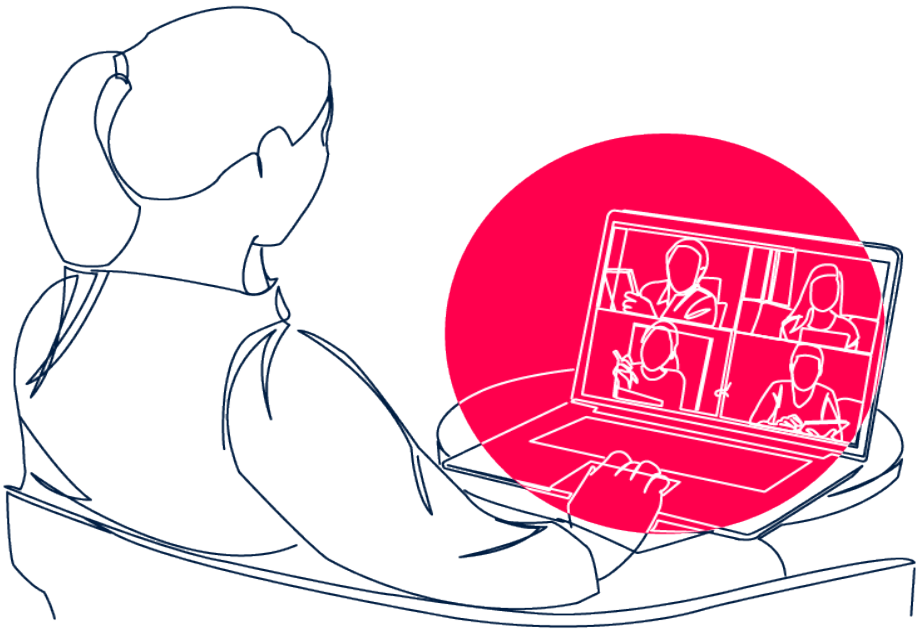

Not Just A Prescription Pad: A Multimodal Approach To Chronic Non-Cancer Pain Management

RESOURCES

2.25 MOC Section 1, Mainpro+

Part 1: Monday, March 28, 2022
Part 2: Thursday, April 7, 2022

THE UNIVERSITY OF BRITISH COLUMBIA
Continuing Professional Development
Faculty of Medicine

WorkSafeBC

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Not just a prescription pad:

A multimodal approach to chronic pain management

Learn more about engaging with patients with complex chronic non-cancer pain and identifying appropriate evidence-based treatments

Speakers: Dr. Peter Rothfels and Dr. Launette Rieb

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Part 1	
6:30–6:40 pm	• Introduction • Enacted scenario: James
6:40- 7:30 pm	• Persistent pain overview • WorkSafeBC programs and community resources • Case 1: Sue — demonstrating a bio-psycho-social approach
7:30–7:35 pm	Break
7:35–7:55 pm	Non-pharmacological modalities
7:55–8:15 pm	Q&A
Part 2	
6:30–6:35 pm	Introduction
6:35–7:25 pm	Case 2: Phillip — complex chronic pain requiring integration of pharmacological and non-pharmacological pain management strategies including opioid tapering; variations
7:25–7:30 pm	Break
7:30–7:40 pm	Putting it all together: James follow up
7:40–8:00 pm	Q&A

Learning objectives

This session is designed to help you:

1. Develop confidence in having difficult conversations related to broadening pain education and treatment options beyond the prescription pad
2. Apply key pharmacological principles including tapering of opioids, initiating substitution therapy, and medication exit strategies
3. Identify community and regional resources and supports including WorkSafeBC programs

WorkSafeBC

Presenters

Dr. Peter Rothfels

B.Ed., M.D., ASAM

Dr. Rothfels graduated from the University of Alberta, with a B.Ed with Distinction in 1976, and as an MD in 1981. After spending 6 years of practicing Emergency Medicine in the U.S., he returned to Canada and spent 13 years as a solo physician in a small rural community in Nova Scotia. Dr. Rothfels then moved to Victoria, B.C. in 2000, and after doing locums for 2 years, joined WorkSafeBC as a Medical Advisor in 2002 where he became a Senior Medical Advisor in July 2006, and became Chief Medical Officer and Director of Clinical Services in January 2008. Peter has a particular interest in Chronic Pain and Addiction Medicine. He has been asked to speak at numerous conferences and outreach seminars, on the interplay of chronic pain, opioids, and addictions.

Dr. Launette Rieb

MSc, MD, CCFP, FCFP

Dr. Launette Rieb is a family physician and Clinical Associate Professor in the Department of Family Practice at UBC. Her graduate work was in the area of pain neurophysiology. She is certified by the American Board of Addiction Medicine and the Canadian Society of Addiction Medicine. She was the co-creator and initial Physician Director of the St. Paul's Hospital Goldcorp Addiction Medicine Fellowship. Dr. Rieb works clinically at OrionHealth (Vancouver Pain Clinic), The Orchard Recovery Centre, and in the Rapid Access Addiction Clinic at St Paul's hospital. She is the recipient of a UBC Post Graduate Teaching Award.

Centre for Effective Practice

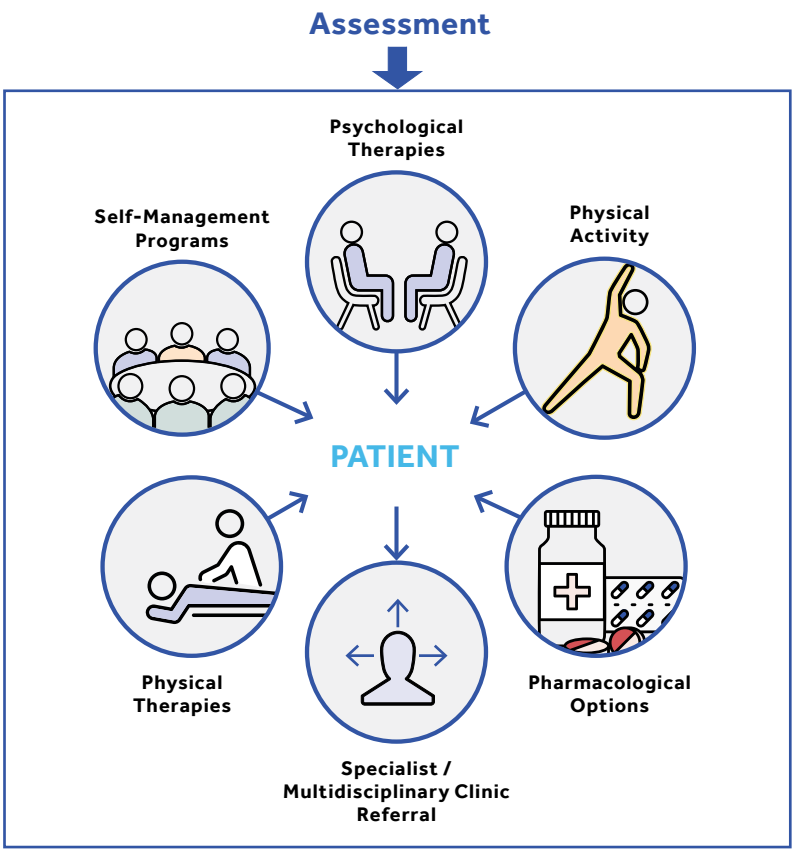
Management of Chronic Non Cancer Pain

Introduction

This tool is designed to help family physicians and nurse practitioners (primary care providers) develop and implement a management plan for adult patients with Chronic Non Cancer Pain (CNCP) in the primary care setting. CNCP is defined as pain that typically persists or recurs for more than 3 months or past the time of normal tissue healing.[1,2,3,4] This tool applies to, but is not limited to pain conditions such as osteoarthritis (OA), low back pain (LBP), musculoskeletal (MSK) pain, fibromyalgia (FM) and neuropathic pain (NP).

This tool focuses on a multi-modal approach to manage CNCP. Primary care providers (PCPs) should use non-pharmacological options, with or without pharmacological options, to build a comprehensive and personalized plan that incorporates the patient's goals.[5]

This tool is not suitable for use in the management of acute pain and is not designed to assist in diagnosing various CNCP conditions. (Please see Supporting Material and References for links to tools and guidelines to assist with diagnosis). Management of chronic pelvic pain is not within the scope of this tool.



General Approach

Work with your patients to identify and understand the complex bio-psycho-social elements involved in their pain and emphasize the value of a multi-modal approach to manage their pain. Management is often a process of repeated trials to determine the effects of specific treatments and can take a few months or years to optimize. Once a treatment plan is identified, then initiate, adapt and evaluate how it improves daily function, pain, mood and quality of life, while assessing the risks/benefits for long-term use. It is also important to optimally manage any active underlying health issues related to a patient's pain (e.g., diabetes, inflammatory arthritis).

Step 1

Assessment

Start with a thorough baseline assessment, which may need to be completed over more than one visit.[1]

- Begin to develop a rapport with the patient to encourage trust and information sharing.

Section 1: Baseline and Ongoing Assessment

Step 2

Management options

Select non-pharmacological and/or pharmacological therapies.

Based on the assessment, identify treatments that you and your patient feel comfortable starting.

Section 2: Non-Pharmacological Therapies

Section 3: Non-Opioid Medications

Section 4: Opioid Medications

Step 3

Initiate, adapt & evaluate

Use the Patient Record and Treatment Plan to help initiate, adapt and evaluate treatments.

Details on individual therapies can be found in **Sections 2-4 and in the Appendix**

Step 4

Refer as appropriate

Consider referral to a specialist or multidisciplinary clinic.

Section 5: Intervention Management and Referral

Section 1: Baseline and Ongoing Assessment

The guides for assessment outlined below are to help develop and monitor a treatment plan for patients with CNCP. **They are not designed to diagnose specific CNCP conditions.** During an assessment, work to develop a rapport with the patient to establish trust and encourage sharing of information. Consider completing a thorough baseline assessment in the following patients:

- Patients with a new diagnosis of CNCP, patients who are new to your practice with a diagnosis of CNCP, and patients currently in your practice with a diagnosis of CNCP.

1. Baseline Assessment

Assessment Parameter	Factors to consider[2,3,5]
Pain Condition	☐ Identify pain diagnoses, e.g., OA, FM or NP ☐ If suspected Complex Regional Pain Syndrome (CRPS)[i], consider urgent referral ☐ Assess biomedical yellow flags (see table below) ☐ Pain: Brief Pain Inventory (BPI)[ii]: • Intensity • Exacerbating and alleviating factors • Character • Systemic symptoms • Duration ☐ Past investigations/consultations ☐ Response to current/past treatments (consider whether trial was long enough to evaluate efficacy/side effects) ☐ Past medical history ☐ Current medications (including prescription, non-prescription, and natural products)
Functional and Social History	☐ Assess functional status and impairment (e.g., BPI) ☐ Psychosocial history: living arrangements, family/social support, family obligations, work status, sleep, relationships ☐ Assess social yellow flags (see table below)
Mental Health	☐ Current and past psychiatric history (e.g., depression PHQ-9[iii], anxiety GAD-7[iv], PTSD) ☐ Family psychiatric history ☐ Assess psychological yellow flags (see table below)
Substance Use History & Opioid Risk Assessment	☐ Review history of substance use, abuse, and addiction (start with family history then personal history): ☐ Alcohol, cannabis, prescription medications, illicit drugs ☐ Attendance at an addiction treatment program ☐ If on opioids, review for the presence of any opioid use disorder features. May use Opioid Risk Tool[v], however, it has insufficient accuracy for risk stratification[2,6] ☐ Use urine drug testing before starting opioid therapy. Consider annual urine drug testing (or more often, as appropriate) for the use of opioid medication and/or illicit drugs[2]
Physical Examination	☐ Document relevant physical examination based on diagnosed pain condition(s)

YELLOW FLAGS[1]

Assess the following to identify patients with CNCP who are at risk for poor outcomes:

Biomedical	• Severe pain or increased disability at presentation • Previous significant pain episodes • Multiple site pain • Non-organic signs • Iatrogenic factors
Psychological	• Belief that pain indicates harm • Expectation that passive rather than active treatments are most helpful • Fear-avoidance behaviour • Catastrophic thinking • Poor problem-solving ability • Passive coping strategies • Atypical health beliefs • Psychosomatic perceptions • High levels of distress
Social	• Low expectations of return to work • Lack of confidence in performing work activities • Heavier workload • Low levels of control over rate of workload • Poor work relationships • Social dysfunction/isolation • Medico-legal issues

Patients at higher risk of poor outcomes may require closer follow-up and greater emphasis on a diversified non-pharmacological and pharmacological, multi-modal approach to treatment.[7]

2. Ongoing Assessment

Assessment Elements	Comments
☐ Identify new pain, related symptoms or significant change	Physical examination as indicated
☐ Adherence to treatment	n/a
☐ Adverse event related to treatment	n/a
☐ Treatment(s) effect on: • Pain • Function • Quality of life • Mood • Social function	Assess and document using: • Narrative assessment • Validated tools (e.g., BPI) Note: 30% improvement is meaningful for pain and function[2]
☐ Progress towards patient goals (SMART goals: Specific, Measurable, Agreed-upon, Realistic, Time-based)	Examples • Taking walks/walking dog • Attending family/social events • Returning to part-time work • Participating in recreational activities
☐ If on opioids, monitor for: • Aberrant drug-related behaviours • Clinical features of opioid use disorder (see below) ☐ Use urine drug testing as indicated	**See Table 3** below for list of behaviours
☐ In patients with current or past substance use disorder (SUD), monitor for destabilization of disease	Monitor for aberrant use of prescribed medications

3. Clinical Features of Opioid Use Disorder (OUD)[8]

Indicator	Examples
Altering the route of delivery	• Injecting, biting or crushing oral formulations
Accessing opioids from other sources	• Taking the drug from friends or relatives • Purchasing the drug from the 'street' • Double-doctoring
Unsanctioned use	• Multiple unauthorized dose escalations • Binge use rather than scheduled use
Drug seeking	• Recurrent prescription losses • Aggressive complaining about the need for higher doses • Harassing medical office staff for faxed scripts or 'fit-in' appointments • Nothing else 'works'
Repeated withdrawal symptoms	• Marked dysphoria, myalgia, GI symptoms, cravings
Accompanying conditions	• Currently addicted to alcohol, cocaine, cannabis, or other drugs • Underlying mood or anxiety disorders are not responsive to treatment
Social features	• Deteriorating or poor social function • Concern expressed by family members
Views on the opioid medication	• Sometimes acknowledges being addicted • Strong resistance to tapering or switching opioids • May admit to mood-leveling effect • May acknowledge distressing withdrawal symptoms

Non-pharmacological treatments should be considered for all patients with CNCP.[1] Choose treatments that you and the patient feel comfortable with and then initiate, adapt, and evaluate the treatment plan (use motivational interviewing techniques, as appropriate).

When determining the benefit of a therapy, an improvement of 30% in pain and function scores is considered clinically meaningful;[2] however, even a smaller improvement may be meaningful to the patient.

Talking Points[9,10]

If patients are reluctant to try physical activity/ exercise therapy:

Try the Elicit-Provide-Elicit technique

Elicit the patient's thoughts/feelings:
"How do you feel about trying some exercise therapy for your pain?"

Provide information (a common patient concern is that exercise therapy will increase pain):
"If I understand correctly, you are concerned that physical activity will increase your pain. Interestingly, it actually tends to do the opposite; physical activity can be an effective way of decreasing pain."

Elicit the patient's opinion:
"What do you think about this?"

