

Opioid Prescribing: Chronic Opioid Therapy

Updated: August 21, 2019

Background-Addressing the patient on chronic opioid therapy (COT)

This supplement was developed by the Dr. Robert Bree Collaborative (Bree Collaborative) and the Washington Agency Medical Directors' Group (AMDG) in collaboration with an advisory group of the state's academic pain leaders, pain experts, providers in primary care and specialty areas, addiction medicine experts, and patients. The supplement updates the evidence and aligns best practice recommendations with those from the 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain. The recommendations in this supplement are based on the current best available clinical and scientific evidence from the literature and a consensus of expert opinion and are intended for use in addition to, rather than a replacement of, the guidelines for addressing patients on chronic opioid therapy in the 2015 AMDG guidelines. The overall intent is to improve health outcomes and reduce morbidity and mortality related to the opioid epidemic.

This supplement is designed to help primary care and other providers managing patients with chronic pain who are receiving chronic opioid therapy. The overall goal is to develop best practice recommendations on patient engagement, assessment, treatment pathways, and health system interventions related to improving outcomes for patients on chronic opioid therapy. Providing appropriate opioid therapy and pain management for these patients should be individualized and focus on goals of clinically meaningful improvement in function, as well as improved quality of life, and greater patient functional independence rather than on pain relief. In addition, patient safety and avoidance of serious adverse outcomes is a priority.

Guiding principles for systematically addressing, to the extent possible, every patient on COT should follow those laid out in the vision of the [National Pain Strategy](#):

- Patient-centered, accounting for individual preferences, risks, and social contexts
- Comprehensive, meeting biopsychosocial needs
- Multimodal and integrated, using evidence-based treatments

Primary care providers should follow the 2019 Bree [Collaborative Care for Chronic Pain Report and Recommendations](#) that outline a chronic pain management model within primary care. The model includes a team with care coordination function, multi-modal treatments based in evidence-informed care, and patient-centered supported self-management tools. These components are referenced in the 2015 AMDG Guideline, in the 2016 CDC opioid guideline, and throughout the guideline below.

This supplement is organized into:

- Patient engagement
- Assessment
- Develop a treatment plan
- Treatment pathways
 - Maintain and monitor
 - Reduce Dosage
 - Transition to Medication Assisted Treatment (MAT)
- Health systems support

Patient Engagement

A trusting relationship is foundational to engaging a person in clinical care, especially when discussing chronic pain and chronic opioid therapy.¹ Patient engagement, like chronic pain management, should always be individualized.^{2,3}

Key components of patient engagement in chronic pain care include discussing goals of care and preferences, setting expectations, understanding individual patient needs and talking about concerns and fears around pain and around potentially changing treatment.^{4,5,6} The positive effect of goals of care discussions are well-documented.^{7,8} Motivational interviewing may be helpful with engaging patients in chronic pain management^{9,10} *including: a non-adversarial interviewing style developed in substance abuse, seeks to highlight patient ambivalence: aspirations vs behavior, place conflict inside patient's own head, and PODS: used to elicit downside of opioid use from patient's perspective.*

For some, group visits or group educational sessions on chronic pain have been shown to be helpful.¹¹

- **Discuss goals of care.** (e.g., “what are your expectations,” “what do you hope to accomplish,” “what parts of your life are meaningful to you that you may not be able to accomplish right now”).¹² Work to understand the social and emotional dynamics that may impact chronic pain management.¹
 - Goals are about things patients want to do (e.g., walk around the block), not what they want to be (e.g., be pain-free)
 - Functional goals should not be about getting other people to do things (e.g., get husband to stop drinking, get spine surgery)
 - Having a goal discussion helps you get to know the patient as a person, demonstrates you care about their individual experience, and provides a basis for future conversations (esp the difficult ones)
 - Clarifying “bigger picture”/life goals and short term goals driven by the longer term goals is critical. The short term goals should be specific, measurable, achievable, relevant and time-bound. (SMART). These will prove helpful for reframing conversations and promoting behavior change.
- **Set expectations.** Assure the patient that you will not abandon them, that your **goal is to keep them safe while maximizing function.**^{13,14,15}
 - If this is the first visit, do not discuss changing medication until assessment is complete.
 - Make sure the patient knows who to contact on the care team with questions or concerns.
- **Assess knowledge about pain and medication(s), educate on knowledge gaps.** Discuss how the medications work, side effects, and risks and their diagnoses.¹⁶ Discuss differences between addiction, dependence, tolerance, and misuse and the patient's feelings about those. Talk about chronic pain treatment approaches outside of chronic opioid therapy.
- **Assess concerns.** Discuss any fear or concern around pain, abandonment, stigma, and safety. Understand that fear of pain may be more meaningful to a patient than risk of overdose.¹⁷

