PrescQIPP Community Interest Company

Chronic pain

Chronic pain (also known as persistent or long-term pain) is complex with challenges for assessment and long term management. There has been a marked and progressive rise in prescribing of opioid medicines in the UK over the past decade and the trend of increased prescribing continues despite safety concerns.

The National Institute for Health and Care Excellence (NICE) guidance on chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain [NG193] does not recommend the prescribing of analgesia for chronic primary pain.[1]

This project reviews pain pathways and facilitates appropriate primary care management in all people aged 16 years and over living with chronic pain. This document does not cover the specific management of pain associated with cancer or neuropathic pain. For further information on neuropathic pain refer to PrescQIPP Bulletin 216: Neuropathic pain. https://www.prescqipp.info/our-resources/bulletins/bulletin-216-neuropathic-pain/

Recommendations

- Assess for the presence of acute or chronic (persistent pain or long-term) pain.
- Differentiate where possible, between chronic primary pain, chronic secondary pain, and mixed chronic primary and secondary pain. Follow the relevant pain treatment pathway for the type of chronic pain. Recognise that this may change over time and that chronic primary pain can co-exist with secondary pain.
- Adopt self-management strategies and non-pharmacological approaches for chronic pain. These non-pharmacological approaches include physical exercise, psychological wellbeing (acceptance and commitment therapy (ACT) or cognitive behavioural therapy (CBT)), manual manipulation and acupuncture. Strategies to improve these approaches should be used e.g. supervised group exercise and on-line CBT. Be aware of how to access or commission local psychological services.
- For chronic primary pain review prescribing to ensure it is in line with NICE recommendations.
- For chronic secondary pain, follow the relevant NICE guidance on the condition.
- If pharmacological treatment is needed for chronic pain, use only as part of a wider management plan aimed at improving physical function, reducing disability and improving quality of life (QoL).
- Agree individualised treatment goals with each person. Treatment success is demonstrated by pain relief and progress towards treatment goals. Make clear to people that if a trial is unsuccessful, then treatment will be stopped.
- If an unlicensed treatment is prescribed, ensure people understand where treatments are unlicensed and that informed consent is given.
- Where prescribing is not in line with NICE guidance, review medication and consider tapering or stopping in consultation with the person. Consider whether referral to specialist services is needed to support withdrawal.

Recommendations

Opioids

- When considering initiating opioids take into account best practice in prescribing opioids as advised in the Opioids Aware resources.
- Review people on opioids who are at high risk of opioid side effects, with frailty or on high dose opioids. High dose opioids are defined as:
  - ≥120mg/day morphine equivalent
  - In Scotland, opioid doses of >50mg/day morphine equivalent (for people on doses >90mg/day morphine equivalent pain specialist advice or review should be sought.)
- For people at high risk or on high dose opioids, review with a view to reducing the dose or stopping in consultation with the individual.
- As there is little evidence that one opioid is more effective and associated with fewer side effects than another, the least costly products should be considered first line choices in local medicines formularies.
- Comparing doses and switching between opioids should be done with caution as there is limited evidence for the accuracy of dose equivalents.
- If opioids are started in secondary care, the GP should be informed of the indication, expected treatment length, and tapering and stopping regime. If use is considered to be medium or long term then there should be an agreement between the hospital and the patient's GP regarding where, and by whom, the person will be reviewed and who should provide the repeat prescriptions.

Background

Pain is defined by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage".[2]

The NICE guideline on chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain [NG193] defines chronic pain (sometimes known as long-term pain or persistent pain) as pain that lasts for more than 3 months. Pain can be secondary to (caused by) an underlying condition. Chronic pain can also be primary. Chronic primary pain has no clear underlying condition or the pain or its impact is out of proportion to any observable injury or disease.[1]

Further NICE guidance on the management and withdrawal of drugs associated with dependence and withdrawal is due for publication on 20 April 2022.[3]

Chronic Pain

For chronic secondary pain management, the relevant NICE guidance for these conditions should be followed, for example, osteoarthritis, rheumatoid arthritis, endometriosis, headaches, irritable bowel syndrome, low back pain and sciatica, neuropathic pain, spondyloarthritis.

IASP, the British Pain Society (BPS) and Scottish Intercollegiate Guidelines Network (SIGN) define chronic pain as persistent pain beyond the time that tissue healing would normally be expected, taken as beyond three months.[2,4,5]

Chronic pain is a complex phenomenon with consequent challenges for assessment and management both in clinical trials and routine clinical practice. This is further complicated by the fact that even in the same condition there may be quite different pain mechanisms among people; either peripheral or central pain might predominate.[5]

The World Health Organisation (WHO) 11th revision of the International Classification of Diseases (ICD) diagnostic classification will include for the first time a systematic classification of clinical conditions associated with chronic pain. The new ICD-11 classification will come into effect on 1 January 2022.[2]

Chronic Primary Pain

Chronic primary pain has no clear underlying condition or the pain (or its impact) appears to be out of proportion to any observable injury or disease. The decisions about the search for any injury or disease that may be causing the pain, and about whether the pain or its impact are out of proportion to any identified injury or disease, are matters for clinical judgement in discussion with the patient. The mechanisms underlying chronic primary pain are only partially understood and the definitions are fairly new. All forms of pain can cause distress and disability, but these features are particularly prominent in presentations of chronic primary pain. The NICE guideline NG193 is consistent with the ICD-11 definition of chronic primary pain.[1]

ICD-11 gives examples of chronic primary pain clinical conditions, including fibromyalgia (chronic widespread pain), complex regional pain syndrome, chronic primary headache and orofacial pain, chronic primary visceral pain and chronic primary musculoskeletal pain. These specific conditions were used as search terms for the evidence underpinning the recommendations in NG193, along with more general terms that describe studies in chronic pain populations.[1]