Non-pharmacological treatments:

Physical Activity

Examples of pain conditions indicated for: FM, LBP, headache, OA

A) Initiate

- Recommend general activity and exercise therapies, as appropriate
- Recommend combined home and group physical activities to help increase activity levels
- Pick a low impact physical activity, such as walking, pilates, Tai Chi, yoga or aquatic therapy (see **Appendix A**)
- Start low and go slow (e.g., 5 min every other day) and aim for a moderate level of intensity of activity[2,11]
- Consider referral to a physiotherapist if more intensive support is required

B) Adapt

- Improve adherence to home physical activity by encouraging graded activity
- Encourage graded activity – add 10 min every 3-4 weeks[12]
- Minimal goal: 30 min of exercise 5 days a week[2,13]
- Add in other activities as tolerated

C) Evaluate

- Measure benefits at 8 or more weeks[13]
- Use BPI to evaluate effect on pain, function and quality of life
- If benefits are not identified, try other activity types and continue to counsel about the value of exercise and activity

Self-Management Programs[14]

Examples of pain conditions indicated for: FM, LBP, headache, OA, neck pain, rheumatoid arthritis, NP

A) Initiate

- A self-management program should be considered to complement other therapies patients have initiated[1]
- Identify a self-management program that best suits the patient's need (see **Supporting Material & Resources** section)

B) Adapt

- Encourage patients to continue to use strategies learned from the program

C) Evaluate

After program completion:
- Use tools like BPI to evaluate effect on pain, function and quality of life

Psychological Therapies

Examples of pain conditions indicated for: FM, LBP, headache, OA, neck pain, rheumatoid arthritis, NP

A) Initiate

- Cognitive behavioural therapy (CBT) should be considered for the treatment of patients with chronic pain[1]
- Particularly valuable for those with co-morbid depression and/ or anxiety

Start with one of the following psychological therapies:
- CBT, Mindfulness Based Intervention (MBI), Acceptance Commitment Therapy (ACT) or Respondent Behavioural Therapy (see **Appendix A**)
- Consider referral to a psychotherapist, social worker, occupational therapist and/or other mental health professional if more intensive support is required

B) Adapt

- Encourage patients to continue to use strategies learned from therapies

C) Evaluate

- Use tools like BPI, PHQ-9 to evaluate effect on pain, function and quality of life
- Add other types of therapies as appropriate (see **Appendix A**)
- Rarely, may exacerbate some underlying mental illnesses

Physical Therapies

Examples of pain conditions indicated for: LBP, neck pain, NP

A) Initiate

- Consider any of the following for short-term relief of pain:[1]
  - Manual therapy
  - TENS
  - Low level laser therapy

Consider referral to a physiotherapist, chiropractor or osteopath, as appropriate

B) Adapt

- Encourage patients to participate in 8 therapy sessions over 4-6 weeks[14]

C) Evaluate

- Follow up after completion of 8 sessions
- Use BPI to evaluate effect on pain, function and quality of life

See a list of patient resources in the Supporting Materials section:

- Online videos & webinars
- Physical activity resources
- Online tools and programs
- Patient networks, communities and support groups

See a listing of resources in your LHIN

thewellhealth.ca/cncp

Section 3: Non-Opioid Medications

Non-opioid medications, in combination with non-pharmacological therapies, are the preferred treatment for CNCP.[1]
Choose a treatment that you and the patient feel comfortable with and then initiate, adapt, and evaluate the treatment plan.

See **Appendix B** for details on evidence, benefits and harms.

Most patients have either a good response (an improvement of 30% in pain and function scores is considered clinically meaningful) or have no response.[2]

**Start with ONE medication and evaluate.
Use a sequential manner (versus parallel) to trial a second medication, if needed. Minimize polypharmacy as much as possible.**

A) Initiate[1]

Select one medication from the table based on patient's pain type and professional judgment of risks/benefits.

- Agree with patient on goals (pain reduction, improved function/ mood, other)
- Agree on length of initial trial (usually 2 weeks at optimum dose, up to 4 weeks for antidepressants)
- Discuss potential side effects/risks (see **Appendix B**)
- Be aware of concomitant over-the-counter treatments and advise accordingly.
- Where possible, avoid concomitant sedative and hypnotic medications; be aware of concomitant alcohol use and counsel that there is an increased risk of overdose if alcohol and opioids are used together[1,2]
- Start at recommended dose

Tip: Some antidepressants can have a role for neuropathic pain, as well as for nociceptive pain, such as osteoarthritis

See **Appendix B** for details on evidence, benefits/harms, and dosing.

B) Titrate[1]

- Adjust, as needed, up to an effective dose, unless limited by side effects. Do not exceed the maximum dose.
- Minimize polypharmacy as much as possible.

See **Appendix B** for details on dosing and titration.

C) Evaluate[15]

- Evaluate effects on pain, function, mood and set goals
- Use pain and function assessment scales:[15]
  - Brief Pain Inventory (BPI)[ii]

- **Consider trialling two or three drugs in succession from the same class if one is ineffective[1]**
- **Avoid co-prescribing two drugs from the same class**
- **Due to safety risks associated with use of oral NSAIDs, use conservative dosing for the shortest possible duration consistent with approved prescribing limits[16]**

Regularly review ongoing value of each medication. If drug does not produce a meaningful improvement, stop or taper drug[1] (see **table on p6 for tapering instructions**)

Drug Class	Drug	Pain types[1]
General	Acetaminophen	Osteoarthritis (hip or knee)
	Nonsteroidal anti-inflammatory drugs (NSAIDs)	Low back pain
Anti-convulsants	Carbamazepine	1st-line for trigeminal neuralgia (may also be used for general neuropathic pain)
	Gabapentin	Neuropathic pain (Amitriptyline or gabapentin are usually the first choice)
	Pregabalin	If amitriptyline or gabapentin are not effective/tolerated, pregabalin may be used as an alternative for neuropathic pain or fibromyalgia
Anti-depressants	Amitriptyline (nortriptyline or imipramine may be used if amitriptyline not effective)[1]	Neuropathic pain (Amitriptyline or gabapentin are usually the first choice)
	Duloxetine	Neuropathic pain due to diabetes, fibromyalgia, or osteoarthritis
	Fluoxetine	Fibromyalgia
Topical	Topical NSAIDs	Musculoskeletal pain[1] and osteoarthritis[17]
	Topical rubifacients	Musculoskeletal pain (if other drug treatments are not effective)

- **Cannabinoids are not equivalent in effectiveness to anti-depressants or anti-convulsants[18]**

Cannabinoid forms that can be considered for neuropathic pain:[18]

- Synthetic tetrahydrocannabinol (nabilone)
- Nabiximols
- Dried cannabis (vaporizer or edible product)

Opioid medications are not the preferred treatment for CNCP but may be considered in selected patients. If opioids are used, they should be combined with non-pharmacological treatments and non-opioid medications as appropriate.[2]

See **Appendix C** for details on evidence, benefits and harms.

Talking Points

Patient wants opioids but they are not clinically appropriate.

Try the Elicit-Provide-Elicit technique

Elicit how patient feels they would benefit from an opioid:
"You mentioned you would like to try an opioid. How are you hoping it will help you?"

Provide information that addresses the patient's concerns:
"If it's all right, I can give you more information about opioids and how they work for pain. Opioids may seem like they are very strong and effective drugs for pain; however, they are not effective for all types of pain. When opioids are effective, your pain may be reduced by about 1or 2 points on a scale from 0 to 10 and you may notice a small improvement in your ability to function.[1] They also come with risks, and sometimes this means that opioids are not a safe and effective approach for pain relief. We may find that other approaches and medications could work better for you."[3]

Elicit the patient's thoughts:
"How do you feel about trying some non-opioid options? What do you think makes sense for you right now?"

A) Initiate[1,19]

Before trying opioids, it is not necessary to sequentially "fail" non-pharmacological or non-opioid pharmacological therapies, though it is important to weigh expected benefits and risks of therapy[2] (see **Appendix C**). There is no high quality evidence showing that opioids improve pain or function with long term use.

1. Patient Selection:

- Opioids should be reserved for patients that meet the following criteria:
  - A biomedical pain diagnosis, with evidence for an indication of opioids. Currently, there is limited evidence for the use of opioids in FM and headaches (see **Appendix C**).
  - Non-opioid treatments have been trialled or are being trialled concurrently.
  - Pain is severe enough to interfere with daily function.
  - Patients with a low risk of opioid use disorder. Patients with a high risk (active substance use disorder) may require further consultation with an addictions expert.
- May use the Opioid Risk Tool[v] to gauge potential risk.[2,6] Supplement with a history identifying high risk factors such as:
  - Current anxiety, depression, PTSD
  - Current or past history of problematic substance use (e.g., alcohol, opioids, cannabis)

2. Opioid Selection:

- Start with weak opioids (e.g. tramadol, codeine)
- Potent opioids are second line (e.g., morphine, oxycodone, hydromorphone, fentanyl, methadone)

3. Opioid Initiation:

- Set goals with patient (pain reduction, improved function/mood)
- Discuss the short-term benefits and potential side effects/risks, such as potential loss of efficacy over time (see **Appendix C**)
- Avoid prescription of sedative and hypnotic medication when possible
- Be aware of concomitant use of alcohol and over the counter medications
- Agree on duration of an opioid trial (e.g., typically 2 weeks at optimal dose)
- For patients on opioids over 90 morphine milligram equivalents (MME) or patients on opioids with a potential risk for overdose (i.e., past/active/evolving opioid use disorder or concurrent benzodiazepine use), encourage the patient to obtain take home naloxone (kit or intranasal spray) from their pharmacist[2]
- Before starting opioids, discuss an "exit strategy" for how opioids will be discontinued if they do not produce benefits that outweigh risks[2]

B) Titrate[1,19]

Start with immediate-release opioids instead of sustained-release or long-acting opioids. Do not use long-acting opioids unless the patient has severe, continuous pain and has been taking immediate-release opioids daily for at least 1 week.[2]

- Titrate oral opioids until efficacious* (an improvement in function and/or pain of 2 points on a 10-point scale).[19,20]
- Most patients respond to doses in the range of 0-50 MME. As the dose increases, the risk of overdose, addiction, falls, motor vehicle accidents and sleep apnea increase as well.
- Opioids have a medium effect on pain (10-20% reduction) and a small effect on function (<10% change): function can improve even when pain is still present.[2,5]
- Use the lowest effective dose - aim to keep the dose under 90 MME. If a larger dose is required, consider obtaining a second opinion.[2,19]

*See below on the watchful dose and Appendix C for details on dosing.

C) Evaluate[15]

For conditions where opioids may be effective, establish realistic expectations:[2]

- After titration, evaluate benefits and risks of continued therapy at least every 3 months[2]
- If drug does not produce a meaningful improvement, discontinue/taper
- If opioids are inappropriately used, the risk of overdose, hypogonadism, sleep disorders or respiratory function can worsen.

Recommendations in the above tables have been developed in part from a consensus of expert opinion.

WATCHFUL DOSE: Recent guidelines recommend reassessing the benefit/risk of doses ≥50 MME/day and to "avoid or justify increasing dosage" at doses ≥90 MME/day.[2,19,21]

Section 4: Opioid Medications

Tapering Opioids	How to taper[6]	Tapering Pearls
Indications to taper and discontinue opioids: • Insufficient analgesia, insufficient effect on function, or a failed opioid trial • Significant side effects (e.g., sedation, fatigue, depression, sleep apnea, falls, motor vehicle accidents, testosterone suppression) • Suspected opioid use disorder • High opioid dose (well above 90 MME), even if no obvious side effects are present Explain to the patient that tapering often improves pain, mood and function.	• Opioids should never be abruptly stopped, as it may trigger unauthorized use and is an increased risk for overdose • There are many protocols for an opioid taper – the following is an example: 1. Decrease dose by 10% of total daily dose, every 1-2 weeks or monthly. Continue until one-third of the original dose is reached. 2. When one-third of the original dose is reached, decrease dose by 5% every 2-4 weeks. 3. A taper may be paused for a period of time to help the patient adjust.	• In patients who have been on opioids for years a slower taper is more likely to be successful • Taper more cautiously during pregnancy and/or seek out expert consultation – acute withdrawal increases the risk of premature labour and spontaneous abortion • Avoid sedative-hypnotic medications, especially benzodiazepines, during the taper[22] • Optimize non-opioid management of pain and provide psychosocial support for anxiety related to the taper • Some patients may begin to manifest an OUD during the taper. Arrange for appropriate treatment and consider naloxone use.

Strategies to Prevent Opioid Use Disorder (OUD)

1. Identify high risk patients: individuals with current anxiety, depression, PTSD; individuals with current or past history of problematic alcohol or drug use.
2. Do not prescribe opioids to patients at high risk for OUD unless they have a biomedical pain condition affecting function, and have failed at all first-line non opioid treatments. Do not prescribe for fibromyalgia or simple low back pain.
3. Take a baseline urine drug sample. Do not prescribe opioids if cocaine or non-authorized drugs are present.
4. Dispense small amounts frequently – weekly, twice weekly, daily if necessary; especially if patient runs out early.
5. Set the maintenance dose at the lowest possible dose – in most cases, it should be no more than 50 MME.
6. Avoid any drug that is commonly misused in the community (e.g., hydromorphone, fentanyl, oxycodone).
7. If patient shows clinical features of OUD, refer for methadone or buprenorphine treatment. Prescribe buprenorphine yourself if specialized addiction clinic is not available or acceptable to the patient.

Note: *Continuing to prescribe opioids in the face of opioid addiction may put the patient at risk of harm. However, stopping or refusing to prescribe opioids can also cause harm, such as severe withdrawal symptoms or driving the patient to obtain opioids from the street. It is important to mitigate these risks by finding a safe way to reduce and manage opioid use.*

Naloxone

Advise patients at high risk of an opioid overdose (i.e., on opioids over 90 MME; active opioid use disorder; using illicit opioids or concurrent benzodiazepine use) to obtain take home naloxone (kit or intranasal spray) from their pharmacist (consider also communicating with pharmacist directly).[2]

Section 5: Intervention Management & Referral

Ensure that all necessary and relevant information, as required by the clinic or specialist, is included when initiating a referral.

Type of Referral	Consider when:[1]
Referral to Psychological Therapy	• Patient has moderate to high levels of distress • Patient has difficulty adjusting to a life with pain • Patient is struggling to change their behaviour and maintain normal activities • Referral to specialist pain service

Referral to Pain Specialist Service (may include interventional management)	• Treatment failure after trial of 4 drugs for neuropathic pain
	• Opioid dose is greater than 90 MME[2]
	• Inadequate response to non-specialist management
	Intervention Management:
	• Interventional procedures can provide short-term relief of pain, though some interventions are associated with rare but significant adverse outcomes (e.g., stroke, death)
	• Consider the following procedures for the specified conditions:
	  • Lumbar or cervical epidurals in hospital-based centres (e.g., spinal stenosis, discogenic pain +/- radicular pain)
	  • Facet joint injections, medial branch blocks (e.g., facet joint pain)
	  • Radiofrequency nerve ablation (e.g., facet and sacroiliac joint pain)
	  • Spinal cord stimulators (e.g., low back and associated limb-based pain in failed back surgery)
	  • Trigger point injections (e.g., myofascial pain syndromes)

Multidisciplinary Pain Management Program Features: • Rehabilitation and exercise therapy • Patient education • Vocational therapy • Medical management	• Patient has poor functional capacity • Patient has moderate to high levels of distress • Patient has social and occupational problems related to pain • Patient has failed to benefit from other, less comprehensive therapies • Patient prefers self-management rather than a medical approach • If referring patient for CRPS, urgent consultation and management required

Consider using the following resources to support complex cases:

- Medical Mentoring for Addictions and Pain (MMAP)[vi]
- Project ECHO[vii]
- eConsult[viii]
- Toronto Academic Pain Medicine Institute (TAPMI)[ix]
- The Inter-professional Spine Assessment and Education Clinics (ISAEC)[x]

See a listing of resources in your LHIN
thewellhealth.ca/cncp

Patient Record and Treatment Plan

This table is designed to help providers document the 'agreed-on' plan that can be filed in a patient's chart and referred to during subsequent visits to follow up and continue discussion.

