochrane review found the addition of counseling to medication conferred no added benefit; MAT plays a central, not adjunctive, role in the treatment of OUD.⁸
- + Clinicians should be familiar with the three medications approved by the FDA for the treatment of OUD (Table 6). Methadone is a full opioid agonist and buprenorphine is a partial agonist. Naltrexone, in contrast, is a full opioid antagonist.





Table 1 | Characteristics of Medication for Addiction Treatment (MAT)

Characteristics of Medication for Opioid – Addiction Treatment					
Characteristic	Methadone	Buprenorphine	Naltrexone		
Brand Names	Dolophine, Methadose	Subutex, Suboxone, Zubsolv	Depade, ReVita, Vivitorl		
Class	Agonist (fully activates opioid receptors)	Partial agonist (activates opioid receptors but produces a diminished response even with full occupancy)	Antagonist (blocks the opioid receptors and interferes with the rewarding and analgesic effects of opioids)		
Use and Effects	Taken once per day orally to reduce opioid cravings and withdrawal symptoms	Taken orally or sublingually (usually once a day) to relieve opioid cravings and withdrawal symptoms	Taken orally or by injection to diminish the reinforcing effects of opioids (potentially extinguishing the association between the conditioned stimuli and opioid use)		
Advantages	High strength and efficacy as long as oral dosing (which sloes brain uptake and reduces euphoria) is adhered to; excellent option for patients who have no response to other medications	Eligible to be prescribed by certified physicians, which eliminates the need to visit specialized treatment clinics and thus widens availability	Not addictive or sedating and does not result in physical dependance; a recently approved depot injection formulation, Vivitrol, eliminates need for daily dosing		
Disadvantages	Mostly available through approved outpatient treatment programs, which patients must visit daily	Subutex has measurable abuse liability; Suboxone diminishes this risk by including naloxone, an antagonist that induces withdrawal if the drug is injected	Poor patient compliance (but Vivitrol should improve compliance); initiation requires attaining prolonged (e.g., 7 day) abstinence, during which withdrawal, relapse and early dropout may occur		

Source: NEJM, 9





- + MAT for OUD can be maintained for years or be a lifelong drug, and buprenorphine or methadone for addiction treatment should not be prematurely tapered.
 - + Patients on appropriate therapeutic doses of methadone or buprenorphine are cognitively normal and function normally in society.
 - + MAT is not "substituting one addiction for another." While patients may continue to have a physiologic dependence on buprenorphine or methadone, they do not exhibit the behavioral hallmarks of addiction. MAT substitutes dependence for addiction and in so doing decreases morbidity and mortality while improving quality of life.

"Detox" and Other Abstinence-Oriented Therapies Have Shown to Be Ineffective for the Treatment Of OUD, and Clinicians Are Discouraged from Endorsing These Treatments for OUD.

- + "Detox" and abstinence-based therapies for the treatment of OUD have unacceptably high failure rates, with markedly elevated risks of relapse and overdose death.¹⁰
 - + The neurophysiology of opioid dependence is such that willpower is rarely sufficient to tolerate opioid withdrawal or override craving for opioids.
 - + Abstinence-oriented treatments have been shown to be not only ineffective for the treatment of OUD but also dangerous, as they increase the risk of overdose when patients relapse. Relapse rates are greater than 80% where treatment is abstinence based. 11,12
 - + A study of IV opioid users comparing detoxification versus buprenorphine treatment highlights the potential harms of abstinence and detoxification care versus MAT. In this cohort, 0% of patients who underwent abstinence-based therapy remained in treatment for over 90 days, and 20% died. In contrast, in the group of patients receiving buprenorphine, 75% remained in treatment at one year, and no patient died. 12
- + Clinicians should educate patients, families and caregivers on the high failure rates of "detox" and abstinence-oriented therapies and address any misconceptions and stigma surrounding MAT.
- + If abstinence is desired by the patient, it is best to achieve this over the course of months or years and through a slow, cautious tapering process.
 - + It is still unknown if discontinuation is a safe, appropriate goal as several studies show relapse rates consistently surpassing 50% at one month after discontinuation of buprenorphine maintenance therapy. 13-15
 - + The choice to taper and/or discontinue MAT should be a shared decision between the patient and an addiction medicine specialist.





Patients Who Are Receiving Methadone or Buprenorphine While Being Treated for Acute Pain or an Injury Should Be Maintained on Their MAT Regimens.

- + All patients receiving methadone or buprenorphine should be continued on their medication even in the setting of acute pain, chronic pain or planned surgical intervention.
 - + Continuing these medications improves pain control, reduces the use of additional opioid analgesia 16 and reduces the risk of relapse. 17
 - Discontinuation of MAT in these settings is strongly discouraged, as it may complicate clinical assessment, increase risk of relapse and increase discomfort during reinduction.
- + Clinicians should verify a patient's methodone or buprenorphine dose and ensure that the patient continues addiction treatment while receiving care for acute pain or an injury.
- + Providers should ensure that the MAT provider is aware of the injury and the treatment plan so that continuity of care is maintained.
- + All patients should be counseled that treatment may not alleviate all pain and that manageable pain can be a useful guide to assessment and recovery.

Patients receiving MAT that are injured or experiencing acute pain should be provided adequate analgesia with nonopioid medications and treatments and, if required, opioid agonists.

- + Multimodal nonopioid analgesia should be the first line of treatment for all patients, including those on MAT.
- + The use of MAT will often alter the management of pain. Patients should be counseled that treatment may not eliminate all pain and that manageable pain can be a useful guide to assessment and recovery.
- + Daily dosing of buprenorphine or methadone is generally inadequate for analgesia.
 - + The analgesic effects of both buprenorphine and methadone occur early in dosing and then wear off, so splitting doses provides superior analgesia. Splitting dosing of buprenorphine or methadone to three times a day can leverage the short-lived analgesia that follows dosing, though this change will only provide modestly improved analgesia.
 - + Though buprenorphine is a partial agonist, it does not block the analgesic effects of opioids 13.20 (The naloxone present in combination products [e.g., Suboxone] is added as a deterrent to IV use; it is not bioavailable with sublingual use.)
- + Psychosocial support can be offered to any patient with OUD, particularly those in pain.
 - + Pain is a biopsychosocial phenomenon, and the importance of addressing the cognitive and affective components of pain cannot be understated. Consultation with a





behavioral health clinician may help patients better manage pain, depression, and anxiety.

- + Opioid analgesics may be considered for patients on MAT when nonopioids fail to control pain. Consultation with an addiction medicine and/or pain medicine specialist is recommended.
 - + Patients on MAT may have greater sensitivity to pain and will have higher tolerance to opioids; they often require greater-than-typical doses of opioids to manage pain²¹
 - + The prevalence of opioid-induced hyperalgesia (OIH) is unknown but likely complicates pain management for some opioid-dependent patients.





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Buprenorphine Prescribing Protocol for Opioid Addiction:

Outpatient

Summary

Opioid addiction treatment as an outpatient medical provider, can be a very fulfilling aspect of practice and help you achieve excellent results for your patients with opioid use disorder (OUD). Medications for Opioid Use Disorder (MOUD), also known as Medications for Addiction Treatment (MAT) has strong validation and includes the medications naltrexone by depot injection, methadone delivered through an Opioid Treatment Program (OTP), and buprenorphine provided on an outpatient basis. There also is independent validation for addiction therapy and some, but less research support for mutual help programs such as Narcotic Anonymous. Although research does not (yet) show additional benefit to adding addiction counseling to MOUD, that is not to say that they are without value and may be due to methodological problems with previously conducted studies. The combination of MOUD and counseling is generally recommended by many in the field who, based on clinical experience, feel it may be the best means to establish early and durable recovery for those addicted to illicit and / or prescription opioids. The combination of medications and counseling is considered a "whole patient" approach. Addiction therapy focuses on recovery typically through cognitive behavioral therapy (CBT) and trigger management.

Mutual help programs like 12-step (Narcotics Anonymous [NA], Pills Anonymous, and Prescriptions Anonymous) are not facilitated by trained therapists but can be effective in supporting recovery. "12-Step Facilitation" (TSF) is the term used to indicate the professional component by which medical providers guide patients in the use of mutual help programs and is recommended. It is also recommended that providers who chose to use services of 12-step programs get to know their local programs, as many consider patients on MOUD as still actively using and there is stigma associated with that label that may interfere with a patient's medical treatment. Assuring that the mutual help program is supportive of the patient's treatment regimen and goals is essential.

This protocol makes the following assumptions:

- 1. Buprenorphine products will be used in your outpatient practice. While clinicians should also consider the use of methodone (via OTP referral) and naltrexone, these medications are not addressed here.
- 2. The use of mutual help programs and addiction therapy in combination with the use of buprenorphine. Since validation for mutual help and therapy has not been established, it is acceptable to not require it, although it may be deemed necessary based on the treatment system within which care is delivered or considered a requirement for the x-waiver. In regards to the X-waiver, if you are treating <30 patients via the NOI tract counseling requirement is waived. If you are treating >30 patients, you must have undergone further training (8-hour X-waiver course or addiction medicine certification) and have the ability to refer to addiction counseling. Apply for X-waiver and buprenorphine for OUD.
- 3. The induction onto buprenorphine described here takes place in person, in an office setting. Home induction and micro-induction are not addressed here although resources for these types of inductions are available via the Compass Opioid Stewardship Program.





The protocol outlines how the medical provider(s) - addiction therapy team can initiate and maintain the patient on buprenorphine based on literature-based evidence and clinical experience. It is only meant to be a guide for the patients in an outpatient treatment setting. It is not intended to be applicable to all patients, clinical settings, and clinical circumstances. It can be used as a starting point, and each clinical setting should develop its own specific protocol, making adjustments based on current regulatory and health system requirements, resources available and the experience of the clinicians. All care should be personalized to the patient, and this protocol is not designed to be applicable to any one specific patient. The medical team must also address co-occurring addictions, psychiatric comorbidities, and other co-occurring medical conditions in order to optimize the chances for sustained recovery.

