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Opioid prescribing in general practice: a proposed approach

MILTON L. COHEN MD, FRACP, FFPMANZCA
ALEX D. WODAK AM, MB BS, FRACP, FAChAM

Key points

- The experience of chronic pain has biological, psychological and social contributions, each of which you need to assess.
- Drug therapy for patients with chronic noncancer pain is only part of a multifaceted, if not also multidisciplinary, treatment approach. If drugs are needed to treat patients with chronic noncancer pain, ensure you also pay attention to psychological and social stresses.
- Ensure opioid pharmacotherapy for patients with chronic noncancer pain is always an ongoing trial of therapy.
- Be aware of the regulations regarding opioid prescribing in your jurisdiction and of the 'rules' regarding PBS-subsidised opioids.
- Document any opioid trial carefully and if it is not working start tapering the dose to zero. If you are not sure what to do, ask for advice from a colleague experienced in chronic pain, a pain specialist, an addiction medicine specialist or a psychiatrist.

GPs can facilitate opioid prescribing in their practices by following the five principles of opioid prescribing, utilising the five tools for assessment of use and using the five criteria for evaluating outcomes of an opioid trial.

This is a sequel to a previous article (*Medicine Today* 2010; 11(2): 10-18) in which we discussed the shared predicament of the patient with chronic noncancer pain and the primary care physician, both grappling with management of this complex problem.[1] We acknowledged that applying the desired biopsychosocial framework for assessment requires skill and time, the latter being at a premium in general practice. It was not at all surprising, therefore, that in practice the management of such patients generally defaults to the use of analgesic drugs, frequently opioids. Accordingly, we presented a set of principles that could be applied for the more judicious use of opioids in this context.

In this current article we propose to translate the principles previously described into a practical approach to opioid prescribing for patients with chronic noncancer pain. It reflects consensus views and practices. The framework for this approach comprises the five principles previously presented, five tools that may assist assessment and five criteria for evaluating the outcome of the ongoing trial of opioid pharmacotherapy in patients with chronic pain (see the box on page 25).

STEP 1. COMPREHENSIVE ('BIOPSYCHOSOCIAL') ASSESSMENT

The experience of chronic pain has biological, psychological and social contributions, each of which needs to be assessed.

'Bio-' (what's happening to the body)

Try to identify an underlying treatable condition, if suspected, on the basis of clinical 'red-flag' features (e.g. inflammation, infection, neural pathology, neoplasm). However, most chronic pain is not due to a 'broken part' but is more likely to reflect altered function (in particular altered central nociceptive processing). This is especially so for pain experienced in musculoskeletal tissues. Finding the correct

Associate Professor Cohen is a Specialist Pain Medicine Physician, St Vincent's Campus, Sydney.
Dr Wodak is Director of the Alcohol and Drug Service, St Vincent's Hospital, Sydney, NSW.

FRAMEWORK FOR A PRACTICAL APPROACH TO OPIOID PRESCRIBING IN CHRONIC NONCANCER PAIN

5 principles

- Comprehensive assessment
- Poor response to other therapies
- Agreement regarding opioid trial
- Conduct of opioid trial
- Responses to difficulty achieving or maintaining goals in an opioid trial

5 tools

- Brief Pain Inventory
- Opioid risk tool (or other instrument)
- Contact numbers for advice regarding prescribing regulations in the different Australian jurisdictions
- Opioid contract
- Chart of opioid 'equianalgesic' doses

5 criteria

- Analgesia
- Activity
- Adverse effects
- Affect
- Aberrant behaviours

PROBLEMATIC OR ABERRANT DRUG-TAKING BEHAVIOURS

- Overwhelming focus on opioid issues, impeding progress with other issues
- Resistance to change in therapy despite evidence of adverse drug effects
- Aggressive complaining about the need for more drugs
- Noncompliance with use instructions, including nonsanctioned dosage escalation
- Pattern of prescription problems (i.e. lost, spilled or stolen medications)
- Supplemental opioids (from other providers, emergency departments or illicit sources)
- Stealing or 'borrowing' drugs
- Selling prescription drugs
- Prescription forgery
- Evidence of deterioration in function including family, work and social life
- Concurrent abuse of alcohol or other illicit drugs
- Injecting oral formulations

diagnostic language to use is difficult here. For example, 'lumbar spondylosis' is a statement of age-related anatomical fact and does not imply either the presence or mechanism of pain.