Name: ____________________ Date of Birth: ____________________

	Assessment				**Treatment Plan** (note frequency and duration of therapy; adverse reactions; adherence)				
Date	**Pain** *(BPI scores for 3 domains, 0-10)*	**Function** *(BPI score, 0-10)*	**General Activity** *(BPI score, 0-10)*	**Mood** *(PHQ-9 depression score, 0-20 or higher; GAD-7 anxiety score, 0-21)*	**Physical Activity** *(e.g., yoga, Tai chi, aqua therapy, pilates, physical activity)* ***Frequency*** ***Duration***	**Self-Management / Psychological Therapy** *(e.g., self-management program, CBT, MBI)* ***Frequency*** ***Duration***	**Non-opioid medications** • ***Regimen*** • ***Adverse Reactions*** • ***Adherence***	**Opioid medications** • ***Dosing*** • ***Adverse Effects (A/E)*** • ***Adherence*** • ***Aberrant Behaviours***	**Monitor & Follow-Up** *(e.g., include notes on time frame for follow-up and issues to discuss at next visit, etc.)*
Nov 8, 2016	*8* *7* *7*		*5 daily walks, ~5mins*	*6*	*Activity: Yoga* *Frequency: weekly* *Duration: 1hr*	*Therapy: n/a* *Frequency: n/a* *Duration: n/a*	*Naproxen* *Dosing: 220mg, twice daily* *A/E: none* *Adherence: patient takes medication daily*	*Dosing: n/a* *A/E: n/a* *Adherence: n/a* *Aberrant Behaviours: n/a*	*Follow up in 3-4 weeks*
					Activity: Frequency: Duration:	Therapy: Frequency: Duration:	Dosing: A/E: Adherence:	Dosing: A/E: Adherence: Aberrant Behaviours:	
					Activity: Frequency: Duration:	Therapy: Frequency: Duration:	Dosing: A/E: Adherence:	Dosing: A/E: Adherence: Aberrant Behaviours:	
					Activity: Frequency: Duration:	Therapy: Frequency: Duration:	Dosing: A/E: Adherence:	Dosing: A/E: Adherence: Aberrant Behaviours:	
					Activity: Frequency: Duration:	Therapy: Frequency: Duration:	Dosing: A/E: Adherence:	Dosing: A/E: Adherence: Aberrant Behaviours:	
					Activity: Frequency: Duration:	Therapy: Frequency: Duration:	Dosing: A/E: Adherence:	Dosing: A/E: Adherence: Aberrant Behaviours:	

Referral
☐ Specialist ☐ Multi-disciplinary clinic ☐ Interventional procedure

Medications Trialled	**Notes/Comments**

Notes

Supporting Material*

[i] **Complex Regional Pain Syndrome (CRPS)**
Bruehl, S. Complex regional pain syndrome. BMJ. 2015;351.
http://rsds.org/wp-content/uploads/2014/12/CRPS-bruehl.pdf

[ii] **Brief Pain Inventory (BPI)**
http://nationalpaincentre.mcmaster.ca/documents/brief_pain_inventory.pdf

[iii] **PHQ-9**
http://www.ubcmood.ca/sad/PHQ-9.pdf

[iv] **GAD-7**
http://www.integration.samhsa.gov/clinical-practice/GAD708.19.08Cartwright.pdf

[v] **Opioid Risk Tool**
http://nationalpaincentre.mcmaster.ca/opioid/cgop_b_app_b02.html

[vi] **Medical Mentoring for Addictions and Pain (MMAP)**
http://ocfp.on.ca/cpd/collaborative-networks/mmap

[vii] **Project ECHO**
http://www.echoontario.ca/Echo-Clinic/Chronic-Pain/Curriculum.aspx

[viii] **eConsult (OTN Hub)**
https://otnhub.ca/patient-care/

[ix] **Toronto Academic Pain Medicine Institute (TAPMI)**
http://www.womenscollegehospital.ca/Education-and-Training/tapmi

[x] **The Inter-professional Spine Assessment and Education Clinics (ISAEC)**
http://www.isaec.org/refer-to-isaec.html

Additional supporting materials and resources that may be useful for providers and patients:

Provider Resources

[xi] **CORE Neck and Headache tool**
https://thewellhealth.ca/neckheadpain/

[xii] **CORE Back Pain tool**
https://thewellhealth.ca/low-back-pain/

[xiii] **RxFiles Opioid Tapering template**
http://www.rxfiles.ca/rxfiles/uploads/documents/opioid-taper-template.pdf

[xiv] **CFP Family Physician Summary of Canadian Opioid Guidelines**
http://www.cfp.ca/content/57/11/1257.full.pdf+html

[xv] **SBIRT (Screening, Brief Intervention, and Referral to Treatment)**
http://www.samhsa.gov/sbirt

[xvi] **McMaster Health Sciences: Practice toolkit**
http://nationalpaincentre.mcmaster.ca/documents/practicetoolkit.pdf

[xvii] **College of Physicians and Surgeons of Ontario (CPSO). Practice Partner: When and how to taper opioids.**
https://www.cpso.on.ca/uploadedFiles/members/resources/Opioid-Tapering-Protocols_Dial-I_2012.pdf

[xix] **Centres for Disease Control. Pocket Guide: Tapering opioids for chronic pain.**
https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf

[xx] **Ontario Pharmacy Evidence Network (OPEN). Evidence-based deprescribing algorithm for benzodiazepine receptor agonists.**
http://www.open-pharmacy-research.ca/evidence-based-deprescribing-algorithm-for-benzodiazepines/

[xxi] **RxFiles. Urine Drug Screening – Frequently Asked Questions.**
http://www.rxfiles.ca/rxfiles/uploads/documents/Urine-Drug-Screening-UDS-QandA.pdf

[xxii] **Opioid Risk: Urine Drug Testing Guide.**
https://www.nhms.org/sites/default/files/Pdfs/UrineDrugTestingguide.pdf

Patient Resources

[xxiii] **Centers for Disease Control and Prevention (CDC) - Prescription opioids: What you need to know**
http://www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf

[xxiv] **McMaster University: Messages for patients taking opioids**
http://nationalpaincentre.mcmaster.ca/opioid/cgop_b_app_b04.html

[xxv] **The Pain Toolkit**
http://www.paintoolkit.org/resources/videos

[xxvi] **RNAO Fact sheets: Helping people manage their pain**
http://rnao.ca/bpg/guidelines/fact-sheets/helping-you-manage-your-pain

[xxvii] **Mike Evans - Best Advice for People Taking Opioid Medication**
http://www.evanshealthlab.com/opioids/

[xxviii] **The Arthritis Society of Canada: Managing Chronic Pain**
https://arthritis.ca/manage-arthritis/living-well-with-arthritis/managing-chronic-pain

[xxiv] **My Opioid Manager (Book and App)**
http://prc.canadianpaincoalition.ca/en/my_opioid_manager_book.html

[xxv] **Understanding Pain in less than 5 minutes, and what to do about it!**
https://www.youtube.com/watch?v=C_3phB93rvI

[xxvi] **Institute for Safe Medication Practices (ISMP) Canada Opioid Stewardship**
https://www.ismp-canada.org/opioid_stewardship/

[xxvii] **Canadian Pain Coalition - Pain Resource Centre**
http://prc.canadianpaincoalition.ca/en/

[xxviii] **People in Pain Network**
http://www.pipain.com/

[xxix] **British Columbia Chronic Pain Self-Management Program**
http://www.selfmanagementbc.ca/chronicpainprogram

[xxx] **NeuroNovo Centre for Mindful Solutions (formerly "for Mindfulness-Based Chronic Pain Management")**
http://neuronovacentre.com

[xxxi] **Fact Sheet: Chronic Pain**
http://www.cpa.ca/docs/File/Publications/FactSheets/PsychologyWorksFactSheet_ChronicPain.pdf

[xxxii] **The Art of Pain Management**
https://theacpa.org/uploads/Art_and_Music_final.pdf

[xxxiii] **Self-Management of Chronic Pain**
http://www.cirpd.org/PainManagement/WhatIsChronicPain/Pages/Self-Management.aspx#selfmanage

[xxxiv] **Webinar - Intro to Mindfulness for Chronic Pain (5 part series)**
http://www.cirpd.org/Webinars/Pages/Webinar.aspx?wbID=24

[xxxv] **Webinar - Yoga for people in pain (5 part series)**
http://www.cirpd.org/Webinars/Pages/Webinar.aspx?wbID=16

[xxxvi] **MoodGym - online CBT program**
https://moodgym.anu.edu.au/welcome

[xxxvii] **Canadian Mental Health Association (CMHA)**
http://cmha-yr.on.ca/

*These supporting materials are hosted by external organizations and as such, the accuracy and accessibility of their links are not guaranteed. CEP will make every effort to keep these links up to date.

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[12] Centers for Disease Control and Prevention (CDC): Physical activity for arthritis. [cited 2016 July 12] Available from: http://www.cdc.gov/arthritis/basics/physical-activity-overview.html

[13] Office of Disease Prevention and Health Promotion (ODPHP). Physical activity guidelines advisory committee report. [cited 2016 August 12] Available from: https://health.gov/paguidelines/Report/G5_musculo.aspx

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This Tool was developed as part of the Knowledge Translation in Primary Care Initiative, led by Centre for Effective Practice with collaboration from the Ontario College of Family Physicians and the Nurse Practitioners' Association of Ontario. Clinical leadership for the development of the tool was provided by Dr. Arun Radhakrishnan, MSc, MD, CM CCFP and was subject to external review by health care providers and other relevant stakeholders. This Tool was funded by the Government of Ontario as part of the Knowledge Translation in Primary Care Initiative.

Developed by:

Centre for Effective Practice

In collaboration with:

Ontario College of Family Physicians

Nurse Practitioners' Association of Ontario

Opioid conversion chart[1]

Opioids* Oral preparations (mg/d)	To convert to oral morphine equivalent multiple by:	To convert from oral morphine equivalent multiple by:	50 MED equivalent dose	90 MED equivalent dose
Codeine	0.15 (0.1–0.2)	6.67	334 mg/d	600 mg/d
Hydromorphone	5.0	0.2	10 mg/d	18 mg/d
Morphine	1.0	1	50 mg/d	90 mg/d
Oxycodone	1.5	0.667	33 mg/d	60 mg/d
Tapentadol	0.3–0.4	2.5–3.33	160	300
Tramadol	0.1–0.2	6	300	540**

* Conversion ratios for opioids are subject to variations in kinetics governed by genetics and other drugs.

** The maximum recommended daily dose of tramadol is 300 mg-400 mg depending on the formulation.

1 Busse, Jason ed. *The 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain.* Hamilton, Ontario: McMaster University.

CPSBC | College of Physicians and Surgeons of British Columbia

Practice Standard

Safe Prescribing of Opioids and Sedatives

Effective:	June 1, 2016
Last revised:	November 4, 2021
Version:	4.4
Next review:	June 2021
Related topic(s):	Access to Medical Care Without Discrimination; Prescribing Methadone

A **practice standard** reflects the minimum standard of professional behaviour and ethical conduct on a specific topic or issue expected by the College of its registrants (all physicians and surgeons who practise medicine in British Columbia). Standards also reflect relevant legal requirements and are enforceable under the *Health Professions Act*, RSBC 1996, c.183 (*HPA*) and College Bylaws under the *HPA*.

Registrants may seek advice on these issues by contacting the College and asking to speak with a member of the registrar staff, or by seeking medical legal advice from the CMPA or other entity.

PREAMBLE

This document is a practice standard of the Board of the College of Physicians and Surgeons of British Columbia.

COLLEGE'S POSITION

Opioids and sedative medications have high-risk profiles. Historically, prescribing these medications has contributed to the rise in people living with substance use disorder (SUD).

The profession has a collective ethical responsibility to mitigate its contribution to problematic prescription medication use, particularly the over-prescribing of opioids and sedatives. The fundamental purpose of this standard is **primary prevention** of overdose, addiction, and other harms of the use of opioids and sedatives. Registrants are expected to follow the *2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain,* which is complementary to, and should be read in conjunction with, this standard.

This standard does not apply to active cancer care, palliative care, and management of substance use disorders. Registrants are expected to follow relevant clinical guidelines and established best practices in managing patients with these conditions. Nothing in this standard interferes with a registrant's obligation to provide aggressive symptom management to patients with active cancer or nearing the end of their lives.

In the treatment of opioid use disorder (OUD), registrants are directed to follow accepted clinical guidelines and the *Prescribing Methadone* practice standard, when initiating and implementing opioid agonist treatment (OAT). It is incumbent on all registrants to have an approach to identify patients with these complex care needs, and to manage or refer these patients in a manner consistent with their training, scope of practice, and location.

The high-risk medications covered by this standard include opioids, benzodiazepines (including the Z-drugs zopiclone and zolpidem), and other sedative-hypnotics such as barbiturates.

Long-term opioid treatment (LTOT) refers to the prescribing of opioid medications on a continuous daily schedule.

STANDARDS

1. The CMA *Code of Ethics and Professionalism* and the College standard *Access to Medical Care Without Discrimination* prohibit discrimination based on medical condition and complexity. **Registrants must not exclude or dismiss patients from their practice based on their current use of, or request for, opioids or sedatives, or a suspicion of problematic use of prescription medications.**

2. Registrants must base decisions to prescribe opioids and sedatives on a thorough understanding of their patient. This includes:

    a. Conducting and documenting a comprehensive assessment including patient history, physical examination, and relevant investigation results.

    b. Conducting a comprehensive reassessment at least every three months.

   c. Basing decisions to continue long-term treatment with opioids and sedatives on objective evidence of benefit. Continuing to prescribe only because these medications were previously prescribed is not acceptable.

3. When initiating treatment with an opioid or sedative medication, patients must be fully informed of the risks and benefits of such treatment. This includes holding and documenting a discussion about the rationale for a treatment regimen, expectations and goals of patient and registrant, alternative treatment strategies, and a plan for the eventual possible discontinuation of the medication.

4. Registrants must use appropriate and available strategies to mitigate risk of harm when asked to prescribe or renew a prescription for opioid or sedative medications, including:

   a. Reviewing patients' medication profile, and consulting PharmaNet (if available) before prescribing the high-risk medication. This will prevent harmful drug interactions and combinations and prevent patients from obtaining multiple prescriptions from multiple providers for the same medication.

   b. Considering random urine drug testing (rUDT) before initiating treatment, or as a baseline test for patients on long-term opioids and sedatives. Annual, or more frequent, rUDT and/or random pill counts must be considered for patients at risk of SUD, or if medication diversion is suspected.

   c. Documenting their recommendation of take-home naloxone to all patients who are at risk of respiratory depression as a consequence of receiving opioid medications.

5. Patients must be advised about the dangers of taking opioid or sedative medications while performing safety-sensitive occupations, providing child or elder care, and driving.