Prevalence of chronic pain

In 2016, £537 million was spent on prescribing analgesia, with at least an additional 50% cost incurred from prescribing other medications including antidepressants and antiepileptics.[6] A meta-analysis of population studies estimated that chronic pain affects between one third and one half of the UK population, and that between 10.4% and 14.3% of the population of the UK report disabling chronic pain that is moderate or severe. The National Pain Audit estimated that 11% of adults and 8% of children in the UK suffer from severe pain. Prevalence figures vary however depending on the criteria and definitions used.[7] The prevalence of chronic primary pain is unknown, but is estimated to be between 1% and 6% in England.[1]

Complexities of chronic pain

Complexities of chronic pain include sensory, emotional, cognitive and behavioural aspects. People with chronic pain commonly experience depression, sleep disturbance, fatigue, and decreased overall physical and mental functioning.[4] Almost half of people with chronic pain have depression and two thirds of people are unable to work resulting in high economic burden with absence from work and poor productivity.[6] Unlike acute pain and cancer pain at the end of life, chronic pain not associated with cancer has an unpredictable course and may continue for many years.[7] Consequently NICE recommends to offer a person-centred assessment to those presenting with chronic pain (chronic primary pain, chronic secondary pain, or both), to identify factors contributing to the pain and how the pain affects the person's life. All forms of pain can cause distress and disability, but these features are particularly prominent in presentations of chronic primary pain.[1]

Non-pharmacological interventions for chronic pain

Non-pharmacological treatment may be effective in reducing long-term pain and disability in some patients with chronic pain. They may also augment and complement analgesic use. Non-pharmacological interventions for chronic pain include psychologically based interventions, such as behavioural therapies, and physical therapies.[8]

People with chronic pain often require an interdisciplinary model of care, to allow care givers to address the multiple components of the patient's pain experience. Pain Management Programmes (PMPs), based on cognitive behavioural principles, are the treatment of choice for people with persistent pain which adversely affects their quality of life and where there is significant impact on physical, psychological and

social function.[4] It should be emphasised that medicines play only a minor part in managing chronic pain. Maintaining fitness, weight loss, pacing activities, normal activities and a generally healthy lifestyle are important. Non pharmacological methods of pain relief such as acupuncture and meditation are equally important.[7] The principal aims of PMPs are to enable people with chronic pain to achieve as normal a life as possible by reducing physical disability and emotional distress and improving the individual's ability to self-manage pain-associated disability and reduce reliance on healthcare resources.[4]

Mental health, emotional factors, social factors, expectations and beliefs, and biological factors as potential contributors to the experience of pain should be considered.[1]

The NICE guideline NG193 recommends the following non-pharmacological management options in chronic primary pain:[1]

- Supervised group exercise programmes for people aged 16 years and over taking people's specific needs, preferences and abilities into account and physical activity.
- Encourage people with chronic primary pain to remain physically active for longer-term general health benefits.
- Psychological therapy - acceptance and commitment therapy (ACT) or cognitive behavioural therapy (CBT). Do not offer biofeedback therapy to people aged 16 years and over.
- Acupuncture or dry needling – single course within a traditional Chinese or Western acupuncture system if delivered in a community setting, by a band seven (equivalent or lower) healthcare professional with appropriate training or another healthcare professional with appropriate training and/or in another setting for equivalent or lower cost and is made up of no more than 5 hours of healthcare professional time (the number and length of sessions can be adapted within these boundaries).
- Do not offer any of the following to people aged 16 years and over because there is no evidence of benefit:
  - TENS
  - Ultrasound
  - Interferential therapy

The Improving Access to Psychological Therapies (IAPT) Manual was originally developed to support setting up psychological therapy services for the treatment of anxiety and depression. NICE recommended psychological therapies for chronic pain are now included in the manual. This may be useful for commissioners looking to commission new psychological therapies for chronic pain. The manual describes the IAPT model and how to deliver it with a focus on NICE recommended care. It also aims to support the further implementation and expansion of IAPT services.[9]

Examples of self-management support resources are found in Attachment 2.

Pharmacological management

Chronic pain

In 1986 the World Health Organisation (WHO) proposed a step-wise approach to the use of medication in cancer related pain. The underlying principle was that medications should be used in an incremental fashion according to the person's reported pain intensity i.e.:

- Step 1 (mild pain): non-opioid analgesic such as paracetamol and/or nonsteroidal anti-inflammatory drug.
- Step 2 (mild-to-moderate pain): weak opioid such as codeine, dihydrocodeine or tramadol (controlled drug), with or without a non-opioid analgesic.

- Step 3 (severe pain): strong opioid such as morphine, oxycodone, fentanyl, buprenorphine, tramadol with or without a non-opioid analgesic.

The 'ladder' approach encourages use of adjunctive medicines (e.g. antidepressants, anti-epileptics) at each rung of the ladder and use of strong opioids only at the top of the ladder. Different classes are used alone or in combination according to the type of pain and response to treatment; it will usually be appropriate to continue effective or partially effective interventions in parallel with opioid therapy.[5,7,10]

The Faculty of Pain Medicine states that the analgesic ladder is unhelpful in chronic pain as it has an unpredictable course and may continue for many years. Substantial reduction in pain intensity is rarely an achievable goal.[7] SIGN also states that there is little good quality evidence for use of the ladder in chronic pain, but it does provide an analgesic strategy for non-specialists. Careful assessment and diagnosis is key to initiating appropriate non pharmacological assessment and pharmacotherapy. Continuing success requires regular, scheduled re-assessment of individual functionality, pain relief and side effects.[5]

Consider using the pain assessment tools in Appendix 1.