Opioid Addiction Treatment Protocol Overview

- 1. Initial patient contact with the office
- 2. Patient initial evaluation with physician
- 3. Patient makes business arrangement for participation
- 4. Week 1 (after initial evaluation)
 - a. Buprenorphine induction in office "Day 1"
 - b. Buprenorphine stabilization office visit "Day 2"
 - c. Subsequent buprenorphine stabilization
 - d. Addiction therapy, mutual help program referral
 - e. Treatment and / or referral for co-occurring psychiatric or mood problems
- 5. Buprenorphine maintenance and addiction recovery after Week 1
 - a. Patient follow-up with buprenorphine prescriber Q 1-3 months depending on clinical status
- 6. Termination of buprenorphine therapy if indicated
 - a. Due to recurrent aberrancies or recurrent relapses
 - **b.** When patient ready to stop buprenorphine in sustained, stable recovery





Opioid Addiction Process Detail

- 1. Initial patient contact with the office
 - a. Welcome to the practice
 - b. Introduce the basic office and program operations
 - c. Invitation for an appointment with a physician if indicated
- 2. Patient initial medical evaluation with buprenorphine prescriber (pre-induction)
 - a. Addiction evaluation
 - + Establish presence of Opioid Use Disorder using DSM-5 criteria (Appendix A)
 - Obtain history, exam, corroboration, prescription database, body fluid drug testing
 - + Record in the problem list indicating "mild", "moderate", or "severe" OUD
 - + Identify use and relationship (salience) with other addiction-prone substances
 - + Screen initially with the screening portion of <u>Screening</u>, <u>Brief Intervention</u>, <u>and</u> <u>Referral to Treatment</u>: Do you now or have you ever used _____?
 - Consider table in Appendix B to catalog current use or history of other substances
 - The following screening are useful to establish or qualify diagnosis of other use disorders:
 - → Affirmative Tobacco → Fagerström Test
 - → Affirmative Alcohol → AUDIT
 - → Affirmative Cannabis → CUDIT-R
 - → Affirmative Other Drugs → DAST-10
 - Obtain history, exam, corroboration, prescription database, body fluid drug testing
 - + Establish presence of other Substance Use Disorder (SUD) using DSM-5 criteria
 - + Record in the problem list indicating "mild, moderate, or severe" for each
 - b. Establish if co-occurring psychiatric problems are present
 - + Consider the following screening tools:
 - + PHQ-2 For depressed and anxious mood
 - → PHQ-9 if affirmative for depressed mood
 - → GAD-7 if affirmative for anxiety
 - + Adverse Childhood Experience questionnaire (ACE) for trauma
 - + Other screeners when suggested by history or initial screeners
 - Post-Traumatic Stress Disorder: PTSD Check List (PCL-C)
 - + Bipolar Disease: Mood Disorder Questionnaire (MDQ)
 - + Attention Deficit Hyperactivity Disorder: Adult ADHD Self-Report Scale (ASRS)
 - + Psychosis: Psychosis Screener (PS)
 - + Insomnia: Sleep Condition Indicator (SCI)
 - + Suicidality: Patient Safety Screener (PSS-3)
 - Refer, if indicated, for diagnostic clarity and / or co-managing to psychiatry or addiction medicine
 - + Record in the problem list indicating "mild, moderate, or severe" for each
 - c. Establish presence or not of other co-occurring medical problems
 - + Obtain history, exam, corroboration
 - + Lab: CBC, CMP, HIV, Hep B, Hep C, testosterone (men), HCG (women), PPD
 - + Pain: Acute (up to 2 weeks), Subacute (2-12 weeks), Chronic (>12 weeks)
 - + <u>PEG-3</u> (Pain, Enjoyment, General Function)
 - + Respiratory:
 - + <u>STOP-BANG</u> for obstructive sleep apnea risk → sleep study if indicated
 - Pulmonary workup for established / suspected disease





- + Consider baseline nocturnal oximetry for all patients
- + Sign lab printout(s) for the chart and reference results in office visit note(s)
 - + Respond to abnormalities, including referral / coordination with PCP / specialists
 - + Note especially hepatic, respiratory, cognitive, psychomotor problems
- d. Establish lowest necessary level of care for the patient
 - Using the ASAM Patient Placement Criteria (Appendix C)
 - + Determine if outpatient treatment will meet the needs of the patient
- e. Establish baseline functional status (Appendix D)
- f. Estimate level of risk for return to opioid use: "Low" "Intermediate" "High"
 - + Record in problem list and office visit note under "Assessment"
- g. Determine personalized goals with the patient
 - + Addiction prone substance abstinence (excepting buprenorphine)
 - + + Tobacco abstinence: indicate
 - + Functional goals
 - + Record in the office visit note under "Plan"

Buprenorphine safe use <u>Risk Baseline Evaluation</u> (Appendix E)

- c. Identify personal / family risk factors and resiliencies
 - + Corroborate information with family, friends, medical records
 - + Identify and list past medication-related aberrancies
- d. Online prescription database (Prescription Drug Monitoring Program [PDMP]) review
 - + Sign printout(s) for chart, reference in office visit note, address results
- e. Definitive (Gas Chromatography / Mass Spectrometry [GC/MS] or Liquid Chromatography /Tandem Mass Spectrometry [LC/MS-MS]) body fluid drug testing (typically urine)
 - + Sign printout(s) for chart, reference in office visit note, address results
- f. Determine Level of Risk for safe use of buprenorphine: "Low" "Intermediate" "High"
 - + Consider frequency/intensity of prior episode(s) of opioid return to use
 - + Record in problem list and office visit note under "Assessment"
- g. Establish Urine Drug Testing (UDT) plan based on level of risk
 - + Initial frequency of routine and random evaluation
 - + Initial frequency of in-office screening: Point-of-care (POC) immunoassay
 - + Initial frequency of definitive testing: GC/MS or LC/MS-MS establish with a vendor
- h. Establish initial frequency of PDMP review based on level of risk
- i. Establish initial frequency of product (tablet, film) counts based on level of risk
- j. Initiate a tracking mechanism (e.g., flow sheet such as Appendix G) to record past and new aberrancies as they occur (if any)

4. Risk Mitigation (Appendix F) - strategies to limit risks going forward

- a. Informed consent regarding buprenorphine and other treatment approaches employed
- b. Review and have patient sign treatment agreement which outlines:
 - + Expected behavior
 - Prohibited behavior
 - + Consent for risk monitoring
 - + Potential responses to aberrancies
- c. Provide buprenorphine secure storage and safe disposal instructions
- d. Consider which buprenorphine product to select i.e., with or without naloxone
- e. Naloxone prescription and overdose rescue instructions to include family and support network.

5. Outline treatment plan with the patient

- a. Treatment goals:
 - + Addiction recovery goals
 - + Functional aoals
- b. Treatment schedule:





- Medical provider visit schedule
- + Addiction therapy referral therapist to establish schedule based on need
- + Recommend mutual help (12-step) (cf., Meeting locators: Appendix H)
- c. Monitoring outline:
 - + Behavioral, PDMP and body fluid drug testing (Appendix E)
- d. Buprenorphine use (document discussion in office visit notes)
 - + Traditional medication informed consent: Risks, Benefits, Alternatives
 - + Potential adverse reactions
 - + Buprenorphine induction procedure
 - + Proper buprenorphine use after induction

6. Pre-induction process

- a. Patient to be off all opioids
 - + At least 24 hours for most opioids except:
 - + Fentanyl at least 48 hours
 - + Methadone at least 72 hours after being tapered down to 30 mg or less
- b. Prescribe medications to ameliorate opioid withdrawal symptoms, considering these options:

Naproxen1 po q6h prn musculoskeletal pain OTC or#20 RF0Cyclobenzaprine10 mg po q6h prn back spasm#20 RF0Clonidine0.1 mg po q6h prn shakes / sweats#20 RF0Hyoscyamine0.125 mg SL q6h prn abdominal cramps#20 RF0Gabapentin300 mg 1 po qHS prn sleep#20 RF0

Avoid benzodiazepines, trazodone, Z drugs (Ambien, Lunesta)

- 7. Patient makes business arrangements for participation, schedules induction, obtains withdrawal meds
- 8. Buprenorphine initiation: Week 1
 - a. Buprenorphine induction in office: Day 1
 - + Patient is brought to and from office by a reliable attendant due to possible impairment
 - + Patient affirmed to be in significant withdrawal use COWS scale
 - + Review buprenorphine induction risks, benefits, alternatives
 - + Patient questions answered and patient agrees to move forward with induction
 - Patient's attendant obtains buprenorphine from pharmacy: 2 mg #40 RF0
 - + Combination buprenorphine with naloxone highly recommended
 - → Except if coming off methadone consider mono-agent buprenorphine
 - + Complete prior authorization as necessary
 - + Initiate buprenorphine induction: 2-4 mg SL depending on withdrawal severity
 - + Recheck patient in 1.5 hours or prn: VS, symptoms
 - + If still withdrawing (expected), give another 2 mg buprenorphine
 - + If bad headache, hypotension, N/V: hold buprenorphine and monitor
 - + Recheck patient in 1.0 hours or prn: VS, symptoms
 - + If still withdrawing (expected), give another 2 mg buprenorphine
 - + If bad headache, hypotension, N/V: hold buprenorphine and monitor
 - + Recheck patient in 1.0 hours (after lunch) or prn: VS, symptoms
 - + If still withdrawing and <8 mg buprenorphine already given, give 2mg buprenorphine
 - If bad headache, hypotension, N/V: hold buprenorphine and monitor
 - + Maximum dose of buprenorphine for day 1 Induction: 8 mg
 - + This should improve but not necessarily eliminate opioid withdrawal
 - → Have patient continue prn withdrawal meds already prescribed
 - + This should improve but not necessarily eliminate opioid craving





- → Have patient employ behavioral anti-craving measures
- b. Buprenorphine stabilization office visit: Day 2
 - + Patient takes total # mg buprenorphine taken on 1st day all at once on day 2 at home
 - + Patient seen in office 2 hours after taking buprenorphine at home for VS, clinical status
 - + If withdrawal / craving substantial, add buprenorphine in 2 mg increments g2h up to
 - + Maximum dose 16 mg day 2
- c. Buprenorphine stabilization: the rest of Week 1
 - + Phone or virtual contact to adjust buprenorphine dose
 - + Typical dose ranges 12 24 mg. Evidence that 16mg or greater has better treatment retention; rarely is 32 mg required
 - + Caution: Increased risk of diversion, and 32 mg dose is not FDA approved
 - + Office visits at least twice to address clinical status:
 - Addiction recovery
 - + Abstinence determined by report, PDMP, definitive body fluid drug test
 - + Addiction therapy, mutual help program(s) initiation (Appendix H)
 - + Buprenorphine proper and safe use (Appendix G)
 - + Buprenorphine efficacy / adverse events, if any
 - + Behavioral aberrancy inquiry
 - + On-line PDMP review
 - + Definitive body fluid (typically urine) drug test

9. Buprenorphine maintenance and addiction recovery: after week 1

- a. Typical follow-up medical office visit frequency:
 - Weekly for the first month
 - + Monthly thereafter
 - + Over time every 2-3 months only if:
 - + Confirmed abstinence
 - + Confirmed safe use and absence of aberrancies
 - + Craving is minimal and manageable
 - + Buprenorphine adverse reactions are absent or manageable
 - + Mood is stable and well managed:
 - → PHQ-2 For depressed and anxious mood
 - → PHQ-9 if affirmative for depressed mood
 - → GAD-7 if affirmative for anxiety
 - + No new major stressors are present
 - + Patient is actively involved and progressing in addiction therapy
 - + Patient is participating in mutual help program(s) as recommended
- b. Continue to address other medical problems
- c. Consider monitoring nocturnal oximetry, testosterone (men), pregnancy test (women)