6. When considering continuing LTOT registrants must **document their discussion** with patients that non-pharmacologic therapy and non-opioid analgesics are preferred for chronic non-cancer pain (CNCP), and that the potential benefit of LTOT is modest and the risk significant.

7. For patients on LTOT, registrants must always prescribe the lowest effective dose of opioid medication.

   a. Registrants must be confident, and document, that there is **substantive evidence of exceptional need and benefit** for doses >90 morphine equivalent daily dose (MEDD) of prescribed opioids.

   b. For all patients on LTOT, but particularly those on >90 MEDD, the merits of tapering to the lowest effective dose must be emphasized. Such tapers must be slow to minimize patient discomfort. Patients attempting a taper need supportive counselling and frequent follow-up.

   c. The College recognizes that these attempts may not always be successful; however, the option must not be abandoned.

8. The College recognizes the particular challenge of patients who have been receiving high-dose opioids, and other high-risk profile medications, for many years. It is unacceptable to decline to accept these individuals as patients. Management of such patients must be individualized, but all of the considerations of this standard apply including regular thorough assessments, and regularly offering to taper high-risk medications. Medications must not be abruptly discontinued—"bridging" prescriptions during assessment of these patients is entirely acceptable to avoid dangers of withdrawal.
9. Registrants must play an active role in controlling the amount of opioid and sedative medication in the community. Excessive prescribing exposes patients to the risk of more chronic use, and unused medication can be stolen or diverted for non-medical use.
10. Registrants must carefully consider concurrent medical conditions in the context of decisions to prescribe or continue to prescribe opioid or sedative medications:
    a. Heart failure, obesity, sleep apnea, chronic lung disease, and renal or hepatic insufficiency compound the risk of these medications in unique ways. Elderly patients are also particularly vulnerable.
    b. Patients must be regularly screened for the presence or emergence of mental health disorders (particularly mood disorders) which may complicate management.
    c. In the course of managing patients on opioids or sedatives (particularly while tapering), a substance use disorder may develop and registrants must be able to diagnose and manage this appropriately, or refer to a clinician with experience in addiction medicine. Medications such as opioids and benzodiazepines must not be abruptly discontinued and must be tapered slowly to minimize the effects of withdrawal.
11. Combining opioids or sedatives with other medications compounds risk of harm:
    a. Co-prescribing medications such as benzodiazepines, sedatives, and opioids significantly compounds risk of death due to overdose. If long-term treatment is considered for these medications, the registrant must taper and discontinue one of them after making all efforts to involve the patient in this decision and providing a thorough explanation.
    b. If prescribing opioids or sedatives, registrants must document their advice to patients that they must avoid other central nervous system and respiratory depressants including alcohol, cannabis, and some over-the-counter medications.
    c. Registrants must exercise caution in prescribing opioid and sedative medications with muscle relaxants, sedating antidepressants, anticonvulsants, antipsychotics and other sedating medications.

If patients with complex care needs are receiving multiple sedating medications, the registrant must consider seeking the opinion of relevant consultants such as psychiatrists, pain specialists, addiction medicine specialists, pharmacists, and others to work toward a collaborative medication regimen that minimizes risk as much as possible.

WorkSafeBC Treatments and Therapies

This Guide is designed to help physicians and nurse practitioners understand the evidence-based therapies and treatments that may be available to someone with a WorkSafeBC claim. As every situation is unique, if you would like to discuss treatment or therapy for a patient, please call our Call Centre (at 604.231.8888 or toll-free at 1.888.967.5377) to be connected with the claim owner or a medical advisor.

Addiction and mental health programs

- **ASAM Addiction Physician (ASAM)** — ASAM is an outpatient assessment and treatment program for injured workers with pain and addiction issues. Services are provided by an ASAM Addiction Physician. The program includes a one day comprehensive assessment by an addiction physician as well as outpatient treatment which includes medication management.
- **Concurrent Care Program (CCP)** — CPP is an outpatient treatment program for injured workers with mental health and substance use disorder, where integrated interdisciplinary services address the individual's complex needs. The primary goal is to stabilize the worker's mental health and substance use disorder through a biopsychosocial treatment model, to achieve abstinence, medication management, and long term recovery.
- **Intensive Outpatient Program (for Addictions) (IOP)** — This outpatient program provides integrated outpatient treatment for addictions. This includes a group based component in addition to the option for supportive counselling.
- **Recovery and Return to Work Standard Treatment** — This is targeted individual psychotherapy provided to Injured Workers with one or more accepted psychological conditions. The over-arching goal of Standard Treatment is to assist the injured worker to remain at or Return to Work and to promote a return to pre-injury psychological functioning. This must include the consideration of Return to Work factors, including a plan to address psychological recovery.
- **Residential Addiction Services (RAS)** — These are medically supervised abstinence-based multidisciplinary inpatient programs that include detoxification, inpatient treatment, extended care, and after care which utilize a bio-psychosocial model to treat injured workers with alcohol and drug addictions. These programs provide medical and psychological treatment for drug effects, teach behavioral skills that promote lasting change, and provide long-term support to help clients live a drug-free lifestyle. Programs consist of peer and self-assessments, group and individual therapy, lectures, as well as conferences with family and referral sources.
- **Residential Trauma and Addictions Services (RTAS)** — This is a medically supervised abstinence-based multidisciplinary inpatient program that provides the same components for addictions as RAS while also integrating trauma-focused treatment for co-occurring PTSD (i.e. safety and stabilization; symptom management and trauma processing; re-integration and re-connecting).
- **Resiliency Support Service (RSS)** — The over-arching goal of RSS is to assist injured workers with the development of active coping strategies and/or access to community supports and services so that they may either remain at or return to work. No DSM-V diagnosis is required for this service.

- **Supplemental Service** — Is a service available to injured workers with accepted psychological conditions who continue to experience severe Psychological Impairment Maximal Clinical Recovery (MCR) is reached. The over-arching goals of Supplemental Service are to reinforce the skills the Injured Worker needs to maintain their maximal level of psychological functioning, to promote independent functioning by establishing links to community supports for long-term support, and to prevent significant decompensation or deterioration of psychological functioning.
- **Support Recovery Services (SRS)** — SRS focuses on decreasing reliance on health care personnel and increasing responsibility and accountability of the injured worker to allow for increased functioning in the community. Services include 24 hour access to an addiction counselor or psychologist, and access to a Canadian Society of Addiction Medicine (CSAM) or ASAM Physician. The aim is to provide a safe, supportive, and stable environment to facilitate recovery, promote life skills, and allow for re-integration into the community.

Pain management program

- **Pain and Medication Management Program (PMMP)** — PMMP is an outpatient multidisciplinary treatment program offered by physical therapists, occupational therapists, psychologists, physicians, and pharmacists for injured workers with complex pain issues. The PMMP is able to provide medication management for patients with chronic pain who may need modification to medication regime. When addiction becomes a co-occurring disorder, the injured worker should be referred to Addiction Services.

Physical therapy programs

Please note that typically we cannot pay for more than one type of treatment at one time. For example, we can usually only pay for treatment from a physiotherapist, or a chiropractor, or a registered massage therapist at any one time.

- **Activity Related Soft Tissue Disorder Services (ASTD)** — ASTD Services are designed for injured workers with pathology related to overuse. The services consist of an ASTD Medical Assessment and ASTD Treatment Program. The multidisciplinary treatment program duration is up to 12 weeks with a focus on returning to work.
- **Hand Therapy Program** — This program provides treatment and consultation for injured workers with acute traumatic or repetitive injuries of the upper extremity, below the level of the shoulder. This includes injuries to the hands and wrists such as open wounds, crush injuries, tendon repairs, and burns. The treatment is provided by certified hand therapists with specialized skills in assessing and treating upper extremity conditions.
- **Massage Therapy** — involves a trained and registered massage therapist working and acting on the body with pressure – structured, unstructured, stationary, or moving – tension, motion, or vibration, done manually or with mechanical aids.
- **Occupational Rehabilitation 1 Program (OR1)** — OR1 is a structured, active rehabilitation program offered by physiotherapists supported by kinesiologists. The program is designed to assist injured workers with soft-tissue injuries, resolved surgery, or healed fractures to achieve a safe and durable return to work. Treatment may be provided at a rehabilitation clinic and/or at the work site.

- **Occupational Rehabilitation 2 Program (OR2)** — OR2 is a structured, active rehabilitation program focused on return to work through physical and functional conditioning, education, and supported return to work. It is a multidisciplinary program, offered by physiotherapists, occupational therapists, psychologists, kinesiologists, and physicians. Treatment services may be provided at a rehabilitation clinic and/or at the work site.
- **Physiotherapy** — WorkSafeBC has a contracted network of Physical Therapists (PT) that provide therapy to injured workers. The goal physiotherapy is to provide workers with early access to return-to-work-focused physiotherapy treatment that is directed towards reintegrating them back into the workplace in a safe and timely manner and focuses treatment goals on pre-injury critical job demands to ensure durability upon return.
- **Return to Work Support Services (RTWSS)** — RTWSS is designed for the injured worker who does not require a structured treatment program but would benefit from a supported return-to-work. RTWSS may be performed by a physiotherapist, occupational therapist, or a kinesiologist experienced in the performance of return-to-work services and job-site visits. The goal of RTWSS is to return injured workers to their pre-injury duties at the work place.

Musculoskeletal treatment programs

- **Chiropractor** — The main chiropractic treatment technique involves manual therapy, especially manipulation of the spine, other joints, and soft tissues, but may also include exercises and health and lifestyle counseling. Chiropractic treatment is limited to the compensable area of injury and requires the treatment to be reasonably necessary for the worker's compensable personal injury.
- **Community Occupational Therapy (COT)** — These services are designed to help injured workers gain, maintain, and improve skills in self-care, and productivity that allow them to live, participate, and work in their local community. The occupational therapist may provide service in the home and/or in a community setting to assist the injured worker in acquiring, retaining, and improving independence and physical adaptive skills and return to a productive life.

Questions about opioid, other pharmacological, or non-pharmacological treatment strategies for a patient with chronic non-cancer pain related to a workers' compensation claim?

Call **WorkSafeBC's Physician's Hotline** at **1.855.476.3049**

WorkSafeBC

Our team can help by providing information on:

- Prescribing opioids and sedative/hypnotics
- Choosing other pharmacological and non-pharmacological treatment strategies
- Tapering and exit strategies
- Making referrals to WorkSafeBC-funded treatment programs such as pain medication management and addiction treatment programs

WorkSafeBC

Resources

Forms

- Bounce Back — practitioner referral form
  www.cmha.bc.ca/wp-content/uploads/2016/05/BB-Practitioner-Referral-Form2017-01-12.pdf
- Sample Patient Agreement for Long-term Opioid Therapy
  http://www.rxfiles.ca/rxfiles/uploads/documents/Pain-CNMP-Opioid-TreatmentAGREEMENT.pdf

Questionnaires

- ACE (Adverse Childhood Experiences)
  www.aceresponse.org/img/uploads/file/ace_score_questionnaire.pdf
- ASSIST — alcohol, tobacco and drug screen
  www.who.int/substance_abuse/activities/assist_v3_english.pdf
- AUDIT — alcohol misuse screen
  www.agencymeddirectors.wa.gov/Files/aas.pdf
- Brief Pain Inventory, short form
  www.npcrc.org/files/news/briefpain_short.pdf
- CAGE (Cut, Annoyed, Guilty, Eye) — alcohol problem screening questionnaire
  http://nationalpaincentre.mcmaster.ca/documents/cage_questionnaire.pdf
- COMM (Current Opioid Misuse Measure)
  www.opioidprescribing.com/documents/09-comm-inflexxion.pdf
- DN4 — neuropathic pain diagnostic questionnaire
  http://nperesource.casn.ca/wp-content/uploads/2017/02/20100922NAIH3NeuropathicPainDiagnosticQuestionnaireDN4-1.pdf
- GAD7 (Generalized Anxiety Disorder 7-item scale)
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  https://laws-lois.justice.gc.ca/eng/acts/A-2/FullText.html
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- Law Enforcement Officer Guides (ACOEM)
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- Major Depressive Disorder in Adults — Diagnosis and Management
  www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/bc-guidelines/depression-in-adults
- Railways Workers Medical Guides (RAC)
  www.railcan.ca/publication/canadian-railway-medical-rules-handbook/

Other resources

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  1.866.639.0522
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Non-Pharmacological Treatment Modalities

This document provides an overview of non-pharmacological treatments that are supported by some evidence and in certain conditions. Without endorsing any one modality, WorkSafeBC is providing this information to increase awareness of treatment modalities that could be considered based on a patient's needs and situation.

Psychotherapy modalities

- **Cognitive-behavioral therapy (CBT)** has been used in the treatment of chronic pain for over 30 years. The goals of CBT in the management of chronic pain are to improve physical functioning, assist patients in returning to work, reduce disability, reduce pain-related fear/avoidance, and reduce psychological distress and depression.
- **Relaxation therapy** aims to lower general arousal and promote a state of relaxation, and includes biofeedback, imagery, diaphragmatic breathing, autogenic training and progressive muscle relaxation training.
- **Mindfulness-Based Stress Reduction (MBSR)** uses mindfulness meditation to challenge habitual patterns of cognitive reactivity that increases distress and exacerbate pain. The aim of MBSR is to empower patients to engage in active coping by encouraging them to be aware of the present, where difficult thoughts, feelings, and sensations are acknowledged and accepted without judgment. It involves directing patients to focus their attention on the present moment by observing their breath, and bodily sensations, while becoming aware of, and accepting without judgment, any thoughts and feelings that arise.

Complementary and integrative medicine

By definition, **complementary medicine** is a non-mainstream practice used together with conventional medicine; while **alternative medicine** is a non-mainstream practice used in place of conventional medicine and **integrative medicine** is a therapeutic modality that combines complementary treatments with conventional medicine in a coordinated way.

- **Acupuncture** involves the stimulation of points on the body using thin solid metallic needles manipulated by hands, electrical stimulation or low-level laser that releases chi or qi, causing reduction in pain or dysfunction.
- **Qi-gong** or **healing touch therapy** (such as Healing Touch, Therapeutic Touch, and Reiki) is a gentle energy field therapy that is thought to facilitate a deep sense of calm and relaxation in the body-mind-spirit.
- **Tai-chi** and **yoga** are mind and body practices that combine physical posturing with breathing, meditation, and relaxation, improving the perception of pain.

- The **Pilates method** consists of comprehensive body conditioning, which aims to develop better body awareness and improved posture. Pilates exercises mainly involve isometric contractions of the core muscles, which make up the muscular centre responsible for the stabilization of the body, both while it is moving or at rest.
- **Prolotherapy** is defined as the rehabilitation of an incompetent structure, such as ligament or tendon, by the induced proliferation of cells. The theory behind Prolotherapy is that it induces the proliferation of collagen tissue that make up structure such as ligaments, tendons, and joint capsular tissue by the injection of proliferant substance such as extract of corn, glucose, pitcher plant, zinc manganese, extract of cod liver oil together with local anesthetic agents into the involved body area.
- **Medical marijuana** is the term used for the medical use, cultivation, and dispensing of marijuana for medical purposes, which may or may not include specific medical conditions for which a physician (or other licensed health care provider) authorizes a patient to obtain and use marijuana. At present, Health Canada has not issued a Notice of Compliance, which is required for a drug to be introduced to the market, for marijuana for medical purposes. Medical marijuana is not an approved therapeutic product in Canada and has no approved therapeutic indications. Furthermore, there is no currently accepted medical therapy that involves smoking.