'-psycho-' (what's happening to the person)

Assess the impact of pain on the patient's daily activities (work and recreation) and sleep. Explore the role of fatigue in the patient's condition. Chronic pain is often associated with changes in mood, especially depression and anxiety, and with loss of self-esteem. Much pain-related behaviour stems from patients' beliefs regarding diagnosis and prognosis that are frequently catastrophic and incorrect. Much distress can be alleviated by careful, accurate and realistic explanations, often about what is not wrong.

'-social' (what's happening in the person's world)

Assess not only the effects of pain on relationships – family, friends, work and leisure – but also the influence of other life events, ranging from changes within families to environmental disasters.

A useful tool to aid this assessment is the Brief Pain Inventory (see Toolbox 1). It allows patients to rate their pain on a scale of 0 to 10, where 0 is no pain and 10 is the worst pain possible.

An important part of this step is to assess the risk of problematic opioid use, by asking the following questions:

- Is there a personal or family history of past or current alcohol or drug problems?
- Is an active or recent psychiatric disorder present?
- Is there evidence of problematic drug-taking behaviours? (See the box on this page.)

'Positive' responses here do not necessarily preclude a trial of opioid therapy but rather act as an alert to guide monitoring of a trial. A useful tool is the opioid risk tool (see Toolbox 2).[2]

STEP 2. ADEQUATE TRIAL OF OTHER REASONABLE THERAPIES

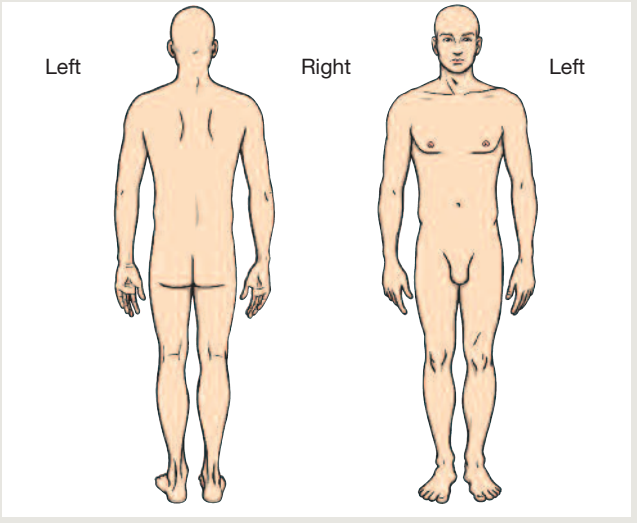
Drug therapy – for symptom control – is an adjunct to a comprehensive care plan. Often

TOOLBOX 1. BRIEF PAIN INVENTORY*

Name: _____
Date: _____
Time: _____

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains and toothaches). Have you had pain other than these everyday kinds of pain today?
1. Yes **2. No**

2. On the diagram, shade in the area where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on average.

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

* Reproduced with permission from Dr Charles S. Cleeland (1991).

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

_____

8. In the past 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No relief										Complete relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

TOOLBOX 2. OPIOID RISK TOOL*[2]

Risk factor	Male (score)	Female (score)
Family history (parents and siblings)		
• Alcohol abuse	❑ (3)	❑ (1)
• Illegal drug use	❑ (3)	❑ (2)
• Prescription drug abuse	❑ (4)	❑ (4)
Personal history		
• Alcohol abuse	❑ (3)	❑ (3)
• Illegal drug use	❑ (4)	❑ (4)
• Prescription drug abuse	❑ (5)	❑ (5)
Mental health		
• Diagnosis of ADD, OCD, bipolar disorder or schizophrenia	❑ (2)	❑ (2)
• Diagnosis of depression	❑ (1)	❑ (1)
Other		
• Age 16 to 45 years	❑ (1)	❑ (1)
• History of preadolescent sexual abuse	❑ (0)	❑ (3)
Total score	____	____

Total score risk category:

0 to 3 = Low risk: 6% chance of developing problematic behaviours.

4 to 7 = Moderate risk: 28% chance of developing problematic behaviours.

≥ 8 = High risk: more than 90% chance of developing problematic behaviours.

ABBREVIATIONS: ADD = attention deficit disorder; OCD = obsessive compulsive disorder.
*Adapted with permission from Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the opioid risk tool. Pain Med 2005; 6: 432-442.

that plan will need to include the help of other health professionals.