10. If the patient returns to active opioid use

- a. Return to use is frequent and should not automatically prompt dismissal from the practice
- b. Make return to recovery a positive learning experience
- c. Address urgent medical concerns: overdose, infection, suicidality, HIV/hepatitis testing
- d. Identify and address trigger(s) that led to return to use
- e. Consider medication alternatives to buprenorphine: methadone, depot naltrexone
- f. Consider consultation/referral to specialty care
 - + Reassess level of care per ASAM PPC-2 criteria and plan accordingly
- g. Reinduction onto buprenorphine consider increased dosage
- h. Increase therapies
- i. Increase monitorina
- j. Adjustment treatment plan otherwise as indicated





11. Termination of buprenorphine therapy

- a. If due to identified diversion
 - Do not refill buprenorphine
 - + Withdrawal medications probably not needed
 - + Terminate from practice following standard guidelines for proper dismissal
- b. Prior to considering termination due to frequent aberrancies, recurrent return to use
 - + Consider undiagnosed or inadequately treated psychiatric problem and treat
 - + Notably undiagnosed or inadequately treated PTSD due to sexual trauma
 - + Review and update trigger management plan
 - + Consider medication alternatives to buprenorphine: methadone, depot naltrexone
 - Refer to addictionologist for care following guidelines for dismissal from practice
 - Decide whether or not to bridge buprenorphine until seen by a new provider
- c. Tone of termination from practice to be that of a "therapeutic discharge"
 - + To encourage adherence to Opioid Use Disorder treatment plan of the new provider
- d. Upon patient request or when buprenorphine is no longer felt necessary to help sustain abstinence / recovery
 - + Ensure patient is quite stable in recovery and agrees to a tapering process
 - + Ensure no current stressors that could precipitate return to use
 - + Typically, do not try to taper until 9-12 months after starting buprenorphine
 - + Reduce buprenorphine by 2 mg per month initially as tolerated
 - + Reduce buprenorphine by 1 mg per month below 4 mg daily dose as tolerated
 - + After 1 mg qd successful, reduce to q2d, then q3d, then q4d, then discontinue
 - + If craving reappears, hold buprenorphine dose and engage the addiction therapist
 - + If craving persists, return to previous buprenorphine dose with which craving absent
 - Manage withdrawal symptoms as indicated with medication and non-med strategies
 - + Armodafinil (not addiction prone) may help if fatigue is pronounced and unrelenting
 - + Encourage ongoing 12-step and addiction therapy as indicated
 - + Continue to monitor for abstinence with history, exam, definitive drug testing, and PDMP
 - Communicate tapering plan / results to others involved in the patient's care
- e. Note that there is no limit to amount of time patients can be on buprenorphine, there are no studies that define when relapse risk decreases. If patients are stable on buprenorphine it is reasonable to continue care indefinitely. The decision to discontinue a patient who is stable is one that should be patient guided and done with shared decision making.





Appendix A Diagnosis of Opioid Addiction

DSM-5 Diagnoses

- + Opioid Use Disorder
- + Opioid Intoxication
- + Opioid Withdrawal
- Other Opioid-Induced Disorders
- + Unspecified Opioid-Related Disorders

Opioid Use Disorder Diagnostic Criteria

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period. Check all that apply.

Opioids are often taken in larger amounts or over a longer period of time than was intended. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
Craving, or a strong desire or urge to use opioids.
Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home.
Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
Important social, occupational, or recreational activities are given up or reduced because of opioid use.
Recurrent opioid use in situations in which it is physically hazardous.
Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
Tolerance*, as defined by with of the following:
 + A need for markedly increased amounts of opioids to achieve intoxication or desired effect. + A markedly diminished effect with continued use of the same amount of an opioid.
Withdrawal*, as manifested by either of the following:
 The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal.
+ Opioids (or a closely related substance are taken to relieve or avoid withdrawal symptoms
MILD = 2-3 Moderate = 4-5 Severe = 6 or more

*Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision, who may exhibit physiologic factors such as tolerance & withdrawal.

Specify if:

- + In early remission: previously met criteria are no longer met for 3-12 months.
- + In sustained remission: previously met criteria are no longer met for 12 months or more.
- On maintenance therapy: such as, buprenorphine, methadone, naltrexone

^{**}Note there is no longer a diagnosis of "opioid abuse." Opioid Use Disorder criteria are intended to reflect a continuum: mild, moderate, and severe. The criteria above are not applicable to pain patients unable to cut down solely due to the level of pain.





Appendix B Patient Experience Substance Experience Table

Patient Experience	Effect	Problems
Addiction Prone Substances, Behaviors		
Alcohol		
Amphetamine / Methamphetamine		
Anabolic steroids (Nandrolone, etc.)		
Barbiturates (Fioricet, Esgic, phenobarbital)		
Bath salts (mephedrone, MDPV)		
Benzodiazepines		
Betel-quid		
Carisoprodol (Soma)		
Cocaine		
Dextromethorphan (DM)		
Driving While Under the Influence		
Ecstasy (MDMA) / MDA		
Food		
Gambling		
GHB / GBL		
Hallucinogens (LSD, mushrooms, peyote)		
Inhalants (paint, glue, white out, gas, amyl nitrate, etc.)		
Internet / Video games		
Intravenous Drug Use		
K2		
Ketamine		
Khat (cathinone)		
Kratom		
Marijuana		
Methoxyetamine		
Methylphenidate (Ritalin, Concerta, Methylin, etc.)		
Nicotine / Tobacco		





Opioids (heroin, oxycodone, morphine, tramadol, etc.)	
Phencyclidine (PCP)	
Prescription Medications that are Controlled	
Propofol	
Quaaludes	
Rohypnol (date rape drug)	
Salvia	
Sex	
Shopping	
Spice (synthetic cannabinoids: JWH-018 etc.)	
Addiction Treatment	
Acomprosate (Campral)	
Alternative Medications	
Anticonvulsants	
Gabapentin (Neurontin)	
Topiramate (Topamax)	
Valproic acid / divalproex sodium (Depakote)	
Vigabatrin	
Buprenorphine combination with naloxone	
Buprenorphine alone without naloxone	
Buproprion (Wellbutrin)	
Disulfiram (Antabuse)	
Ibogaine	
Methadone (Dolophine)	
Modalities	
Addiction Therapy	
Cognitive Behavioral Therapy (CBT)	
Coercion / Drug Court	
Contingency	
Faith-based (Celebrate Recovery)	
Mutual Help (AA, CA, NA, PA, Rational Recovery)	
Rapid Detox under Anesthesia	





Residential / Inpatient	
Addiction Treatment	
Sober Living	
Naltrexone	
Oral (Trexan, Revia)	
Vivitrol intramuscular depot	
Nicotine Replacement Therapy (patch, gum, lozenge)	
Ondansetron (Zofran)	
Quetiapine (Seroquel)	
Varenecline (Chantix)	
Topiramate (Topamax)	
Withdrawal Medications	





Appendix C American Society of Addiction Medicine Patient Placement Criteria for the Treatment of Substance Related Disorders

ASAM Patient Placement Dimensional Assessment

ASAM PPC Levels

Level 0.5 Early intervention
Level I Outpatient treatment
Level II IOP/ Partial Hospitalization

Level III Residential / Intensive Inpatient Treatment

Level IV Medically Managed Intensive Inpatient Treatment





Appendix D Personalized Functional Assessment and Goals

REMS Surveillance			Goal Monitoring	Goal Monitoring				
Numerical Rating Scale 0 - 10:			: 0 = worst 10 = best	0 = worst 10 = best		0 = best 10 = worst		
Energy			1º relationship		Anxiety			
Strength			Sexual function		Sadness			
Endurance		Social life		Insomnia				
Coordination		Memory		Sleepiness				
Exercise		Appetite		Accidents				
Ability work			Outlook		Pain			
Ability home			Enjoyment		Med misuse			
Personalized Function Goals			Process	Process Outcome				
1.								
2.								
3.								

Regarding pain level: 1st number is pain level before out of bed, 2nd number is level out of bed before meds settle in, 3rd number is best for the day after meds settle in.





Appendix E Risk Evaluation Baseline for Buprenorphine Safe Use

Risk Evaluation		Date Initiated:	
SBIRT Evaluation (current use)	Tobacco:		
	Alcohol:	Average # drinks / day:	Last time > 3, 4 drinks in a day:
	Illicit Drugs:		
	Prescription drug non-medical use:		
Patient History	Addiction:		
	Harmful Use:		
	Diversion:		
	Aberrancies:		
	Neuro:		
	Psych:		
	Trauma: Physical / Head / Sexual:		
Family History	Chronic intractable pain:		
	Substance Use Disorder:		
	Obesity:		
	Sudden death:		
	Neuro:		
	Psych:		
	Other:		
Risk Screening Tool			
Other Risks:			
Resiliency Factors:			
Medical Records:			
↑ increased ↓ decrease	ed → change to	⊢ begun ⊣ €	ended √ present

Risk Stratification taking into consideration all of the above elements:

- 1. Level of risk for opioid return to use: Low / Intermediate / High
- 2. Level of risk for safe buprenorphine use: Low / Intermediate / High





Appendix F Risk Mitigation for Buprenorphine Safe Use

Risk Mitig	ation				
Designated Prescribers:					
Medication Prescribed:					
Informed Consent:		Medical Cannabis:			
Controlled Substances Agreement:	Signed on:	Nocturnal oximetry baseline:			
Secure Storage:		Safe Disposal:			
Patient Self-Management:		Bowel Program:			
Mutual Help:					
Addiction Therapy:		Other:			
Screening:		HIV	Нер В	Нер С	





Appendix G Risk Monitoring for Buprenorphine Safe Use

		Risk Monitoring		
Behavioral Aberrancies				
PDMP	<u>1st Quarter</u>	2nd Quarter	<u>3rd Quarter</u>	<u>4th Quarter</u>
<u>Consistent</u>				
<u>Inconsistent</u>				
<u>Drug Testing</u>	<u>1st Quarter</u>	2nd Quarter	<u>3rd Quarter</u>	4th Quarter
<u>Consistent</u>				
<u>Inconsistent</u>				
Date	Testosterone level	ALT	Cr / eGFR	Nocturnal oximetry % time < 89% sat
$\sqrt{\ }$ = OK				





Appendix H 12 Step Meeting Locators

Alanon Alateen Alanon / Alateen

 Alcoholics Anonymous
 AA

 Cocaine Anonymous
 CA

 Codependents Anonymous
 CODA

 Gamblers Anonymous
 MA

 Marijuana Anonymous
 MA

 Narcotics Anonymous
 NA

 Pills Anonymous
 PA

 Sex Addicts Anonymous
 SAA

This material was prepared by the lowa Healthcare Collaborative, the Opioid Prescriber Safety and Support contractor, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS.





Buprenorphine and

X-Waivers

In this document we will attempt to simplify the seemingly complex regulations about buprenorphine and provide more information on what is a great opioid for both chronic pain and the treatment of opioid use disorder (OUD).