There are also a variety of outcome scales that are completed by people themselves before and after treatment. https://www.britishpainsociety.org/static/uploads/resources/files/Outcome_Measures_January_2019.pdf

The NICE guideline NG193 outlines management options for people with chronic pain according to whether the pain is chronic primary pain, chronic secondary pain or a mixture of the two. For chronic secondary pain, NICE recommend management in line with the NICE guideline for the underlying chronic pain condition. When chronic primary pain and chronic secondary pain co-exist, clinicians are recommended to use their clinical judgement to inform shared decision making about management options for chronic primary pain and / or the individual NICE guideline for the chronic pain condition. For the management of chronic primary pain, NICE provides new recommendations and these are outlined below.[1]

Chronic primary pain

The NICE guideline NG193 recommends to consider an antidepressant, either amitriptyline, citalopram, duloxetine, fluoxetine, paroxetine or sertraline, for people aged 18 years and over to manage chronic primary pain, after a full discussion of the benefits and harms. If an antidepressant is offered to manage chronic primary pain, explain that this is because these medicines may help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Note that this is an off-label use.[1]

Seek specialist advice if pharmacological management with antidepressants is being considered for young people aged 16 to 17 years.[1]

The NICE guideline NG193 advises to **not initiate** any of the following medicines to manage chronic primary pain in people aged 16 years and over:

- Antiepileptic drugs including gabapentinoids, unless gabapentinoids are offered as part of a clinical trial for complex regional pain syndrome (see the recommendation for research on pharmacological interventions).
- Antipsychotic drugs.
- Benzodiazepines.
- Corticosteroid trigger point injections.
- Ketamine.
- Local anaesthetics (topical or intravenous), unless as part of a clinical trial for complex regional pain syndrome (see the recommendation for research on pharmacological interventions).

- Local anaesthetic/corticosteroid combination trigger point injections.
- Non-steroidal anti-inflammatory drugs.
- Opioids.
- Paracetamol.

If a person is already taking these medications:

- Review these medications as part of shared decision making with the person and explain the lack of evidence in chronic primary pain and;
  - » agree a shared plan for continuing safely if they report benefit at a safe dose and few harms or,
  - » explain the risks of continuing if they report little benefit or significant harm, and encourage and support them to reduce and stop the medicine if possible.
- When making shared decisions about whether to stop antidepressants, opioids, gabapentinoids or benzodiazepines, discuss with the person any problems associated with withdrawal.[1]

Prescribing of opioids

Over the last few decades there has been a significant increase in opioid prescribing for people with chronic pain, despite limited evidence for long-term efficacy. Evidence from the United States indicates that peri-operative opioid use may have contributed to the large increase in prolonged opioid use.[5] Opioids Aware has highlighted that there is a large body of evidence, including randomised controlled trials and systematic reviews, that opioids may reduce pain for some people for a number of chronic painful conditions in the short and medium term (less than 12 weeks).[7] Reduction of pain at the end of life is well established.[8] There is, however, a lack of consistent good-quality evidence to support a strong clinical recommendation for the long-term use of opioids for people with chronic pain. It is suggested that they are only effective in a minority of people, however it is difficult to identify these people at the start of treatment.[6,7]

Concerns about increased usage and safety are present at a national and international level. A Public Health England (PHE) resource outlines how providers and commissioners can prevent deaths from drug misuse.[11] The Office for National Statistics gives data from 2012-2019 on the numbers of deaths involving legal and illegal drugs. It reported that:

- In 2017 although two-thirds of drug-related deaths were related to drug misuse, three-quarters of all drug-related deaths involved accidental poisoning.
- Deaths involving heroin or morphine doubled from 579 in 2012 to 1,209 in 2016 but declined to 1,164 in 2017, the first decline since 2012.
- Fentanyl deaths increased by 29%, rising from 34 deaths in 2015 and 58 deaths in 2016 to 75 deaths in 2017. Fentanyl and its analogues had been found mixed with heroin, causing accidental overdose in users; possibly due to their cheaper cost and higher potency. Public Health England issued a warning to heroin users and health officials regarding the contamination of heroin with potent synthetic opiates such as fentanyl.[12] Of note, 59 drug poisonings involving fentanyl were registered in 2019 (a rate of 1.0 death per million people). This was similar to the rate observed in 2018 when there were 1.3 deaths per million people (74 deaths).[13]
- Codeine deaths increased from 131 in 2016 to 156 in 2017, an increase of nearly 20%. However, most other opioid-related deaths decreased, with buprenorphine, methadone and oxycodone recording fewer deaths in 2017 than in 2016. Tramadol deaths remained stable, with 184 and 185 deaths in 2016 and 2017, respectively. In June 2014, tramadol was reclassified under the Misuse of Drugs Act 1971 as a class C substance.[6,12]

This has prompted the IASP to produce a statement in 2018 on the use of opioids in people with chronic pain, which concludes that, "There may be a role for medium-term, low-dose opioid therapy in carefully selected people with chronic pain who can be managed in a monitored setting. However, with continuous longer-term use, tolerance, dependence and other neuroadaptations compromise both efficacy and safety".[2]

Action of opioids

For the majority of clinically-used opioids, analgesic effects are predominantly, although not exclusively, via the opioid receptor (MOR). The potency of different opioids at this receptor varies.[5] Tramadol and tapentadol additionally inhibit noradrenaline reuptake and tramadol also inhibits serotonin reuptake. These additional actions on pain systems may have advantages in some chronic pain conditions such as neuropathic or mixed pains but they can also limit further upward titration.[5,10]

Opioids are classified as weak or strong opioids as follows:

- Weak opioids - codeine and dihydrocodeine
- Strong opioids – morphine, oxycodone, pentazocine, buprenorphine, diamorphine, tapentadol, tramadol.[5,10]

Some opioids, such as codeine, dihydrocodeine, tramadol and tapentadol, have defined upper dose limits in the British National Formulary (BNF).[10]

