

East Lancashire Health Economy Medicine Management Board

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ELHE Opioid Prescribing for Chronic Pain: Resource Pack



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Foreword

- 1. This document brings together a number of resources clinicians can use to support the appropriate use and review of opioids used for chronic pain. The information included refers to the management of adult patients although some of the principles may also apply to use in older children. The information in this document does not apply to palliative care and end of life care where use of opioids should follow the World Health Organisation (WHO) pain ladder and relevant guidance.
- 2. The term chronic pain is used throughout this document and refers to a continuous pain that persists beyond the expected time of healing or for longer than 3 months excluding cancer related pain and pain experienced at the end of life care.
- 3. Opioids are increasingly being prescribed to manage chronic pain; however, the clinical evidence shows limited effectiveness and patient safety concerns due to the risks associated with long-term use of opioids such as fractures and falls, endocrine abnormalities, immunomodulation, opioid induced hyperalgesia and dependence.
- 4. Based on the clinical evidence Public Health England and the Faculty of Pain Medicine have advised:
 - Opioids are very good analgesics for acute pain and for pain at the end of life but there is little evidence that they are helpful for long term pain.
 - A small proportion of people may obtain good pain relief with opioids in the long term if the dose can be kept low and especially if use is intermittent (however it is difficult to identify these people at the point of initiation).
 - The risk of harm increases substantially at doses above an oral morphine equivalent of 120mg/day, but there is no increased benefit.
 - If a patient is using opioids but is still in pain, the opioids are not effective and should be discontinued, even if no other treatment is available.
 - Chronic pain is very complex and if patients have refractory and disabling symptoms, particularly if they are on high opioid doses, a very detailed assessment of the many emotional influences on their pain is essential.
- 5. Drug treatments:
 - Should be reserved for when non-pharmacological therapies alone have failed.
 - Should be given on a trial basis initially.
 - Should only be continued with good objective evidence of improved function (not just pain perception).
- 6. The British National Formulary (BNF) advises that the prescriber has three main responsibilities:
 - To avoid creating dependence by introducing drugs to patients without sufficient reason.
 - To see that the patient does not gradually increase the dose of a drug, given for good medical reasons, to the point where dependence becomes more likely.
 - To avoid being used as an unwitting source of supply for addicts and being vigilant to methods for obtaining medicines.
- Appendix 1 provides a patient story highlighting the issues that can occur with long term opioid use - <u>Appendix 1 – Faye's Story</u>

Managing Patient Expectation

- 8. Chronic pain is difficult to treat. Complete relief of pain is rarely achieved with opioids. The goal of therapy should be to reduce symptoms sufficiently to support improvement in physical, social and emotional functioning.
- **9.** The decision to start long term opioid therapy should be considered carefully by the Prescriber, the patient and his/her carers and other members of the healthcare team.
- 10. It is difficult to predict how individual people with chronic pain will respond to any given medicine. Opioids for long-term pain only benefit around one in every four or five people achieving a 30-50% reduction in pain at best. This means that for every 10 patients initiated on opioids for chronic pain they will be ineffective and so should be stopped for 7 8 patients.
- **11.** Around 80% of patients taking opioid's will experience at least one adverse effect. These should be discussed with the patient before treatment begins. Patients should be aware of uncertainty regarding the long term effects of opioids, particularly in relation to endocrine and immune function.
- **12.** Where opioids are to be prescribed the patient should have a carefully supervised trial of opioid therapy with evaluation of analgesic efficacy and adverse effects.
- **13.** Patients who do not achieve useful pain relief from opioids within 2-4 weeks are unlikely to gain benefit in the long term.
- 14. Short-term efficacy does not guarantee long-term efficacy, therefore, regardless of which opioid analgesic is used, regular review and reassessment to determine that there is continued value from using a particular medication is important in providing ongoing good quality chronic pain management.

Practice Resources

Appendix 2 – What to discuss with the patient when considering opioid treatment Appendix 3 – Ten Footsteps Patient Information Leaflet Appendix 4 – About Pain Patient Information Leaflet Appendix 5 – Thinking About Opioid Treatment for Pain Patient Information Leaflet Appendix 6 – Pain Diary



Reducing opioid prescribing in chronic pain e-learning



The Reducing opioid prescribing in chronic pain e-learning course is CPD certified and is aimed at medicines management teams, GPs, practice nurses, practice pharmacists and non-medical prescribers.

There has been a marked and progressive rise in prescribing of opioid drugs in the UK over the past decade and the trend to increased prescribing continues. The increase in prescribing has been predominantly for the treatment of noncancer pain.

Opioids have demonstrable effectiveness in the treatment of acute pain and pain related to cancer but there is little evidence for the effectiveness of opioids for the treatment

of chronic pain. This e-learning course will help equip healthcare professionals to tackle this growth in use and to improve care for patients with chronic pain and is comprised of eight modules:



MODULE 1	 Background to chronic pain Definition and the suffering and disability caused by chronic pain The expectations of chronic pain management The approach to chronic pain management with NICE guidelines
MODULE 2	 Opioid efficacy and trial of treatment The lack of evidence of efficacy of opioids in chronic pain and expectations How an opioid trial should be undertaken, the appropriate duration and how to assess and document the outcomes of the trial
MODULE 3	 Choice of strong opioid The evidence comparing non-morphine opioids with morphine The rationale for different formulations and routes of administration The approximate dose equivalence of opioids
MODULE 4	 Adverse effects of opioids The short-term and long-term adverse effects of opioids Withdrawal and addiction symptoms
MODULE 5	 Duration of opioid therapy and review The rise in prescribing of opioid medicines in the UK The repeat prescribing of opioids is discouraged The need for medication review

MODULE 6	 Tapering and stopping opioids Improved outcomes anticipated after opioid dose reductions How to taper and stop opioids in practice
MODULE 7	 Prescription opioid dependence Indicators that suggest the possibility of dependence on prescription opioids The potential need for specialist support for dependent patients The pharmacotherapy that may be prescribed by specialist service for opioid dependant patients during withdrawal
MODULE 8	 Specialist services Specialist pain services and the variation in access to these across the UK Potential role of specialist drug and alcohol dependence treatment services for patients with opioid dependency

The course includes contributions from Dr Ruth Bastable, a GP with experience of working in health care of patients who are homeless and at risk of homelessness and health care of patients in secure environments. She has an interest in substance misuse, and an interest in prescription drug misuse.

This course should take approximately 3 hours. You'll need to complete all the modules and get at least 70% in the final assessment to pass the course, but you can attempt it up to three times. You'll also need to get 60% in each of the quizzes before you can move on to the next lesson, but you can retake these as many times as necessary.

Course access

This course is available for all members of our medicines management team and GP practices in our commissioning area.

You will need to be logged in to the PrescQIPP site to access the course, so that it can record your progress and issue your e-learning certificate. If you do not already have a log in for the PrescQIPP site, you can <u>register here</u>. Please ensure that you specify the commissioning area on registration as this will ensure that you are provided with the correct access and do not have to pay for the course.

- 1. Log in to the <u>PrescQIPP site</u>
- 2. Click on the 'PrescQIPP e-learning' link under the 'Learning' menu, then once on the <u>E-learning Hub</u> click on 'Access e-learning' on the right hand side
- 3. Find the course and select 'Access course'

Don't forget that you can complete the course over a period of time. To return to the course and pick up where you left off at any time, simply log back into the site and follow the steps above.

Please note that you will need an up to date browser and sufficient bandwidth to view the course. If you have any questions about the course, please contact <u>help@prescqipp.info</u>.

Opioid Trial

15. The opioid trial establishes whether the patient achieves any reduction in pain with use of opioids. Achieving optimal doses and managing side effects of opioids is not the purpose of the trial; these can be explored once it has been shown whether opioids are helpful for the patient.

Patient Agreement

16. A written, structured agreement including information on the desired outcomes of treatment, frequency of review, dose prescribed and circumstances in which opioid treatment may be stopped e.g. evidence of dependence should be part of routine practice and can act as a helpful starting point when discussing progress and therapy.

Starting the Trial

17. Agree some readily assessable outcomes that indicate that opioids may play a role in the patient's management. These will usually include reduction in pain intensity and ability to achieve specific functional improvement facilitated by the medication. For patients in whom sleep is significantly impaired by pain, improved sleep would be a reasonable outcome.

Duration of the Opioid Trial

- 18. If the patient has constant pain, the opioid trial may be concluded in one or two weeks.
- **19.** If the patient has intermittent disabling flare ups of pain on a background of more manageable symptoms, the trial should be long enough to observe the effect of opioids on two or three episodes of increased pain.

Choice of Opioid Formulation and Dose

- **20.** Where possible, the usefulness of opioids should be explored by prescribing a short supply (1-2 weeks) of immediate release oral opioid.
- **21.** If a weak opioid is required codeine should be used.
- 22. If a strong opioid is required immediate release morphine should be used.
- **23.** The patient may be advised to explore different doses within a specified range eg, morphine 5-10mg. If reduction in pain is not achieved following a single dose of immediate relief morphine 20mg, opioids are unlikely to be beneficial in the long term.
- 24. A trial of fixed dose regimens using modified release preparations needs to allow for one or two upwards dose adjustments and may therefore take three weeks or more.

Patient Monitoring

25. The patient should keep a diary during the opioid trial. This should include a twice-daily report of pain intensity, comment on sleep, note of activity levels and how any of these are changed following a dose of opioid. All doses of opioid should be recorded in the diary with a comment on side effects.

Documentation

- 26. Clinical records should include:
 - relevant clinical findings that support the decision to prescribe opioids
 - agreed outcomes of opioid therapy
 - the choice of drug, formulation, starting dose, details of any planned dose escalation and duration of treatment
 - the circumstances under which opioid therapy should be discontinued
 - arrangements for follow up
 - the information given to patients

Assessing whether the Opioid Trial is a success

- 27. The patient should be reviewed within four weeks of initiation of opioid treatment.
- **28.** If the opioid trial demonstrates that the medicines are unhelpful, the reasons for this should be clearly documented e.g. lack of efficacy, intolerable adverse effects.
- **29.** If the patient reports no improvement in symptoms following the trial it is very unlikely that long-term opioid therapy will be helpful.
- **30.** If the opioid trial is not successful, the drugs should be tapered and stopped within one week.
- **31.** There is little evidence that one opioid is more effective and associated with fewer side effects than others. There is a theoretical rationale for trying an alternative opioid if the first drug tried is helpful but causes intolerable side effects.