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- *Abandonment*
 - *To pain: without medications, without substitute*
 - *By provider: no prescriber, no advocate, no confidant*
 - *By health care system: sent to streets for meds, for understanding*
- *Stigma*
 - *Labeled as addict even if perfectly adherent to Rx plan*
 - *Persuaded by MD then blamed by MD for bad outcome*
- *Safety*
 - *Prescriber self-protection rather than patient protection*
 - *Population risks don't apply to me*
 - *I should be able to accept risks if relief is worth it to me*
- **Respect.** Treat patients with respect and address using a non-judgmental manner.
- **Involve others.** Ask if the patient's spouse, parents, children or others could be included in any treatment plan. Social support has been shown to be a facilitator to effective chronic pain management.¹² Understand concerns from family including:
 - The patient
 - When is my spouse going to get better?
 - How can I help him?
 - The treatment
 - Are the opioids making him better or worse?
 - How can I tell if he is becoming dependent or addicted?
 - I am worried about having opioids in my house
 - Will he just be more miserable on less opioids?
- **Consistency.** Use consistent messaging from all team members and in all visits.

Assessment

The following assessment will likely entail a substantial commitment of time; therefore, both appropriate reimbursement for such a complex assessment, as well as a staged approach over several visits, may be necessary

- Complete a history including details on opioid and other substance use. The history of prescription opioids should detail prescribed opioid use from the very first prescription of opioids to the present.
- History of all pain related interventions, including all spine and extremity surgery, all injections, and impact on pain and function
- Using a pictorial representation of the body, fill in all the parts of the body affected by chronic pain. The key here is to determine how many parts of the body are affected.
- Complete physical exam including all pain-related diagnoses
- Assess pain and functional status with PEG pain intensity and interference scale
- Query the Prescription Monitoring Program over the past 6 months and document all findings.
- Review and document the current treatment agreement.
- Conduct a urine drug screen. If results are aberrant, discuss this with the patient.
- Screen for depression, anxiety, suicidality, and alcohol and illicit drug use including the safety and security of the information. Screen for mental health and substance use conditions, using a validated instrument(s), including:
 - **Depression** (e.g. Patient Health Questionnaire-2, PHQ-3 and/or PHQ-9) and **anxiety** (e.g., Generalized Anxiety Disorder-2), follow guidelines within the 2017 Bree Collaborative [Behavioral Health Integration Report and Recommendations](#).
 - **Suicidality** (e.g. ninth question of the PHQ-9, first and second questions of the Columbia Suicide Severity Rating Scale (C-SSRS), the Ask Suicide-Screening Questions (ASQ) as well as current plans and any past attempts). If suicide risk is detected, follow guidelines within the 2018 Bree Collaborative [Suicide Care Report and Recommendations](#), or more recent if available.
 - **Alcohol misuse** (e.g., AUDIT-C) and **drug use** (e.g., single-item screener, ASSIST, DAST-10, single item cannabis and other drug use questions). If alcohol misuse or illicit drug use is detected, follow guidelines within 2015 Bree Collaborative [Addiction and Dependence Treatment Report and Recommendations](#), or more recent if available following the Screening, Brief Intervention, and Referral to Treatment (SBIRT) protocol.
 - **Post-traumatic stress disorder**
 - **Adverse childhood experiences**. More information [here](#).
- **Conduct inquiry regarding presence of dependence/ODU. The DSM-V criteria for the diagnosis of Opioid Use Disorder can be found in Appendix 1. Some experts consider that severe OUD defined as meeting 6 or more criteria is equivalent to addiction. Meeting fewer than 6 criteria, or having difficulty tapering, would meet mild or moderate OUD.**
 - Refs Koob & Volkow Lancet Psychiatry 2016;3:760, Ballantyne, Sullivan and Koob, 2019 (in press)
 - Opioid dependence includes any/all of the following characteristics, differentiating it from OUD:

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- No uncontrollable craving or compulsive use
- No harmful use that is not medically directed (patient takes opioid exactly as described)
- Withdrawal drug opposite effects: somatic withdrawal symptoms, hyperalgesia, hyperkatefeia, dysphoria
- Potential difficulty tapering
- Stress-like symptoms
- Reward deficiency and social withdrawal
 - Refs: Ballantyne & LaForge, Pain 2007;129:235
 - Ballantyne et al, Arch Int Med 2012;172:1342
 - Nestler, Nature Rev Neurosci 2001;2:119
 - Koob & LeMoal Annu Rev Psychol 2008
 - Koob & LeMoal 2001
 - Shurman et al Pain Med 2010
 - Koob & Volkow Lancet Psychiatry 2016
 - Ballantyne et al Pain 2019

Why Dependence is not Addiction/OD

Dependence	Addiction/OD
Continuous withdrawal	All of Dependence +
Hyper-emotions (hyperkatefeia)	Compulsivity
Symptoms of stress	Lack of control
Reward deficiency	Defined by behaviors
Social withdrawal	Laid down as Memory (hard to eradicate)

Chou, Ballantyne, Lembke Annals Int Med 2019 (in press)

Opioid Dependence is distinguished from Opioid Use Disorder to avoid the binary choice between OUD versus no OUD, which is problematic particularly for the many patients who have Opioid Dependence that does not meet criteria for OUD. These patients need treatment akin to OUD treatment BUT, in contrast to OUD:

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- It is acceptable to continue the patient's usual opioid (but with supplementary monitoring and support) if attempts to taper result in a deterioration in function and quality of life
 - Buprenorphine should be offered specifically to treat Opioid Dependence and pain, and may obviate the need to continue patient's usual opioid
 - Where OD and not OUD diagnostic criteria are met, avoidance of the OUD diagnosis relieves the patient from the stigma, employment implications and possible child custody implications of OUD.
- **Using EHR data, screen for the following. Risk of opioid overdose and problematic opioid use increases with the number of indicators that are present.**
 - Chronic opioid therapy average daily dose (greater than 50 mg. MED)
 - Chronic opioid therapy average daily dose (greater than 90 mg. MED)
 - Use of ER/LA opioids
 - Any use of sedatives/benzodiazapines
 - Chronic use of sedatives/benzodiazapines
 - Opioid abuse/dependence Dx
 - Non-opioid drug or alcohol abuse/dependence Dx
 - Mental disorder Dx
 - Document all important co-morbidities: eg, diabetes, COPD
 - Document all adverse events related to COT use (see Table below)

The following brief simple questions can be used to inquire about substance abuse. Any use of an illegal drug or use of a prescription drug for a non-medical reason indicates increased risk of opioid overdose and opioid use disorder.

How many times in the past year have you used an illegal drug or used a prescription drug for non-medical reasons?

Never Once More than once

IF MALE, Ask:

In the past year, how many times have you had 5 or more drinks (male) in a day?

Never Once More than once

IF FEMALE, Ask:

8B. In the past year, how many times have you had 4 or more drinks (male) in a day?

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Never <input type="checkbox"/> Once <input type="checkbox"/> More than once <input type="checkbox"/>
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Have you more than once tried to give up or cut down on your use of opioid pain medicines and been unable to do so?

No Yes

Have you ever felt a strong urge or desire to take opioid pain medicines?

No Yes

Have you ever continued to use opioid pain medicines despite emotional or physical problems related to their use?

No Yes

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Medical Risks of Long-term Opioid Use

Medical risk	How common?	Description and information
Respiratory depression		
Opioid overdose	< 1% per year but increases with dose	<ul style="list-style-type: none"> - Caused by severely slowed breathing, which you may not notice - Severe cases are treated in the hospital - Can cause death
Breathing problems during sleep	Not known	<ul style="list-style-type: none"> - Opioids may cause or worsen sleep apnea - You may not notice breathing problems
Injuries		
Falls & fractures	Not known	
Motor vehicle crashes	Not known	
Gastrointestinal problems		
Constipation	30 - 40%	<ul style="list-style-type: none"> - It helps to use stool-softeners or drugs that stimulate bowel movements
Serious intestinal blockage	<1% per year	<ul style="list-style-type: none"> - Caused by severe constipation - Severe cases are treated in the hospital
Hormonal effects		
Hypogonadism, impotence, infertility, osteoporosis	25% - 75%	<ul style="list-style-type: none"> - <i>Hypogonadism</i> = lowered sex hormones, which can worsen sexual function - <i>Osteoporosis</i> can make you more likely to fracture or break a bone
Cognitive and neurophysiologic effects		
Sedation	15%	<ul style="list-style-type: none"> - Can cause difficulty driving or thinking clearly
Disruption of sleep	Not known	
Hyperalgesia	Not known	<ul style="list-style-type: none"> - <i>Hyperalgesia</i> = being more sensitive to pain
Psychosocial		
Depression, anxiety, de-activation, apathy	Not known	<ul style="list-style-type: none"> - Depression can worsen pain, while pain can worsen depression. Opioids can cause loss of interest in usual activities, which can increase depression.
Addiction, misuse, and diversion	5 - 30%	<ul style="list-style-type: none"> - Common signs of prescription opioid addiction are preoccupation with opioid use or craving, unsuccessful attempts to discontinue use or cut down, cutting down or giving up activities due to opioid use, and using more medication than prescribed.
Oral Health		
Dry mouth that may sometimes cause tooth decay	Dry mouth is common	<ul style="list-style-type: none"> - Brush your teeth and rinse your mouth often - Chew sugarless gum and drink water or sugar-free, non-carbonated fluids
Myoclonus	Not Known	<ul style="list-style-type: none"> - <i>Myoclonus</i> = muscle twitching

Long-term opioid use can cause diverse adverse effects that differ across patients. A brief, simple information sheet like that shown above can be used with patients to review common medical risks of opioids to identify problems that patients may not realize are being caused by their use of opioid analgesics, while educating patients about opioid-related risks.

Reference: Baldini A, Von Korff M, Lin EHB. A review of potential adverse effects of long-term opioid therapy: A practitioner's guide. *The Primary Care Companion for CNS Disorders* 2012; 14(3): pii: PCC.11m01326. doi: 10.4088/PCC.11m01326.