There is considerable variation in individual responses to analgesia, both in terms of efficacy and side effects. Even with the same chronic pain, the underlying neurobiology will differ between individuals, influencing analgesic response. There is also increasing evidence that variations in opioid responses are linked to genetic factors. Codeine, tramadol and oxycodone are affected by genetic variations in metabolism, mediated by cytochrome P450 enzyme CYP2D6, resulting in unpredictable effects in individuals. As codeine is a prodrug (its main effect relies on being metabolised to morphine), the 5–10% of people who are poor metabolisers experience very little analgesia, whereas hyper-metabolisers will have an increased drug effect, with increased risk of serious adverse effects. Poor metabolisers are commonly Caucasian, although up to 10% of Caucasians are high metabolisers. Twenty-eight percent of North Africans or Arabs are high metabolisers.[5]

In 2014 tramadol was reclassified by the UK Government as a Schedule 3 controlled drug, and re-categorised by the BNF as a strong opioid (despite its relatively low potency at MORs). Strong opioids that do not have defined upper dose limits in the BNF include morphine, diamorphine, hydromorphone, oxycodone, fentanyl, buprenorphine and methadone. Some of the newer formulations (e.g. transdermal patch) allow very low dosing, with an equivalent effect to less potent opioids.[5]

Comparing doses and switching between opioids (weak or strong) should be done with caution as there is limited evidence for the accuracy of dose equivalence tables and considerable variation between individuals.[5,10]

Table 1 provides a comparison of the metabolism, mechanism of action, adverse effects and maximum daily doses of codeine/dihydrocodeine, tramadol, tapentadol and morphine.

Table 1: Summary of metabolism, mechanism of action, adverse effects and maximum daily dose of codeine/dihydrocodeine, tramadol, tapentadol and morphine[7,10,14,15]

	Codeine / dihydrocodeine	Tramadol	Tapentadol	Morphine
Metabolised by	Codeine – CYP2D6 Dihydrocodeine – CYP2D6 and CYP3A4	CYP2D6 and CYP3A4	Glucuronidation	Glucuronidation
Main action	Mu-opioid	Mu-opioid and monoaminergic	Mu-opioid and noradrenaline reuptake	Mu-opioid
Constipation	+++	+	++	++
Nausea and vomiting	++	++++	++	++
Sedation	+++	++++	++	+++
Dizziness	++	+++	++	++
Addiction risk	++	++	++	++
Respiratory depression	++	+	+	++
Serotonin toxicity	-	++	+ (isolated cases)	-
Seizures	+	++	+	+
Maximum daily dose	240mg/day (= morphine 24mg)	400mg/day (= morphine 40mg)	500mg (= morphine 200mg)	Not defined
CD schedule	-	Schedule 3 (CD No reg POM)	Schedule 2	Schedule 2

Efficacy and safety

Data demonstrating sustained opioid analgesic efficacy in the long term are lacking. Trials for use in the short and medium term (up to 12 weeks) are mostly conducted in people with chronic low back pain.[5] Data on the efficacy of long-term use has been limited to assessment in case series and open-label extensions of controlled trials, rather than placebo-controlled studies.[7,8] These limitations have been recognised internationally and in 2002 the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) was developed to examine pain intensity, physical functioning and patient rating of overall improvement. Analysis of these data has allowed firm conclusions with regards to functional improvement or improvement in a patient's quality of life.[5] A 2015 meta-analysis, assessing the efficacy, tolerability and safety of opioid analgesics in open-label extension trials over a duration of six months or more, highlighted that only a minority of people selected for opioid therapy completed the studies, yet sustained effects of pain reduction could be seen in these people, including in those with neuropathic pain.[8] However, SIGN and Opioids Aware recognised that good-quality, adequately-powered double-blinded randomised controlled trials may not provide the best approach for developing a strong evidence base for pain management due to exclusion data including co-morbidities.[5,7]

If a person either fails to tolerate or has inadequate analgesia from a drug, then it is worthwhile considering a different agent from the same class of drug. However, Opioids Aware state that there is little evidence that one opioid is more effective and associated with fewer side effects than others.[7]

A US observational study looked at the relationship between early opioid prescribing patterns and likelihood of long-term use. Opioid continuation beyond one year was seen more frequently in people who were started on long-acting opioids or tramadol. The likelihood of chronic opioid use increased with larger initial opioid supply, longer treatment durations and where higher starting doses were prescribed.[6,16]

A systematic review found that there was some evidence that several types of intervention may be effective at reducing or discontinuing long-term opioid therapy and that pain, function and quality of life may actually improve with opioid dose reduction.[6,17]

The focus of treatment should be on improving people QoL.[8] 30-50% pain relief only at best is likely to be obtained from pharmacological intervention. Treatment success is demonstrated by the person becoming able to perform tasks (including normal household activities) that the pain currently prevents. Improved sleep would also be a reasonable outcome. If there has been no response to treatment within two to four weeks, after titration to adequate dose, people are unlikely to develop a response thereafter. Integral to success is regular reassessment of the person and stopping medication that is not working effectively and using non pharmacological approaches as the same time.[7]

The Oxford League of Analgesics put together the best available data from systematic reviews of analgesic efficacy in acute pain as a league table of Numbers Needed to Treat (NNT) in 2007. Table 2 (below) extracts data for five out of 60 analgesics listed in this league table. Analgesic efficacy is expressed as the NNT which is the number of people who need to receive the active drug for one to achieve at least 50% relief of pain compared with placebo over a four to six-hour treatment period. The most effective drugs have an NNT of just over two. This means that for every two people who receive the drug, one person will get at least 50% pain relief because of the treatment.[18] Equivalent doses of opioid analgesics are stated in Table 3.