Physical rehabilitation modalities

- **Exercise** is defined as a structured, repetitive physical activity aimed to improve or maintain physical fitness.
- **Active therapy** is defined as strength training and/or conditioning exercise performed by patients under the direction of a licensed practitioner such as a physician, physical therapist, or athletic trainer.
- **Passive therapies** are defined as the external application of manual and physical treatments to the patient by a clinician. As part of the Choosing Wisely® campaign, the American Physical Therapy Association recommends that clinicians do not employ passive physical agents except when necessary to facilitate participation in an active treatment program. Passive therapies include the following:
    - **Spinal manipulation therapy** is a specific type of manual therapy performed directly on patients by specially trained physicians, chiropractors, and physical therapists. It usually involves applying high-velocity low amplitude thrust movements, or slow passive muscle relaxation techniques to increase range of motion and reduce spinal pain.
    - **Massage therapy** is the manual manipulation of musculoskeletal and connective tissue to improve relaxation and enhance physical rehabilitation.
    - **Transcutaneous electrical nerve stimulation (TENS)** is the application of low-voltage electrical stimulation to the skin with contact electrodes. Conventional technique uses four electrodes placed around the painful region, delivering 10–30 mA electrical intensity at high frequency (40–150Hz) for 30–60 minutes duration once or twice daily.

- **Ultrasound therapy** is the application of high-frequency sound waves (> 20,000 Hz) to the skin for deep soft tissue heating using a piezoelectric sound generator, which is also called a transducer. Treatment goal is to increase tissue temperature to 40–45ºC (104–113ºF) for therapeutic effects of increased blood flow, decreased chronic inflammation, increased soft tissue flexibility, and reduced pain.
- **Traction therapy** is an applied external force to physically distract spinal facet joints and intervertebral foramina.
- **Extracorporeal shockwave therapy (ESWT)** is a treatment utilized for a variety of healing applications in soft tissue and bone-related musculoskeletal disorders. A shock wave is an intense, but very short energy wave traveling faster than the speed of sound. Specific conditions where ESWT is utilized include refractory or chronic pain associated with ligament injuries, muscle strain injuries, osteoarthritis, and tendinopathies.
- **Low level laser or low energy lasers**, which is also known as cold lasers or class III (sometimes also class IV) lasers, have been promoted as an effective way to produce analgesia and accelerate healing of a variety of clinical conditions. By definition, low level laser therapy (LLLT) uses irradiation intensities that induce minimal temperature elevation (not more than 0.1 to 0.5°C), if any. For practical purposes, this restricts treatment energies to a few J/cm2 and laser powers to 500 mW or less.
- **Photonic stimulators** are devices that produce infrared light. This light is directed at specific parts of the body to increase blood flow and, allegedly, relieve pain.
- **Superficial heat or cold**

Interventional modalities

In general, interventional treatments refer to various percutaneous or minor surgical procedures targeting specific anatomical structures identified as possible sources of pain.

- **Diagnostic injections**, such as nerve block, intra- or extra articular block, discography, are used to confirm a putative diagnosis and to identify patients who may be candidates for further interventional treatments.
- The use of **therapeutic injections** and other minimally invasive interventions has risen dramatically over the past decade, but increased utilization has not been generally accompanied by a concomitant reduction in disability rates or surgical procedures. These injections include:
  - Epidural steroid injection, which is the most frequently performed image-guided pain medicine procedures for radicular pain.
  - Facet joint injection
  - Sacroiliac joint injection

- **Percutaneous radio frequency (RF)** neurotomy is a treatment for facet-related neck and back pain. This procedure has also been used to treat sacroiliac joint pain. The RF procedure is performed by placing an insulated needle electrode with an exposed tip adjacent to and in parallel with the medial or lateral branch nerves that supply the target joints. Radio frequency current applied to the electrode then heats the adjacent tissues and coagulates the nerve supply to the joint.
- **Intervertebral disc procedures**. A variety of interventions, such as intradiscal steroids, intradiscal cytokine inhibitors, intradiscal electrothermal therapy, and biacuplasty, have been developed to treat discogenic pain. However, it should be noted there is a risk of disc injury after annulus puncture in these procedures.
- **Myofascial trigger point injections** for myofascial pain which is characterized by the presence of trigger points, which are hyperirritable tense bands of skeletal muscles. Local anesthetic, steroid, botulinum toxin, or dry needle may be employed in this procedure.
- **Spinal cord stimulation**, the most widely used neurostimulation technique, involves placement of electrodes in the epidural space. It is typically reserved for patients who have failed other pain therapies including medications, injections, and physical modalities. It is thought that spinal cord stimulation exerts analgesic effects by stimulating large, fast-conducting sensory fibers, thereby inhibiting the slower conducting A-delta and C nociceptive fibers responsible for pain transmission.
- **Intrathecal drug delivery systems**, a.k.a pain pumps or morphine pumps, administer medications directly to the intrathecal space. A small caliber catheter is placed percutaneously in the intrathecal space and tunneled subcutaneously to a programmable reservoir pump that is typically implanted in the subcutaneous tissues of the lower abdominal region. Medications that are typically used as solo therapy or in combination include opioids (such as morphine, hydromorphone, or fentanyl), local anesthetics (such as bupivacaine), clonidine and ziconotide.
- **Intramuscular stimulation (IMS)** is a type of dry needling approach that combines features of acupuncture, type of needles and needle techniques, with neurological and tender point models.

Age-specific prevalence estimates of degenerative spine imaging findings in asymptomatic patients

Image finding	Age (yrs.)						
	20	30	40	50	60	70	80
Disk degeneration	37%	52%	68%	80%	88%	93%	96%
Disk signal loss	17%	33%	54%	73%	86%	94%	97%
Disk height loss	24%	34%	45%	56%	67%	76%	84%
Disk bulge	30%	40%	50%	60%	69%	77%	84%
Disk protrusion	29%	31%	33%	36%	38%	40%	43%
Annular fissure	19%	20%	22%	23%	25%	27%	29%
Facet degeneration	4%	9%	18%	32%	50%	69%	83%
Spondylolisthesis	3%	5%	8%	14%	23%	35%	50%

Brinjikl W. et al. Systematic literature review of spinal degeneration in asymptomatic populations American Journal of Neuroradiology Nov 27, 2014

Anticipating a difficult conversation with your patient?

Discussing a treatment plan for pain can be challenging. Consider these ten tips.

1. Prepare before the meeting and have a plan for what you want to accomplish and how you will approach it.
2. Demonstrate that you are fully engaged by maintaining good eye contact and listening attentively.
3. Develop trust through honesty and show that you genuinely want to help.
4. Keep emotion out of the conversation. Be empathetic, not sympathetic.
5. Gather sufficient history without spending too much time in the past. Don't get caught in the trap of discussing previous doctors.
6. Acknowledge symptoms and move on; prevent your patient from fixating on pain.
7. Focus on functional goals and empower your patient. For example:
   - Ask "What activities would you like to get back to?"
   - Ask "What could you do to increase your function?"
8. Use language your patient will understand. Don't confuse or overcomplicate with medical terminology.
9. Consider how you will overcome objections. For example:
   - Provide rationale or evidence.
   - Explain that other patients have had success with the treatment you are recommending.
   - Ask "Is this something you would be willing to try?"
10. Remember it is a process.
    - Don't try to solve the issue in one appointment. Instead, ensure you both feel progress is being made with each appointment.
    - Plant seeds and give your patient time. Schedule a follow-up appointment within a short period of time.

JAMA | Original Investigation

Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain
The SPACE Randomized Clinical Trial

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IMPORTANCE Limited evidence is available regarding long-term outcomes of opioids compared with nonopioid medications for chronic pain.

OBJECTIVE To compare opioid vs nonopioid medications over 12 months on pain-related function, pain intensity, and adverse effects.

DESIGN, SETTING, AND PARTICIPANTS Pragmatic, 12-month, randomized trial with masked outcome assessment. Patients were recruited from Veterans Affairs primary care clinics from June 2013 through December 2015; follow-up was completed December 2016. Eligible patients had moderate to severe chronic back pain or hip or knee osteoarthritis pain despite analgesic use. Of 265 patients enrolled, 25 withdrew prior to randomization and 240 were randomized.

INTERVENTIONS Both interventions (opioid and nonopioid medication therapy) followed a treat-to-target strategy aiming for improved pain and function. Each intervention had its own prescribing strategy that included multiple medication options in 3 steps. In the opioid group, the first step was immediate-release morphine, oxycodone, or hydrocodone/acetaminophen. For the nonopioid group, the first step was acetaminophen (paracetamol) or a nonsteroidal anti-inflammatory drug. Medications were changed, added, or adjusted within the assigned treatment group according to individual patient response.

MAIN OUTCOMES AND MEASURES The primary outcome was pain-related function (Brief Pain Inventory [BPI] interference scale) over 12 months and the main secondary outcome was pain intensity (BPI severity scale). For both BPI scales (range, 0-10; higher scores = worse function or pain intensity), a 1-point improvement was clinically important. The primary adverse outcome was medication-related symptoms (patient-reported checklist; range, 0-19).

RESULTS Among 240 randomized patients (mean age, 58.3 years; women, 32 [13.0%]), 234 (97.5%) completed the trial. Groups did not significantly differ on pain-related function over 12 months (overall $P = .58$); mean 12-month BPI interference was 3.4 for the opioid group and 3.3 for the nonopioid group (difference, 0.1 [95% CI, −0.5 to 0.7]). Pain intensity was significantly better in the nonopioid group over 12 months (overall $P = .03$); mean 12-month BPI severity was 4.0 for the opioid group and 3.5 for the nonopioid group (difference, 0.5 [95% CI, 0.0 to 1.0]). Adverse medication-related symptoms were significantly more common in the opioid group over 12 months (overall $P = .03$); mean medication-related symptoms at 12 months were 1.8 in the opioid group and 0.9 in the nonopioid group (difference, 0.9 [95% CI, 0.3 to 1.5]).

CONCLUSIONS AND RELEVANCE Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01583985

JAMA. 2018;319(9):872-882. doi:10.1001/jama.2018.0899

Supplemental content

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Long-term opioid therapy became a standard approach to managing chronic musculoskeletal pain despite a lack of high-quality data on benefits and harms.[1]

Rising rates of opioid overdose deaths have raised questions about prescribing opioids for chronic pain management. Because of the risk for serious harms without sufficient evidence for benefits, current guidelines discourage opioid prescribing for chronic pain.[2-4] Systematic reviews cited by guidelines identified no randomized trials of opioid therapy that reported long-term pain, function, or quality-of-life outcomes.[4,5]

The Strategies for Prescribing Analgesics Comparative Effectiveness (SPACE) trial was a pragmatic randomized trial that compared opioid therapy vs nonopioid medication therapy over 12 months for primary care patients with chronic back pain or hip or knee osteoarthritis pain of at least moderate severity despite analgesic use. Hypotheses were that opioids compared with nonopioid medications would lead to better pain-related function and pain intensity and more adverse effects.

Key Points

Question For patients with moderate to severe chronic back pain or hip or knee osteoarthritis pain despite analgesic use, does opioid medication compared with nonopioid medication result in better pain-related function?

Findings In this randomized clinical trial that included 240 patients, the use of opioid vs nonopioid medication therapy did not result in significantly better pain-related function over 12 months (3.4 vs 3.3 points on an 11-point scale at 12 months, respectively).

Meaning This study does not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.

Methods

The Minneapolis Veterans Affairs (VA) institutional review board approved the trial protocol and patients provided written informed consent. Recruitment details and the trial protocol have been published.[6] The trial protocol and statistical analysis plan are in Supplement 1.

Pragmatic Trial Design

To maximize applicability to primary care, the trial was designed to be pragmatic.[6,7] Eligibility criteria facilitated enrollment of diverse patients from primary care. Interventions were delivered with flexibility in medication selection and dosage. Patients were allowed to participate in nonpharmacological pain therapies outside of the study and were encouraged to complete outcome assessments regardless of their participation in the active interventions.

Participants

Eligible patients had chronic back pain or hip or knee osteoarthritis pain that was moderate to severe despite analgesic use. Chronic pain was defined as pain nearly every day for 6 months or more. Moderate or greater severity was defined by a score of 5 or more on the 3-item pain intensity, interference with enjoyment of life, and interference with general activity (PEG) scale (range, 0-10).[8]

Patients on long-term opioid therapy were excluded. Other reasons for exclusion included contraindications to all drug classes in either group, including class-level opioid contraindications (eg, active substance use disorder), and conditions that could interfere with outcome assessment (eg, life expectancy <12 months).[6] Patients with severe depression or posttraumatic stress disorder symptoms were not excluded because these patients often receive opioids in practice.

Patients were recruited from 62 Minneapolis VA primary care clinicians from June 2013 to December 2015 (**Figure**). Primary care clinicians were located at multiple clinics affiliated with the Minneapolis VA Health Care System, including clinics in the main medical center building and 4 outpatient clinics in the greater Minneapolis-Saint Paul metropolitan area. Potentially eligible patients were identified by searching the electronic health record (EHR) for back, hip, or knee pain diagnoses at a primary care visit in the prior month. Study personnel screened patients by telephone and then conducted a focused chart review.

Randomization and Blinding

To ensure balanced numbers of patients with back and osteoarthritis pain in each group, randomization was stratified by primary pain diagnosis. The SAS (SAS Institute), version 9.4, uniform random number generator was used to produce a computerized randomization table. Approximately 1 week after the enrollment visit, patients met with the study clinical pharmacist, who initiated random group assignment using a programmed study application that automatically assigned the next unused position in the randomization table. This process simultaneously informed the pharmacist and patient of group assignment. EHR documentation informed patients' primary care clinicians of study participation and group assignment. Study medications were visible in the EHR. Outcome assessors were blinded to group assignment.