Develop a Treatment Plan

Treatment plans should be developed in collaboration with the patient, and family or others if appropriate.

- Chronic pain be managed through collaborative care as described in the 2019 Bree Collaborative [Collaborative Care for Chronic Pain Report and Recommendations](#). These guidelines focus on goals of improved function, increased quality of life, and greater patient autonomy rather than a primary focus on pain relief supported by a care team.
 - If possible, involve behaviorists.²
 - *“To help them through these changes”*
 - *Remember pain alone doesn't cause depression, anxiety, or alcohol use disorder, although it can exacerbate these problems*
 - *Opioids are effective at suppressing symptoms of anxiety, PTSD*
 - *Sleep dysfunction makes everything worse*
 - *Anger, shame, grief, questioning whether life has meaning or purpose*
- *Review central sensitization syndrome²*
 - *“New understanding since you were started on opioids”*
 - *Correlated with Adverse Childhood Experiences, PTSD*
 - *Correlated with high dose chronic opioids*
 - *Fibromyalgia, chronic daily headache, chronic pelvic pain, IBS, interstitial cystitis, chronic fatigue*
 - *Best managed with behavioral techniques*
- Review non-opioid pharmacological management of chronic pain including acetaminophen, topicals, intermittent steroid injections, serotonin and norepinephrine reuptake inhibitors, and others as indicated.
- Review non-opioid, non-pharmacological management of pain. Identify, support and enhance what patients are already doing to manage chronic pain with life activity impacts. Discuss:
 - Pain amplifiers (e.g., sleep problems).
 - Cognitive-behavioral therapy

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- Integrative health practices (e.g., massage, acupuncture, spinal manipulation).
- Reactivation methods, eg via psychologically informed physical therapy, activity coaching,)
- Movement and body awareness strategies.
- Determine together with the patient and their families whether to stay on opioids, reduce opioid prescriptions or dose at a rate consistent with patient's clinical and social situation or transition to medication-assisted treatment (MAT). People may want to stop chronic opioid therapy due to a variety of reasons including lack of efficacy, impact on quality of life, and concerns about addiction.¹⁸ Shared decision-making in the context of use of controlled substances does not require the physician to give up prescribing decision authority. However, it does involve the patient and physician BOTH sharing information, deliberating about options, an agreeing on a course of action. The latter would also depend on both the overall assessment and whether the patient meets criteria for tapering.
 - Refs: Charles C et al. Social Sci Med 1999;49:651-61; Makoul and Clayman. Patient Educ Couns 2006;60(3):301-12.

Treatment Pathways

Review the [CDC Pocket Guide: Tapering Opioids for Chronic Pain](#), that follows similar principals to the 2015 AMDG Opioid guideline on whether to reduce, taper, or discontinue chronic opioid analgesic therapy (COT) using the following case definition (Table 8 in 2015 AMDG Guideline); new or adapted criteria from the CDC are marked with an:*

- Patient requests opioid taper.
- Patient is maintained on opioids for at least 3 months, and there is no sustained clinically meaningful improvement in function (CMIF), as measured by validated instruments (Appendix B: Validated Tools for Screening and Assessment)
- Patient's risk from continued treatment outweighs the benefit (e.g. decreased function and increased risk for opioid-related toxicity from concurrent drug therapy or comorbid medical conditions)
- Patient has experienced a severe adverse outcome or overdose event
- Patient has a substance use disorder (except tobacco)
- Use of opioids is not in compliance with DOH's pain management rules or consistent with the AMDG Guideline
- Patient exhibits aberrant behaviors (Table 9 in 2015 AMDG opioid Guideline)
- *Is on dosages \geq 50 MME without benefit or opioids are combined with benzodiazepines
- *Shows signs of substance use disorder (e.g., work or family problems related to opioid use, difficulty controlling use)

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- *shows early warning signs for overdose risk such as confusion, sedation, or slurred speech
- **Patient has cannabis use disorder

In determining a treatment pathway, clinicians and patients may have divergent priorities. While clinicians may be most concerned about overdose or addiction, many patients may consider that they personally may have low risk of serious adverse outcomes. Patients are more likely to fear pain, suffering, and loss of control more than a serious event. However, patients also are likely to have priorities for effective pain treatment beyond simple pain relief, including wanting better emotional well being, improved physical activity, better sleep, and greater social participation.