Table 2: Analgesic efficacy in acute pain[18]

Analgesic and dose	Number of people in comparison	Percent with at least 50% pain relief	NNT
Codeine 60mg	1305	15	16.7
Paracetamol 1000mg + codeine 60mg	197	57	2.2
Tramadol 50mg	770	19	8.3
Tramadol 100mg	882	30	4.8
Tramadol 75mg	563	32	5.3

Table 3: Approximate equivalence of oral opioids with morphine daily dose

Drug	Dose		
	Faculty of Pain Medicine[7]	BNF[10]	SIGN[5]
Morphine equivalent	10mg	10mg	10mg
Oral codeine	100mg	100mg	100mg
Oral dihydrocodeine	100mg	100mg	Not stated
Oral tramadol	100mg	100mg	50mg
Oral tapentadol	25mg	Not stated	Not stated
Oral oxycodone	6.6mg	6.6mg*	5mg

*SPC for OxyContin states ratio of 1:2 to morphine.[19]

The Faculty of Pain Medicine recommends that use of immediate release preparations can provide effective symptomatic relief and use of such regimens may be justified when:

- The pain is intermittent and short-lived.
- Pain intensity varies significantly - use of regimens including immediate release preparations allows flexibility to reduce dose on days when pain is or is expected to be less severe.
- Background pain is well controlled with modified release preparations, but the person has infrequent, short-lived episodes of increased pain.

Modified release opioids administered at regular intervals may be more appropriate for people with chronic pain.[7]

Choice of strong opioid

There is little evidence that one opioid is more effective and associated with fewer side effects than another.[7] Non-morphine opioids, such as fentanyl, buprenorphine and oxycodone are significantly more expensive than oral morphine.[10]

Oral morphine should be the strong opioid of first choice. However, there is a theoretical rationale for trying an alternative opioid if the first drug tried is helpful but causes intolerable side effects.[7]

Opioids Aware suggests that for a small number of people, the transdermal route may be a suitable alternative.[7]

The PrescQIPP bulletin 213 recommends oxycodone as an option only in people who are intolerant of morphine sulfate, i.e. develop unacceptable side effects when taking morphine even when adjunct treatment is added to reduce these side effects.[20]

There is no advice from NICE on the use of strong opioids for long term pain that is outside of palliative care. The NICE guidance on Opioids in Palliative Care recommends that when starting treatment with strong opioids, to offer people with advanced and progressive disease regular oral sustained-release or oral immediate-release morphine (depending on individual preference), with rescue doses of oral immediate-release morphine for fluctuating pain. This recommendation is based on the evidence review where NICE identified 25 randomised controlled trials that compared the effectiveness of immediate-release morphine with sustained-released morphine, and immediate-release oxycodone with sustained-release oxycodone in people with various cancers. NICE found evidence that immediate-release opioids and sustained-released opioids had equivalent efficacy in both the titration and maintenance phase, in terms of pain relief, adverse effects, and health related quality of life. The NICE Guideline Development Group (GDG) were unable to recommend one formulation over another and agreed that offering the person a choice between immediate-release and sustained-release formulation would be likely to improve adherence.[21]

Laxatives/and or antiemetic treatment should be prescribed and optimised before considering changing oral opioid therapy. For people experiencing drowsiness from therapy, consider either reducing the treatment dose if pain is controlled or switching the opioid if pain is not controlled.[21]

In renal impairment, avoid use or reduce dose; opioid effects are increased and prolonged and increased cerebral sensitivity occurs. In severe liver disease opioids can further impair cerebral function and may precipitate hepatic encephalopathy.[10]

Adverse effects

SIGN reports systematic reviews that primarily examined adverse events, but these were restricted to reporting of nausea, constipation and somnolence. Significantly less constipation was experienced with the use of tramadol and fentanyl than other opioids. Other commonly reported adverse events with long-term use of opioids included dyspepsia, headache, fatigue, lethargy, and urinary complications (retention hesitancy, disturbance). A few serious side effects such as sedation and respiratory depression were

reported.[5] A Cochrane review reported that adverse effects led to discontinuation in 11% of people on weak opioids and 35–39% in strong opioids.[5,22]

No randomised controlled trials (RCTs) evaluating the risk of adverse effects, such as abuse or addiction, from long-term opioid therapy in people with chronic pain were identified; however, there is evidence from observational data.[5]

- Between 50% and 80% of people in clinical trials taking opioids will experience at least one adverse effect.[7]
- People should be advised about side effects and the likelihood of their occurrence before starting opioid therapy. The most common adverse effects are constipation, nausea, somnolence, confusion, falls, sexual dysfunction, reduced ability to fight infection, tachyphylaxis, itching, dizziness and vomiting. Adverse effects should be managed actively with antiemetics, laxatives and antihistamines as appropriate.[7]
- Tolerance to some side effects usually occurs within the first few days of initiating treatment; pruritis and constipation tend to persist. People using intermittent dosing schedules might not become tolerant to side effects or side effects may develop over time.[7]
- Respiratory depression is only likely to be a potential problem in chronic pain if there have been major changes in dose, formulation or route of administration. Accidental overdose is likely to be the commonest cause of respiratory depression. Particular caution is necessary for people taking more than one class of sedative medication and in those with pre-existing disorders of respiratory control, such as obstructive sleep apnoea.[7]
- There is little evidence that, in equi-analgesic doses, commonly used opioids differ markedly in their side effects.[7]
- Avoid codeine in breast feeding. Although the amount is usually too small to be harmful, mothers vary considerably in their capacity to metabolise codeine with the risk of morphine overdose in the infant.[10]