Practice Resources

Appendix 2 – What to discuss with the patient when considering opioid treatment Appendix 4 – About Pain Patient Information Leaflet Appendix 5 – Thinking About Opioid Treatment for Pain Patient Information Leaflet Appendix 6 – Pain Diary Appendix 7 – Opioid Management Plan: Treatment agreement Appendix 8 – Taking Opioids for Pain Patient Information Leaflet Appendix 9 – Driving and Pain Patient Information Leaflet Appendix 10 – Summary of NICE Guidance: Related to pain relief and opioids Appendix 11 – Useful Read Codes

Arrangement for Review

- **32.** Where practical, review of long term opioid therapy should be carried out by the initial prescriber.
- **33.** The frequency of review once the opioid regimen has been established will depend on the early effectiveness of treatment, the frequency of troublesome side effects, the timing of additional interventions to control pain e.g. surgery, and the presence of concerns in relation to problematic use of opioids.
- **34.** When a regimen is stable and the patient reports substantial relief of symptoms and where additional concerns do not dictate otherwise, opioid treatment should be reviewed **at least** six monthly.

- **35.** Consider intermittent dose reductions or drug holidays to demonstrate that on-going prescriptions are clinically appropriate and beneficial.
- **36.** See *Stopping Opioids in Primary Care* section for advice on discontinuing opioids where they are no longer needed, ineffective, not tolerated or dependence/problematic use is identified.

Practice Resources

<u>Appendix 11 – Useful Read Codes</u> <u>Appendix 12 – Letter inviting patients for review</u> <u>Appendix 13 – Letter suggesting drug holiday</u>

Responsibility for Prescribing

- **37.** Where practical, the patient should receive prescriptions from a single prescriber.
- **38.** If the patient needs a prescription from someone other than the usual prescriber, documentation should be clear and accurate to support consistency of safe care.

Practice Resources

<u>Appendix 14 – Opioid policy new patients</u> <u>Appendix 15 – Opioid policy- issuing prescriptions</u>

Repeat Prescribing

- **39.** In general, opioids should not be added to the repeat prescribing system but should be generated as acute prescriptions.
- **40.** If an opioid has a demonstrable positive benefit for an individual patient and there is a robust system for monitoring use then consideration may be given for short-term authorisation of repeat prescriptions.

Practice Resources

<u>Appendix 14 – Opioid policy new patients</u>

Appendix 15 – Opioid policy- issuing prescriptions

<u>Appendix 16 – Practice procedure for lost/stolen controlled drug prescriptions</u>

<u>Appendix 17 – Practice procedure for patients where dependence on, or diversion of,</u> <u>controlled drugs has been identified</u>

<u>Appendix 18 – Reporting of controlled drug incidents via cdreporting.co.uk</u>

Rational Prescribing

Keep pain relief simple and effective

- 41. Follow these S.T.E.P.S. to answer the following questions:
 - Is it Safe for the patient to continue on this medication long term?
 - Can they Tolerate this medication with its side effects?
 - Is the medication Effective? Some patients can't tell one way or another.
 - Are they are on the best **P**riced treatment? (Expensive treatment is acceptable if it works.)
 - Is the taking of analgesics as **S**imple as possible? Would a long-acting preparation be preferable to frequent doses of short-acting analgesics?
- **42.** It is easier to manage opioid prescribing if a single opioid is used rather than combining several opioids. If several opioids are being used when reviewing treatment the total opioid load must be considered.
- **43.** Drugs should be used for their licensed indication only.
- 44. The oral route should **always** be used where possible. Use of opioid formulations with a rapid onset, such as fentanyl for transmucosal or sublingual administration, is **inappropriate** for the management of chronic pain. Injectable opioids should **not** be used in the management of patients with chronic non-cancer pain. Patches should only be used if oral opioids are not suitable and analgesic requirements are stable.
- **45.** The minimum effective dose should always be used. When medicines do not give sufficient analgesia there is a risk of dose escalation which is rarely helpful. For chronic pain, 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 patient to increased harm.

East Lancashire Medicines Management Board Formulary

	First Choice	Alternative
Weak opioid	Codeine	Dihydrocodeine
Moderate opioid	Tramadol	
Strong opioid	Morphine	Oxycodone

46. It is helpful to calculate total daily dose of opioid (total opioid load) in morphine equivalents, particularly when more than one opioid is used.

	Dose approximately	For chronic pain do not
	equivalent to 120mg	exceed
	morphine	
Morphine	120mg	60mg bd
Oxycodone	60mg	30mg bd
Fentanyl patch	33mcg/hr	37mcg/hr (1x25mcg +
		1x12mcg patch)
Buprenorphine patch	50mcg/hr	52.5mcg/hr



Green Traffic Light

Amber Traffic Light

Fentanyl Safety Concerns

Overdose Risk

- Inappropriate strength of fentanyl patches prescribed in opioid naive patients.
- Failure to remove an old patch before applying a new fentanyl patch.
- Exposure of the patch application site to a heat source (e.g. hot bath, hot water bottle, electric blanket, heating pad etc.) or increased body temperature (e.g. fever).

Accidental Ingestion

- Poorly affixed fentanyl patches transferring to another person for whom fentanyl is not intended.
- Applying improperly disposed patches to the body believing the patches to be stickers or plasters e.g. children, adults with dementia or visual impairment.

Practice Resources

Appendix 10 – Summary of NICE Guidance: Related to pain relief and opioids Appendix 19 – Dose equivalence table Appendix 20 – CQC and NHSE guidance on safer use of oxycodone Appendix 21 – CQC and NHSE guidance on safer use of fentanyl and buprenorphine transdermal patches Appendix 22 – MHRA Fentanyl Skin Patches Patient Information Leaflet

Stopping Opioids in Primary Care

- **47.** It is important to taper or stop the opioid regimen if:
 - The medication is not providing useful pain relief.
 - The underlying painful condition resolves.
 - The patient receives a definitive pain relieving intervention (e.g. joint replacement).
 - The patient develops intolerable side effects.
 - There is strong evidence that the patient is diverting his/her medications to others.
- **48.** Withdrawal symptoms (e.g. sweating, yawning and abdominal cramps, restlessness, and anxiety) occur if an opioid is stopped/dose reduced abruptly and so doses should be gradually reduced.
- **49.** The decision to taper/stop an established opioid regimen needs to be discussed carefully with the patient including:
 - The rationale for stopping opioids including the potential benefits of opioid reduction (avoidance of long term harms and improvement in ability to engage in self-management strategies).
 - Agreeing outcomes of opioid tapering e.g. stopping opioid completely, for patient on high doses reducing dose to 120mg/day morphine equivalence.
 - Arrangements for monitoring and support during opioid taper.
 - Documented agreement of tapering schedule.
- **50.** The dose of drug can be tapered by 10% weekly or two weekly.
- **51.** The reduction becomes a larger proportion of the dose that the patient is taking as their dose reduces. This is why patients may run into difficulty as they reach lower doses. Consider smaller dose reductions as the dose becomes lower.

- **52.** Tapering can be paused but should not be reversed except in exceptional circumstances.
- **53.** Patients who are failing to derive benefit from large doses of opioids (greater than oral morphine equivalent of around 300mg/day) may need support from specialist services in order to reduce medication. Opioid tapering/cessation when patients are taking high doses is more likely to succeed if patients' emotional and mental health needs are identified and an appropriate plan for support established.

What if the patient isn't keen?

- **54.** General Medical Council (GMC) guidance is that doctors have to act in the patients best interests this may involve reducing an opioid prescription against the patient's wishes.
- **55.** Document your reasons for embarking on an enforced wean, and on your attempts to gain patient agreement. A documented Multi-disciplinary team (MDT) discussion is advisable. Consider contacting secondary care (such as the pain clinic) for advice.
- **56.** A suggested strategy for an enforced wean:
 - Pick a reduction dose (e.g. 10%).
 - Inform the patient that you will reduce their prescription by that amount every month. They can decide at what point during the month they wish to reduce their intake, but need to be ready for the lower dose when they collect their next prescription.
 - Make sure you implement the dose reductions.
 - You will need to ensure that the patient is not inadvertently prescribed opioids by colleagues. This requires good communication within the practice, with locum services and if necessary out of hours and emergency services.

Practice Resources

<u>Appendix 11 – Useful Read Codes</u> <u>Appendix 12 – Letter inviting patients for review</u> <u>Appendix 13 – Letter suggesting drug holiday</u> Appendix 23 – Preparation for dose reduction

Converting Opioids

- **57.** Conversion factors are an approximate guide only because comprehensive data are lacking and there is significant inter-individual variation.
- **58.** In most cases, when switching between different opioids, the calculated dose-equivalent must be reduced to ensure safety.
- **59.** The starting point for dose reduction from the calculated equi-analgesic dose is around 25-50%.
- **60.** A dose reduction of at least 50% is recommended when switching at high doses, in elderly or frail patients, or because of intolerable side effects.

- **61.** The half-life and time to onset of action of the two drugs needs to be considered when converting so that the patient does not experience breakthrough pain or receive too much opioid during the conversion period. Patches have a particularly long half-life.
- **62.** Once the conversion has occurred, the dose of new opioid should be titrated carefully according to individual response and the patient monitored closely for side effects and efficacy, especially when switching at high doses.

Practice Resources

<u>Appendix 19 – Dose equivalence table</u> <u>Appendix 20 – CQC and NHSE guidance on safer use of oxycodone</u> <u>Appendix 21 – CQC and NHSE guidance on safer use of fentanyl and buprenorphine</u> <u>transdermal patches</u>

Prescribing Drugs likely to cause dependence or misuse

- **63.** The BNF advises that the prescriber has three main responsibilities:
 - To avoid creating dependence by introducing drugs to patients without sufficient reason.
 - To see that the patient does not gradually increase the dose of a drug, given for good medical reasons, to the point where dependence becomes more likely. The prescriber should keep a close eye on the amount prescribed to prevent patients from accumulating stocks. A minimal amount should be prescribed in the first instance, or when seeing a patient for the first time.
 - To avoid being used as an unwitting source of supply for addicts and being vigilant to methods for obtaining medicines. Methods include visiting more than one doctor, fabricating stories, and forging prescriptions.
- **64.** Patients under temporary care should be given only small supplies of drugs unless they present an unequivocal letter from their own doctor.
- **65.** Prescribers should also remember that their own patients may be attempting to collect prescriptions from other prescribers, especially in hospitals.