Refs: Frank J, et al. Pain Med 2016;17:1838-1845; Wilder CM, et al. J Addict Dis 2016; Kennedy LC et al, Pain Med 2018;19:2201-2211

Pathway #1: Maintain and Monitor

This pathway can be considered if the patient does not meet criteria, derived from the assessment, for tapering as enumerated above. Potential criteria for this pathway may include:

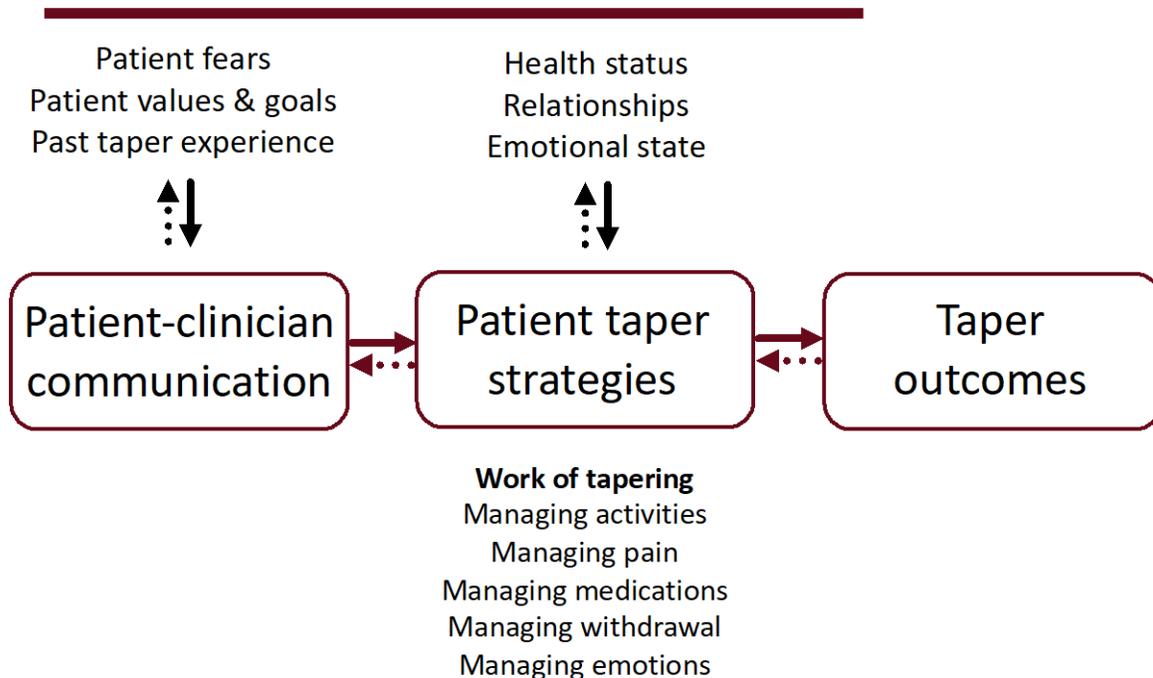
1. Clear evidence of clinically meaningful improved function on opioids along with satisfactory work/home productivity consonant with the functional level
2. No history of serious or life threatening adverse events
3. Not on combinations of opioids and sedative/hypnotics
4. Has a clearly destructive disease process such as SLE, sickle cell anemia
5. Patient is not receiving opioids primarily for a centralized pain condition (eg, non-specific musculoskeletal disorder, fibromyalgia, headaches)
6. No history of alcohol abuse or illicit substance use
7. No history of misuse or diversion
8. Patient has already successfully tapered to <90 mg/day MED

Pathway #2: Taper (Wean)

The taper plan could include tapering to a safer dose level or tapering completely off opioids

A recent model, based on patient's taper experience, is summarized in this Figure:

Model of patients' taper experience



Henry SG et al. J Pain 2019;20(2):181-191

- **Individualize.** All tapering schedules should be individualized to a specific patient and take into account patient preferences and life circumstances.
- **Address concerns about uncontrolled pain, withdrawal, abandonment, and loss of control**
- Involve patient in developing a taper plan
- **Go slow.** In most cases 10% per week or as slow as 10% per month. Use of the updated AMDG taper plan calculator can be extremely useful ([Washington State Opioid Taper Plan Calculator](#)). Some patients with complex medical and psychiatric co-morbidities may require a slower taper. Tapers may be paused regarding the patient's feedback regarding severity of withdrawal symptoms. but, in general, should not be reversed.
- **Protocol.** In general patients should be tapered using their long-term opioid medication with the same dosing schedule. Patients taking intermittent opioids do not need to be tapered. Patients taking only short-acting opioids can be tapered more quickly.
- **Consult with other providers.** Specific consultation may be important for patients at high risk of harm, such as pregnant women or patients other substance use disorder.
- **Use non-opioid medication.** Table 10 in the 2015 AMDG Opioid Guideline summarizes the array of available treatments for the main symptoms associated with withdrawal during tapering (opioid abstinence syndrome). The most commonly used treatments include alpha adrenergic

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agonists such as clonidine for restlessness, sweating and tremors, antiemetics (eg, ondansetron or prochlorperazine) for nausea, loperamide or anti-spasmodics (eg, dicyclomine) for diarrhea, NSAIDs, gabapentin or muscle relaxants (eg, cyclobenzaprine, tizanidine or methocarbamol) for muscle pain, neuropathic pain, or myoclonus, or antidepressants such as nortriptyline (25 mg hs), mirtazapine (15 mg hs), or trazodone (50 mg hs). Benzodiazepines and sedative-hypnotics should not be used.