Long term effects of opioids

- Opioids increase the risk and incidence of falls. This is of particular importance in elderly people. In a systematic review of observational studies, there was a marginal yet a significant association between opioid use and falls with moderate heterogeneity (I2 = 43.1%), suggesting an increased risk of falls, fractures, and fall injuries among older adults who used opioids.[23] In six studies: three case-control studies and three cohort studies, opioid use was associated with a significantly increased risk of fracture; the RR was 1.38 (95% CI: 1.15, 1.66). Statistically significant heterogeneity was detected (p=0.004). Cohort studies were statistically homogeneous but case-control studies were not.[24]
- Endocrine effects are probably dose related and can lead to amenorrhoea in women, reduced libido in both sexes, erectile dysfunction in men, infertility, depression and fatigue.[5,7]
- Both animal and human studies have demonstrated that opioids have an immunomodulating effect. These effects are mediated via opioid receptors both on immune effector cells and in the central nervous system.[7]
- Opioid induced hyperalgesia has been demonstrated in people being treated with opioids for addiction and for pain. Clinically, the individual on long term opioid therapy presents with increased pain. This might be qualitatively distinct from pain related to disease progression or to fluctuating pain resulting from development of opioid tolerance. Pain associated with hyperalgesia is more diffuse than the pre-existing pain and less defined in quality. The management of opioid induced hyperalgesia is opioid dose reduction or changing to an alternative opioid preparation; consider referral to specialist pain services.[7,8]

- Withdrawal symptoms occur if an opioid is stopped or the dose reduced abruptly, e.g. sweating, yawning, abdominal cramps, vomiting and diarrhoea.[7]
- The problems seen in patients taking opioids for pain vary considerably from difficulty in reducing opioid dose because of withdrawal effects or re-emergence of pain to much more complex presentations characterised by many of the more difficult behaviours and complex psychosocial effects of continued opioid use.[7]

The MHRA have produced guidance on opioid medicines and the risk of addiction to help patients and their families reduce the risks of harm. The signs of opioid addiction are outlined:[25]

- Craving for the medicine.
- Feeling that you need to take more medicine than prescribed or as instructed even though the medicine is causing unwanted effects on your overall health.
- Feeling that you need to take additional medicines containing opioids or other pain relief medicines to achieve the same relief.
- Taking opioid medicines for reasons other than pain relief, e.g. to stay calm.
- Experiencing withdrawal side effects when you stop taking the medicine suddenly.

The guidance also provides the following advice on how to safely stop opioid medicines. People taking an opioid medicine for a long time, should not stop taking it suddenly because it may cause unpleasant withdrawal side effects. It is important to get the right help and support when a person is ready to stop taking the medicine.

Starting opioid therapy

The SIGN guidelines on the management of chronic pain (136) recommend that there are two potential options for starting strong opioids:

- Start with a low dose of a long-acting preparation. If the person is already on co-codamol or dihydrocodeine, then they are not opioid naive, particularly if they are on the maximum dose or more than one of these agents.

or

- While establishing a dose, use an immediate release preparation for short term use, only to determine approximate dose range, then convert to equivalent long-acting preparation as soon as possible. This may be more appropriate if the person has multiple co-morbidities.

The aim is to establish the person on a long-acting opioid with no immediate release opioid if the chronic pain is stable. For people with mild fluctuating or variable pain, recommendations are to consider non-opioids (e.g. paracetamol, NSAIDs) or weak opioids.[5]

Shared decision making

Shared decision making in relation to opioid treatment should include the person, the prescriber, the person's GP (if not the prescriber) and other key individuals involved in the person's care.[7] Dosing errors with opioid medicines has been part of a National Patient Safety alert. Every member of the team has a responsibility to check that the intended dose is safe for the individual.[26]

If care is shared between hospital and community, be clear who is responsible for prescribing.

Where practicable, the individual should receive prescriptions from a single prescriber and the drugs dispensed from a specified pharmacist. Documentation should be clear and accurate to support consistency of safe care if the person needs a prescription from other than the usual prescriber.

- In general, opioids should not be added to the repeat prescribing system but should be generated as acute prescriptions.

- If an opioid has a demonstrable positive benefit for an individual and there is a robust system for monitoring use then consideration may be given for short-term authorisation of repeat prescriptions.[7]

As opioids play an important role in acute pain management, many people in hospital with physical trauma or following surgery will be expected to have some pain for a short period following discharge. It may be appropriate to offer the person a supply of opioid medicine sufficient for a few days after which opioids are unlikely to be needed. The person must be given clear instructions regarding how to taper the dose of drug as natural recovery takes place and the treatment plan including the estimated time of cessation of opioid therapy should be communicated to the person's GP.[7]

Checklist to aid assessment

A written agreement should be considered.[7] See attachment 5.

The Pain Assessment and Documentation Tool (PADT, listed in appendix 1) is an example of a tool that can be used to record baseline levels of pain score and functional ability. The PADT tool can then be used for ongoing assessment. For people with dementia use the Pain Assessment In Advanced Dementia (PAINAD, listed in appendix 1) tool.

- The individual and prescriber should agree goals of treatment to improve QoL and function e.g. ability to walk, general activity, mood, sleep.
- Discuss side effects/potential problems. People should be advised about side effects and the likelihood of their occurrence before starting opioid therapy. The most common adverse effects are constipation, confusion, falls, sexual dysfunction, reduced ability to fight infection, tachyphylaxis, nausea, somnolence, itching, dizziness, vomiting. Adverse effects should be managed actively with laxatives, antiemetics, and antihistamines as appropriate.
- Consideration also needs to be given to communicating concerns such as addiction, tolerance, side effects and providing written and verbal information. People with a history of addiction to opioids or other drugs need referral to services with expertise in pain medicine and addiction management. See the Opioid Risk Tool (Appendix 1).
- Set a timescale for the trial and frequency of review or guidance to stop. Note that people who do not achieve useful pain relief from opioids within two to four weeks are unlikely to gain benefit in the long term. People who may benefit from opioids in the long term will demonstrate a favourable response within two to four weeks. See attachment 3.
- All drugs prescribed for pain should be subject to regular review to evaluate continued efficacy, and periodic dose tapering is necessary to evaluate on-going need for treatment.
- The prescriber and individual together should review the continuing benefit of opioid therapy and potential harms at regular intervals (at least twice each year) and more frequently if problems arise.[5,7]