Practice Resources

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<u>Appendix 16 – Practice procedure for lost/stolen controlled drug prescriptions</u>

<u>Appendix 17 – Practice procedure for patients where dependence on, or diversion of,</u> <u>controlled drugs has been identified</u>

<u>Appendix 18 – Reporting of controlled drug incidents via cdreporting.co.uk</u> <u>Appendix 23 – Preparation for dose reduction</u>

Identification of Prescription Opioid Dependent Patients

- **66.** Indicators that suggest the possibility of dependence should be explored in those on a long term opioid prescription:
 - Long-term prescribing of opioids for non-cancer conditions.
 - Current or past psychiatric illness or profound emotional trauma.
 - Reports of concern by family members or carers about opioid use.
 - Concerns expressed by a pharmacist or other healthcare professionals about long-term opioid use.
 - Insistence that only opioid treatment will alleviate pain and refusal to explore other avenues of treatment.
 - Refusal to attend or failure to attend appointments to review opioid prescription.
 - Resisting referral for specialist addiction assessment.
 - The repeated seeking of prescriptions for opioids with no review by a clinician.
 - Repeatedly losing medications or prescriptions.
 - Taking doses larger than those prescribed or increasing dosage without consulting the clinician; often coupled with seeking early replacement prescriptions. Associated with continued requests for dose escalations.
 - Seeking opioids from different doctors and other prescribers. This can take place within GP practices, often identifying locum doctors or doctors unfamiliar with their case. This may be associated with attempting unscheduled visits.
 - Obtaining medication from multiple different providers, NHS and private GPs, repeatedly and rapidly deregistering and registering with GPs, seeking treatment for the same condition from both specialists and GP; or seeking treatment from multiple specialists. This may be coupled with a refusal to agree to writing to the main primary care provider.
 - Obtaining medications from the internet or from family members or friends.
 - Resisting referrals to acute specialists about complex physical conditions or failing to attend specialist appointments.
 - Appearing sedated in clinic appointments.
 - Misusing alcohol or using illicit or over-the counter, internet or other prescribed drugs or a past history of alcohol or other drug dependence.
 - Deteriorating social functioning including at work and at home.
 - Resisting or refusing drug screening.
 - Signs or symptoms of injecting opioids or snorting oral formulations.
- **67.** It is sensible to reduce dosages steadily or to issue weekly or daily prescriptions for small amounts if it is apparent that dependence is occurring.

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CONTROLLED DRUGS NEWSLETTER



SHARING GOOD PRACTICE IN THE SOUTH WEST

April 2017 SPECIAL EDITION – FAYE'S STORY

What can happen when things go wrong with prescribing for chronic pain – lessons that must be learned by all healthcare professionals

As told by her parents, Linda and Steve



Faye (right), when she was well

Our daughter Faye injured her back lifting an empty fish tank into a car boot in 2009. Her pain did not resolve, so she was referred for surgery in 2010. This did not go well, and she left hospital still in pain, on oxycodone. As her pain continued, the doses and numbers of medications prescribed increased. Faye put on 7 stone, and developed sleep apnoea, and then in June 2013, she developed diabetes. In September 2013 Faye had a respiratory arrest, and died - she was just 32 years old.

Before Faye injured her back, her life was pretty normal. She worked as deputy manager at a major pet store, and she was planning to get married, and start a family. She and her fiancé both had a horse, and a social life that revolved around this.

Following her operation in May 2010, Faye was taking 80mg oxycodone daily, and by June 2013, she was taking more than 200mg oxycodone daily, along with diazepam, amitriptyline, prochlorperazine, sertraline, diclofenac, esomeprazole and paracetamol. Gabapentin had been tried, and withdrawn. Her symptoms and health problems had become steadily worse as the dose of oxycodone increased, and more medicines were added in to manage the side effects. As well as the pain, she suffered from nausea, sleepiness, fainting, muscle spasms, blistering skin problems and depression. She had become a compulsive home shopper. Despite the prochlorperazine, her nausea was so bad she sometimes could not bear to use the CPAP face mask at night, for her sleep apnoea.

Whilst waiting inpatient rehabilitation (for 20 months), Faye had some sessions of cognitive behaviour therapy from the NHS counselling service, and also started a pain management course. She did show signs of improvement - she managed to lose 3 stone, started to look after her appearance again, and managed to go out for a walk with her Dad. We really thought that

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she had turned a corner, and would finally start getting better. Then out of the blue, she had a respiratory arrest and died.

We believe that her death was avoidable, and that there are still a lot of people like Faye receiving unsafe treatment for long term pain, who are, at worst, at risk of dying suddenly, or at least, of leading a twilight life.

What went wrong?

How did our daughter go from having a normal life in July 2009, to dying suddenly in September 2013? Was the treatment she received to blame? The inquest did not supply the answers that we had hoped for, so we set about trying to find out for ourselves. There are several ways that her medicines could have been doing more harm than good;

- Her dose of oxycodone was repeatedly increased, against the advice of the pain clinic, and despite her pain not being effectively managed by it. It was way above the safe limit, now set at 120mg morphine daily equivalent dose (see Opioids Aware <u>http://www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware</u>
- She was taking oxycodone with diazepam opioid and benzodiazepine medications taken together can lead to respiratory depression, and she already had sleep apnoea <u>https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm518110.htm</u>
- Several of her medicines are known to increase the QT interval, especially in combination – long QT syndrome is a leading cause of sudden cardiac death in young, otherwise healthy people
- Diclofenac there is a small risk of heart attack or stroke in patients taking systemic diclofenac regularly, especially at high doses (150 mg daily) and for long periods
- Erythromycin just before her death, Faye received a course of erythromycin for infected in-growing toenails. There is a small risk that when taken with amitriptyline or prochlorperazine, erythromycin can increase the risk of an irregular heart rhythm. Although Faye was told to stop taking the amitriptyline and prochlorperazine whilst on the erythromycin, the long half-life of amitriptyline may not have been taken into consideration. On the day she died, Faye had texted a friend to say that the erythromycin was making her feel strange
- Faye may have had an allergic reaction to erythromycin her face and upper body were very swollen after death

Any or all of the above could have contributed to Faye's death. Also, given that her MRI scan showed nothing clinically significant, should Faye have been offered the operation on her back? That seemed to make things worse too.

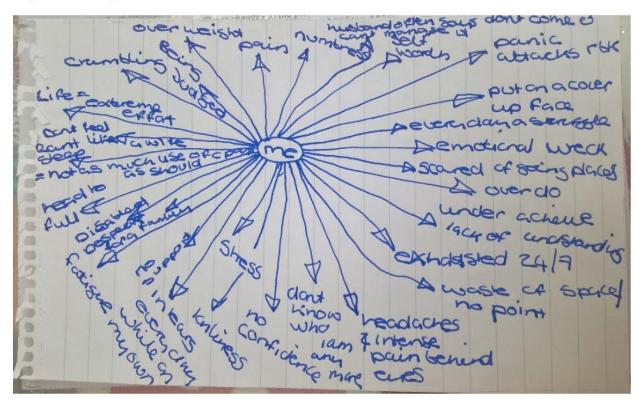
Faye's state of mind

As a nine year old, Faye suffered from a nine month long period of intense pain and illness, which was diagnosed at the time as ME. It left her, as an adult, with a tendency to headaches and joint pains. We don't think that doctors treating her as an adult were aware of this.

Faye put herself under a lot of pressure to succeed in her plans. She was determined and ambitious. Her job was difficult and she worked very long hours. She had to go and look after her horse after work, and got home late most nights.

Faye did not smoke, rarely drank alcohol, and had a real aversion to swallowing tablets. She ended up taking 40-50 tablets a day, using fruit pastilles and grapes to help her swallow them.

When all of this started, if she had been questioned about her mood, and her past experiences of pain, would this have made the doctors think twice about giving her opioids? Or increasing the dose, when they were clearly not working?



Faye's mind map, which was found after she died

What could have been done differently?

Nobody should end up dying of a bad back, especially a young woman like Faye with her whole life ahead of her. Yet we know that there are a lot of people with bad backs, and other sorts of

Page 3 of 4

long term pain. Many are still on high dose opioids, and medicine combinations which may well be doing more harm than good.

We discussed these concerns with the new larger GP practice, which has incorporated Faye's GP practice. They have given this a lot of thought, and have made the following changes, to try to avoid another person like Faye dying unnecessarily.

The GPs at the practice are now focusing on these key learning points:

- Safety issues around opiate prescribing
- The role of oxycodone, and an understanding of the dose equivalence of different opiates
- Alternatives to opiates for managing ongoing pain
- Mechanisms for reducing high doses of medication, e.g. weekly scripts, MOS
- Review of current prescribing in the practice
- Mechanisms for group discussions around difficult to manage cases, including a monthly
 patient safety meeting to review concerns about medication levels

We have thought about what message we want to send out ourselves, as grieving parents, and we believe that all healthcare professionals in every GP practice in the country should think about these points:

- First, do no harm
- Follow evidence based practice
- You have a duty of care
- Do not authorise prescriptions, even on specialist recommendation, if you don't think they are safe

Guidelines are published, and circulated, and yet change in practice is too slow, in the face of new safety evidence. What should your practice be doing differently, today? How could you spot another person like Faye, struggling and failing on their medicines, and save them?

Sue Mulvenna CD Accountable Officer 09.06.17

Appendix 2 – What to discuss with the Patient when considering Opioid Treatment

- Explain that the evidence for the use of opioids as analgesics is best when used in the management of acute pain, over a period of hours from onset but tapering dose over days to a few weeks.
- Explain that opioids are poorly effective for long-term pain. For a small proportion of patients, opioids may be successfully used as part of a broader plan including non-medication treatments and self-management.
- Discuss the degree of pain relief that might be expected and understand that the aim is not complete pain relief but rather reducing pain sufficiently to engage in self-management.
- Agree specific functional goals that might be achieved.
- Discuss the potential harms of opioid treatment including:
 - Sedation
 - o Nausea
 - Constipation
 - Effects on hormones
 - Effects on the immune system
 - Potential for the drugs to worsen pain
 - Potential for problematic drug use and addiction
- Discuss opioids and impairment of driving skills
- Discuss the opioid trial
- Discuss the circumstances in which opioid therapy will be stopped
- Discuss arrangements for review

Appendix 3 - Ten Footsteps Patient Information Leaflet

Ten Footsteps Withp Your Journey to Living Well with Pain

Learning how to manage your pain is a journey. Like any journey, it takes time and everyone's experience is different. We know from people living with pain that there are some things which can be really helpful. We've called these the **Ten Footsteps** and we'll tell you something about them in this leaflet.

Footstep 1: What do we know about persistent pain?

Persistent pain is very different from the kind of pain you experience when you touch something hot or injure yourself. It goes on long after normal healing and repair time, and affects different parts of the brain and nervous system.