The Science (5 Interesting Facts)

- 1. Buprenorphine is a schedule III narcotic pain medication and is a high affinity partial agonist @ the mu receptor, antagonist @ the kappa receptor (helping prevent opioid induced hyperalgesia aka OIH and tolerance) and possesses anti-NMDA and activity. The kappa and NMDA activity are thought to help prevent OIH. This unique pharmacology presents several benefits to utilizing buprenorphine.
- 2. It is an estimated 25 100x more powerful than morphine when it comes to analgesic effect and can be dosed IV, SL or via patch.
- 3. It is many times safer than normal agonist given it has a ceiling effect on respiratory depression and sedation making it ideal for physiologically fragile patients. The CDC specifically excludes buprenorphine from its MME table because it is not likely to be associated with overdose in the same dose-dependent manner as are pure opioid agonists.
- 4. In general buprenorphine has less side effects than full agonist opioids, although side effects are still common (nausea, constipation, etc.).
- 5. Buprenorphine shows a distinct benefit in improving neuropathic pain syndromes due to its unique pharmacology.

For more please refer to this <u>great article by Dr. Rudolf.</u> It is one of the best in discussing the unique properties of buprenorphine. <u>This Consensus Statement</u> from back in 2008 also highlights some of Buprenorphine's benefits.

The Regulations

- + To prescribe Buprenorphine products for pain you do not need an X-waiver!
- + To prescribe Buprenorphine products for OUD, you do need an X-waiver!
- + You can now obtain an X-Waiver **without** sitting through an 8-hour course and with your X-Waiver treat up to 30 patients with OUD through the Notification of Intent! You can read instructions <u>here</u> and <u>apply here!</u>

We strongly encourage any physician who is using chronic opioid therapy for patients to become X-Waivered! It demonstrates a commitment to comprehensive opioid stewardship, allows you to care for patients who you identify as developing an OUD, and is one of the measured outcomes by CMS of the Compass Opioid Stewardship Certificate Program!





In Practice

- + Buprenorphine is a versatile and effective opioid. It is perhaps the safest of all opioids in physiologically fragile patients.
- + Buprenorphine sometimes requires prior authorizations especially Belbuca (SL) and Butrans (Transdermal). However, several states have added buprenorphine products to the Medicaid preferred formulary list and/or do not require prior authorizations for certain products.
- + Buprenorphine sublingual tabs can be used off-label for pain and are often a cheaper alternative to Belbuca and Butrans a GoodRX search on 12/27/2021 showed that Sixty 2mg SL buprenorphine tablets cost \$32.89 with the GoodRx Coupon. Affordable for patients on self pay!
- To optimize buprenorphine for management of chronic pain, it is recommended to split dosing TID or QID.
- + When you identify a patient with OUD, buprenorphine is an approved drug to treat the disease and dosing can be split to a TID regiment that also helps with pain.
- + It is possible to cross taper patients from full agonist opioids to buprenorphine and hence minimize withdrawal symptoms (Compass Opioid Stewardship Toolkit has several resources).

For any questions about buprenorphine please feel free to reach out to our Compass Opioid Stewardship Subject Matter Experts via email or schedule a coaching call.

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Patient Education Material





Opioid Use Disorder Patient Education Resource

Facts

- + People can develop opioid use disorder with any opioid, even those prescribed for pain.
- You are at risk of opioid use disorder if you take prescription opioid medications, such as hydrocodone, oxycodone, morphine, fentanyl, codeine, tramadol, or hydromorphone, or if you use heroin.
- + Opioids are not usually a safe or effective therapy for the long-term management of pain.
- Opioid use disorder develops over time and is not a choice or weakness; it's a brain disease that needs treatment, just like other diseases like diabetes and high blood pressure.
- + Signs of opioid use disorder include:
 - + Cravings
 - Difficulty with work, relationships, and activities
 - Trouble controlling drug use, even when it causes harm
- People with opioid use disorder can recover and live meaningful, productive lives.
- + There are multiple **medication choices that can treat opioid use disorder**, including buprenorphine, methadone, and naltrexone.

Talking to Your Clinician

- + Ask if there are safer ways to manage your pain.
- + Your clinician should **regularly screen you for opioid use disorder**; this is a normal and expected part of your health care plan that keeps you safe and healthy.
- + If you think you might be dependent on your opioid medication or have an opioid use disorder, ask your clinician about **treatment options**.
- + Opioid use disorder is a disease don't feel guilty or ashamed to ask for help!

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Patient Communication Skills





Optimizing Patient Communication The Key to a Successful Taper

Create Therapeutic Alliance

Avoid Stigmatization

- Developmental process¹
 - + Identified difference(s)--> difference(s) deemed undesirable
- + Out-group is assigned a negative judgement1
 - + Exaggerated negative cognitive-affective orientation toward pain or other symptoms
- Resulting in densely woven patterns of disadvantage²
- + Maintained through the exercise of power1
 - + Mediated by policy, law
- + Accepted as natural and sensible, without reflection, and often invisibl3
- + Especially tenacious regarding persons who use drugs4
 - + Non-medical use, addiction, pain, mental health
- + Caution:
 - + Evidence-based medicine speaks in categories
 - + Complete reliance on evidence-based medicine can be stigmatizing

Use Person-First Language

- + Difficult patients"
 - + Instead:
 - Difficult conversations
 - Patient in difficult circumstancese
 - + Patients with ambivalence
- + "Catastrophizing" 5
 - + Instead: Exaggerated negative cognitive-affective orientation toward pain
- "Psychosomatic"
 - + Instead:
 - + Somatoform disorder
 - + Somatic symptom disorder
 - + Severity may be more physiologic than psychological
- "Drug seeking"
 - + Blaming conclusion that may be unwarranted
- + "Relapse"
 - + Instead: Return to use
 - + What do we need to do that we weren't doing before?





Engage Patients

Set the Stage

- + Prepare yourself beforehand
 - + Scripts for difficult conversations
- + Use motivational interviewing 6-9
 - + Patient identification of behavior-goal disconnect, ownership, move towards change
- + Share medical decision-making process
- + Make judgments ≠ judgemental
- + Solutions non-linear and iterative
- + Listen authentically to patients who may have the next best idea

Understand the Stages of Change 10-13

- + Precontemplation
- + Contemplation
- + Preparation
- + Action
- + Maintenance
- + Relapse

Encourage Change with Motivational Interviewing

- + Express empathy-->validate hard feelings
- Develop discrepancy
 - + What are your values/goals?
 - + What are your current behaviors?
 - + Are they connected?
- + Roll with resistance
- + Support self-efficacy

Navigate Difficult Conversations¹⁴

Understand Why Conversations Can Be Difficult

- + Stakes are high
- + Patients feel powerless
- + Emotions run high
- + Clashing needs
- + Clashing desires
- + Absence of authentic listening
- + Specific patient concerns:
 - + Distrusted
 - + Made to feel like a drug addict
 - + Made to feel like a criminal, punished
 - + Made to feel stupid, talked down to





- + Discredited knowledge or me as a person
- + Absence of concern or attention to my symptoms
- + Absence of authentic listening

Example

- + One patient's experience:
 - + 28-year chronic pain sufferer
 - + Tried multiple treatment options
 - + Explored, but ultimately avoided surgery
 - + Prescribed opioids for 10 years and thankfully, never became addicted
 - + Was in pursuit of living life without pain (did not fully appreciate improved function)
 - + Was unknowingly afraid of what was required to find alternatives the life change was dramatic
- + Challenge of treatment plan:
 - + Taking medication as prescribed created problems
 - + Hyperalgesia
 - + Cognitive impairment
 - + Mobility challenges
 - + My body did not respond positively to treatments that were investigated
 - + Allergic response to iodine and materials for neurostimulator
 - + Difficulty with neurotomy
 - + PTSD around treatment options
 - + Ultimately believed they stayed with one provider too long
- + Lessons learned:
 - + Opioids can be extremely effective and create immediate relief
 - + What is not clear is when the opioids stopped being effective
 - + There is long-term value in finding non-opioid treatments, which can be empowering
 - + My pain is transitory
 - + There is intermittent hope in seeing signs of improvement that you can have a better life at the other end
 - I had no idea it was possible to get better, I CAN live with chronic pain, and I do not need daily medication
 - + Medical providers do not **ALWAYS** have **ALL** the answers

Tapering Suggestions

- Identify potential patients
- + Create the partnership: patient can benefit if they feel supported and that they are not in it alone
- Understand their fears or concerns
- + Discuss their support structure or how to shore up one
- + Convey that this is a journey, not a moment
- + Consider what will work for THIS patient at THIS moment
- + Be mindful of the pacing of the taper
- Patient suggestions
 - + Lunderstand the fear of change and fear of the unknown
 - + Look to the other side of what is possible





- + The doctor can be a part of that journey
- + If you have the will or desire and the medical team can be part of it, it can be powerful
- + What is your best self?
- + What is your best life?
- + Thank you!

Conversation Trap¹⁵

Compassion Traps

- + Patient: Do you want me to lose my job, do you want me to be on the street?
- + Provider: I want you to have safe and effective pain control and it is my medical opinion that your current medicine won't give you that.
- + Patient: I wish you could feel my pain.
- Provider: I know you're suffering and I'm sure that we can work together to reduce pain, so you
 don't have to suffer.

All-or-Nothing Traps

- + Patient: You're cutting me off and I have to live with my pain?
- + Provider: There are many, many things that people with chronic pain can do other than opioids to manage their pain. Would you like to hear about them?
- + Patient: I've tried all that stuff, none of it works.
- + Provider: I want to hear what you've tried so we can find a way for it to be more helpful this time.

Addiction Labeling Traps

- + Patient: Don't label me as a druggie.
- + Provider: I have no interest in labels at all; I am interested in helping people who are struggling with medical problems.
- + Patient: So you're basically saying that I'm a junkie.
- + Provider: I'm saying that addiction is a medical problem that responds to treatment, not a problem of bad morals or behaviors.

Desperate and Threatening Traps

- + Patient: I heard it's illegal for you to let me go into withdrawal.
- + Provider: Withdrawal is uncomfortable but not life threatening. I can prescribe you medicines to help with withdrawal symptoms.
- + Patient: I'm getting a lawyer (the medical board, your boss, etc.)
- + Provider: You do what you feel is right, of course. That's what I'm doing for you, too.





Endgame Traps

- + Patient: (Behavior is angry, despondent, avoidant, etc.)
- + Provider: At this point, I suggest we agree to disagree, what I have laid out is what I believe to be the safest and most effective course of action right now.
- + Patient: I hate you, I am leaving, you suck, etc.
- + Provider: It is understandable that you are upset, it is my job to keep you safe and I care about you. You are free to go any time. I will be having my medical assistant call you in the next couple of days to check on you and invite you to come back in to talk about next steps.