Nondrug treatment options include an accurate explanation, especially realistic prognostication (there is often no 'cure' for chronic pain) and advice regarding nutrition, exercise, sleep hygiene and the pursuit of pleasurable activities. Emphasise the need for daily activity, not rest, and the important role of pacing to limit fatigue. Consider referral of the patient to appropriate healthcare personnel, if available, for more intensive exploration of these options.

As symptom control is important, consider the role of nonopioid analgesic medications, especially paracetamol. So-called adjuvant analgesics include tricyclic antidepressants, such as amitriptyline and nortriptyline (both used off label), serotonin noradrenaline reuptake inhibitors, such as duloxetine and venlafaxine (both used off label), and anticonvulsants, such as gabapentin and pregabalin (both indicated for the treatment of neuropathic pain). These analgesics may have a role but may be limited by cognitive side effects, drowsiness or, in some cases, high cost.

In this context, invasive therapies, ranging from injections to implants, may not be considered 'reasonable', especially when there is no local 'broken part' to be fixed. Opioid use should be considered before invasive options.

STEP 3. AGREEMENT REGARDING OPIOID TRIAL

Opioid pharmacotherapy for patients with chronic pain is an ongoing trial, repeatedly addressing the question, 'Is this patient's predicament opioid-responsive?'

Such a trial is always a part of a multimodal treatment plan. Given that opioids are restricted and tightly controlled drugs, a 'contract' between prescriber and patient should be explicit, with ongoing prescription depending on the evidence of worthwhile ongoing benefit and minimal harm. The agreement extends to:

- identifying realistic activity goals, tailored to the individual patient, that emphasise improved function, not just less discomfort
- one prescriber (and deputy) and a single pharmacy dispensing according to risk assessment and no early repeat prescriptions or loss replacements
- setting review intervals, perhaps weekly for initial trial and up to third-monthly for stable patients
- tapering termination of the opioid trial if treatment goals (including review appointments) are not met, there are serious adverse outcomes or there is evidence of misuse, especially unsanctioned use such as self-injection, stock-piling, selling or giving drugs to others
- including an option for random drug monitoring, such as by urine drug screen or pill counts.

Prescribers should be familiar with the regulatory requirements in the state or territory jurisdiction of their practice (see Toolbox 3 for contact numbers for Pharmaceutical Services Branches in each jurisdiction in Australia). Some jurisdictions may require an opioid contract to be signed by the patient and medical practitioner (see Toolbox 4). All prescribers should note the importance of attention to documentation, regulation and adherence to advice from the Pharmaceutical Services Branch in their jurisdiction of practice.

STEP 4. CONDUCT OF AN OPIOID TRIAL

A trial of opioid analgesic therapy requires goal-setting, explicit agreements, skilled titration of dose and regular monitoring of the 5A criteria.

The pharmacological principle of an opioid trial is to use long-acting (long half-life) oral or transdermal opioid

preparations, dosing according to age (see Table). The starting dose should be low if the patient is opioid naïve, of the order of 10 mg/day oral morphine equivalent. If the patient is already taking an immediate-release opioid (e.g. codeine, morphine or oxycodone) or tramadol, calculate the daily dose and use the equianalgesic chart (see Toolbox 5) to convert it to an approximate daily equivalent of a long-acting oral or transdermal preparation.

Regularly reassess the patient and document details, according to the 5A criteria, which are:

- analgesia
- activity
- adverse effects
- affect
- aberrant behaviour.

Whether initiating or continuing therapy, review weekly initially, then according to achievement of goals. Titration of dose according to the 5A assessment over four to six weeks should allow the fundamental question, 'Is this person's predicament opioid-responsive?', to be answered. A decision can then be made to continue maintenance therapy, subject to ongoing satisfactory assessments of the 5As, test the effects of dose reduction or taper to withdrawal.

The main focus of the opioid trial should be on improved function – physical, cognitive and social. How active does the patient want to be? Is the patient able to achieve this level of activity? Is that level of activity appropriate under the circumstances? Given the variable course of chronic pain, it may well be that over time opioid requirements fluctuate, not necessarily upward.

Try to tailor the drug regimen to individual patient needs, such as only taking the drug at night to ameliorate sleep, or asymmetrically varying the dose during the day according to required or anticipated activity levels. Limit the dose to a maximum of 100 mg/day oral morphine equivalent (see Toolbox 5). It is suggested that an apparent opioid requirement approaching this should trigger a comprehensive reassessment of the patient. If tapering of opioid therapy is required, the suggested rate is by 10% per day at weekly intervals.