The best way of reducing pain is to help your mind and brain to turn it down. *Read the other nine footsteps to find out how to do this.*

Persistent pain can cause a range of problems, including:

- **Excitable nerves**. Slight pressure can cause unpleasant and painful sensations like pins and needles or electric shocks.
- **Sensitivity**. Skin, muscles or nerves can be more sensitive to pressure, touch or heat.
- Faulty brain activity. The systems that turn down pain don't work.
- **Low mood.** Living with persistent pain can cause strong feelings such as anger and frustration.



Accepting persistent pain as part of your everyday life is a huge help. Rather than struggling to avoid or reduce your pain, you can learn to observe, understand and accept it. This is not easy –

it can be hard to accept that you are not the person you were. However, as you accept things have changed, you can switch your energy and focus to living well.

acceptance PACE RACE

Things that help with acceptance:

- Slowly adjust how you do things.
- Try to think and view yourself and life differently.
- Patiently shift your focus to what you really want to do each day.
- Learn how to switch your attention from your pain to other things your breathing, for example.
- Use some techniques from mindfulness, such as mindful stretching.
- Find the best type of support and help.

The long and winding road to acceptance

Footstep 3: Pacing every day for better times

Pacing is taking a break before pain, tiredness or exhaustion force you to stop. Many people use pain to guide their activity levels. On a 'good day' they try to get as much done as possible until their pain and tiredness increase, forcing them to stop and rest for much longer. This is called the 'boom-and-bust' cycle.



Activity - Rest - Repeat!

How to pace well:

- Decide which activities you need to pace. If any daily activities are difficult because of your pain or they cause your pain to increase, they probably need to be paced.
- 2. Work out how much effort to put into each activity without causing more pain. Reduce your activity so that you stop or take a rest long before you would usually experience pain. Then, steadily build up your body stamina by increasing what you do before each break.
- 3. Find the balance of activity and rest breaks so if your body is feeling stiffer, more tired or pain than usual, you can adjust the balance. This means you take more breaks, use less effort or go more slowly or change to an easier activity at that time.

Footstep 4: Set goals, action plans and rewards

Goal setting is about focusing on the things in your life that you want to change. Your goals need to be SMART:

SMART goals

- **S = Specific.** State clearly what you want to achieve.
- **M = Meaningful.** The goals really matter to you.
- A = Achievable. They require some effort but are not too difficult.
- **R = Realistic.** You can fit them into your life.
- T = Time-based. They can be achieved within the next few weeks or a couple of months.

A few examples of SMART goals:

- Read a good book within the next month.
- Pot plants in the greenhouse by the end of the month.
- Try out a new recipe every weekend.
- Go to the next midweek football match with friends.
- Swim and relax in the sauna every week.

Action plans help you work out how to achieve your goal, what you need to do, when you will do it, how often and who else you can involve.

Regular rewards can help you to make progress. Whether big or small, make sure that your rewards are things you really value and make them pleasurable.



To get from A to B... you're going to need a plan!

Footstep 5: Getting fit and staying active

Being more active and building fitness can help – even if it was not really part of your life before pain arrived. Three things are important:

- **1. Stretching** helps loosen tight muscles, ligaments and joints and increases flexibility.
- **2. Strengthening exercises** will build stronger muscles and joints and improve balance.
- **3. Stamina activities** help you to do things for longer without more pain or tiredness.



Footstep 6: Managing moods

It is normal to struggle with moods when you have persistent pain. People often feel angry, frustrated, fearful and unmotivated because of it.



Things that will help you to get fitter and stay active:

- Create SMART goals and an action plan to guide you (see Footstep 4).
- Find out what's available in your local area.
- Choose things that are fun and easy to do.
- Enjoy activities with other people.
- Gently increase the amount of time spent doing activities.
- Give yourself regular rewards.
- Tell others about your progress.



Here are some things that you can do to manage your moods better:

- Notice negative and unhelpful thoughts, and find ways to balance or soothe them.
- Practise balanced thinking imagine what a best friend would say if they knew what you were thinking. Ask yourself, 'Are my thoughts 100 per cent true and believable?'
- Do things that unwind and soothe your mind, such as walking the dog, listening to music and breathing calmly.
- Create a list of positive things you have done that day or week.
- Practise being kind to yourself by pacing and giving yourself pleasurable rewards.
- Learn from others with similar pain issues.
- Find out about self-help resources to manage your moods.
- Share your plans with people you trust and get their support.

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Footstep 7: Sleep well more often



Many people with pain find that their sleep is disrupted. New research shows that by adjusting what you do during the day, as well as night, it is possible to achieve a healthier sleep pattern.



Time for new sleep skills!

Four things are important for better sleep:

- **1. Your daily routines.** Try to go to bed and get up at the same time each day.
- 2. Your activity levels. Increasing activity in the day can help you to sleep better at night. Take care to avoid energetic exercise shortly before sleep.
- **3. Your food and drink habits.** Avoid caffeinated drinks late in the day and big meals late in the evening. You should also avoid drinking too much before bed.
- 4. Your bedtime routine. Follow the same wind-down routine every evening and make sure your bedroom is dark and used only for sleep – don't watch TV or do work in bed!



Footstep 8: Healthy eating, managing relationships and work

Healthy eating

Eating well and having a normal-range weight will help you to build better health and cope well with pain.

There are many things that you can do to help achieve a healthy weight – and they don't always involve a diet! Ask your doctor or pharmacist for a medication review, as some drugs can contribute to weight gain. Reducing portion sizes, cutting out snacks and switching to a Mediterranean diet can help, too.

Managing relationships

Connecting with others can feel like the last thing you want to do when pain dominates your life. Yet doing things with other people is likely to lift your mood and distract you from focusing on your pain. It can also motivate you to do more of the activities you enjoy.



Coping with work

Staying at work or returning to work gives your life routine, structure and purpose. Here are some tips that can help:

- Think about what needs to happen for you to return to work.
- If you are looking for work, be flexible about what you might do.
- Ask for a phased return starting with just two to three hours per day and building up from there.
- Be prepared to accept any support that is offered at work.

Footstep 9: Relaxation and mindfulness

Unwinding your body and mind can make a positive difference to your life and your pain. We know that relaxation and mindfulness lessen pain levels, reduce stress and improve concentration.

Mindfulness is being aware of your body and mind in the 'now'. It's about noticing what you think, feel or want at this moment without being too critical or judging yourself. There is plenty of evidence showing that mindfulness can help us to live better with difficult health problems such as pain.

Like any other skill, mindfulness needs daily practice and guidance to use it confidently. You can learn it from someone who knows about mindfulness, sign up for an internet course or join a local class.

Footstep 10: Managing setbacks

Setbacks are common while managing pain. Having the confidence to deal with them is a 'must have' skill. A setback plan helps you to cope better and reduces the sense of panic that they sometimes cause.



Here are the different types of relaxation that you can practise:

1. Breathing and muscle relaxation. This includes techniques such as 'belly breathing' or tightening and then relaxing parts of the body.

2. Refocusing your attention. You can do this by shifting your attention away from your pain using visualisation techniques.

3. Choosing relaxing activities. Anything that helps you to unwind will be good for your pain, such as reading a magazine, listening to music, walking the dog or doing a puzzle.



Here are some things that you can include in your setback plan:

- Cut back on normal activities for a few days and take more regular breaks.
- Keep gently active and avoid long periods of bed rest.
- Begin gentle stretching as soon as possible to regain flexibility.
- Practise relaxation or mindfulness breathing.
- Try not to get into negative thinking tell yourself this is temporary and you have a plan to get back on track.

Find out more

Discover more ways to manage pain...

Overcoming Chronic Pain self help CBT book, Cole et al, 2005 (ISBN 9781472105738)

Manage your Pain Nicolas et al, 2012 (ISBN 9780285640481)

Pain is Really Strange Steve Haines and Sophie Standing, 2015 (ISBN 9781848192645)

Find out about free books on prescription at libraries at www.reading-well.org.uk

www.painconcern.org.uk

- useful range of videos and sources of help

www.healthtalkonline.org

- people with pain share ways to cope and live well

www.nhs.uk – for guides to healthy eating, exercise, fitness and a pain toolkit resource

www.breathworks-mindfulness.org.uk

- explores mindful practice with courses and resources

www.paincd.org.uk

- audio resource about ways to living with chronic pain

People with pain and clinicians in pain self management have created the *Ten Footsteps* to help you find your feet and start to live well with pain. Contact **info@livewellwithpain.co.uk** with ideas to share or feedback. V1. 02/18 © Live Well with Pain 2018



Appendix 4 – About Pain Patient Information Leaflet



Most of us have experience of everyday pain including headaches, pain from minor injuries and muscular pain for example following exercise. These pains don't last long and often don't need treatment. All pain we feel is affected by how we are feeling generally, our past experience of pain and any concerns we have about the cause of the pain. If we are worried and distressed about how pain may affect us in the future, our pain will feel worse. Also, unpleasant thoughts, feelings and memories (even if these are not to do with pain) can influence how we feel pain. Anxiety, depression, Post-Traumatic Stress Disorder, previous emotional upsets or other mental health problems, are likely to worsen our experience of pain and make it more difficult to treat.

Types of Pain

Pain is usually described as acute (short-term) or chronic (long-term) pain (usually more than three months).

- Acute pain is usually related to an obvious injury such as dental infection, bone fracture or operation.
- **Chronic pain** sometimes begins with an injury but the pain doesn't get better as expected: often it is not clear how a chronic pain has started. Common types of chronic pain include low back pain, pain related to arthritis and pain related to injury to a nerve or other part of the nervous system (neuropathic pain). Chronic pain is usually not a sign of on-going injury or damage but may be to do with changes in the nervous system that occur over time so that the pain signalling becomes self-sustaining over a prolonged period.
- **Cancer pain** is usually described separately and may be short or long lasting. The pain can relate to the cancer itself or the cancer treatment. Additionally, people with cancer may experience acute or chronic pain unrelated to their cancer.

Acute and chronic pain can range from mild or severe with the difference being how long the symptoms last.

Treatments for different types of pain (you may have more than one type of pain)

Acute Pain

Acute pain can be severe but usually gets better quite quickly (days or weeks). Treatments usually only need to be given for a short time while healing of the injury begins. Acute pain is often straightforward to treat with a range of medicines and other treatments depending on how severe the pain is. Opioid medicines are useful for treating acute pain and usually only need to be given for a period of a few days. The dose of opioid should be reduced as healing occurs.

Chronic Pain

Chronic pain can cause low mood, irritability, poor sleep and reduced ability to move around. Unlike acute pain, chronic pain is difficult to treat with most types of treatment helping less than a third of patients. Most treatments aim to help you self-manage your pain and improve what you can do.