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Provider Resources

Patient Communication Skills

Physicians and advanced practice providers have an ever increasing need to improve patient communication skills, particularly those practicing in primary care. When managing a high-risk patient population such as those on chronic opioid therapy and other controlled substances, effective communication skills become even more important. Whether trying to relay treatment plans, discussing alternative treatment options, or validating patient concerns, active listening and shared decision making play a key part in developing a therapeutic relationship with the patient. These skills are not likely learned in school, nor inherent to most providers, and therefore require additional training and practice. Thankfully there are several resources now available on such topics, including learning new communication strategies, developing skills such as motivational interviewing, and becoming an expert at de-escalation.

Free Online Access

- + Counseling Patients in Primary Care: Evidence-Based Strategies
- + Encouraging Patients to Change Unhealthy Behaviors with Motivational Interviewing
- + Motivational Interviewing: Talking with Someone Struggling with Opioid Use Disorder
- + Incivility in Health Care: Strategies for De-escalating Troubling Encounters
- + The Joint Commission: De-escalation in Healthcare
- + CDC Module: Communicating with Patients on Chronic Opioid Therapy

Subscription/Purchase Required

- + Cochrane Review: Motivational Interviewing for Substance Abuse
- Motivational Interviewing: A Guide for Medical Trainees
- + Motivational Interviewing for Clinical Practice

Formal Training Courses

+ <u>Motivational Interviewing Training</u>

Access the "Patient Resources" tab for tailored patient-facing education resources.

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Patient Education Resources





Prescription Opioids

What You Need to Know

Prescription opioids can be used to help relieve moderate-to-severe pain and are sometimes prescribed following a surgery or injury, or for certain painful health conditions. These medications can be an important part of treatment, but they also come with **serious risks**. It is important to work with your clinician to get the safest, most effective care.

What are the Risks and Side Effects of Opioid Use?

Prescription opioids carry serious risks of addiction and overdose, especially with prolonged use. An opioid overdose, often marked by slowed breathing, can cause sudden death. The use of prescription opioids can have a number of **side effects** as well, even when taken as directed, including:

Tolerance	Physical Dependence	
(Meaning you might need to take more of your	(Meaning you have symptoms of withdrawal when	
opioid medication for the same pain relief)	your opioid medication is stopped)	
Constipation	Sleepiness and Dizziness	
Increased Sensitivity to Pain	Confusion	
Lower Energy, Strength, and Sex Drive Due to Low	Denvesien	
Levels of Testosterone	Depression	
Nausea, Vomiting, and Dry Mouth	Itching and Sweating	

As many as **1 in 4** people receiving prescription opioids long term in a primary care setting struggles with addiction.

It only takes **fewer than 7 days** of opioid therapy to develop a long-term opioid use disorder.

Risks are Greater with:

- + Mental health conditions (such as depression or anxiety)
- + Personal or family history of drug misuse, substance use disorder, or overdose
- + Older age (65 years or older)
- + Sleep apnea or organ dysfunction

Avoid Alcohol

while taking prescription opioids. Also, unless specifically advised by your clinician, avoid certain medications:

- + Benzodiazepines (such as Xanax or Valium)
- + Muscle relaxants (such as Soma or Flexeril)
- + Hypnotics (such as Ambien or Lunesta)
- + Other prescription opioids





Know Your Options

Talk to your clinician about ways to manage your pain that don't involve prescription opioids. Many nonopioid medications **actually work better** and have fewer risks and side effects. Options may include:

- + Over-the-counter pain relievers like acetaminophen (Tylenol) and ibuprofen (Motrin)
- Topical medications, such as lidocaine patches (Lidoderm) or diclofenac gel (Voltaren)
- + Nonopioid prescription medications that are also used for depression or seizures
- + Physical therapy, stretching, and exercise
- + Cognitive behavioral therapy = a psychological, goal-directed approach, in which patients learn how to modify physical, behavioral, and emotional triggers of pain and stress.

If You Are Prescribed an Opioid Medication for Pain

- + Never take opioids in greater amounts or more often than prescribed.
- + You may also be prescribed a medication called naloxone (Narcan) that will reverse the effects of your opioid medication if an overdose is suspected.
- + Unless instructed otherwise by your clinician, continue using your nonopioid medications and therapies as primary treatment of your pain.
- + In most cases, reserve use of your opioid medication for severe or "breakthrough" pain.
- + Follow up with your prescribing clinician within a week.
 - + Talk about any concerns and side effects related to your opioid medication.
 - + Work together to create a plan on how to manage your pain without prescription opioids.
- + Help prevent misuse and abuse.
 - + Never sell or share prescription opioids.
 - + Never use another person's prescription opioids.
- + Store prescription opioids in a secure place and out of reach of others (this may include visitors, children, friends, family, pets).
- + Safely dispose of unused prescription opioids.
 - + Find your community drug take-back program, pharmacy drop box, or other ways to properly dispose at www.fda.gov/Drugs/ResourcesForYou.
- + If you believe you may be struggling with addiction, tell your clinicians and ask for help, or call SAMHSA's National Helpline at 1-800-662-HELP

Adopted from the CDC and AHA Patient Opioid Factsheet https://www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf

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Switching to BuprenorphineIs it Right for Me?

Buprenorphine Comes in Five Formulations:

- + Buccal film (dissolves in cheek)
- + Sublingual (dissolves under tongue; approved only for opioid addiction)
- + Transdermal (topical patch)
- + Monthly subcutaneous injection (approved only for opioid addiction)
- + Subcutaneous implant (once every 6 months; approved only for opioid addiction)

Benefits of Buprenorphine Over Other Chronic Opioid Therapies:

- + Stronger: Buprenorphine is among the strongest pain relievers in the opioid class.
- + **Safer:** It is less likely to cause respiratory depression, unintentional overdose, and opioid addiction.
- + **Better quality of life:** Buprenorphine provides additional pain relief, reduces mental depression, and is less likely to lead to constipation, dysphoria, and drug abuse.
- + **Fewer access barriers:** The drug's Schedule III classification enables health care providers to prescribe pharmacy refills.

You Should Consider Switching from Chronic Opioid Medication to Buprenorphine IF:

- + Your current opioid therapy is no longer effective, or you are needing to increase your dose to dangerous levels to feel an effect. The need to increase your dose is caused by tolerance or hyperalgesia (increase sensitivity to pain). This problem is common with most opioids, but it is significantly less common with buprenorphine.
- + You have had an adverse event from your current opioid (e.g., accidental overdose, pneumonia, a fall, severe constipation) or are developing a problem with your pain medications, including opioid addiction.
- + Your health care provider has expressed concern about prescribing a Schedule II opioid due to the associated risk of addiction, misuse, and/or overdose death.
- + There is concern about interactions between your current medications and other sedatives (e.g., benzodiazepines or muscle relaxants).
- + You have a limited ability to use or tolerate oral formulations. Buprenorphine can be given as a dissolving tablet or skin patch.
- + You are receiving immediate-release treatment and would benefit from a longer-acting analgesic with a relatively favorable safety profile and Schedule III classification.

^{*}Starting or switching to buprenorphine may cause nausea, which can be managed by your provider.





There Are Two Methods for Converting from Chronic Opioid Medication to Buprenorphine:

- + A tapered approach in which your doctor slowly increases buprenorphine while decreasing your previous opioid dose. This often prevents withdrawal.
- + An abrupt method that prompts a brief period of moderate opioid withdrawal, which can be managed with medications followed by a transition to buprenorphine.

*For certain patients on high doses of chronic opioid therapy, health care providers may recommend a gradual taper to a lower dose of opioid medication prior to prescribing buprenorphine.

Note: Although buprenorphine is safer than opioids, it still poses a risk of opioid-type adverse reactions, including respiratory depression, addiction, overdose, and death. It must be used with caution!

Speak with your health care provider to learn more!

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Tapering off OpioidsIs it Right for Me?

Benefits of Stopping Opioid Therapy

Many patients experience the following:

- + Less overall pain
- + Improved function with less drowsiness and more energy
- + Reduced risk of misuse, addiction, and accidental overdose
- + Fewer side effects like sedation, decreased concentration and memory, changes in mood, constipation, abdominal pain and nausea, sexual dysfunction, increased falls/accidents, and bone loss
- + Easier for health care providers to control your pain if you require surgery or have an acute injury

What Signs Indicate That It May be Time to Stop Taking Opioids?

- + Reduced pain relief from the same medications over time (tolerance)
- + Lack of meaningful improvement in pain and function
- + Feeling that you cannot stop taking opioids or have concerns about their addictive potential or side effects
- + New or worsening lung-related symptoms, breathing difficulties, snoring, or sleep apnea
- + Serious side effects

Precautions

- + Do <u>NOT</u> stop cold turkey. Opioid withdrawal can be dangerous and symptoms can be severe. When it's time for you to stop taking opioids, work with your provider to develop a withdrawal plan (called a taper) that gradually reduces the amount of medication you take. It may take weeks or even months to gradually and safely reduce your dose until you can stop taking opioid medications completely.
- + Do <u>NOT</u> go it alone. Stopping opioids can be difficult, but you can do it with help. You're much more likely to succeed if you partner with your health care team, plan a taper schedule, manage your symptoms, and learn alternative ways to cope with pain.

Achieving Success

- + Tapering plans should be individualized to minimize the symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacologic therapies and nonopioid medications.
- + Go at your own pace! Many patients want to start slow. Faster tapers are more uncomfortable and are associated with greater withdrawal symptoms.
- + A decrease of 10% per month is a reasonable starting point if you've been taking opioids for 1 year or more. A decrease of 10% per week may be reasonable if you've been taking opioids for weeks to months (assuming the initial decrease is well tolerated).





Getting Support

- + Coordinate with your provider and/or health care specialist.
 - + Medical guidance is especially important for patients at high risk of harm, including pregnant women.
- + Your providers will regularly assess your pain and function.
- + Nonpharmacologic and other nonopioid medication therapies can help.
- + Your provider will regularly assess you for signs of withdrawal.
 - + Nonpharmacologic therapies and other nonopioid medication can help. Your physician may manage your symptoms with the treatments described in **Table 1**.
- + Make sure you have access to appropriate psychosocial support.
 - Ask to work with a mental health provider if needed.
- Ask family and friends to watch for signs of anxiety and depression during the taper and offer support when needed.
- + If you have difficulties especially withdrawal symptoms ask for assistance regarding transportation, childcare, and other important activities.

Table 1 | Treating Withdrawal Symptoms

Withdrawal Symptom	Nonpharmacologic Treatment	Pharmacologic Treatment	
Nausea and vomiting	Bland diet, frequent small meals	Ondansetron, prochlorperazine	
Diarrhea	Diarrhea Hydration, electrolytes		
Muscle aches Stretching, exercise, heat, ice, topicals		Acetaminophen, ibuprofen	
Abdominal cramping	Heating pad	Dicyclomine, hyoscyamine	
Restlessness, shakes, sweats, rapid heart rate	Decrease stimulation (limit noise, dim lights)	Clonidine	
Anxieły, insomnia	Psychosocial support, cognitive behavioral therapy, meditation	Gabapentin, hydroxyzine, trazodone	

Understanding the Process

- + Fear about tapering is normal, but the process can be managed by:
 - + Discussing your fears
 - + Having a full understanding of the benefits and risks of reducing the use of opioids
 - + Remembering that there are no "stupid questions"
 - Tapering slowly, keeping your provider fully informed of any successes or challenges you experience
- + Pain may initially get worse, but this experience is usually followed by improved function and decreased pain. There is good reason to feel optimistic about the ultimate outcome.