- **Use support and adjunctive therapies.** Evidence-based treatments known to be effective for chronic pain, such as cognitive behavioral therapy and reactivation via psychologically informed physical therapy, should be provided. The delivery of more integrated care via the six building blocks on a community-wide basis is emphasized in the Health Systems section of this report. Also reference the Bree report on Collaborative Care for Pain. In addition, multimodal care through a structured intensive multidisciplinary program (SIMP) has been demonstrated to be effective.
- **Monitor.** Patients being tapered require close follow-up by the principal tapering provider, both during and after the taper. Patients undergoing a taper should be monitored for worsening depression and anxiety and for emergence of Opioid Use Disorder. The State PDMP should be checked regularly throughout this period.
- **Engage and encourage.** Many may experience improved function with stable and sometimes improved pain, but typically no worsening of pain, in the long term, following successful tapers. However, fear of withdrawal symptoms can make engaging patients in initiating and conducting a successful taper difficult. Appropriate education regarding the potential benefits of tapering should be part of the initial effort prior to initiating a taper. While the goal is to reach mutual agreement on the decision to initiate a taper as often as possible, for patients meeting the case definition for a taper, particularly those at risk of harm, this decision is the provider's decision.
- **Use of Buprenorphine to assist with taper.** Use of Buprenorphine on a temporary basis may be effective in achieving a successful taper regime while avoiding more severe withdrawal symptoms. A Buprenorphine-naloxone option potentially addresses barriers to high-dose opioid tapering
 - May increase patient willingness to attempt dose reduction
 - May facilitate more rapid dose reduction
 - May address physiological consequences of high-dose long-term opioid use (craving, withdrawal, prolonged abstinence syndrome)
 - Refs: Oldfield BJ, et al. Pain Medicine 2018;19(S1):S38-S45. Guillod P, Edens EL, Becker WC. JAMA Intern Med. 2017;177(1):17-18. Becker WC, et al. J Subst Abuse Treat. 2015; 48(1):128-31
 -

Pathway #3: Transition to Medication Assisted Treatment (MAT) for OUD

Start with the foundation in 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain, Part VI (Recognition and Treatment of Opioid Use Disorder)

- Use evidence-based therapy including medication-assisted treatment (MAT) if opioid use disorder is present. Follow the 2017 Bree Collaborative [Opioid Use Disorder Treatment Report](#)

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[and Recommendations](#) and the [2015 Agency Medical Directors Guideline on Prescribing Opioids for Pain](#) Part VI Recognition and Treatment of Opioid Use Disorder.

- In many cases, a clear diagnosis of OUD using DSM-V criteria may not be apparent. Failed attempts at tapering, or persistent and severe withdrawal symptoms in spite of best medical treatment to address these symptoms, or failed multidisciplinary treatment for chronic pain, may indicate the need for a trial of MAT.
- Patients must abstain from opioid agonists for at least 8 to 12 hr (best accomplished overnight) and be in mild-to-moderate withdrawal (a score of ≥ 8 on the Clinical Opiate Withdrawal Scale)
- Once a patient is having mild-to-moderate withdrawal, administer 2 to 4 mg of sublingual buprenorphine or buprenorphine plus naloxone. If patient has no unacceptable side effects, administer an additional 4–8 mg sublingually at 1–2 hr, followed by adjustment according to response up to 32 mg daily in divided doses

Health System and Community based Support

Use of the **Six Building Blocks**, as originally devised for chronic disease management at Group Health Cooperative of WA, and expanded by work at the MacColl Institute, has been recently applied to assist primary care practitioners in safety net clinics, such as Federally Qualified Health Centers, to improve management of patients on COT. The Bree Collaborative Care model for Chronic Pain

(<http://www.breecollaborative.org/wp-content/uploads/Recommendations-Chronic-Pain-Final-2018.pdf>) follows the principals of the Six Building Blocks. Use of telecare to deliver collaborative management is an emerging area (Kroenke K et al, Contemp Clin Trials 2013;34:270-281; Kroenke K et al, JAMA 2014;312(3):240-248). In this model, lower intensity intervention can be delivered by a pharmacist care manager.

Delivery of **multimodal pain care** in the community has the most evidence in randomized controlled trials for the effective treatment for chronic musculoskeletal pain, one of the most important contributors to years lived with disability in the US (Murray et al)

Ref: Peterson K, et al. J Gen Intern Med 2018;33(S1):S71-81

A **peer support specialist** has been used in the Southern Oregon Pain Guidance effort to assist the patient on COT throughout, including as a teacher/mentor, as a tapering and withdrawal coach, as an advocate, and as a resource purveyor, for example, with available community resources. The peer support specialist has also worked with providers on difficult conversation training.

Institutional multidisciplinary panel support for primary care practitioners to assist with the care and assessment of patients on COT has been employed at Veterans Administration health Centers in Portland and New Haven. The Department of Labor and Industries is now exploring similar types of support mechanisms through its Centers for Occupational Health and Education.