Different treatments work for different people. Medicines generally and opioids in particular are often not very effective for chronic pain. Other non-medicine treatments may be used such as electrical stimulating techniques (TENS machine), acupuncture, advice about activity and increasing physical fitness, and psychological treatments such as Cognitive Behaviour Therapy and meditation techniques such as mindfulness.

Helping you understand about chronic pain is important and in particular helping you understand that physical activity does not usually cause further injury and is therefore safe. It is important that you understand that treatments tend not to be very effective and that the aim is to support you in functioning as well as possible.

Neuropathic Pain

Neuropathic pain is a type of chronic pain associated with injury to nerves or the nervous system. Types of neuropathic pain include, sciatica following disc prolapse, nerve injury following spinal surgery, pain after infection such as shingles or HIV/AIDS, pain associated with diabetes, pain after amputation (phantom limb pain or stump pain) and pain associated with multiple sclerosis or stroke. Neuropathic pain is usually severe and unpleasant.

Medicines may be used to treat neuropathic pain but are usually not very effective and work for a small proportion of people. You may not benefit from the first drug tried so you may need to try more than one drug to try and improve symptoms.

Cancer Pain

Cancer pain is usually associated with an obvious source of tissue damage and may be acute or chronic. Neuropathic pain can occur with cancer diagnoses and treatments (such as radiotherapy). Because cancer pain treatment, particularly at the end of life, is often for a short duration, it is usually more successful than chronic pain treatment. People who recover from cancer or who survive a long time with cancer may have pain that is more difficult to treat.

Appendix 5 – Thinking about Opioid Treatment for Pain Patient Information Leaflet



Pain is complicated and influenced by many factors, including:

- how you are feeling in general
- your previous experience of pain
- your understanding of why you have pain and any worries you have about it
- how you deal with your pain and how your pain affects your life

Pain that doesn't get better tends to cause distress, tiredness and irritability. Your sleep may also be affected and it can cause problems with daytime activities and moving around. Because of this, it can also affect relationships with friends and family.

You should discuss, with your doctor, what you expect from the treatment. It is easier to treat pain after surgery or an injury with painkiller medicines; however it is rarely possible to relieve long-term pain completely by using painkillers. The aim of treatment is to reduce your pain enough to help you get on with your life. In trials most medicines for long-term pain only benefit around one in every four or five people and on average only provide 30% reduction in pain.

Medicines work best if you combine them with other ways of managing symptoms such as regular activity and exercise, and doing things that are satisfying or enjoyable, such as work or study, and social activities. Setting goals to help improve your life is an important way to see if these drugs are helping.

'Why don't my painkillers work?' is a commonly asked question, and often one without any easy answers. Long-term pain arises through many different mechanisms, and most drugs only work for one of these. Some pains do not seem to respond to any painkilling medicines. You can get used to painkillers, including opioids, so that you need more and more to have the same effect (this is called building up tolerance.) However, we know that high doses of opioid medicines taken for long periods are unlikely to give better pain relief and are associated with a number of problematic adverse effects.

You should also consider:

- if you are allergic to any drugs or medicines
- if you are taking any other medicines or herbal medicines
- if you are pregnant or breast feeding, or if you are planning to become pregnant in the future
- if you have a kidney problem
- if you have or have had a history of excessive alcohol use, recreational drug use or addiction to prescribed or over-the-counter medication

Appendix 6 – Pain Diary

Pain Diary

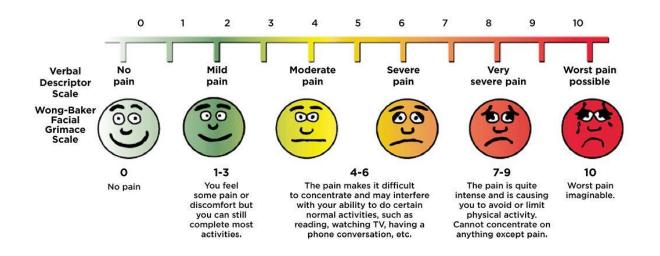
Your doctor, nurse or pharmacist will explain to you how to take your pain relief medications.

This diary will help you and your doctor, nurse or pharmacist to decide whether the pain relief medications you take are suitable for you.

Please fill in the pain diary every time you take your pain relief medication or at least twice a day.

When you fill in your pain intensity please use the pain assessment tool below to help you describe the pain you are experiencing.

Record your pain intensity just before taking your pain relief medications, take your medications, then wait 30 – 60 minutes and record your pain intensity again.



Please keep a note of any side effects that your pain relief medications cause and how the pain is affecting your daily activities such as stopping you doing activities, or limiting how far you can walk.

Please bring the completed pain diary to the next appointment for your pain. You and your doctor, nurse or pharmacist can use the information you record to decide if your pain relief medications are right for you.

Date and time	Name of medication and dose taken	Pain intensity before taking pain relief	Pain intensity after taking pain relief	Any side effects? What are they?	Is your pain affecting daily activity? In what way?	Was my sleep disturbed by pain?
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Appendix 7 - Opioid Management Plan: Treatment Agreement

Patient Name:

NHS number:

Condition(s) being managed with opioids:

New opioids being commenced as this agreement is being implemented:

(This is for a trial period during which the prescriber will need good evidence of improvement in function to embark on long term treatment)

Period before next mandatory review:

(For new trials 2-4 weeks, for long-term prescription 6–12 months)

Patient Declaration

In signing this agreement, the patient agrees to the following conditions regarding his/her treatment and the prescribing of an opioid medication:

- 1. I have read the Thinking About Opioid Treatment For Pain and Taking Opioids For Pain information leaflets and I will tell my GP if I experience on-going/intolerable side effects.
- 2. My GP is responsible for prescribing a safe and effective dose of the opioid medication. My GP will control my dose, perhaps with advice from one or more hospital specialist in a condition relevant to my pain.
- 3. I will follow the directions given to me by my GP; I will not increase my dose and will discuss any changes in my dose with my GP.
- 4. I will not use any other opioids in addition to those prescribed by my GP.
- 5. I will only obtain my opioid medication from my GP.
- 6. I understand that no early prescriptions will be provided.
- 7. Any evidence of unsafe use such as: drug hoarding, acquisition of any opioid medication or other pain medication from other sources, uncontrolled dose escalation, loss of prescriptions, or failure to follow the agreement may result in termination of the agreement and withdrawal of opioids.
- 8. I am responsible for the security of my opioid medication at home. Lost, misplaced or stolen medication or prescriptions for opioid medicines may not be replaced. In the event that opioid medication is stolen, I will report this to the police.
- 9. I am aware that giving my opioid medication to other people is illegal and could be dangerous to them.
- 10. I understand that if my level of activity has not improved, I do not show a significant reduction in my pain, or if I fail to comply with any of the conditions listed above my opioid prescription may be changed or stopped.

Patient's Signature:	. Date:		
Medical Practitioner's Signature:	Date:		

Appendix 8 – Taking Opioids for Pain Patient Information Leaflet



How do Opioids Work?

Opioids provide pain relief by acting on areas in the spinal cord and brain to block the transmission of pain signals. Opioids are considered to be some of the strongest painkillers available and are used to treat pain after surgery, serious injury and cancer. Opioid drugs can help manage some but not all types of chronic pain.

How are Opioids Taken?

Opioid medicines come in many different forms, such as injections, tablets, capsules, liquids, and patches.

When should I take my Opioid Medicines?

For continuous long-term pain you may be given a slow-release tablet which gives a steady level of medicine in the blood that is the best way to manage pain. Your healthcare team will adjust the dose to give you pain relief most of the time, and so you don't get too many side effects. Fast-acting opioid medicines and opioids that can be injected are not very useful for managing continuous pain.

What dose of Opioid should I take?

The correct dose of any medicine is the lowest dose that produces a noticeable benefit. It is not usual to get complete relief of pain from opioids.

You should always take the correct dose of prescribed medicines. If you feel the dose isn't enough, or if the side effects interfere with your life, you should discuss this with your healthcare team.

How long will it take to work?

This depends on the form that has been prescribed. Long-term pain tablets or skin patches are prescribed most commonly. Fast acting tablets may be used when you first start trying opioid treatment. They may work within an hour and last for around three to four hours. Slow release tablets or patches take longer, up to two or three days to begin to have any noticeable effect.

What are the possible side effects?

When you first start taking opioids you can get some side effects, which usually stop after a few days. These include:-

- feeling dizzy
- feeling sick (nausea)
- being sick (vomiting)
- feeling sleepy
- feeling confused

Sometimes these side effects can go on for longer than a few days. Your healthcare team may give you some other medicines to help, such as anti-sickness tablets. If pain has affected your sleep, opioids may help you to recover your normal pattern of sleep, but they should not make you drowsy in the daytime.

Opioid medicines can cause some problems when you take them for long periods of time. These problems include:-

- constipation*
- itching
- weight gain
- lack of sex drive
- difficulty breathing at night**

* This is a common problem when taking opioids and does not tend to go away the longer you take opioid medicines. You may need to try laxatives to treat constipation. If you experience a lot of side effects your team may suggest changing to another opioid drug.

* This is most common if you are overweight and if you snore heavily. If you have a condition called obstructive sleep appoea it may not be safe for you to take opioids.

Can I drive when I'm taking Opioids?

The law in the UK allows you to drive if you are taking prescribed opioid medicines in accordance with the instructions from your prescriber (including what your prescriber advises you about driving safely). You should never drive if you feel unsafe. Your ability to drive may be affected by other medicines you are taking in addition to opioids, whether you feel tired and by your pain. You are responsible for making sure you are safe on each occasion that you drive.

The law on drugs and driving in the UK changed in 2015. If your driving is impaired for any reason, including taking medicines, it is illegal to drive. It is also now illegal to drive when you are taking opioid medicines without them being prescribed, even if you are not impaired. Preparation for the new drug driving laws involved extensive scientific research to investigate what effect opioid drugs have on ability to drive safely. We now know that if a person is taking more than 220mg of morphine a day they are likely to have a blood level of the medicine which impairs them nearly as much as someone who is over the legal limit of alcohol. All opioid medicines have the potential to impair driving and your prescriber will advise whether the dose of opioid you are taking is likely to impair you. If you are taking a high dose of opioid your prescriber will advise you that you are probably not safe to drive and will document this in your medical notes.

The doses of opioid medicine that are likely to affect your driving are quite high and are above the level that we know is safe and effective for pain treatment.

It is unsafe to drive in the first few days after starting an opioid and for a few days after dose change (up or down). Drinking alcohol reduces the amount of opioid medicine you can take and drive safely so do not drive if you have drunk alcohol and taken opioid medicines.

What if I forget or miss a dose?

Take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your medication as normal.

Do not take two doses together.