Driving and opioids

People taking appropriate doses of prescribed opioids are permitted by law to drive in the UK if they are using no more than the prescribed dose and feel fit to drive. However, it is illegal to drive if the driver is unfit to do so because they are taking legal or illegal drugs. There is no requirement to inform the DVLA if people are taking opioids.[27]

When considering opioid treatment, prescribers should discuss impairment of driving skills with the individual. It is unsafe to drive in the first few days after starting an opioid and for a few days after a dose change (up or down). It remains the responsibility of all drivers to decide whether they consider their driving is or might be impaired on any given occasion and they should not drive if this is the case.[7]

Stopping opioid therapy

The BMA recognises that sufficient investment and resources for primary care, including longer consultation times and competencies in prescribing, are required to support improvements in analgesic prescribing for people with chronic pain.[8]

NICE is developing guidance on safe prescribing and withdrawal management for adults for medicines associated with dependence or withdrawal symptoms. The expected publication is 20 April 2022.[3]

If the prescriber and individual agree that opioid therapy may play a role in further management of the individual's pain, a trial of opioid therapy should be planned. However, short-term response to opioid therapy does not predict long term therapy which may be limited by adverse effects or declining efficacy.[7]

It is important to taper or stop the opioid regimen if:

- The medication is not providing useful pain relief. The dose above which harms outweigh benefits is 120mg oral morphine equivalent/24hours. Increasing opioid load above this dose is unlikely to yield further benefits but exposes the person to increased harm.[8] SIGN guidelines state that all patients receiving opioid doses of >50mg/day morphine equivalent should be reviewed regularly (at least annually). Pain specialist advice or review should be sought at doses >90mg/day morphine equivalent.[5]
- The underlying painful condition resolves.[7]
- The person receives a definitive pain relieving intervention, e.g. joint replacement.[7]
- The person develops intolerable side effects.[7]
- There is strong evidence that the person is diverting his/her medications to others.[7]

The Faculty of Pain Medicine suggests that the dose can be tapered by 10% weekly or every two weeks. It is important to note that tapering may need to be slower and reviewed in manageable steps; the decision to taper/stop an established opioid regimen needs to be discussed carefully with the individual.[7] Factors that will influence reduction include:

- People' willingness to reduce or stop medication.
- Previous attempts to reduce dose.
- Known side effects.
- Length of time on current dose.

Prescribing for pain in older people

A literature review found that there were few studies investigating the effects of analgesic drugs performed specifically in older people (those over 65 years). They suggest that some physiological changes in older people affect drug handling and these may have clinical consequences, such as:[28]

- Increased risk of gastro-intestinal-related side effects including opioid-related gut motility disturbance
- Reduced distribution of water soluble drugs.
- Lipid soluble drugs have longer effective half-life.
- Increased potential for drug-drug interactions.
- Reduced first pass metabolism.
- Reduced excretion of drugs and metabolites eliminated by the kidney leading to accumulation and prolonged effects.
- Increased sensitivity to the therapeutic and side effects.

Evidence from the literature search suggested that paracetamol should be considered first-line treatment for the management of both acute and persistent pain, particularly musculoskeletal pain due to demonstrated efficacy and good safety profile. Non-steroidal anti-inflammatory drugs (NSAIDs) should be used with caution after other safer treatments have not provided sufficient pain relief. The lowest dose for the shortest duration should be prescribed. For older adults NSAIDs or cyclooxygenase-2 (COX-2) inhibitors should be co-prescribed with a proton pump inhibitor. Opioids may be considered for moderate or severe pain, particularly if the pain is causing functional impairment or is reducing their quality of life. However, this must be individualised and carefully monitored. Opioid side effects including nausea and vomiting should be anticipated and suitable prophylaxis considered. Appropriate laxative therapy, such as the combination of a stool softener and a stimulant laxative, should be prescribed throughout treatment for all older people who are prescribed opioids. Intra-articular corticosteroid injections in osteoarthritis of the knee are effective in relieving pain in the short term, with little risk of complications and/or joint damage. Intra-articular hyaluronic acid is effective and free of systemic adverse effects. It should be considered in patients who are intolerant to systemic therapy. Intra-articular hyaluronic acid appears to have a slower onset of action than intra-articular steroids, but the effects seem to last longer.[28]

Increasing activity through exercise involving strengthening, flexibility, endurance and balance, along with a programme of education should be considered. A number of complementary therapies were found to have some efficacy among the older population, including acupuncture, transcutaneous electrical nerve stimulation (TENS) and massage. Some psychological approaches were found to be useful for the older population, including guided imagery, biofeedback training and relaxation. There was also some evidence supporting the use of cognitive behavioural therapy (CBT) among nursing home populations.[28]

Costs and savings

Current spend on analgesia across England, Wales and Scotland is approximately £135 million annually (NHSBSA and Public Health Scotland February 2021 to April 2021).

If reviewing prescribing and discontinuing treatment no longer needed resulted in a 20% reduction in the use of analgesics (excluding nefopam, pethidine and self-care products), this would lead to savings of £69 million in England, £5.2 million in Wales and £9.8 million in Scotland (NHSBSA and Public Health Scotland February 2021 to April 2021). This equates to £120,385 per 100,000 patients.

Analgesia available for purchase OTC such as paracetamol, ibuprofen, Panadol®, Migraleve®, Nurofen® Max Strength and Migraine Pain® Caplets should not routinely be prescribed. The current cost of these formulations in England is £23.4 million, £1.8 million in Wales and £3.1 million in Scotland. **A 20% reduction in prescribing of OTC analgesia could lead to savings of £18.7 million in England, £1.4 million in Wales and £2.5 million in Scotland (NHSBSA and Public Health Scotland February 2021 to April 2021). This equates to £32,397 per 100,000 patients.**

Pethidine

The BPS and the Faculty of Pain Medicine advise to **never** prescribe pethidine in any form for the management of chronic non-cancer pain (unless on the advice of a specialist pain management team).[7]

The current annual cost of pethidine is £123,058 in England, £15,315 in Wales and £18,217 in Scotland annually (NHSBSA and Public Health Scotland February 2021 to April 2021).