Intervention Delivery

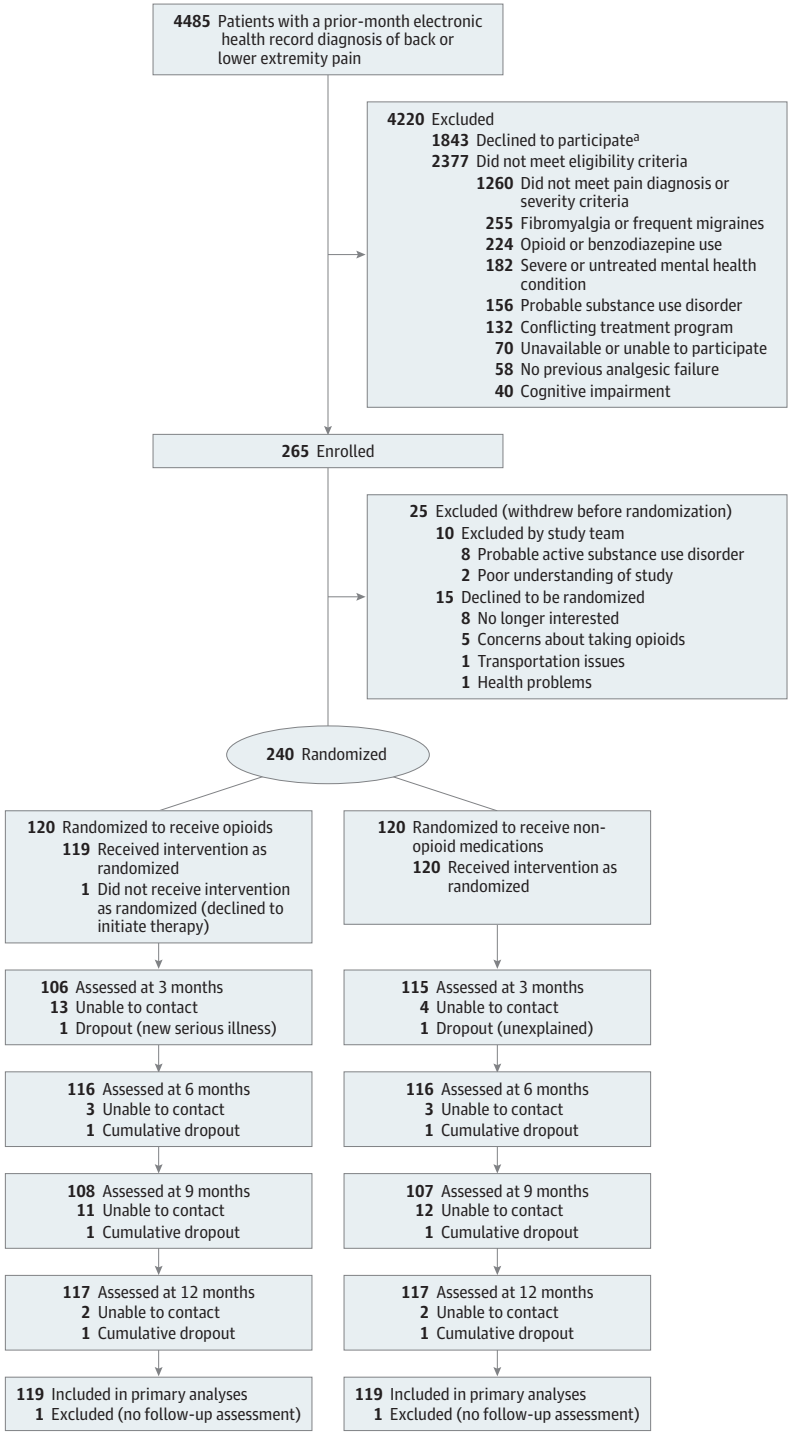
Medication was delivered using a collaborative pain care model with demonstrated effectiveness.[9,10] In both groups, patients received structured symptom monitoring and a treat-to-target approach to medication management delivered primarily by a single pharmacist. After randomization, the pharmacist reviewed past medications and identified individual functional goals. The initial medication regimen was determined by the assigned group and considerations such as patient preference and comorbidities. Follow-up visits were monthly until a stable regimen was established, then visits occurred every 1 to 3 months. Visits were in-person at 6 and 12 months when possible and otherwise mostly by telephone.

Both interventions used 3 medication steps. Medications were adjusted within the assigned group to achieve targets of improved PEG scores and progress toward individual goals. Study medications were dispensed from the VA pharmacy.

Opioid Prescribing Strategy

Per protocol, patients in the opioid group started taking immediate-release (IR) opioids. Step 1 was morphine IR,

Figure. Flow of Participants Through the Study



[a] Patients could decline to participate at any point in the screening process, including before the telephone eligibility interview; therefore, patients who declined to participate were not necessarily eligible.

hydrocodone/acetaminophen, and oxycodone IR. Step 2 was morphine sustained-action (SA) and oxycodone SA. Step 3 was transdermal fentanyl. Single-opioid therapy was preferred, but dual therapy with a scheduled SA opioid and as-needed IR opioid was considered based on patient needs and preferences. Opioids were titrated to a maximum daily dosage of 100 morphine-equivalent (ME) mg. If dosages were titrated to 60 ME mg/d without a response, rotation to another opioid was considered before dosage escalation.[11]

Nonopioid Prescribing Strategy

In the nonopioid medication group, step 1 was acetaminophen (paracetamol) and nonsteroidal anti-inflammatory drugs (NSAIDs). Step 2 included adjuvant oral medications

(ie, nortriptyline, amitriptyline, gabapentin) and topical analgesics (ie, capsaicin, lidocaine). Step 3 included drugs requiring prior authorization from the VA clinic (ie, pregabalin, duloxetine) and tramadol. Patients were initially prescribed a step 1 medication, unless all were clinically inappropriate. Subsequent changes included titrating, replacing, or adding medications.

Intervention Adherence

Patients were instructed to receive medications for back, hip, or knee pain only from the study. Nonpharmacological therapies were allowed outside of the study. If patients desired discontinuation of all study medications, they were transitioned back to preenrollment pain medications. Medication adherence was monitored by discussion with patients and checking the state prescription monitoring program website.

Descriptive Measures

Before randomization, patients were asked to state their preferred treatment group, perceptions of effectiveness and safety of opioid and nonopioid medications, and expectations for improvement on 0 to 10 scales (higher scores = more favorable).[12,13] To characterize the study population and provide data required by federal funders, self-identified race/ethnicity was assessed by asking patients to select from 6 categories.

Main Outcomes

The primary outcome was pain-related function, assessed with the 7-item Brief Pain Inventory (BPI) interference scale.[14] Pain intensity, the main secondary outcome, was assessed with the 4-item BPI severity scale. Both BPI scales yield 0 to 10 scores (higher score = worse function or intensity). A prior study of chronic pain in primary care estimated a minimal clinically important difference (MCID) of 0.7 points for both BPI interference and BPI severity.[15] Following consensus guidelines, this trial used a 1-point difference as the MCID for BPI interference and BPI severity, and used a 30% reduction from baseline as MCID for moderate improvement.[16] The primary adverse outcome was a patient-reported checklist of 19 medication-related symptoms,[17] modified from the original version by adding common analgesic adverse effects (eg, memory problems, sweating).[18]

Secondary Health Outcomes

Secondary outcomes were as follows: the Veterans RAND 12-item Health Survey (VR-12) quality-of-life measure (range, 0-100; higher score = better quality of life, standardized to mean of 50),[19] the 11-item Roland-Morris Disability Questionnaire (RMDQ) measure of pain-related physical function (range, 0-11; higher score = worse function, MCID = 2.0),[20] the 8-Item Patient Health Questionnaire (PHQ-8) depression measure (range, 0-24; higher score = worse depression, MCID = 5), the 7-Item Generalized Anxiety Disorder measure (GAD-7; range, 0-21; higher score = worse anxiety, MCID = 5)[21]; the Patient-Reported Outcomes Measurement Information System (PROMIS) sleep disturbance short form (range, 8-32; higher score = worse sleep disturbance)[22]; the Migraine Disability Assessment (MIDAS) questionnaire (range, 0-270; higher score = worse headache disability),[23] the Arizona Sexual Experience Scale (ASEX; range 5-30; higher score = worse sexual function)[24]; and the Multidimensional Fatigue Inventory (MFI) general fatigue, mental fatigue, physical fatigue, reduced activity, and reduced motivation scales (for each scale: range, 4-20; higher score = worse, MCID = 2).[25] Additional secondary outcomes not reported here were the global impression of pain change, the Fullerton Advanced Balance scale, 6-m gait speed, chair stand, grip strength tests, cold pain tolerance, free testosterone, and the Indiana University Telephone-Based Assessment of Neuropsychological Status.

Assessment for Adverse Events and Potential Opioid Misuse

At each assessment, patients reported new hospitalizations, emergency department (ED) visits, and falls. VA hospitalizations and ED events were identified by searching EHR databases from enrollment to 13 months after randomization. Two independent raters determined whether events were analgesic-related.[26] Discrepancies were resolved by discussion.

Opioid misuse describes use of prescription opioids in a manner other than as prescribed. This study used multiple approaches to evaluate for potential misuse, including medical record surveillance for evidence of "doctor-shopping" (seeking medication from multiple physicians), diversion, substance use disorder, or death; checking the state prescription monitoring program website at each visit and as needed; and completing the Addiction Behavior Checklist[27] at each intervention visit. The Addiction Behavior Checklist measures aberrant medication-related behaviors that may indicate misuse (range, 0-20; higher score = more aberrant behavior; 3 = threshold for opioid misuse). At 6-month and 12-month assessments, patients completed self-report measures and had urine drug testing. Substance use was assessed with the Alcohol Use Disorders Identification Test (AUDIT) and drug use questions from a National Institute on Drug Abuse screening tool.[28,29]

Assessment of Study Treatment Received and Nonstudy Co-Interventions

Pain medication dispensing data were obtained from EHR databases. Total study visit duration was calculated for each patient as the sum of minutes from clinician-entered *Current Procedural Terminology* (*CPT*) codes for all intervention encounters; for *CPT* codes that include a range of minutes (ie, 5-10, 11-20, 21-30), the highest value was used. Nonstudy co-interventions were obtained from patient report and EHR data.

Statistical Analysis

Assuming a 2-sided α level of .05 and a standard deviation of 2.7,[30] 115 patients completing the study per group were required for 80% power to detect a 1-point between-group difference in mean BPI interference at 12 months.[16] The initial target was 276 randomized patients, but enrollment was stopped at 265 due to difficulty recruiting and better-than-anticipated retention.

Analyses were intention-to-treat, with all patients included in their assigned treatment group. Scales were not scored if less than 70% of items were completed. When less than 30% of items were missing, the average of nonmissing

Table 1. Baseline Characteristics of Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain Randomized to Opioid vs Nonopioid Medication

Characteristic	Opioid Group, No. (%) (n = 120)	Nonopioid Group, No. (%) (n = 120)
Age, y		
Mean (SD)	56.8 (13.3)	59.7 (14.0)
Median (IQR)	59.5 (46.5-67.0)	64.0 (53.0-69.0)
Women	36 (13)	36 (13)
Race/ethnicity		
White	105 (88)	102 (86)
Black	7 (6)	11 (9)
Other or multiple	7 (6)	6 (5)
Education ≥4-y degree	29 (24)	31 (26)
Employment		
Employed for wages	50 (42)	31 (26)
Self-employed	7 (6)	7 (6)
Retired	43 (36)	56 (47)
Other	19 (16)	24 (20)
Primary pain diagnosis[a]		
Back pain	78 (65)	78 (65)
Hip or knee osteoarthritis pain	42 (35)	42 (35)
Substance use assessment		
Current smoker	25 (21)	13 (11)
Hazardous alcohol use (AUDIT score ≥8)	3 (3)	2 (2)
Past-year illicit drug use	8 (7)	15 (13)
Mental health measures		
Moderate depression (PHQ-9 score ≥10)	28 (23)	25 (21)
Moderate anxiety (GAD-7 score ≥10)	11 (9)	11 (9)
Positive PTSD screen (PC-PTSD score ≥3)	25 (21)	25 (21)
Prerandomization treatment group preference[b]		
Unsure or no preference	72 (60)	51 (43)
Opioid medication group	25 (21)	44 (37)
Nonopioid medication group	23 (19)	25 (21)
Prerandomization perceptions of treatment groups, mean (SD)[c]		
Opioid effectiveness	7.8 (2.1)	7.8 (2.0)
Opioid safety	5.8 (2.5)	5.8 (2.8)
Nonopioid effectiveness	5.7 (2.7)	5.6 (2.8)
Nonopioid safety	6.6 (2.7)	6.5 (2.8)
Expectations for improvement[d]	7.6 (1.8)	7.4 (2.0)

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; GAD-7, 7-Item Generalized Anxiety Disorder Questionnaire; IQR, interquartile range; PHQ-9, 9-Item Patient Health Questionnaire; PC-PTSD, primary care posttraumatic stress disorder screener.

[a] Patients self-identified 1 condition as their most bothersome pain problem.

[b] Patients were asked, "Now, imagine if you were given a choice between groups. Considering what you know so far, which treatment group would you choose?"

[c] Patients were asked, "In general, how (effective or safe) do you consider (opioid medications or nonopioid medications) for long-term treatment of pain?" (range, 0-10; 0 = not at all [effective or safe], 10 = most [effective or safe] possible).

[d] Patients were asked, "In terms of your pain, how much improvement do you think is likely for you personally during this study?" (range, 0-10; 0 = no improvement to 10 = a great deal of improvement).

items was used for measures scored as an average, and missing "count" data were scored as 0.

Two-sided *t* tests and χ^2 tests were used for unadjusted between-group comparisons of primary and secondary outcomes at each assessment time point. Main analyses included data from all time points in mixed models (logistic, Poisson, Gaussian) for repeated measures to compare mean scores between treatment groups over 12 months, adjusting for baseline values, with time as fixed effects and intercept as random effects. For medication-related symptoms, groups were compared using a statistical test for treatment × time interaction. Individual patient-level functional response and pain intensity response were defined as 30% or more reduction from baseline to 12-month follow-up in BPI interference and severity, respectively.[16] χ^2 Tests were used to compare response rates as a secondary measure of effectiveness. The threshold for statistical significance was a *P* value less than .05. Analyses of secondary outcomes were exploratory and not adjusted for multiple testing. Post hoc treatment group by primary pain diagnosis interaction tests were used to explore possible differential treatment effects. Post hoc sensitivity analyses adjusting for smoking status were conducted to examine potential effects of the baseline group imbalance in current smoking. SAS (SAS Institute), version 9.2, was used for statistical analysis.

Results

Of 265 enrolled patients, 25 withdrew prior to randomization and 240 were randomized (Figure). Follow-up rates were 92% at 3 months (106 in the opioid group and 115 in the nonopioid group), 97% at 6 months (116 in each group), 90% at 9 months (108 in the opioid group and 107 in the nonopioid group), and 98% at 12 months (117 in each group). Two patients dropped out before completing follow-up assessments and were excluded; 1 patient randomized to opioids declined to initiate opioid therapy; all others received assigned therapy (Figure).

Mean age was 58.3 years (range, 21-80) and 32 patients (13.0%) were women (**Table 1**). For primary pain diagnosis, 156 patients (65%) had back pain and 84 patients (35%) had hip or knee osteoarthritis pain. The opioid group had 25 current smokers (21%) and the nonopioid group had 13 current smokers (11%). Regarding treatment group preference, in the opioid group, 72 patients (60%) had no preference and 25 patients (21%) preferred opioids. In the nonopioid group, 51 patients (43%) had no preference and 44 patients (37%) preferred opioids.

Pain and Health Outcomes

There was no significant difference in pain-related function between the 2 groups over 12 months (overall *P* = .58). At 12 months, mean BPI interference was 3.4 in the opioid group (SD, 2.5) vs 3.3 in the nonopioid group (SD, 2.6); difference, 0.1 (95% CI, −0.5 to 0.7). Pain intensity was significantly better in the nonopioid group over 12 months (overall *P* = .03). At 12 months, mean BPI severity was 4.0 in the opioid group (SD, 2.0) vs 3.5 in the nonopioid group (SD, 1.9); difference, 0.5 (95% CI, 0.0 to 1.0).