Can I take this medicine long-term?

While opioids can have a positive benefit for some people living with long-term pain they can have serious consequences when they are not providing sufficient benefit or are being taken in a manner that was not intended.

It is important to consider the risks and benefits of continued opioid therapy with your prescriber on a regular basis. Recent medical literature suggests that the risks to your health increase significantly when prescribing opioids at high doses for a long period of time. If you take opioid drugs for many months or years it can affect your body in a number of ways. These problems include:-

- reduced fertility
- low sex drive
- irregular periods
- erectile dysfunction in men (the inability to keep an erection)
- reduced ability to fight infection
- increased levels of pain

If you are worried about any of these problems, please discuss this with your healthcare team. Your team will be able to tell you whether you are at risk of developing these problems.

Everyone prescribed opioid medicines in the long-term should have them reviewed by their prescriber at regular intervals. If this does not happen ask your General Practitioner.

If you want to try reducing your dose, you should discuss this with your doctor and bring the dose down slowly.

Many people find that after a few months they can reduce their opioid dose without the pain increasing. Many individuals are able to reduce gradually their opioid dose and find that their pain is no worse. As fewer side effects are experienced, quality and enjoyment of life can improve. All of this contributes to greater physical fitness.

Can I drink alcohol?

Alcohol and opioids can both cause sleepiness and poor concentration. You should avoid alcohol completely when you first start on opioids or when your dose has just been increased. If you are taking opioids, you should avoid alcohol if you are going to drive or use tools or machines. When you get on a steady dose of opioid, you should be able to drink modest amounts of alcohol without getting any extra unusual effects.

Will my body get used to Opioid Medicines?

Opioids can become less effective with time (this is called tolerance) meaning your body has got used to the pain relieving effect of the medicine.

You can also become dependent on opioid medicines (dependence). This means that if you stop taking the drug suddenly, or lower the dose too quickly, you can get symptoms of withdrawal. If you run out of medicine, you can experience the same symptoms that include:-

- tiredness
- sweating
- a runny nose
- stomach cramps
- stomach cramps
- diarrhoea
- aching muscles

What about addiction to Opioids?

It is rare for people in pain to become addicted to opioids. People who are addicted to opioids can:-

- feel out of control about how much medicine they take or how often they take it
- crave the drug
- continue to take the drug even when it has a negative effect on their physical or mental health

We do not know exactly how many people get addicted when they are taking opioids for pain relief but it is very uncommon. It is more common if you have been addicted to opioids (including heroin) or to other drugs (or alcohol) before. Addiction may be more common in people with severe depression or anxiety. This does not mean that if you have had an addiction problem before or you are very depressed and anxious you will become addicted. It only means that you are more likely to become addicted than someone who has not had these problems. Most people do not become addicted.

So, if you have had a problem with drug or alcohol addiction in the past this doesn't mean that you cannot take opioid medicines for your pain. However, your healthcare team will need to know about your past or current drug-taking to prescribe opioids safely and to help you watch out for warning signs.

What if I want to stop taking an Opioid?

Do not stop taking your opioid suddenly, you may experience withdrawal symptoms. Speak to your healthcare professional (doctor, nurse, pharmacist) who will be able to supervise a gradual reduction.

Is there anything else my prescriber needs to know?

- If you are allergic to any drugs or medicines
- If you are taking any other medicines or herbal medicines
- If you are pregnant or breast feeding, or if you are planning to become pregnant in the future
- If you have a kidney problem
- If you have or have had a history of excessive alcohol use, recreational drug use or addiction to prescribed or over-the counter medication.

Appendix 9 – Driving and Pain Patient Information Leaflet



Am I able to drive whilst taking medications prescribed for pain? Yes, but only if your ability to drive is not impaired.

Medications prescribed to help manage pain may cause side-effects such as dizziness or sleepiness and so may impair your driving.

It remains the responsibility of all drivers to decide whether they consider their driving is, or might be impaired on any given occasion. Do not drive if this is the case. Sometimes your doctor may advise you not to drive. If this is the case, even if you do not feel impaired, you must not drive as it is against the law to do so.

What symptoms may mean I cannot drive safely?

Do not drive if you experience symptoms that may impair your driving such as sleepiness, poor coordination, impaired or slow thinking, dizziness or visual problems.

These symptoms can occur as side effects of medication, but be aware that pain itself can also affect sleep, concentration and impair physical function.

When might I be at risk of my driving being impaired?

This includes the following circumstances that may increase the risk of your driving being impaired:

- When first starting a new pain medication
- When increasing or reducing the dose of pain medication
- If another prescribed medication is added that could also impair your driving
- If you take an over the counter medicine that could also impair your driving
- If you have a pain condition that could physically impair your driving

Be aware that alcohol taken in combination with some pain medications can substantially increase the risk of accidents.

Do I need to inform the DVLA when I start a new medication?

You do not need to routinely inform the DVLA when you start medications for pain. However, there may be other information about your illness that the DVLA needs to know. Your doctor or the DVLA can advise you about this.

Do I need to inform my Motor Vehicle Insurance Company?

We would strongly advise you to inform your motor vehicle insurance company about your current state of health and what medication you are taking to ensure your motor insurance is valid.

The 'Drug Driving' law

If you have been prescribed one of the following medications you may be affected by this law: morphine or related drugs (such as codeine, tramadol or fentanyl), ketamine, clonazepam, diazepam, methadone, oxazepam, temazepam, lorazepam, flunitrazepam, amphetamine (e.g. dexamphetamine or selegiline), cannabinoids (e.g. sativex).

From 2015 there is a new offence of driving above a specified limit for these medications (like the current rules on alcohol and driving). If you are stopped and tested by the police you may test above the legal limit - depending on the dose you have been prescribed or the type of medicine.

If you are taking these medications in line with advice from a Doctor or Pharmacist **and your** *driving is not impaired* you may use a 'medical defence'.

If the police are satisfied that a driver is taking the relevant medicine on the advice of a healthcare professional, and their driving is not impaired, they should not be prosecuted.

It may be useful for you to keep suitable evidence with you (such as a copy of your clinic letter and prescription) to show the police if you are ever stopped.

However, if your doctor feels it is not safe for you to drive and you continue to do so, you will be breaking the law.

The following government website provides further information on the drug driving law: https://www.gov.uk/drug-driving-law

NICE Guidance	Non-pharmacological options	First choice medications	Alternative options
Low back pain (NG59)	Self-management Information on nature of low back pain and	NSAIDs	Consider weak opioids (with or without paracetamol) for managing
Do Not Do statements:	sciatica.		acute low back pain only if an NSAID
	Encouragement to continue with normal		is contraindicated, not tolerated or
Do not offer paracetamol	activities.		has been ineffective.
alone for managing low			
back pain.	Non-pharmacological options Exercise for people with a specific episode or		
Do not routinely offer	flare-up of low back pain with or without sciatica.		
opioids for managing	Manual therapy (spinal manipulation,		
acute low back pain	mobilisation or soft tissue techniques such as		
	massage) for managing low back pain with or		
Do not offer opioids for	without sciatica, but only as part of a treatment		
managing chronic low	package including exercise, with or without		
back pain.	psychological therapy. Combined physical and psychological		
Do not offer selective	Combined physical and psychological programme, incorporating a cognitive		
serotonin reuptake	behavioural approach (preferably in a group		
inhibitors, serotonin–	context that takes into account a person's		
norepinephrine reuptake	specific needs and capabilities), for people with		
inhibitors or tricyclic	persistent low back pain or sciatica:		
antidepressants for	when they have significant psychosocial		
managing low back pain.	obstacles to recovery (for example, avoiding		
Do not offer	normal activities based on inappropriate beliefs about their condition) or		
anticonvulsants for	when previous treatments have not been		
managing low back pain.	effective.		
	Promote and facilitate return to work or normal		
	activities of daily living for people with low back		
	pain with or without sciatica.		
	, , , , ,		

Appendix 10 – Summary of NICE Guidance related to Pain Relief and Opioids

NICE Guidance	Non-pharmacological options	First choice medications	Alternative options
Osteoarthritis (CG177)	Self-management Offer accurate verbal and written information to	Paracetamol	If paracetamol or topical NSAIDs are insufficient for pain relief then the
Do Not Do statements: Do not offer rubefacients	all people with osteoarthritis to enhance understanding of the condition and its management, and to counter misconceptions,	Topical NSAIDs for people with knee or hand	addition of opioid analgesics should be considered. Risks and benefits should be considered, particularly in
Do not offer glucosamine or chondroitin products	such as that it inevitably progresses and cannot be treated	osteoarthritis	older people
Do not offer intra-articular hyaluronan injections	 Non-pharmacological options Core treatments to all people with clinical osteoarthritis: Access to appropriate information Activity and exercise (should include local muscle strengthening and general aerobic fitness). Interventions to achieve weight loss if the person is overweight or obese Use of local heat or cold Manipulation and stretching particularly for osteoarthritis of the hip. Advice on appropriate footwear for people with lower limb osteoarthritis. People with biomechanical joint pain or instability should be considered for assessment for bracing/joint supports/insoles Transcutaneous electrical nerve stimulation (TENS) Assistive devices (for example, walking sticks and tap turners) for people who have specific problems with activities of daily living. 	Topical capsaicin for knee or hand osteoarthritis.	Where paracetamol or topical NSAIDs are ineffective for pain relief for people with osteoarthritis, then substitution or addition of an oral NSAID/COX-2 inhibitor should be considered. Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.

NICE Guidance	Non-pharmacological options	First choice medications	Alternative options
Neuropathic pain (CG173) Do Not Do statement: Do not start the following to treat neuropathic pain in non-specialist settings, unless advised by a specialist to do so: • cannabis sativa extract • capsaicin patch • lacosamide • lamotrigine • levetiracetam • morphine • oxcarbazepine • topiramate • tramadol long-term • venlafaxine • sodium valproate		Amitriptyline, duloxetine, gabapentin or pregabalin Trigeminal neuralgia carbamazepine	Consider tramadol only if acute rescue therapy is needed Consider capsaicin cream for people with localised neuropathic pain (except trigeminal neuralgia) who wish to avoid, or who cannot tolerate, oral treatments

NICE Guidance	Non-pharmacological options	First choice medications	Alternative options
Tension headache (CG150)		Aspirin (not if under 16), paracetamol or an	
Do Not Do statement:		NSAID	
You should not be offered an opioid to treat tension-type headache.			
Migraine (CG150) Do Not Do statements: You should not be offered an ergot or an opioid to treat migraine.		Triptan together with either an NSAID or paracetamol	If you prefer to take only 1 drug, they may offer you a triptan, an NSAID, high-dose aspirin or paracetamol.
Do not offer gabapentin for the prophylactic treatment of migraine			
Cluster headache (CG150)		Oxygen and/or a triptan	
Do Not Do statement: You should not be offered paracetamol, an NSAID, an opioid, an ergot or a triptan in tablet or capsule form to help relieve cluster headache.			