Staying Safe

- + After stopping or tapering to a lower dose of opioids, you are at an increased risk of overdose if you quickly return to a previously prescribed higher dose.
- + Have naloxone on hand for overdose treatment, and make sure your family members and friends know how to use it and are prepared to call 911 and provide rescue breathing if necessary.

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Documentation + Charting Best Practices





Informed Consent and Controlled Substance Agreements

Controlled substance agreements (CSA) and informed consent for opioid therapy are pillars of good, comprehensive opioid stewardship. CSAs and informed consent can be presented as separate documents or as part of the same document, but they are distinct processes with differing goals.

- + A Controlled Substance Agreement is a planning document that clearly delineates patient expectations and sets the rules of the road for your practice. A CSA reinforces good opioid stewardship. It helps standardize clinician practice and educates patients on behaviors that are unsafe, illegal or are necessary to monitor for and mitigate risk of drug diversion, aberrancy or substance use disorder (ie urine drug screening & pill counts).
- Informed consent is a process which occurs between a physician and a competent patient regarding a specific medical intervention. Informed consent assures that patients are aware of their diagnosis, the purpose of the recommended medical intervention and the risks, benefits and alternatives to the medical intervention proposed. Informed consent for chronic opioid therapy is essential, considering the many risks and complications associated with opioids as a treatment modality.

It is best practice to review and update a patient's CSA and informed consent on a yearly basis. Below are examples of different controlled substance agreements, informed consent documents, patient education tools and risk mitigation tools with a brief descriptor.

Controlled Substance Agreements

Short, Controlled Substance Agreement

+ Example 1 - adopted from the AAFP Chronic Pain Toolkit (CSA is on page 31)

Longer, Controlled Substance Agreements

- + Example 2 shared by Dr. Steven Wright
- + Example 3 CSAs by the Oregon Pain Guidance
- + Example 4 CSA developed by Greater Louisville Medical Society

Informed Consent Documents

- + One Page Informed Consent with Patient Graphic
- Prescription Opioids for Patient Education

Combined Informed Consent / Controlled Substance Agreement Documents

- + Example 5 shared by Johns Hopkins is a combined informed consent & CSA
- + Example 6 Pennsylvania Sample Treatment Agreement
- + Example 7 Michigan OPEN Sample Treatment Agreement

Additional Documents

- + <u>High Risk Consent and Planning Form</u> is meant for patients identified at increased risk for adverse effects from COT, aids in safety planning and documentation of informed consent for increased risk.
- + Chronic Opioid Therapy Shared Decision-Making Tool

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Chart Review Guidance Tools





Medical Care Chart

Review Evaluation

Provider:	Key
Reviewer:	✓ = Good
De-identified Chart:	NA = Not Applicable
Date of Review:	Other terms: Not seen, Insufficient

Instructions for Use

The following evaluation is meant to be used as an assessment tool for charts related to those patients on chronic controlled substance therapy, including chronic opioid therapy. The evaluation is split into two sections, the first focused on pain management and second on risk management. While it is highly recommended that providers include all components of this chart review tool in every chart encounter for the patient, each component listed does not necessarily need to be addressed and newly charted at every patient encounter. Rather, there should be documentation over the course of the patient's care that encompasses all or nearly all of the following requirements.

If doing a self-assessment, please indicate the quality of what is documented, not what you remember and did not document. It is recommended to review each patient's chart annually to ensure that these requirements are being met and updated.

Pain Management

Pain History	Assessment	Comment
Pain Intensity: 0-10		
Pain Description		
Functional Consequence		
Red Flags?		
Injury Description		
Past Diagnostic Studies		
Past/Current Consultants		
Past or Current Therapeutic	S	
Medications		
Self Management		
Modalities		
Procedures		





Pain Physical Exam	Assessment	Comment
Observed Function, Motion, Physical Exam		
Current Lab tests		
Current Imaging		
Neurodiagnostics		
Exam consistent w/ report		

Pain Assessment	Tool Links	Assessment	Comment
Self Assessment	PEG-3		
Provider Assessment			
Acute, Subacute, Chronic			
Mild, Moderate, Severe			
Trajectory: Better, Worse, Same			
Specific Pain Diagnosis			

Pain Plan	Tool Links	Assessment	Comment
Diagnostics			
Consultations			
Therapeutics			
Self-Management	Non-Pharmacologic (self-directed)		
Modalities	Non-Pharmacologic (prof-directed)		
Medications	<u>Nonopioid</u> <u>Pharmacologic</u>		
Procedures			
Pain education topic	<u>Resources</u>		
Informed Consent			
Follow-up Time			

Key Questions for Pain Management Charting

Y/N	Question
	Is the use of opioids indicated based on diagnosis?
	Does the severity of pain warrant opioids?
	Is there adequate documentation of previous or current non-opioid pain management?
	Is there adequate documentation of functional assessment and improvement with COT?





Risk Management

Risk Screening and Monitoring	Tool Links	Assessment	Comment
*Personal and/or family hx: SUD	Risk Screening		
*Personal hx: Psychiatric/Mood	<u>Screening</u>		
*Personal hx: Trauma (ACE)	Tools		
Screen for Opioid Misuse	<u>COMM</u>		
*Oxygenation: COPD, asthma			
*OSA risk: sleep study			
*Other concerning comorbidity: Renal/hepatic dz, age >65yo			
Behavioral aberrancy surveillance: Reported	Risk Manitoring		
Behavioral aberrancy surveillance: Observed	<u>Monitoring</u>		
PDMP review			
Drug testing			
EKG (methadone)			
Co-medication review			
Current MME	MME Calc		

^{*}Appropriate to address and document initially and annually, vs. at monthly or quarterly visits for the remainder of elements listed.

Risk Stratification	Tool Links	Assessment	Comment
Low, Intermediate, High	Risk Strat Tool		

Risk Mitigation	Tool Links	Assessment	Comment
Goal setting, ALTOs, switch to lower risk opioid	Risk Mit Tool		
Overdose Education, Naloxone + Instructions	<u>Patient</u> <u>Handout</u>		
Secure Storage Instructions Safe Disposal Instructions	<u>Patient</u> <u>Handout</u>		
Informed Consent	Informed		
CSA and/or High- Risk Consent	Consent and CSAs		
Co-medication warnings (ie bzd, stimulants, depressants)			





Aberrancy Management	Tool Links	Assessment	Comment
Low/Intermediate/High	Aberrancy Tool		
Appropriate Resulting Action:			
Warning, increased monitoring			
Specialty referral			
Cross-taper to buprenorphine	<u>Patient Handout</u>		
Taper/discontinuing opioid(s)	<u>Patient Handout</u>		
Discontinuing benzodiazepine(s)			
Therapeutic discharge			

Key Questions for Use of Chronic Opioid Therapy and Risk Management

Y/N	Question					
	Do benefits of opioids outweigh real or potential harms at this juncture?					
	If there was an adverse outcome with this patient (overdose, hospitalization, malpractice case, medical board complaint) would this be an easy case to defend SOLELY on the documentation provided?					
	Are there changes that should be made to the medication regimen? Were those changes made?					
	Has naloxone been prescribed?					
	Has tapering been mentioned or discussed? Is tapering a valid consideration @ this time?					

Summary Assessment

Charting

Organization Comprehensiveness	Problem List	Medication List Reconciliation	Medical Problem Tracking	Prior Medical Record Review	Consultant Collaboration

Medical Care Management

History	Physical Exam	Studies/Consult	Assessment	Treatment/Plan

Medical Risk Management

Risk Screening	Risk Satisfaction	Risk Mitigation	Risk Monitoring	Aberrancy Management		
Are all these elements collected together in the chart? On each encounter note?						





Team-Based Management

Goal: Active bidirectional communication at a minimum

Ideal: Collaboration on plan

Level of Engagement	Pain Management	Addiction Medicine	Psychiatry	Behavioral Health
Communication				
Collaboration				

Three Areas to Improve in Next Charting Cycle

1.

2.

3.

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Medical Encounter Example

Neuro:

Psych:

Denied Denied

Pain-Opioids: Minimum Standard of Care

	or: Pain Management or: Risk Management	
Office V	/isit Date:	<u></u>
	Name:	DOB:
spine dem		v back. Prior diagnostic workup includes MRI of the LS a small paracentral disc protrusion at L4-5 without pain concerns.
L3-5 centro	ally and in the right paraspinous region without r	d worse (sharp) with rotation to the right. It is located radiation. Back pain severity is described as 5/10, and oxycodone IR which allow him to be active.
Taking opi	oids without problems. He does not use alcohol	or cannabis.
Review of S	Systems, Symptoms, Function	
+ HE	ENT Denied	
+ CR	R: Denied	
+ GI:	: Constipation controlled, otherwise de	nied
+ Gl	J: Denied including no incontinence	
+ MS	S: Otherwise denied	





0

- + WD WN WH
- + Normal LOC, orientation.
- + No impairment or confusion.
- + Mild distress
- + Vital Signs:
 - + 142/96 + 246 lb BMI 32
 - + 85 + O₂ 94% on oxygen
 - + 14 + Afebrile
- + **HEENT**: Negative
- + Chest: Clear, diminished BS
- + **Abd:** Soft, non-tender

No palpable HSM / masses

+ MS: LS-spine tender 1-2+ midline

R paraspinous muscles with mod paraspinous muscle tension SLR negative bilaterally

+ Neuro: Slight antalgic gait with listing to the right as before - relies on cane. Achilles reflex 2+

bilaterally

Motor: 5/5 strength bilateral lower extremities

+ Cor: Regular without MGT line in there

Risk Management

Risk Screening

- + Personal / Family history of SUD: Denied
- + Personal history psych / mood: Mild depression, manageable
- + Personal history trauma: Denied
- + SBIRT screen on initial visit 2013 positive for tobacco only

Risk Stratification: Intermediate Level of Controlled Substance Risk

Risk Mitigation

- + Informed consent provided on initial visit
- Controlled substances agreement last signed on xx/xx/2020
- + Naloxone prescription provided with instructions xx/xx/2019 spouse knows how to use





Risk Monitoring

- Behavioral aberrancies: Reported cannabis use 2017 discontinued cannabis use after warning
- PDMP consistent with prescribing continuously since 1st visit 2013
- + UDT consistent with prescribing since first visit 2014,

Aberrancy Management

- + Patient reported cannabis use 2017 → warning → cannabis use stopped
- + Ultimatum: None

A

- + Chronic intractable pain, well controlled
- + On opioids: MME 82.5 mg
- + Degenerative disc disease L3-5
- + Pain, function benefit present and medications are considered necessary for continued benefit
- + Intermediate Level of Controlled Substance Risk
- No identified aberrancies

P

- + Discussed rationale for opioid tapering he agrees to consider
- + In anticipation of tapering start meloxicam 7.5 mg po bid #60 RF0
- + Refill, no change: oxycodone CR 15 mg po q8h #90 RF0
- + Refill, no change: oxycodone IR 5 mg 1 po g4h prn pain, < 3/d #60 RF0
- + Continue duloxetine at current dosage appears effective for depression without AEs
- Send out for definitive UDT
- + Baseline CBC, BMP, Fe studies (hemacult next visit) b/o meloxicam initiation
- + F/U here in 1m, sooner prn

Steven Wright, MD

Family Medicine Addiction Medicine Medical Pain Management

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Medical Encounter Example

Pain Opioids: Best Practices

Red color: Risk Management

Office Visit Date:
Name:
DOB:

S

53 yo male here for f/u chronic intractable pain of the low back. Prior diagnostic workup includes MRI of the LS spine demonstrating degenerative disc disease L3-5 and a small paracentral disc protrusion at L4-5 without foraminal encroachment. He indicates there are no other pain concerns.