Table 2. Patient-Reported Primary and Secondary Outcomes Among Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain Randomized to Opioid vs Nonopioid Medication

Outcome	Opioid Group, Mean (SD) (n = 119)	Nonopioid Group, Mean (SD) (n = 119)	Between-Group Difference (95% CI)[a]	Overall *P* Value[b]
Pain-Related Function (Primary Outcome)				
BPI interference scale (range, 0-10; higher score = worse)[c]				.58
Baseline	5.4 (1.8)	5.5 (2.0)	−0.1 (−0.6 to 0.4)	
3 mo	3.7 (2.1)	3.7 (2.2)	0.0 (−0.6 to 0.6)	
6 mo	3.4 (2.1)	3.6 (2.4)	−0.2 (−0.8 to 0.4)	
9 mo	3.6 (2.2)	3.3 (2.4)	0.4 (−0.2 to 1.0)	
12 mo	3.4 (2.5)	3.3 (2.6)	0.1 (−0.5 to 0.7)	
Pain Intensity (Secondary Outcome)				
BPI severity scale (range, 0-10; higher score = worse)[d]				.03
Baseline	5.4 (1.5)	5.4 (1.2)	0.0 (−0.4 to 0.3)	
3 mo	4.3 (1.8)	4.0 (1.7)	0.3 (−0.2 to 0.7)	
6 mo	4.1 (1.8)	4.1 (1.9)	0.0 (−0.5 to 0.5)	
9 mo	4.2 (1.7)	3.6 (1.7)	0.7 (0.2 to 1.2)	
12 mo	4.0 (2.0)	3.5 (1.9)	0.5 (0.0 to 1.0)	
Additional Secondary Health Outcomes				
VR-12 physical health (range, 0-100; lower score = worse)				.23
Baseline	27.2 (9.0)	27.0 (7.2)	0.2 (−1.9 to 2.2)	
3 mo	32.5 (9.8)	33.5 (9.9)	−1.0 (−3.6 to 1.6)	
6 mo	33.3 (9.7)	33.6 (10.0)	−0.3 (−2.8 to 2.2)	
9 mo	32.0 (10.5)	34.8 (10.9)	−2.9 (−5.8 to 0.0)	
12 mo	32.7 (10.1)	33.9 (9.9)	−1.3 (−3.8 to 1.3)	
VR-12 mental health (range, 0-100; lower score = worse)				.40
Baseline	47.3 (11.2)	47.8 (13.0)	−0.3 (−3.4 to 2.8)	
3 mo	51.8 (10.1)	50.5 (12.0)	1.3 (−1.6 to 4.3)	
6 mo	51.6 (9.8)	50.3 (12.5)	1.4 (−1.5 to 4.3)	
9 mo	51.8 (10.7)	52.6 (11.5)	−0.8 (−3.8 to 2.2)	
12 mo	51.2 (11.6)	50.4 (12.6)	0.7 (−2.4 to 3.8)	
RMDQ-11 pain-related physical function (range, 0-11; higher score = worse)[e]				.47
Baseline	8.0 (2.5)	8.6 (1.9)	−0.5 (−1.1 to 0.0)	
6 mo	6.3 (3.3)	7.1 (3.1)	−0.8 (−1.7 to 0.0)	
12 mo	5.8 (3.4)	5.9 (3.5)	−0.1 (−1.0 to 0.8)	
PHQ-8 depression symptoms (range, 0-24; higher score = worse)[f]				.13
Baseline	6.3 (4.5)	5.8 (5.0)	0.5 (−0.7 to 1.7)	
6 mo	4.4 (3.9)	4.8 (5.2)	−0.4 (−1.6 to 0.8)	
12 mo	4.3 (4.0)	4.5 (5.3)	−0.2 (−1.5 to 1.1)	
GAD-7 anxiety symptoms (range, 0-21; higher score = worse)[g]				.02
Baseline	4.0 (3.6)	3.5 (4.0)	0.5 (−0.5 to 1.4)	
6 mo	3.0 (3.5)	3.2 (4.5)	−0.2 (−1.3 to 0.8)	
12 mo	2.5 (3.3)	2.8 (4.2)	−0.4 (−1.4 to 0.7)	
PROMIS sleep disturbance (range, 8-32; higher score = worse)[g]				.33
Baseline	25.5 (7.8)	24.2 (8.4)	1.2 (−0.8 to 3.3)	
6 mo	22.2 (8.8)	22.0 (9.0)	0.2 (−2.2 to 2.5)	
12 mo	23.4 (8.2)	21.0 (8.3)	2.3 (0.1 to 4.6)	

(continued)

Functional response (≥30% improvement in BPI interference) occurred in 69 patients (59.0%) in the opioid group vs 71 patients (60.7%) in the nonopioid group; difference, −1.7% (95% CI, −14.4 to 11.0); *P* = .79. Pain intensity response (≥30% improvement in BPI severity) occurred in 48 patients (41.0%) in the opioid group vs 63 patients

Table 2. Patient-Reported Primary and Secondary Outcomes Among Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain Randomized to Opioid vs Nonopioid Medication (continued)

Outcome	Opioid Group, Mean (SD) (n = 119)	Nonopioid Group, Mean (SD) (n = 119)	Between-Group Difference (95% CI)[a]	Overall *P* Value[b]
MIDAS headache disability (range, 0-270; higher score = worse)[h]				
Baseline	6.1 (16.5)	6.1 (16.2)	−0.1 (−4.2 to 4.1)	.82
6 mo	3.8 (12.6)	5.5 (18.8)	−1.7 (−6.0 to 2.5)	
12 mo	3.7 (11.6)	3.2 (11.6)	−0.5 (−2.7 to 3.6)	
ASEX sexual function (range, 5-30; higher score = worse)[i]				
Baseline	17.4 (5.6)	17.7 (6.0)	−0.3 (−1.8 to 1.3)	.49
12 mo	17.9 (6.0)	19.0 (6.5)	−1.1 (−2.8 to 0.7)	
MFI general fatigue (range, 4-20; higher score = worse)[j]				
Baseline	13.8 (3.8)	12.8 (4.1)	1.0 (−0.0 to 2.0)	.68
6 mo	12.7 (3.9)	12.5 (4.3)	0.2 (−0.9 to 1.3)	
12 mo	12.5 (3.9)	12.0 (4.4)	0.6 (−0.6 to 1.7)	
MFI mental fatigue (range, 4-20; higher score = worse)[j]				
Baseline	10.0 (4.2)	9.6 (4.7)	0.4 (−0.7 to 1.6)	.39
6 mo	9.0 (4.2)	9.3 (4.4)	−0.3 (−1.4 to 0.9)	
12 mo	9.2 (3.9)	9.3 (4.3)	0.1 (−1.3 to 1.0)	
MFI physical fatigue (range, 4-20; higher score = worse)[j]				
Baseline	13.6 (4.1)	12.9 (4.1)	0.7 (−0.3 to 1.8)	.73
6 mo	12.9 (4.4)	12.5 (4.5)	0.4 (−0.8 to 1.5)	
12 mo	12.4 (4.3)	11.8 (4.3)	0.7 (−0.5 to 1.9)	
MFI reduced activity (range, 4-20; higher score = worse)[j]				
Baseline	11.4 (4.1)	10.9 (4.6)	0.5 (−0.7 to 1.6)	.74
6 mo	10.6 (4.6)	10.5 (4.5)	0.2 (−1.0 to 1.4)	
12 mo	10.6 (4.2)	10.3 (4.5)	0.3 (−1.0 to 1.5)	
MFI reduced motivation (range, 4-20; higher score = worse)[j]				
Baseline	9.8 (3.6)	8.8 (3.8)	1.0 (0.0 to 2.0)	.09
6 mo	9.1 (3.6)	8.9 (4.0)	0.2 (−0.8 to 1.2)	
12 mo	8.6 (3.2)	8.8 (3.7)	−0.2 (−0.7 to 1.6)	

Abbreviations: ASEX, Arizona Sexual Experience Scale; BPI, Brief Pain Inventory; GAD-7, 7-Item Generalized Anxiety Disorder Questionnaire; MFI, Multidimensional Fatigue Inventory; MIDAS, Migraine Disability Assessment Scale; PHQ-8, 8-Item Patient Health Questionnaire; PROMIS, Patient Reported Outcomes Measurement Information System; RMDQ-11, 11-Item Roland-Morris Disability Questionnaire; VR-12, Veterans RAND 12-item Health Survey.

[a] Unadjusted time-specific between-group comparisons.

[b] *P* values are from mixed models for repeated measures comparing between-group difference during the 12-mo trial, controlling for baseline and including all available time points.

[c] Missing data for 1 patient in the opioid group at 9 mo.

[d] Missing data for 1 patient in the opioid group at 3 mo.

[e] Missing data for 2 patients in the nonopioid group at 12 mo.

[f] Missing data for patients: at 6 mo, 3 in the opioid group and 9 in the nonopioid group; at 12 mo, 12 in the opioid group and 15 in the nonopioid group.

[g] Missing data for patients: at 6 mo, 2 in the opioid group and 8 in the nonopioid group; at 12 mo, 11 in the opioid group and 12 in the nonopioid group.

[h] Missing data for patients: at 6 mo, 3 in the opioid group and 8 in the nonopioid group ; at 12 mo, 13 in the opioid group and 14 in the nonopioid group.

[i] Missing data for patients: at baseline, 11 in the opioid group and 9 in the nonopioid group; at 12 mo, 19 in the opioid group and 17 in the nonopioid group.

[j] Missing data for patients: at baseline, 2 in the opioid group and 3 in the nonopioid group; at 6 mo, 2 in the opioid group and 9 in the nonopioid group; at 12 mo, 14 in the opioid group and 18 in the nonopioid group.

(53.9%) in the nonopioid group; difference, −12.8% (95% CI, −25.6 to 0.0); *P* = .05.

Health-related quality of life did not significantly differ between the 2 groups (physical health overall: *P* = .23; difference at 12 months, −1.3 [95% CI, −3.8 to 1.3]; mental health overall: *P* = .40; difference at 12 months, 0.7 [95% CI, −2.4 to 3.8]). Of the remaining secondary outcomes, only anxiety significantly differed between groups (**Table 2**; eTables 1-2 in Supplement 2).

Adverse Outcomes and Potential Misuse

The opioid group had significantly more medication-related symptoms over 12 months than the nonopioid group (overall: *P* = .03; difference at 12 months, 0.9 [95% CI, 0.3 to 1.5]) (**Table 3**).

There were no significant differences in adverse outcomes or potential misuse measures (Table 3). Two hospitalization or ED visit events were determined analgesic-related: 1 hospitalization in the nonopioid group and 1 ED visit in the

Table 3. Adverse Outcomes and Measures of Potential Misuse Among Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain Randomized to Opioid vs Nonopioid Medication

Outcome	Opioid Group	Nonopioid Group	Between-Group Difference (95% CI)[a]	*P* Value
Primary Adverse Outcome				
Medication-related symptom checklist (0-19; higher score = worse), mean (SD)[b]				
Baseline	1.2 (1.9)	1.2 (1.9)	0.0 (−0.5 to 0.5)	.03[c]
3 mo	2.3 (2.5)	1.3 (1.8)	1.0 (0.5 to 1.6)	
6 mo	2.1 (2.7)	1.3 (2.3)	0.7 (0.1 to 1.4)	
9 mo	1.9 (2.8)	0.9 (1.9)	1.0 (0.4 to 1.6)	
12 mo	1.8 (2.6)	0.9 (1.8)	0.9 (0.3 to 1.5)	
Secondary Adverse Outcomes				
All-cause hospitalization, No.(%)[d]				
0	99 (83)	99 (83)	0 (−10 to 10)	.94[e]
1	15 (13)	16 (13)	1 (−9 to 8)	
≥2	6 (5)	5 (4)	1 (−5 to 6)	
All-cause ED visit, No.(%)[d]				
0	60 (50)	73 (61)	−11 (−24 to 2)	.18[e]
1	34 (28)	30 (25)	3 (−8 to 15)	
≥2	26 (22)	17 (14)	8 (−2 to 17)	
Number of falls in 12 mo after enrollment, No.(%)[f]				
0	63 (53)	63 (53)	0 (−13 to 13)	.19[e]
1	26 (22)	17 (14)	8 (−2 to 17)	
≥2	29 (25)	39 (33)	−8 (−20 to 3)	
Potential Misuse Measures				
Patients with ≥1 positive urine drug tests for an illicit drug or unexplained prescription drug, No. (%)[g]				
Illicit drug positive	6 (5)	12 (11)	−5 (−12 to 2)	.13[e]
Unexplained prescription drug positive	11 (10)	9 (8)	3 (−5 to 10)	.67[e]
Clinician-assessed behaviors, No.(%)				
Significant PMP finding at any visit[h]	6 (5)	4 (3)	2 (−3 to 7)	.75[i]
Misuse behavior at any visit[j]	11 (9)	8 (7)	3 (−4 to 9)	.47[e]
Patient-reported substance use at 12 mo, No.(%)				
Hazardous alcohol use[k]	2 (2)	4 (4)	−2 (−6 to 3)	.44[i]
Past-year drug use[l]	17 (16)	13 (13)	3 (−6 to 13)	.56[e]

Abbreviations: ED, emergency department; PMP, Prescription Monitoring Program.

[a] Unadjusted time-specific between-group comparison of means or percentages.

[b] Missing data for patients: at 3 mo, 1 in the nonopioid group; at 6 mo, 1 in the opioid group and 1 in the nonopioid group; at 12 mo, 3 in the opioid group and 3 in the nonopioid group (n = 119 in each group).

[c] *P* value for treatment by time interaction.

[d] Hospitalization and ED visit events were counted until 13 mo after randomization for all randomized patients (n = 120 in each group). Events that started in the ED and resulted in hospitalization were counted as hospitalizations and do not contribute to the ED visit count.

[e] *P* value from χ^2 test.

[f] The sum of falls reported at each follow-up interview. Missing data for 1 patient in the opioid group.

[g] Illicit drugs are illegal substances, including cannabis. Unexplained prescription drugs are potentially prescribed substances for which there was no known prescription. Missing data for patients: 4 in the opioid group and 6 in the nonopioid group.

[h] Significant PMP finding is any prescription that was not disclosed and for which there was no clear acute pain-related indication (n = 119 in each group).

[i] *P* value for Fisher exact test.

[j] Misuse behavior was an Addiction Behavior Checklist score of 3 or more at any visit (n = 119 in each group).

[k] Hazardous alcohol use is Alcohol Use Disorders Identification Test score of 8 or more. Missing data for patients: 4 in the opioid group and 6 in the nonopioid group.

[l] Positive result was defined as a patient report of any past-year use of cannabis, cocaine, methamphetamine, inhalants, hallucinogens, street opioids, or prescription medications (opioids, sedatives, or stimulants) for nonmedical purposes. Missing data for 13 opioid patients and 17 nonopioid patients.

opioid group. No deaths, "doctor-shopping," diversion, or opioid use disorder diagnoses were detected.