NICE Guidance	Non-pharmacological options	First choice medications	Alternative options
Medication overuse headache (CG150)		Stop all headache medications at the same time for at least one month	
Rheumatoid arthritis (NG100)	Non-pharmacological options Physiotherapy Occupational therapy Hand exercising programmes Podiatry Psychological interventions	Conventional disease-modifying anti-rheumatic drugs (DMARDs)	Biological and targeted synthetic DMARDs Short-term glucocorticoids for managing flares.
			NSAIDs or COX-2 inhibitors when control of pain or stiffness is inadequate.

Appendix 11 – Useful Read Codes

- Chronic pain 1M52
- Chronic pain review 66n
- Patient counselled 6721
- Medication stopped ineffective 8BI7
- Doctor stopped drug ineffective 8B350
- Treatment not tolerated 817
- Opioid drug dependence E240z
- Non-dependent opioid abuse E255z
- Poisoning by opioids SyuFB
- Drug dosing regime 8B3A4
- Treatment plan given 8BC1

Appendix 12 – Letter inviting patients for review

Sample Letter Inviting Patients for Review

[Practice name] [Address] Dear [Title] [Surname]

New National Guidance requires that all patients prescribed high dose opioid type pain killers for long term pain must be reviewed. All GPs in Pennine practices have been asked to undertake this work.

This practice follows the latest advances in medical research and continually updates our clinical practice to ensure patient care is of the highest standard. Recent research has highlighted a significant risk to patient safety around the use of opioid type painkillers, such as morphine, oxycodone or fentanyl for long term pain.

We know that these drugs are helpful in pain of recent onset for example a broken bone, surgery or in patients with cancer related pain.

However, recent medical evidence questions the benefit of opioid type painkillers for long term pain. National guidance now advises high doses should not be prescribed long term. Strange as it might sound – we don't think opioid type pains killers are good at killing pain at all when taken for more than a few months. There are some risks too – they can

- sometimes make pain worse
- cause side effects to the intestines and the stomach
- make the body feel dependent on them so if you miss a dose you feel a bit jittery and anxious
- increase the risk of falls
- there's even a risk of overdose and death, especially if taken in overdose with alcohol, pregabalin or benzodiazepines like diazepam.

Our records suggest that you are being prescribed high dose of opioids for long term pain (please tell us if that's incorrect) and, because we don't want our patients put at risk, we would like to see you to discuss weaning off these medicines and new methods of managing long term pain with less emphasis on drug therapy. Please see enclosed leaflet on managing long term pain – Ten Footsteps and follow the link to <u>Sean's Story</u>. [https://tinyurl.com/ y23ykfl7]

Please book a face to face appointment with a doctor we'll work together towards a safer, more effective treatment plan. Please note that a safe reduction schedule will be initiated at your next prescription.

Yours sincerely Dr XXX and partners

Appendix 13 – Letter suggesting Drug Holiday

[Practice name] [Address] [Tel] [Fax] [Email] [Date]

[Title/Initial/Surname] [Patient Address Block]

Dear [Title] [Surname]

You have been given this information sheet because you have been taking painkillers for a time. We are particularly talking about painkillers in the opioid class like co-codamol, co-dydramol, codeine, dihydrocodeine and buprenorphine patches.

Recent medical evidence questions the benefit of drugs like this (which are in the morphine family) for long-term pain. Strange as it might sound – we don't think they are very good at killing pain at all when taken for more than a few months.

There are some risks too – they can

- sometimes make pain worse
- cause side effects to the intestines and the stomach
- make the body feel dependent on them so if you miss a dose you feel a bit jittery and anxious
- increase the risk of falls
- there's even a risk of overdose and death, especially if taken in overdose with alcohol or benzodiazepines like diazepam.

For these reasons we suggest you try a "drug holiday" This means you taper off and stop your painkillers over a month or so to see for sure whether they're helping or not. It's not unusual for pain to flare up a bit when doses are reduced and discontinued but that's to be expected. Once you're off them for a month you'll have a good idea as to whether they're making a positive difference to your life. If they are, feel free to restart them – try to find the lowest dose that works. For those on buprenorphine patches, ask the surgery for lower strength patches and reduce the dose every 2-4 weeks until you are off them.

If you've got any questions about this feel free to make an appointment with a doctor of your choice to discuss.

Best wishes and good luck!

Medical Team

Appendix 14 – Opioid Policy - New Patients

A **controlled** substance is generally a **drug** or chemical whose manufacture, possession, or use is regulated by the government because of the potential for abuse or addiction. Such **drugs** include those classified as narcotics, stimulants, depressants, hallucinogens, and cannabis.

A list of the most commonly encountered controlled drugs can be found at:

https://www.gov.uk/government/publications/controlled-drugs-list--2

Many of our patients require strong, potentially addictive medication to help manage their condition(s). Of concern are 'drugs of dependence' (e.g. opioid medications and benzodiazepines), particularly when these are prescribed on an on-going basis.

Due to increasing reports of abuse of prescription drugs and patient behavioural problems, **[insert practice name]** has established a policy to ensure adequate treatment of your condition, while reducing the risk of problems with drug prescriptions.

If you are a new patient to the practice:

- It may take time to get accurate medical information about your condition. Until such information is available, your GP may choose not to prescribe any medication. It is our policy that GPs do not prescribe drugs of dependence until they have a full clinical picture.
- Your GP may decide not to continue prescribing an opioid medication previously prescribed for you. It may be determined that such a medication is not suitable. It is our policy that GPs do not prescribe drugs of dependence if they feel that previous prescriptions were inappropriate.
- Your GP will evaluate your condition and only prescribe an opioid of the strength necessary for you. This may be different to the drug you had prescribed at your previous GP Practice.

General practice standards:

- If the decision to prescribe is taken after a shared discussion of goals, plans, risks and benefits, you may be required to confirm your consent in writing.
- You will be asked to complete the Opioid Management Plan: Treatment Agreement that will detail our practice's expectations when prescribing drugs of dependence. This agreement details your responsibilities as a patient taking a drug of dependence; any prescriptions issues; advice on taking your medications; how we will monitor your care; and the standards of behaviour that are expected.
- Patients may need to acknowledge that their care requirements may be complex, and that referral for on-going care for all or part of your healthcare may be required. It is our practice policy that patient care is matched with the level of complexity.
- Patients are reminded that we have a zero tolerance on issues relating to staff abuse.

Appendix 15 – Opioid Policy – Issuing Prescriptions

A **controlled** substance is generally a **drug** or chemical whose manufacture, possession, or use is regulated by the government because of the potential for abuse or addiction. Such **drugs** include those classified as narcotics, stimulants, depressants, hallucinogens, and cannabis.

A list of the most commonly encountered controlled drugs can be found at:

https://www.gov.uk/government/publications/controlled-drugs-list--2

Many of our patients require strong, potentially addictive medication to help manage their condition(s). Of concern are 'drugs of dependence' (e.g. opioid medications and benzodiazepines), particularly when these are prescribed on an on-going basis.

Due to increasing reports of abuse of prescription drugs and patient behavioural problems, **[insert practice name]** has established a policy to ensure adequate treatment of your condition, while reducing the risk of problems with drug prescriptions.

- Patients initiated on opioids will be asked to complete the Opioid Management Plan: Treatment Agreement.
- All new opioids will be issued as acute prescriptions.
- Wherever possible, patients will see the same Prescriber for review of the initial prescription.
- Where opioids are initiated by an external provider the Practice will only take over prescribing once a written request has been received.
- All patients will be reviewed within 4 weeks of initiation of an opioid prescription; pain assessed and a decision made as to the effectiveness of the drug.
- Whilst patients are being stabilised on medication this will be issued as an acute prescription.
- Where opioids are ineffective they will be stopped, even if no alternative is available.
- Where patients have been stabilised on an opioid which has been shown to be effective this may be added to the patients repeat medication at the prescribers discretion.
- Where opioids are added to repeat prescription the maximum re-authorisation period will be 6 months.
- Patients on long-term opioids will be reviewed every 6 months. Treatment will only be continued where there is on-going evidence of benefit.
- All opioids will be issued on prescriptions with a maximum duration of 1 month.
- All opioid prescriptions will include full directions wherever possible and use of PRN or MDU directions will be avoided.

Appendix 16 – Practice procedure for lost/stolen Controlled Drug Prescriptions

A **controlled** substance is generally a **drug** or chemical whose manufacture, possession, or use is regulated by the government because of the potential for abuse or addiction. Such **drugs** include those classified as narcotics, stimulants, depressants, hallucinogens, and cannabis.

A list of all controlled drugs can be found at:

https://www.gov.uk/government/publications/controlled-drugs-list--2

For all controlled drugs which includes: benzodiazepine, codeine, dihydrocodeine or a product containing one of these drugs e.g. (Co-codamol, Kapake) in addition to the drugs in the link above:

- 1. The loss or theft of a controlled drug prescription must be recorded in the patients' medical record and a READ code added to enable the Practice to monitor/audit.
- 2. If the prescription is stolen, the patient or the Practice must report the incident to the police and provide the Practice with a crime number.
- 3. The loss or theft of a controlled drug or prescription must be reported to the CD Accountable Officer via <u>www.cdreporting.co.uk</u>
- 4. If Practices need to send out an alert regarding lost or stolen prescriptions, this can be done by sending an alert template to: <u>ENGLAND.EnglandCASalerts@nhs.net</u> the alert template can be downloaded from Sharepoint:

http://sharepoint.wiganboroughccg.nhs.uk/sites/wbccg/gp_section/Meds%20Mgmt/Forms/ AllItems.aspx

- 5. The Practice must review the patient's records when considering if it is appropriate to re-issue a prescription. Notes should be assessed to identify if there is a pattern of regularly requesting additional prescriptions. Practices may consider reviewing ordering patterns for immediate family and household members when considering patterns of behaviour. If a pattern is identified this could indicate an underlying problem such as abuse, diversion or a safeguarding issue, report via cdreporting.co.uk and refer as appropriate.
- 6. The patient should be invited in for review and the appropriate steps taken.
- 7. Practices may issue a small supply of medication to cover the period until the patient attends.
- 8. At the review, Practices should review the appropriateness of the current prescription and steps that can be taken to support the patient such as:
 - Reducing and withdrawing medication
 - Reducing script duration e.g. weekly prescriptions
 - Discussion about future action should there be further issues
 - Working with the community pharmacy e.g. if prescriptions are being stolen could the pharmacy collect prescriptions on the patient's behalf, use of EPS when this module is activated.