If in doubt about any aspect of the opioid trial, enlist the opinion of a colleague or a specialist pain or addiction medicine physician. For regulatory purposes, this should be done at least annually in any case.

TOOLBOX 3. CONTACT NUMBERS FOR ADVICE REGARDING OPIOID PRESCRIBING REGULATIONS IN AUSTRALIAN JURISDICTIONS

Jurisdiction	Agency	Telephone	Fax
ACT	Pharmaceutical Services, ACT Health	02 6205 0998	02 6205 0997
NSW	Pharmaceutical Services Branch, NSW Ministry of Health	02 9879 5239	02 9859 5175
NT	Poisons Control, Department of Health and Community Services	08 8922 7341	08 8922 7200
QLD	Drugs of Dependence Unit, Queensland Health	07 3328 9890	07 3328 9821
SA	Drugs of Dependence Unit, Pharmaceutical Services, SA Health	08 8274 3434	08 8274 3433
TAS	Pharmaceutical Services Branch, Department of Health and Human Services	03 6233 2064	03 6233 3904
VIC	Drugs and Poisons Regulation, Department of Health	1300 364 545	1300 360 830
WA	Pharmaceutical Services, Department of Health	08 9222 4424	08 9222 2463

STEP 5. RESPONSE TO DIFFICULTY ACHIEVING OR MAINTAINING GOALS IN AN OPIOID TRIAL, INCLUDING DEMANDS FOR AN INCREASE IN DOSE

Difficulty achieving or maintaining the goals of an opioid trial should trigger comprehensive reassessment of the patient (steps 1 to 4), which may then require referral.

The two main problems that may be encountered in an opioid trial are:

- a claim that there has been no change in pain despite evidence of increased function
- evidence of unsanctioned use of the drug.

However, the same principles apply, starting with repeat assessment, especially at the '-psycho-' and '-social' levels of the framework. In patients with established chronic pain, it is unlikely that there will be a change in the underlying disease state, although alertness to clinical features suggesting such change is important. It is more likely that difficulty in achieving the goals reflects a change in the patients' psychosocial situation or a response to other life stressors.

In this situation, a new 'contract' can be negotiated, perhaps with revised goals and review plans, provided that the fundamental question, 'Is this person's predicament opioid-responsive?', has a positive answer. If there is evidence of increased function, it is probable that the trial is positive but the patient needs to

TOOLBOX 4. EXAMPLE OF A TREATMENT CONTRACT FOR THE USE OF OPIOIDS FOR THE MANAGEMENT OF CHRONIC PAIN*

Patient name: _____
Address: _____
Date of birth: _____

I, [Add name here], understand that opioid painkillers are being prescribed to me in an attempt to improve my level of functioning and reduce my pain intensity. My medical practitioner and I agree to the following conditions regarding my treatment and the prescribing of opioid medications for my pain. We have discussed that strong opioid (morphine-like) painkillers may be only partially helpful in achieving this goal and on occasion will not help at all. I understand that painkillers are only one part of the management of my chronic pain.

1. My medical practitioner is responsible for prescribing a safe and effective dose of opioids. I will not use opioids other than at the dose prescribed and I will discuss any changes in my dose with my medical practitioner.
2. I am responsible for the security of my opioid medicine. Lost, misplaced or stolen prescriptions or medicine will not be replaced.
3. I will only obtain opioid medications from the medical practitioner who signs this contract, or other doctors in the same practice authorised to prescribe to me. I understand that no early prescriptions will be provided.
4. Whilst most people do not have any serious problems with this type of medicine when used as directed, there can be side effects. My medical practitioner will let me know what these are and I will tell him or her if I experience them.
5. I am aware that my medical practitioner is required to gain authorisation from the Department of Health for continued prescription of these medications.
6. I agree to tell my medical practitioner if I have ever been dependant on alcohol or drugs, or if I have ever been involved in illegal activity related to any drugs including prescription medicines. I am aware that providing my medicine to other people is illegal and could be dangerous to them.
7. My medical practitioner respects my right to participate in decisions about my pain management and will explain the risks, benefits and side effects of any treatment.
8. My medical practitioner and I will work together to improve my level of functioning and reduce my pain.
9. I understand that my medical practitioner may stop prescribing opioids or change the treatment plan if my level of activity has not improved or I do not show a significant reduction in pain intensity, or if I fail to comply with any of the conditions listed above.