Nefopam

The SIGN guidelines state that the evidence identified on the use of nefopam for chronic pain relief is not sufficient to support a recommendation.[5] It is not endorsed in the guidelines issued by NICE for chronic pain or lower back pain.[1,29] The SPC for nefopam does not provide any specific guidance on whether the nefopam dose needs tapering before stopping.[30]

Annual spend on nefopam is £774,035 in England, £8,409 in Wales and £174,552 in Scotland (NHSBSA and Public Health Scotland February 2021 to April 2021). People on nefopam should be reviewed. If ineffective or people cannot tolerate side effects, reduce slowly and discontinue.

If a review of prescribing led to a 80% reduction in nefopam and pethidine formulations then this would lead to annual savings of £2.9 million in England, £75,917 in Wales and £616,860 in Scotland (NHSBSA and Public Health Scotland February 2021 to April 2021). This equates to £5,089 per 100,000 patients.

The PrescQIPP Pain Visual Snapshot may be used by commissioners to identify spend on analgesics (simple analgesics, compound analgesics, weak opioids, strong opioids and NSAIDs) to support prioritisation of chronic pain medicines optimisation projects. https://www.prescqipp.info/our-resources/data-and-analysis/clinical-snapshots/pain-snapshot-reports-and-visual-analytics/

Further resources

This bulletin should be used in conjunction with the following PrescQIPP resources:

Pain Webkit https://www.prescqipp.info/our-resources/webkits/pain/

PrescQIPP Bulletin 199: Oxycodone/naloxone (Targinact®) https://www.prescqipp.info/our-resources/bulletins/oxycodonenaloxone-targinact/

PrescQIPP Bulletin 208: Paracetamol and tramadol combination products https://www.prescqipp.info/our-resources/bulletins/bulletin-208-paracetamol-and-tramadol-combination-products/

PrescQIPP Bulletin 213: Oxycodone MR https://www.prescqipp.info/our-resources/bulletins/bulletin-213-oxycodone/

PrescQIPP Bulletin 215: Opioid patches https://www.prescqipp.info/our-resources/bulletins/bulletin-215-opioid-patches/

PrescQIPP Bulletin 216: Neuropathic pain (Note: includes recommendations on the management of sciatica) https://www.prescqipp.info/our-resources/bulletins/bulletin-216-neuropathic-pain/

PrescQIPP Bulletin 218: Reducing opioid prescribing in chronic pain https://www.prescqipp.info/our-resources/bulletins/bulletin-218-reducing-opioid-prescribing-in-chronic-pain/

PrescQIPP Bulletin 237: Antidepressants https://www.prescqipp.info/our-resources/bulletins/bulletin-237-antidepressants/

PrescQIPP Bulletin 256: Dependence forming medications https://www.prescqipp.info/our-resources/bulletins/bulletin-256-dependence-forming-medications/

PrescQIPP Bulletin 265: NSAIDs https://www.prescqipp.info/our-resources/bulletins/bulletin-265-nsaids/

PrescQIPP Bulletin 266: Tapentadol https://www.prescqipp.info/our-resources/bulletins/bulletin-266-tapentadol/

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Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-284-chronic-pain/
Implementation tools	
Data pack	https://data.prescqipp.info/views/B284_Chronicpain/FrontPage?%3Aembed=y&%3Aiid=1&%3AisGuestRedirectFromVizportal=y

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The use and application of this guidance does not override the individual responsibility of health and social care professionals to make decisions appropriate to local need and the circumstances of individual patients (in consultation with the patient and/or guardian or carer). Terms and conditions

Appendix 1: Useful resources to aid the decision-making process

Assessment tools

British Pain Inventory (short form) – Use to quantify level of pain and provide a baseline

Pain self-efficacy questionnaire (PSEQ) – rating scale to assess how confident people are to do things despite their pain

The Keele STarT Back Screening Tool - A brief validated tool (Hill et al 2008), designed to screen primary care patients with low back pain for prognostic indicators that are relevant to initial decision making

Patient Health Questionnaire (PHQ9) – Validated tool for use in primary care to measure severity of depression and response to treatment

Pain scales in multiple languages

What to discuss with the patient when considering opioid treatment - Checklist for prescriber's

Pain Assessment In Advanced Dementia Scale (PAINAD)

Pain Assessment and Documentation Tool (PADT) – validated tool to assess pain intensity and impact on function over time

Opioid Risk Tool (ORT) - brief, self-reporting screening tool designed for use with adult people in primary care settings to assess risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain

Opioids Aware - A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain

Live Well with Pain - resources for GPs and pain specialists to increase skills and confidence in working with people who live with persistent pain.

For people with pain

The Pain toolkit – a set of twelve tools to help and aid in pain self-management, plus a suite of tailored resources for both healthcare professionals and people living with persistent pain.

Pain UK - an alliance of charities providing a voice for people in pain, signpost people in pain to where help is available

NHS Tayside – list of resources for people with chronic pain Resources to help you take control of your chronic pain

Arthritis Research UK – a guide for people who have long-term musculoskeletal pain Living with long term pain: a guide to self management

Health Improvement Scotland – information for people with chronic pain or their carers e.g. pain assessment, medication, therapies, self help Manging chronic pain

Pain Concern's Navigator Tool – designed to help people navigate their concerns and bring the most important questions up in primary care appointments

Understanding and Managing Long Term Pain – Information for People with Pain (for purchase)

For community pharmacists

The British Pain Society - managing your pain effectively using "Over the Counter" (OTC) medicines https://www.britishpainsociety.org/static/uploads/resources/files/patient_pub_otc.pdf