He describes the pain as aching on a continuous basis and worse (sharp) with rotation to the right. It is located L3-5 centrally and in the right paraspinous region without radiation. Back pain severity is described as 5/10 in bed in the AM before up and around, 6/10 up and around before medications settle in, 3-4/10 best for the day after medications are on board, though it can flare to 7/10 with light lifting. He is taking oxycodone CR which lasts 7h, oxycodone IR which lasts 3h - and together they allow him to continue instrumental activities of daily living as well as therapeutic exercise directed by his physical therapist.

Since the Last Office Visit

Diagnostic studies: none

Blue color: Pain Management

- + Non-medication approaches: Walks 10 minutes 5 days per week. Daily stretching. PT q2w.
- + Consults: none

Medications

- + Non-controlled: Duloxetine increased for depression but not clearly pain.
- + Controlled: Taking medications on a regular basis as prescribed, source here only, of continued benefit and negligible side effects. Not requesting any specific changes. Reports no behavioral aberrancies, alcohol, cannabis, substances of potential addiction excepting as prescribed. He remains abstinent from tobacco for more than a year.

Review of Systems, Symptoms, Function

+ Other medical problems stable.





- + No fever, chills, sweats, generalized aches.
- + Weight is stable though high.
- + He performed at an arts seminar in Seattle had a great time, would not have been able to do this in the absence of the treatments employed.

HEENT Denied

+ CR: Denied

+ GI: Constipation controlled, otherwise denied including no incontinence

+ **GU**: Denied including no incontinence

+ MS: Otherwise denied

Neuro: Denied including no saddle anesthesia

+ Psych: Improvement in depressed mood now that his wife found a job after being laid off PHQ-

2 scored 0 today

Daily living functions are the same since last month with respect to physical, social, sleep, activities, family. There is only modest improvement in function over the last 6-9 months, though there is some. He remains unable to work but states he would like to return to work ultimately.



- + Here by himself
- + Energy appears improved
- + Normal LOC, orientation
- + Coordination and speech at baseline
- No observed track marks
- Shows appropriate and reproducible distracted tenderness, pain-related behavior, pain-protection mechanics, all consistent with pain described and at a moderate level, unchanged from last OV.

- + WD WN WH
- Does not display illness. sadness or anxiety
- + No impairment or confusion
- + No alcohol or cannabis odor
- + Mild distress

Vital Signs:

- + 142/96 + 246 lb BMI 32
- + 85 + O₂ 94% on oxygen
- + 14 + Afebrile





+ HEENT: Negative

+ Chest: Clear, diminished, BS+ Cor: Regular without MGT

+ **Abd:** Soft, non-tender. No palpable HSM / masses.

+ MS: LS-spine tender 1-2+ midline, R paraspinous muscles with mod paraspinous muscle

tension SLR negative bilaterally

Slight antalgic gait with listing to the right as before - relies on cane.

Achilles reflex 2+ bilaterally

Motor: 5/5 strength bilateral lower extremities

Sensory: Intact to light touch bilateral lower extremities

Risk Management

Risk Screening

Personal / Family history of SUD: Denied

+ Personal history psych / mood: Mild depression, manageable

+ Personal history trauma: Negative for physical, sexual, emotional. ACE score 1.

+ SBIRT screen on initial visit xx/xx/13:

+ Positive: tobacco

+ Negative: alcohol, cannabis, illicits, prescribed opioid aberrancies

+ SOAPP-R scored 12 on xx/XX/2013 indicating lower risk

Risk Stratification: Intermediate Level of Controlled Substance Risk

Risk Mitigation

- + Goals of treatment discussed xx/xx/2013 and periodically: Pain and Function improvement 30%
- + Informed consent provided xx/xx/2013 and ongoing
- + Controlled substances agreement last signed on xx/xx/2020
- Naloxone prescription provided with instructions xx/xx/2019 spouse knows how to use
- + Medication security instructions provided xx/xx/2013 and periodically

Risk Monitoring

- Behavioral aberrancies
 - + Reported: Cannabis use xx/xx/2017 discontinued cannabis use after warning





- + Observed: None
- PDMP consistent with prescribing continuously since 1st visit 2013
- + UDT consistent with prescribing since first visit 2014,
- UDS today consistent
- + Nocturnal oximetry 6% of the time <89% saturation

Aberrancy Management

- Patient reported cannabis use 2017 —> warning —> cannabis use stopped
- + Ultimatum: None

A

- + Chronic intractable pain, well controlled
 - + Type: Peripheral
 - + Low back pain without radiation
 - + On opioids: MME 82.5 mg
- + Degenerative disc disease L3-5
- + Obesity
- + Depression responding to duloxetine 60 mg po qd ø analgesic benefit
- + Controlled substances assessment:
 - Pain and function benefit are present and medications are considered necessary for continued benefit
 - + Intermediate Level of Controlled Substance Risk
 - + Patient engagement adequate, and patient appears intent on moving towards goals
 - + Adverse events limited and manageable
 - + No identified aberrancies and patient is felt to be honest in his presentation

P

- Patient education
 - + Discussed attention to functional goals he is to list 3 that he has for himself next visit
 - + Patient is not to make a change in plan or medications unless coordinated with me unless emergency when he is to notify me as ASAP
 - + Reiterated the importance of safe storage





- + Discussed rationale for opioid tapering he agrees to consider
- + In anticipation of tapering:
 - + Increase walking to 11 minutes (5 days per week as before)
 - + Start meloxicam 7.5 mg po bid #60 RF0
- + Refill, no change: oxycodone CR 15 mg po q8h #90 RF0
- + Refill, no change: oxycodone IR 5 mg 1 po q4h prn pain, \leq 3/d #60 RF0
- + Continue duloxetine at current dosage appears effective for depression without AEs
- + Studies:
 - + Definitive UDT with LC/MS-MS due to frequency of UDS false positive / negative rates as well as to identify metabolites, meds, illicit substances not seen on immunoassay
 - + Baseline CBC, BMP, Fe studies (hemacult next visit) b/o meloxicam initiation
- + F/U here in 1m, sooner prn
- + Patient education. He voices understanding, acceptance.
- + Questions answered, decision-making shared.

Steven Wright, MD

Family Medicine
Addiction Medicine
Medical Pain Management

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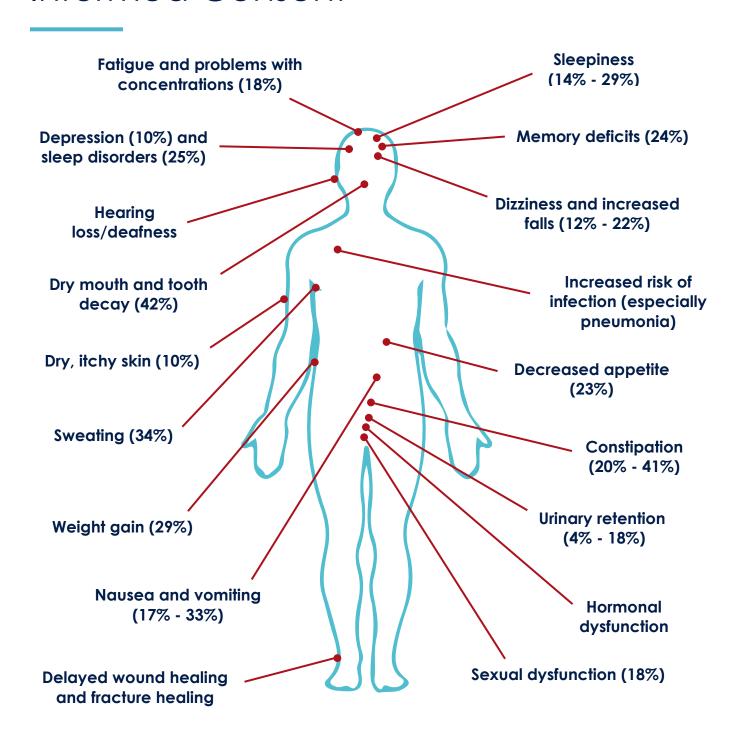
Informed Consent and Controlled Substance Agreement Examples





Opioid Medication

Informed Consent







Quick Facts

- + 78% of patients have at least one adverse event form opioids.
- + 7.5% experience an event that is life-threatening or requires hospitalization.

Risks

- + **Hyperalgesia** (increased sensitivity to pain/decreased pain threshold)
 - + Long-term opioid use may make your pain worse.

+ Opioid dependence

- + Opioids cause significant changes within the brain and body.
- + Dependence is inevitable when taking opioids long term.
- + Dependence makes it very difficult to stop using opioids.

+ Opioid addiction

- Addiction is a treatable, chronic medical disease involving interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction may use substances or engage in compulsive behaviors despite harmful consequences.
- + 2.5 million Americans have an opioid addiction.
- + Addiction is more common in those taking higher doses.

Overdose and death

- + More than 50,000 Americans died of opioid overdose in 2019.
- + Overdose is the number one killer of Americans under the age of 50 years.
- + High doses or the use of opioids with benzodiazepines, alcohol, or other depressants significantly increases the risk of overdose.

Benefits

Opioids can be effective for the short-term treatment of some types of acute pain. Research shows no benefit for the treatment of chronic pain. Potential benefits of opioids include better pain control and increased function.

Alternatives

+ There are many ways to manage pain, including nonopioid medications, procedures, physical therapy, psychotherapy, and complementary and alternative treatments. Many of these approaches can effectively treat chronic pain and can be used with or instead of opioids.

I have read the risks, benefits, and alternatives outlined above, and I understand and consent to my proposed opioid treatment.