Ref: Seal K, et al. J Gen Intern Med. 2017;32(8):931-934; Purcell N, et al. Global Advances in Health and Medicine, 2019;8:1-8, Purcell N, et al. Pain Med. 2017 Pain Med 2017;19:1748–1763

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The **Vermont Hub and spoke model**, also being explored in Washington's Accountable Communities of Health, has been applied to the care of patients with opioid use disorder, but it could also be deployed to assist in the more complex phases of care for the COT patient, particularly those with more severe dependence or OUD.

Multidisciplinary pain clinics have been used at the University of California-San Francisco, Cleveland Clinic, the Mayo Clinic, and by the WA Department of Labor and Industries, to assist with prescription opioid tapering.

DRAFT

Evidence

The PEG assessment should be done at each visit.¹⁹

Medication assisted treatment (MAT) combines the use of medications with behavioral therapy (e.g., counseling) for a whole-person approach, augmenting behavioral therapy alone and has been shown to be more effective than behavioral therapies, medically-supervised withdrawal, or abstinence alone.^{20,21,22}

Substantially more evidence on tapering has been published since the literature review on the 2015 AMDG guideline was completed in December 2014.

Frank et al (2017), using GRADE methodology, conducted a systematic review of 67 studies, including 11 randomized trials.²³ The review concluded that, based on very low quality of evidence, several interventions may be effective and pain, function and quality of life may improve. The strongest evidence with fair-good studies included interdisciplinary programs with mean opioid discontinuation rates of 87%, and behavioral interventions, with mean opioid discontinuation rates of 21%. Very weak studies included buprenorphine dose reduction and ketamine-assisted dose reduction. The authors concluded that 1) education for patients on COAT should include the message that pain severity, function, and quality of life may improve after opioid tapering, 2) there should be consideration of referral to a multidisciplinary, multimodal pain program to support opioid dose reduction, and 3) team-based strategies with close follow-up to support opioid tapering when multidisciplinary programs are not available.

Berna et al (2015) conducted a comprehensive review of 117 articles and offered recommendations for everyday practice targeted at primary care physicians.²⁴ An overarching conclusion was that discontinuing COAT is most often hindered by patients' psychiatric co-morbidities and poor coping skills, as well as a lack of formal guidelines for prescribers to successfully taper. Several issues pointed out by Berna et al (2015) provide additional potential guidance: 1) Immediately following a successful taper of COAT, or after discontinuing post-op opioids, brief, sensory hyperalgesia may occur, 2) the potential utility of use of clinical and subjective opiate withdrawal scales (COWS, SOWS), 3) Overall, aggregating patients across numerous studies, patients report improvements in function without associated worsening in pain (N=1007) or even decreased pain levels (N=513), 4) Patients who take opioids only intermittently (<once daily) do not need a formal taper, 5) Empirical protocols since the 1990s favor tapers using the patient's long term opioid treatment medication, vs switching to another medication for the taper, 6) psychological support may be needed to address possible anxiety related to the taper, underlying depression, and deficient pain- and stress-coping strategies, 7) A taper agreement, including a collaboratively formulated plan, may help foster an effective therapeutic relationship and minimize the risk of breaking trust, 8) in patients with opioid dependence, buprenorphine may reverse opioid-induced hyperalgesia and reduce opioid tolerance, and convincing evidence from 8 studies (aggregated N=14,224), including 3 randomized clinical trials and a large open-label observational study, supports the benefits from this practice.

Several recent randomized trials of tapering have been reported since 2015; they have in common difficulty in recruitment or high drop-out rates, emphasizing the importance of patient and provider engagement in any tapering program. Sullivan et al reported a 22 week RCT with opioid taper support vs usual care (N=35).²⁵ Although this study did not achieve significant differences in opioid dose reduction

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or pain severity ratings between the supported group vs the usual care group, self reported pain interference and pain self-efficacy were improved in the intervention group. This was essentially a feasibility study to launch a larger funded study.

In an observational study at a single pain clinic at Stanford University, Darnall et al (2018) reported that 75% of eligible patients on COAT (82/110) volunteered to enter a tapering protocol.²⁶ Patients were followed for 4 months (completers) on a slow taper, with only education (a self-help book) and physician support, but no behavioral intervention; 38% (31/82) of enrolled patients did not complete the four month end-date survey and were considered drop outs. Among completers, baseline opioid dose (median dose =288 MED/day) was reduced to a median of 150 mg MED. Dose reduction was not associated with worse pain intensity or pain interference. Duration of opioid use did not predict taper success. Thus, even patients on very high doses followed closely in a pain clinic are willing to at least initiate a taper protocol.