Patient signature: _____
Name: _____
Date: _____
Medical practitioner: _____
Provider number: _____
Date: _____

* Adapted from the Drug and Alcohol Office/Pharmaceutical Services Branch, WA Department of Health.

observe better 'pacing' of activity. If relative under-dosage is suspected, a trial of increased dose can be considered, again to be evaluated using the 5A criteria. If adverse effects of the opioid are a problem but the trial is otherwise positive, opioid rotation could be considered (see Toolbox 5). However, if there is evidence of unsanctioned opioid use (see the box on page 25), taper the opioid to withdrawal and refer the patient to a specialist pain or addiction medicine physician.

WHAT ABOUT THE 'INHERITED' PATIENT?

The 'inherited' patient, especially one taking more than 100 mg/day oral morphine equivalent, is a common situation. The same principles apply as for patients undergoing an opioid trial, namely:

- perform a biopsychosocial reassessment (over time)
- establish new contract with set goals
- carry out regular 5A criteria assessment
- refer patient if in doubt.

When conducting an opioid trial in these patients:

- convert all current opioids that the patient is taking to only one form of nonparenteral opioid (but not transdermal fentanyl because rapid tolerance appears to be a problem and dose titration is difficult) in stages. For example, 80% current opioids and 20% new opioid for a week, then 60% current opioids and 40% new opioid for a similar period, then 40% current opioids and 60% new opioid, etc to full conversion
- the patient may find that the current preferred opioid has high 'likeability'. In that case, conversion may take several months. Be prepared to slightly increase the dose of the new main opioid
- seek to establish the lowest dose of the one opioid species that facilitates the patient maintaining activity, reasonable comfort and minimal side effects. Each decrement could be

TABLE. SUSTAINED-RELEASE OR LONG-ACTING OPIOID PREPARATIONS FOR USE IN PATIENTS WITH CHRONIC NONCANCER PAIN

Generic name	Seek advice if dose exceeds
Oral opioid agonists	
Hydromorphone	16 mg daily
Methadone	30 mg daily
Morphine	100 mg daily
Oxycodone	60 mg daily
Oral opioid-like activity	
Tramadol	400 mg daily
Transdermal opioids	
Buprenorphine	40 µg/hr weekly
Fentanyl	25 µg/hr every three days

10% of the current daily dose. It may not matter if the opioid cannot be withdrawn completely provided that the patient is able to be as active as he or she wishes to be

- involve the patient in decision making about the transition unless it becomes clear that the patient is sabotaging the transition. In that case, the patient should be referred to a specialist.

TOOLBOX 5. APPROXIMATE OPIOID DOSES EQUIANALGESIC TO ORAL MORPHINE 30 MG

Oral
- Tramadol 150 mg
- Codeine 180 mg
- Dextropropoxyphene 130 mg
- Methadone 10 mg*
- Oxycodone 20 mg
- Hydromorphone 4 mg

Sublingual
- Buprenorphine 0.4 mg

Parenteral
- Tramadol 100 mg
- Morphine 10 mg
- Hydromorphone 1.5 mg

Transdermal
- Buprenorphine 20 µg/hr
- Fentanyl about 12 µg/hr

* Morphine:methadone 3:1 for morphine less than 100 mg/day only.

PAIN MANAGEMENT IN THE OPIOID- DEPENDENT ('ADDICTED') PATIENT

Many people on opioid-substitution treatment programs (with methadone or buprenorphine) have concurrent chronic pain. This is likely to be as 'incurable' as in other patients and only partly responsive to opioid treatment.

The request for an increased opioid dose to reduce the severity of pain can be considered on a trial basis but any change to a 'preferred' drug should be resisted. If possible try to manage chronic pain in patients on opioid-substitution treatment by increasing the dose of methadone or buprenorphine rather than by introducing another opioid. Otherwise consider referring the patient for specialist advice. An exception might be presentation with an episode of acute nociception, such as bony trauma, in which case a temporary increase in dosage of the current opioid could be considered.

CONCLUSION

The cornerstones of quality use of opioids in the management of patients with chronic noncancer pain are:

- comprehensive biopsychosocial assessment
- ongoing trial of opioid responsiveness using long-acting oral or transdermal preparations
- regular 5A re-evaluation
- careful documentation of goals, decisions and advice received. MT

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FURTHER READING

A list of further reading is available on request to the editorial office.

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MILTON L. COHEN MD, FRACP, FFPMANZCA **ALEX D. WODAK** AM, MB BS, FRACP, FAChAM

FURTHER READING

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