Patient Signature

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Opioid Medication for Chronic Pain Agreement

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his is an agreement between	(patient) and	(clinician)	

Although opioids are unlikely to completely rid me of my pain, they are intended to decrease it enough that I can be more active. Because this medication has risks, side effects, and street value, I understand that my clinician needs to monitor my treatment closely to keep me safe. I acknowledge my treatment plan may change over time to meet my functional goals and that my medication, dosage, and adherence to the plan will be closely monitored. I understand that opioids are not intended to be a sole therapy or lifelong medication.

Patient Initials	Please Read the Statements Below and Initial in the Box at the Left.						
	I have reviewed, understand, and accept the risks associated with opioid therapy and the opioid stewardship policies in place at this institution.						
	I understand that the medication may be stopped or changed to an alternative therapy if it does not help me meet my functional goals.						
	To reduce risk, I will take the medication as prescribed. I will not take more pills or take them more frequently than prescribed.						
	I will inform my clinician of any side effects I experience.						
	To reduce risk, I will not take sedatives, alcohol, or illegal drugs while taking this medication.						
	I will submit to urine and/or blood tests to assist in monitoring my treatment.						
	I understand that my clinician or his/her staff may check the state prescription drug database to guard against overlapping prescriptions.						
	I will receive my prescription for this medication only from						
	I will fill this prescription at only one pharmacy. (Fill in pharmacy information below.)						
	I will keep my medication in a safe place. I understand that if my prescription is lost, damaged, or stolen, it will not be replaced.						
	I will do my best to keep all scheduled follow-up appointments. I understand that I may not receive a prescription refill if I miss my appointment.						





Medication Name, Dose, Frequency:	
Pharmacy Name:	
Pharmacy Phone Number:	
By signing below, we agree that we are comfortable with this agree	
Patient Signature	 Date
Clinician Signature	 Date

Adopted from the American Academy of Family Physicians pain contract.

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Controlled Substances

High-Risk Consent and Planning Form

Patient	name
Physicic	in name
Date _	
has info	viewing my opioid dosage and medical, psychiatric, and substance use history, my physician ormed me that I am at high risk for adverse events from the opioid prescription(s) that I am age for the management of pain. I understand that I am at significantly elevated risk of the g:
+ Op + Im + Ho + Op	pioid overdose, death and permanent disability pioid addiction, also known as opioid use disorder pairment from opioids, which may result in accidents or falls spitalization due to opioid-related complications (breathing difficulty, infection, trauma) pioid side effects, including constipation, depression, hormonal imbalance, urinary problems, dation, and depressed breathing
to trying suggest	sician has explained their concerns regarding my risk of adverse outcomes and is committed g to decrease my risk while balancing the need to control my pain. My physician has red that I take several steps to reduce this risk; I am committed to following the nendations below. (Check all that apply.)
	Exercise increased vigilance to take my medications only as prescribed , to not take additional doses, keep my medications in a secure location and not share my medications.
	I will fill a naloxone prescription , complete naloxone training, and inform my household members, family, and friends of my naloxone prescription, its location, and how to use it.
	I have been referred to a pain specialist , who has greater expertise in using opioids and controlling pain. I will make every effort to meet with this specialist.
	I will taper my opioids to a safer level.

I will transition from my current opioid to buprenorphine, which has a better safety profile.





	I will modify my other medications, decreasing or eliminating the use of other sedatives like benzodiazepines, gabapentinoids, barbiturates, muscle relaxers, and sleeping aides.
	I will decrease or eliminate the use of substances that may interact with opioids, including alcohol, marijuana, and sedatives.
	I consent to increased monitoring of my clinical condition and opioid medications . This includes increased visits, drug screening, and other potential interventions as deemed appropriate by my physician.
my phys adverse	ize my physician's concern and duty to emphasize my safety above all else. I understand ician's desire to monitor my current medication regimen to avoid overdose, disability, and outcomes. I recognize that opioids are a "controlled substance" and that my physician right to make changes or discontinue my medication if they believe that it compromises by.
Patient s	ignature

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Chronic Opioid Therapy Shared Decision-Making Tool

General Approach to Tapering

This document is meant to facilitate discussions between primary care providers and their patients about opioid therapy for the treatment of chronic pain. These clinical guidelines can help identify patients at risk for substance use disorder (SUD) and opioid use disorder (OUD) and outline potential interventions. Prior to the appointment, patients are encouraged to complete the following:

- + Pain, Enjoyment, General (PEG) Activity Screening Tool (Link)
- + The Current Opioid Misuse Measure (COMM) Survey (Link)

Opioid Risk/Benefit Discussion Tool (Check all that apply)

Risk Category	Risk Level	Recommendation
Opioid dosage	Opioid dosage >90 MME/day or extended-release formulation (fentanyl patch, Oxycontin, MS-Contin)	Strongly recommend tapering opioid to a safer level.
	Opioid dosage 50-90 MME	Evaluate efficacy; recommend tapering opioid to a lower level.
	Opioid dosage < 50 MME/day	Evaluate efficacy; consider tapering/discontinuing opioid.
Medication and substance use	Benzodiazepine, barbiturate, sedative	Discontinue sedative and/or opioid. (If taking benzodiazepines, remember to taper to prevent withdrawal; tapers often require 12-18 months). If unable to do either, consider transitioning to buprenorphine.
	SUD or injection drug use	Taper opioid and treat SUD; increase monitoring. In patients with alcohol use disorder, strongly consider tapering opioid. Patients with OUD should be transitioned to medication-assisted treatment (buprenorphine, methadone, or naltrexone).
	Gabapentinoid (gabapentin or pregabalin) and/or carisoprodol	Evaluate for sedation and respiratory depression. Consider discontinuation of either opioid or gabapentinoid.





	Occasional alcohol, marijuana, or drug use (not meeting definition of SUD)	Provide counseling on alcohol and concomitant substance use; increase monitoring. If risky use continues, consider tapering or discontinuing opioids.
	Tobacco use	Provide tobacco-cessation interventions and counseling on how nicotine affects opioids/ pain. (Nicotine decreases the effectiveness of opioids.)
	No medication or substance use issues	Encourage continued healthy substanceuse practices.
Medical comorbidities	Organ failure or disease (lung, kidney, liver)	In patients with lung disease, a further evaluation of respiratory status is strongly recommended. Strongly recommend tapering opioids to a safer level; consider transitioning to buprenorphine (in patients with pulmonary or renal disease).
	Age < 40 years or age > 65 years	For patients < 40 years, provide counseling on the increased risk of dependence and OUD. For those > 65 years, provide counseling on the increased risk of falls/morbidity and mortality.
	Sleep apnea (confirmed or suspected)	Treat sleep apnea or offer diagnostic testing.
	Obesity	Encourage weight loss and discuss how opioids may contribute to weight gain.
	Healthy without additional contributory health comorbidities	Encourage continued health maintenance and routine screening.
Psychiatric comorbidities	Mental health or mood condition (depression, anxiety, bipolar disease, PTSD)	Discuss the effect of opioids on depression and anxiety. Provide suicide screening and safety planning. Consider tapering opioids.
	History of SUD (excluding tobacco)	Provide treatment for SUD. Use extreme caution when prescribing controlled substances. Taper opioids.
	History of childhood/sexual trauma (ACES)	Increase psychiatric services and monitoring. Discuss the effect of opioids on depression and anxiety; consider tapering opioids.
	Personality disorder (antisocial or borderline)	Increase psychiatric services and monitoring.
	Family history of SUD	Increase monitoring and provide counseling with the involvement of a patient support network.
	No psychiatric comorbidities	
Medication history and aberrancy	Opioid started within last year with dose escalations, multiple prescribers for the same condition, a suspicious pattern on the PDMP, or drug screen aberrancies.	Screen for OUD, increase monitoring, and consider tapering or discontinuing opioids.





		Opioid usage stable over 1-2 ye opioid prescriptions from one prewith the exception of medication surgery or appropriate acute preconditions; no drug screen abe	rescriber, ons for ainful	the desired a effects. Use st	ether the opioid is still providing nalgesic and functional nared decision-making if ng would be of benefit.
		Patient stable on opioid dosage years; no dose increases; no co PDMP patterns; no concerning patterns; no drug screen aberro	ncerning PDMP	Evaluate whether the opioid is still having the desired effect. Initiate shared decision-making if opioid tapering would be of benefit.	
Number of HIGH risk factors (7)			x 4	+	
Number of MODERATE risk factors (10)				x 2	
Number of PROTECTIVE factors (5)					=
Total Score					

Risk Rating and Recommended Interventions

Risk Level	Points	Interventions (Use in conjunction with recommendations outlined in the table above.)
Extreme risk	12+	Strongly consider referral to a pain management specialist to oversee opioid regimen and create a concrete plan to decrease risk (opioid tapering, medication modifications, SUD treatment, etc). Consider transitioning to buprenorphine when appropriate. Confirm naloxone prescription has been filled and provide mandatory overdose counseling. Schedule monthly visits or phone checkins if possible; at minimum, schedule quarterly visits and increase monitoring (including but not limited to urine drug screenings, pill counts, and social support). Obtain additional "high risk" consent for treatment.
Very high risk	9-11	Strongly consider referral to a pain management specialist to oversee opioid regimen and create a concrete plan to decrease risk (opioid tapering, medication modifications, SUD treatment, etc). Consider transitioning to buprenorphine when appropriate. Confirm naloxone prescription has been filled and provide mandatory overdose counseling. Schedule monthly visits or phone checkins if possible; at minimum, schedule quarterly visits and increase monitoring (including but not limited to urine drug screenings, pill counts, and social support). Obtain additional "high risk" consent for treatment.





High risk	4-8	Consider referral to a pain management specialist to oversee opioid regimen and create a concrete plan to decrease risk (opioid tapering, medication modifications, SUD treatment, etc). Consider transitioning to buprenorphine when appropriate. Confirm naloxone prescription has been filled and provide mandatory overdose counseling. Schedule quarterly visits or phone checkins and increase monitoring (urine drug screening twice per year, pill counts, social support, physician visits). Obtain additional "high risk" consent for treatment.
Moderate risk	2-3	Consider transitioning to buprenorphine. Provide naloxone prescription and overdose counseling. Provide continued monitoring (urine drug screening, pill counts, social support).
Low risk	0-1	Provide naloxone prescription and overdose counseling. Discuss the risks and benefits of possible opioid tapering or discontinuation. Provide continued monitoring (urine drug screening, pill counts, social support).

Disclaimer: The risk-scoring and discussion tool above is based on expert opinion, established opioid/prescribing guidelines, and studies regarding the risk of opioid overdose and SUD. It is meant to help guide shared decision-making between physicians and patients. Although this document recommends certain interventions, it is not a substitute for the advice of a physician or other knowledgeable health care professional. Individual patients may require different treatments from those specified here and in the MSRH guidelines. This tool is not entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. Although the fool considers variations in clinical settings, resources, and common patient characteristics, it cannot address the unique needs of each case or the combination of resources available to a particular community or health care provider. Deviations from these recommendations may be justified by individual circumstances.

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