Frank et al conducted key informant interviews among 24 Colorado patients who were currently on COAT and had not tried tapering (6/24, 25%), were currently tapering (12/24, 50%), or who had discontinued COAT (6/24, 25%).²⁷ Patients perceived a low risk of overdose and a higher and more immediate risk of increased pain with tapering. Fear of withdrawal and a perceived lack of effectiveness of non-opioid options were identified as barriers. Social support and a trusted health care provider to facilitate tapering were identified as helpful among those with tapering experience. Improved quality of life was reported following successful tapering. Another qualitative study on a small number of patients emphasized the individualized nature of communications regarding possible tapering and emphasized assuring patients they would not be abandoned. (Matthias et al, 2017)²⁸

Evidence on taper speed is almost entirely based on studies of patients with opioid use disorder related to heroin use (not chronic pain). Consensus opinions on taper speed range from 5-10% every 2-4 weeks to 2-10% every 4-8 weeks, with pauses as needed.²⁹ Veterans Administration recommendations are for 5-20% every 4 weeks-detailed example tapers are also offered.³⁰ Sudden discontinuation is strongly NOT recommended. A cohort study from Vermont Medicaid, in whom discontinuation occurred in a median of 1 day, indicated that most patients either had no taper or rapid taper. Forty-nine percent of these patients had an opioid related hospitalization or emergency department visit subsequent to the sudden or rapid discontinuation. A majority (60%) of these Medicaid recipients had a diagnosed substance use disorder prior to tapering, and <1% had been transitioned onto an OUD medication.³¹ On April 9, 2019 the FDA published a Drug Safety Communication strongly advising against abrupt discontinuation among opioid dependent patients.³²

Studies published to date have not been designed to evaluate effects of tapering on overdose risk, use of illicit opioids, or suicidality/suicide events. Research is needed on effectiveness of adjunctive treatments; buprenorphine taper in the context of chronic pain with or without prescription opioid taper; speed of taper; and the effects of patient and clinical factors on taper outcomes. More research is also needed evaluating tapering in primary care and the health systems support necessary for effective tapering in primary care.

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Appendices

DSM-5 Criteria for Diagnosis of Opioid Use Disorder	
Diagnostic Criteria* <small>*These criteria not considered to be met for those individuals taking opioids solely under appropriate medical supervision.</small>	
Check all that apply	
<input type="checkbox"/>	Opioids are often taken in larger amounts or over a longer period of time than intended.
<input type="checkbox"/>	There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
<input type="checkbox"/>	A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
<input type="checkbox"/>	Craving, or a strong desire to use opioids.
<input type="checkbox"/>	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
<input type="checkbox"/>	Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
<input type="checkbox"/>	Important social, occupational or recreational activities are given up or reduced because of opioid use.
<input type="checkbox"/>	Recurrent opioid use in situations in which it is physically hazardous.
<input type="checkbox"/>	Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
<input type="checkbox"/>	*Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid
<input type="checkbox"/>	*Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms

Total Number Boxes Checked: _____

Severity: **Mild:** 2-3 symptoms. **Moderate:** 4-5 symptoms. **Severe:** 6 or more symptoms

Appendix C: [2015 Agency Medical Directors Guideline](#)

Reasons to Discontinue COAT and Considerations Prior to Taper

- Consider tapering patients in an outpatient setting if they are not on high dose opioids or do not have comorbid substance use disorder or an active mental health disorder, as this can be done safely and they are at low risk for failing to complete the taper.
- Seek consultation from a pain management specialist or Structured Intensive Multidisciplinary Pain Program (SIMP; described in Non-opioid Options) for patients who have failed taper in an outpatient setting or who are at greater risk for failure due to

high dose opioids, concurrent benzodiazepine use, comorbid substance use disorder or any active mental health disorder. If SIMP is not available, engage patients in activities that emulate the biopsychosocial approach of such a program. Rarely, inpatient management of withdrawal may be necessary.

- *Refer patients with aberrant behaviors (Table 9) for evaluation and treatment.*

How to Discontinue Opioids

- *Consider sequential tapers for patients who are on chronic benzodiazepines and opioids. Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.*
- *Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naloxone or naltrexone with propofol, methohexital, ketamine or midazolam).*
- *Establish the rate of taper based on safety considerations: a. **Immediate discontinuation if there is diversion or non-medical use**, b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or c. Slow taper for patients with no acute safety concerns. Start with a taper of $\leq 10\%$ of the original dose per week and assess the patient's functional and pain status at each visit.*
- *Adjust the rate, intensity, and duration of the taper according to the patient's response (e.g. emergence of opioid withdrawal symptoms (Table 10)).*
- *Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions (Appendix B: Validated Tools for Screening and Assessment).*
- *Consider the following factors when making a decision to continue, pause or discontinue the taper plan: a. Assess the patient behaviors that may be suggestive of a substance use disorder b. Address increased pain with use of non-opioid options. c. Evaluate patient for mental health disorders. d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is CMIF, reduced pain and no serious adverse outcomes.*
- *Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.*
- *Increase the taper rate when opioid doses reach a low level (e.g. < 15 mg/day MED), since formulations of opioids may not be available to allow smaller decreases.*
- *Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms are rarely medically serious, although they may be extremely unpleasant. Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued (Table 10).*
- *Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.*

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- *Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use.*
- *Consider inpatient withdrawal management if the taper is poorly tolerated.*

DRAFT