Intervention Adherence and Retention

Number and duration of study visits were similar in the 2 groups (**Table 4**). Twenty-three patients (19%) in the opioid group and 10 patients (8%) in the nonopioid group discontinued study medication (eTable 6 in Supplement 2). Most patients in the opioid group received low or moderate dosage therapy (eTables 7-8 in Supplement 2). In each 90-day follow-up period, fewer than 15% of patients in the opioid group had a mean dispensed dosage of 50 ME mg/d or more. In the

Table 4. Medications and Visits Over 12 Months From the Electronic Health Records of Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain Randomized to Opioid vs Nonopioid Medication

	Opioid Group (n = 119)		Nonopioid Group (n = 119)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Study drugs, No.[a]	1.7 (0.8)	2.0 (1.0-2.0)	3.8 (1.7)	4.0 (3.0-5.0)
Study prescribed analgesic, months, No.[b]				
Acetaminophen	0.1 (0.5)	0.0 (0.0-0.0)	2.6 (3.2)	1.0 (0.0-4.0)
Oral NSAID	0.4 (2.0)	0.0 (0.0-0.0)	5.9 (4.9)	5.0 (0.5-10.0)
Analgesic adjunct	0.2 (1.4)	0.0 (0.0-0.0)	3.3 (4.3)	1.0 (0.0-6.2)
Topical	0.0 (0.6)	0.0 (0.0-0.0)	3.5 (3.5)	3.0 (1.0-6.0)
Tramadol	0.1 (0.6)	0.0 (0.0-0.0)	0.4 (1.3)	0.0 (0.0-0.0)
Opioid[c]	8.1 (4.1)	8.4 (5.6-11.2)	0.0 (0.0)	0.0 (0.0-0.0)
Study visits, No.				
In-person visits	2.8 (2.0)	2.0 (2.0-3.0)	2.8 (2.2)	2.0 (2.0-3.0)
Telephone visits	6.2 (2.9)	7.0 (5.0-8.0)	6.2 (2.5)	7.0 (5.0-8.0)
Total study visit duration, min[d]	231 (95)	230 (159-289)	217 (82)	197 (155-267)
Nonstudy outpatient visits, No.[e]				
Primary care	6.8 (6.5)	5.0 (2.0-8.0)	7.1 (7.1)	4.0 (2.0-9.0)
Specialty	6.7 (12.0)	3.0 (1.0-8.0)	6.3 (6.4)	4.0 (1.0-9.0)
Mental health	4.8 (10.3)	0.0 (0.0-6.0)	7.5 (22.1)	0.0 (0.0-5.0)
Rehabilitation	4.5 (15.8)	1.0 (0.0-3.0)	3.1 (6.1)	1.0 (0.0-4.0)

Abbreviations: IQR, interquartile range; NSAIDs, nonsteroidal anti-inflammatory drugs.

[a] Number of unique study-prescribed medication formulations during the intervention, regardless of duration of use.

[b] Analgesic months is the sum of the number of months of medication dispensed from Veterans Affairs outpatient pharmacies for each discrete medication within a category during the 12-mo intervention period. For example, a patient dispensed analgesic A for 6 mo and analgesic B for 12 mo would have 18 analgesic months. Crossover (ie, nonopioid medications in the opioid group and vice versa) is accounted for by patients who desired discontinuation of all medications in their assigned study group. Study clinicians restarted preenrollment medications if requested by these patients, but did not manage or adjust these off-protocol medications.

[c] Opioid months do not include tramadol.

[d] The sum of minutes extracted from clinician-entered *Current Procedural Terminology* codes for all study encounters.

[e] Outpatient visits include both in-person and telephone encounters with any type of clinician, including physicians, mental health providers, physical therapists, and nurses. Encounters for diagnostic testing (eg, radiology examinations, endoscopy) and nonmedical ancillary services (eg, social work, nutrition, education) are not included.

nonopioid group, tramadol was dispensed to 4 patients (3%), 6 patients (5%), 8 patients (7%), and 13 patients (11%) in the first, second, third, and fourth 90-day follow-up windows, respectively. eTables 9 to 10 in Supplement 2 show nonstudy pain treatments.

Subgroup and Sensitivity Analyses

Post hoc tests for interaction of primary pain diagnosis (ie, back pain, osteoarthritis pain) by treatment group on pain outcomes were not statistically significant (P = .25 for BPI interference, P = .34 for BPI severity). For the back pain subgroup at 12 months, BPI interference was 2.9 in the opioid group (SD, 2.1) vs 3.3 in the nonopioid group (SD, 2.6); difference, −0.4 (95% CI, −1.2 to 0.3); BPI severity was 3.7 in the opioid group (SD, 1.8) vs 3.6 in the nonopioid group (SD, 2.0); difference, 0.1 (95% CI, −0.5 to 0.8). For the hip or knee osteoarthritis pain subgroup at 12 months, BPI interference was 4.4 in the opioid group (SD, 2.8) vs 3.4 in the nonopioid group (SD, 2.6); difference, 1.1 (95% CI, −0.1 to 2.3); BPI severity was 4.5 in the opioid group (SD, 2.2) vs 3.4 in the nonopioid group (SD, 1.8); difference, 1.1 (95% CI, 0.2 to 2.0).

In a post hoc sensitivity analysis, adjusting for baseline smoking status, results did not substantially change (BPI interference adjusted overall, P = .65; BPI severity adjusted overall, P = .05; medication-related adverse symptoms adjusted overall, P = .03).

Discussion

Among patients with chronic back pain or hip or knee osteoarthritis pain, treatment with opioids compared with nonopioid medications did not result in significantly better pain-related function over 12 months. Nonopioid treatment was associated with significantly better pain intensity, but the clinical importance of this finding is unclear; the magnitude was small (0.5 points on the 0-10 BPI severity scale) and was less than the MCID of 1.0. Opioids caused significantly more medication-related adverse symptoms than nonopioid medications. Overall, opioids did not demonstrate any advantage over nonopioid medications that could potentially outweigh their greater risk of harms.

Among the secondary outcomes, only anxiety symptoms were statistically better in the opioid group. This finding is consistent with the role of the endogenous opioid system in stress and emotional suffering.[31] The importance of this finding is uncertain because the magnitude of the difference in anxiety was small and the overall level of anxiety

was low (9% of patients had moderate severity anxiety symptoms at baseline).

Recent systematic reviews have concluded that opioids have small beneficial effects on pain compared with placebo that may be outweighed by common adverse effects.[5,32-34] Observational studies have found that treatment with long-term opioid therapy is associated with poor pain outcomes, greater functional impairment, and lower return to work rates.[35-37] In this trial, pain-related function improved for most patients in each group. Poor pain outcomes associated with long-term opioids in observational studies may be attributable to overprescribing and insufficient pain management resources rather than to direct negative effects of opioids.[31,38] This trial did not have sufficient statistical power to estimate rates of death, opioid use disorder, or other serious harms associated with prescribed opioids.[39-41]

This trial's pragmatic design has several advantages. First, enrolled patients had characteristics similar to those of patients receiving opioids in VA primary care, including patients with depression and posttraumatic stress disorder.[6] Second, flexibility of treatment within assigned groups facilitated high study retention. Third, the treat-to-target approach reflects clinical practice more closely than approaches comparing single drugs or fixed dosages and allowed maximized benefit for patients.[9,10] Because individual medications are effective for only a minority of patients with chronic pain,[33,42] structured reassessment and adjustment of medications is likely necessary for effective pharmacological treatment.

Few data are available regarding optimal opioid dosing for pain, function, and tolerability. A meta-analysis of chronic back pain trials found incremental benefits of larger opioid dosages, but concluded benefits were too small "to be clinically important even at high doses."[32] Another meta-analysis of opioid trials for musculoskeletal pain in older adults found no association of dosage with pain or function.[34] Recent opioid prescribing guidelines recommend keeping daily dosages low.[2-4] This study was designed to identify the medication regimen with the best balance of benefits and tolerability for each patient and allowed treatment with a range of low to moderately high opioid dosages.

By pragmatic design, this trial did not require high levels of adherence to study medications. This study had high active treatment continuation and study retention rates, so results reflect outcomes across a range of treatment adherence.

Limitations

This study has several limitations. First, the complexity of interventions precluded masking of patients. Because primary outcomes were patient-reported, results are subject to potential reporting bias that would likely favor opioids. Second, there was an imbalance in prerandomization treatment preference. Any effect of this imbalance would likely favor opioids. Third, because this study was conducted in VA clinics, patient characteristics differ from those of the general population, most notably in sex distribution. Fourth, patients with physiological opioid dependence due to ongoing opioid use were excluded, so results do not apply to this population.

Conclusions

Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.

ARTICLE INFORMATION

Accepted for Publication: February 2, 2018.

Author Contributions: Dr Krebs had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Krebs, Kroenke, Bair.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Krebs, Jensen, DeRonne, Bair.
Critical revision of the manuscript for important intellectual content: Gravely, Nugent, DeRonne, Goldsmith, Kroenke, Bair, Noorbaloochi.
Statistical analysis: Gravely, Noorbaloochi.
Obtained funding: Krebs, Kroenke, Bair.
Administrative, technical, or material support: Nugent, Jensen, DeRonne, Goldsmith.
Supervision: Krebs, Kroenke.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Ms Jensen reported that her spouse is employed as a research chemist by Upsher-Smith Laboratories. No other disclosures are reported

Funding/Support: This trial was funded by the Merit Review Award (I01-HX-000671) from the US Department of Veterans Affairs Health Services Research and Development Service.

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The views expressed in this article are those of the authors and do not represent the views of the VA or the US government.

Additional Contributions: We thank the veterans who participated in the trial; our Minneapolis VA Health Care System primary care colleagues; members of the data and statistics monitoring board and institutional review board. We also thank the members of the research team, including Indulis Rutks, BS, David Leverty, BS, Ruth Balk, BA, Erin Linden, MPH, and Andrea Cutting, MA (all from Minneapolis VA Health Care System). They received compensation for their contribution. We also thank Melvin Donaldson, MS (University of Minnesota), for help with recruitment; Preetanjali Thakur, BDS (University of Minnesota), for reviewing adverse events; Elzie Jones, PharmD, Melissa Bell, PharmD, Howard Fink, MD, MPH, and Steven Fu, MD, MSCE (all from Minneapolis VA Health Care System), for providing clinical coverage; and Doug DeCarolis, PharmD (Minneapolis VA Health Care System), for dispensing research medication. They did not receive compensation for their contribution.

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COMMENTARY

Rethinking "doing well" on chronic opioid therapy

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■ Cite as: *CMAJ* 2017 October 2;189:E1222-3. doi: 10.1503/cmaj.170628

CMAJ Podcasts: author interview at https://soundcloud.com/cmajpodcasts/170628-com

The relief of suffering is the fundamental objective of medical practice. To this end, we often turn to medications, particularly when treating pain, one of the commonest forms of suffering we see. This is understandable. Patients want relief, doctors want to oblige, and it is intuitive that a medication with a known mechanism of action might help.

Unfortunately, the drugs in our pain toolbox are few in number, of limited effectiveness and encumbered by serious risks, particularly for chronic pain which, despite afflicting hundreds of millions worldwide, suffers from a remarkable dearth of evidence-based medications.[1] The treatment of chronic pain is largely based on anecdote, with success or failure determined only after a potentially risky experiment on the individual patient. In the context of a North American crisis that has sparked debate about the role of opioids in medical practice, it is worth reflecting on what, exactly, we are trying to accomplish when we prescribe these drugs for years at a time.

This reflection should begin by acknowledging that the goal of pain medication is not simply pain relief. Like any therapy, the goal is to confer more benefit than harm. With opioids, and at high doses in particular, we meet this objective far less often than we or our patients think. This claim is sometimes met with derision or even hostility — to question the use of opioids for chronic pain is to draw the ire of patients and, sometimes, the displeasure of colleagues.[2] Yet the claim warrants examination, if for no other reason than to understand why the practice has come to be questioned.

Consider the now-familiar narrative sometimes offered by patients with chronic pain: "Opioids don't just reduce my pain, they allow me to function. Nothing else works for me. Without them, I wouldn't even be able to get out of bed. I don't take extra doses or go to multiple doctors, and I certainly don't crush and inject my medication. I'm not an addict; I'm a legitimate pain patient." Anecdotes like this, delivered honestly and with conviction, can be powerful, particularly to those of us who have written the prescriptions.

A widely held view is that absent signs of addiction, patients who seem to be "doing well" on chronic opioid therapy are doing just that, and therapy should continue regardless of dose. This perspective reverberates on social media, is echoed in the popular press[3] and has figured prominently in criticism of guidelines advocating lower opioid doses.

KEY POINTS

- Opioid analgesia attenuates with time, while the harms persist or accrue as doses increase.
- For some patients, the primary benefit of opioids becomes the avoidance of withdrawal. This constitutes harm, but is easily misconstrued as ongoing effectiveness.
- More cautious opioid prescribing (including fewer new starts, avoidance of high doses and slow, collaborative tapers for those already on high doses) can improve the balance of benefits and harms for patients with chronic pain.

What is wrong with this perspective? In other words, why might some of these patients not be doing as well as they or their doctors perceive? Put simply, because the benefits of opioids have attenuated or even become illusory, while the harms, many of which are occult, persist or even accrue. This can happen right under the nose of a watchful, well-meaning physician, especially as the dose increases.

Opioid analgesia wanes over time because of tolerance, opioid-induced hyperalgesia or both. Crucially, this is accompanied by physical dependence, an adaptive response that develops quickly and is defined by symptoms of opioid withdrawal — including pain and dysphoria — when doses are lowered abruptly. Because withdrawal is extinguished by the simple resumption of opioids, is it any wonder that a patient would construe this as evidence of ongoing effectiveness? No, and it is a recipe for self-perpetuating therapy.

Even when opioids confer meaningful improvements in pain and function, harms abound. Aside from the unmistakable harms of addiction, overdose and death, opioids sometimes cause falls, fractures, constipation, reduced libido, infertility, osteoporosis, sleep-disordered breathing and motor vehicle collisions. Moreover, they are an independent risk factor for depression, and in some patients can paradoxically worsen pain, especially at high doses.[1]

Weighing what we now know, an unpleasant fact emerges: patients receiving chronic opioid therapy can easily be harmed more than helped by medications they perceive to be effective or even essential. It is impossible to know how many patients have been harmed in this way since a pill-centric "War on Pain" launched a massive, uncontrolled experiment on the North American population.[4] It is fair, however, to put this number well into the millions, and to characterize the War on Pain as one of the most spectacular failures of modern medicine.

Despite these concerns, some patients can derive improvements in pain and function that outweigh any adverse effects. However, identifying these individuals at the outset of treatment is impossible, and distinguishing them later in therapy can be difficult if benefit has come to be defined, in whole or in part, by the avoidance of withdrawal.

How should these considerations influence our prescribing? The answer depends on who has been asked, but some principles are incontestable. First, opioids should not be started without a clear plan for stopping them, with criteria for success and failure established ahead of time. Second, patients should be fully informed of the risks, including the possibility that dependence can evolve into something masquerading as benefit. Third, the dose should be minimized, because net benefit becomes less likely at higher doses.[5] Finally, the concomitant use of benzodiazepines, alcohol and other sedating drugs should be avoided to the greatest possible extent. The same is true of excessively rapid dose reductions, as might be implemented by physicians wishing to avoid regulatory scrutiny. The importance of this cannot be overstated. Opioid withdrawal causes inexcusable suffering and can drive patients to illicit sources; in some, it can even precipitate suicidality.[3]

It is clear that our approach to treating chronic pain must change, with a greater emphasis on evidence-based nondrug therapies[6] and multidisciplinary models of care. But we must also confront the fact that our prescribing has fuelled twin crises of addiction and of faulty pain management. This will sometimes necessitate difficult conversations with patients who are actively being harmed by opioids but who hold a strenuously different view.

These discussions should acknowledge the patient's perspective, but must also convey a key message: "As your doctor, it's my job to help you manage your pain, but also to be mindful of how pain medications can harm you, sometimes in ways that are hard to recognize." We must emphasize our shared goals of better pain control, improved function and quality of life. This task will be made easier if we explain that, for patients who taper from high-dose opioids, it is only in hindsight that something once unimaginable sometimes becomes apparent: opioids were not making life better — they were making it worse.

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Competing interests: David Juurlink reports personal fees from medicolegal consultation outside the submitted work and is an unpaid member of Physicians for Responsible Opioid Prescribing (PROP), a US-based organization with the general goal of promoting safer opioid therapy. He also served on the steering committee of the 2017 Canadian Guideline for Opioid Therapy and Chronic Noncancer Pain.

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Acknowledgements: The author thanks Moira Kapral, Irfan Dhalla, Keith Humphreys, Stefan Kertesz and Mark Sullivan for comments on earlier drafts of this manuscript.

This article has been peer reviewed.

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