Appendix 17 – Practice Procedure for Patients where dependence on, or diversion of, Controlled Drugs has been identified

A **controlled** substance is generally a **drug** or chemical whose manufacture, possession, or use is regulated by the government because of the potential for abuse or addiction. Such **drugs** include those classified as narcotics, stimulants, depressants, hallucinogens, and cannabis.

A list of all controlled drugs can be found at:

https://www.gov.uk/government/publications/controlled-drugs-list--2

For all controlled drugs which includes: benzodiazepine, codeine, dihydrocodeine or a product containing one of these drugs e.g. (Co-codamol, Kapake) in addition to the drugs in the link above:

- 1. If it has been identified that patients are either dependent on, or diverting, controlled drug prescriptions this must be recorded in the patient's medical record and a READ code added to enable the Practice to monitor/audit.
- 2. The diversion of a controlled drug or prescription **must** be reported to the CD Accountable Officer via <u>www.cdreporting.co.uk</u>
- If practices need to send out an alert regarding lost or stolen prescriptions, this can be done by sending an alert template to: <u>ENGLAND.EnglandCASalerts@nhs.net</u> the alert template can be downloaded from Sharepoint: <u>http://sharepoint.wiganboroughccg.nhs.uk/sites/wbccg/gp_section/Meds%20Mgmt/Forms/ AllItems.aspx</u>
- 4. The Practice must review the patient's records when considering if it is appropriate to continue to prescribe controlled drugs for the patient. Practices may consider reviewing ordering patterns for immediate family and household members when considering patterns of behaviour.
- 5. The patient should be invited in for review and the appropriate steps taken.
- 6. Practices may issue a small supply of medication to cover the period until the patient attends.
- 7. At the review, Practices should review the appropriateness of the current prescription and steps that can be taken to support the patient such as:
 - Reducing and withdrawing medication including an enforced wean
 - · Reducing script duration e.g. weekly or daily prescriptions
 - Discussion about future action should there be further issues
 - Referral to substance misuse services

Appendix 18 – Reporting of Controlled Drug Incidents via cdreporting.co.uk

- 1. All Practices need to be registered to report controlled drug incidents via the CD reporting tool. Register here: <u>https://www.cdreporting.co.uk/reporting_v2/register</u>
- 2. All controlled drug incidents should be reported via the cdreporting.co.uk tool. Please note: a controlled drug incident may occur within your Practice or be reported by a third party.
- 3. A controlled drug incident which you need to report includes:
 - Prescribing errors; before or after they reach the patient
 - Administration errors
 - Dispensing errors
 - Theft or diversion of prescriptions or drugs
 - Incorrect storage or stock control
 - Safeguarding
- 4. Every year you will need to submit an annual declaration for controlled drugs via the reporting tool and disclose whether any staff member has been cautioned or charged by the Police in relation to a controlled substance.
- 5. If you need to have controlled drugs on your premises destroyed there is a module on cdreporting.co.uk to book an authorised witness destruction.

Appendix 19 Dose equivalence table (values are approximate - see notes below)

Morphine	Oxycodone	Fentanyl Matrifen*	Buprenorphine	Codeine Phosphate / Dihydrocodeine	Tramadol	Tapentadol Palexia [®] SR
Oral	Oral	Transdermal	Transdermal	Oral	Oral	Oral
(mg)	(mg)	Patch	Patch	(mg)	(mg)	(mg)
		(mcg / hr)	(mcg / hr)	(0,	,	(0,
24hr total dose	24hr total dose	Patch strength STABLE PAIN ONLY	Patch strength STABLE PAIN ONLY	24 hr total dose	24hr total dose	24hr total dose
5				60	50	
10			5 Butrans [®]	120	100	
15					150	
20	10		10 Butrans [®]	240	200	
30	15				300	
40	20	12	20 Butrans [®]		400	100
60	30		35 Transtec [®]			
80	40					200
100	50	25	52.5 Transtec*			
120	60					300
If patient is		f pain despite opi	oids at this level, then	mended in chronic opioids are not workin		e reduced and
140	70	stopped eve	n if there is no other tr 70 Transtec*	eatment available		
160	80					400
180	90	50	105 Transtec*			
200	100					500
240	120	62				
280	140	75				
320	160		140 Transtec*			
360	180	100	140 Iranstec			

Each row is roughly equivalent e.g.: 60mg bd oral morphine = 30mg bd oral oxycodone = 25mcg/hr fentanyl patch

NB: This is to be used as a guide rather than a set of definite equivalences. Some doses suggested may be 'offlicence', but are based on clinical experience. Refer to the <u>Summary of Product Characteristics</u> for further details . Most data on doses is based on single dose studies so it may be less accurate in chronic use where similar data is unavailable. Consider that individual patients may metabolise different drugs at varying rates. **The advice is to always calculate doses using morphine as standard and to adjust them to suit the patient and the situation – consider making a reduction in morphine equivalence dose of 20 - 50% when changing drugs.** Caution should be used in renal and hepatic failure. Avoid patch use in unstable pain.

Morphine Reduction Schedule

- 120mg oral morphine equivalent/24hours is the dose above which harms outweigh benefits. THIS IS NOT A TARGET DOSE - *if a patient is using opioids but is still in pain, the opioids are not effective and should be discontinued even if no other treatment is available.*
- The rate of withdrawal should be individualised according to the dose, and duration of treatment. Patient factors such as personality, lifestyle, previous experience and specific vulnerabilities should also be taken into account.
- Agree outcomes of opioid tapering. Throughout the process it is important to provide advice on pain management and expectations of treatment.
- Medications are usually a small part of the pain management plan and should be used in conjunction with non-pharmacological interventions such as advice regarding activity, physiotherapy and an explanation that pain may be resistant to medication and complete relief of symptoms is not a goal of therapy.
- At each stage enquire about general progress and withdrawal symptoms.
- If patients experience difficulties with a dose reduction, encourage them to persevere and suggest delaying the next step down by one week. *Do not revert to a higher dosage.*
- Offer information leaflets to help with the withdrawal programme.
- Reassure patients that if they are experiencing any difficulty with the withdrawal schedule, they can contact the surgery for advice.
- A copy of the protocol should be given to the patient and the patient's pharmacy. A copy should also be kept in the practice's records.

Start from the most relevant point of the schedule depending on the patient's current dose. Convert to Zomorph to facilitate dose reduction.

- (300mg/24 morphine is approximately equivalent to 150mg/24 hours oxycodone).
 - Note that the dosage reduction withdrawal schedule is flexible and should be tailored to each individual patient.
 - Reduction can be at weekly or two weekly intervals. Two weekly intervals may be preferential in the final stages.

Starting dose Morphine 300mg (150mg b.d)	Dose	Number of	Number of
Sooning (TSoning b.d)	DOSE	Capsules - TWICE a day	capsules/week
Stage 1 (1-2 weeks)	Morphine MR 140mg b.d	1x100mg b.d 1x 30mg b.d 1x10mg b.d	14x100mg 14x30mg 14X10mg
Stage 2 (1-2 weeks)	Morphine MR 130mg b.d	1x100mg b.d 1x 30mg b.d	14x100mg 14x30mg
Stage 3 (1-2 weeks)	Morphine MR 120mg b.d	1x100mg b.d 2x10mg b.d	14x100mg 28x10mg
Stage 4 (1-2 weeks)	Morphine MR 110mg b.d	1x100mg b.d 1x10mg b.d	14x100mg 14X10mg
Stage 5 (1-2 weeks)	Morphine MR 100mg b.d	1x100mg b.d	14x100mg
Stage 6 (1-2 weeks)	Morphine MR 90mg b.d	1x60mg b.d 1x30mg b.d	14x60mg 14x30mg
Stage 7 (1-2 weeks)	Morphine MR 80mg b.d	1x60mg b.d 2x10mg b.d	14x60mg 28x10mg
Stage 8 (1-2 weeks)	Morphine MR 70mg b.d	1x60mg b.d 1x10mg b.d	14x60mg 14x10mg
Stage 9 (1-2 weeks)	Morphine MR 60mg b.d	1x60mg b.d	14x60mg
Stage 10 (Review)	120mg oral morphine equivalent outweigh benefits. THIS IS NOT consider further reduction as opi	A TARGET DOSE. If patien	

A structured intervention with a written individualised stepped-dose reduction is less timeconsuming and as effective in primary care as a more complex intervention involving follow-up visits.

NHS Eastbourne, Hailsham and Seaford Clinical Commissioning Group

Chair – Dr Martin Writer Chief Officer – Amanda Philpott



BuTrans and Fentanyl Patch Suggested Dose Reduction Protocol

Opioid reduction plans can take place over a longer period if necessary.

Dose Reduction Plan Examples for BuTrans patches

BuTrans 20

Start at next patch change due date [Prescribe BuTrans 10 x 2 patches and BuTrans 5 x 2 patches]

Week 1	Week 2	Week 3	Week 4
BuTrans 5 patch	BuTrans	BuTrans 5	STOP
+ BuTrans 10	10 patch	patch	
patch			

BuTrans 10

Start at next patch change due date [Prescribe BuTrans 5 x 1 patch only]

Week 1	Week 2
BuTrans 5	Stop

Dose Reduction Plan for Fentanyl patches

Each two week period is actually 15 patch days; equivalent to 5 patches changed every 3 days

Fentanyl Patches 25mcg/ hour

	Dosage	Prescribe
Week 1	Fentanyl 12mcg/ hr	5 x fentanyl patch 12mcg then STOP

Fentanyl Patches 50mcg/ hour

	Dosage	Prescribe
Week 1	Fentanyl 25mcg/ hr + 12	10x fentanyl patch 25mcg + 5 x fentanyl
	mcg/ hr	patch 12mcg
Week 3	Fentanyl 25mcg/ hr	
Week 5	Fentanyl 12mcg/ hr	5 x fentanyl patch 12mcg then STOP

Fentanyl Patches 75mcg/ hour

	Dosage	Prescribe
Week 1	Fentanyl 50mcg/ hr +	10x fentanyl patch 50mcg + 5 x fentanyl
	12mcg/hr	patch 12mcg
Week 3	Fentanyl 50 mcg/ hr	
Week 5	Fentanyl 25mcg/ hr + 12	10x fentanyl patch 25mcg + 5 x fentanyl
	mcg/ hr	patch 12mcg
Week 7	Fentanyl 25mcg/ hr	
Week 9	Fentanyl 12mcg/ hr	5 x fentanyl patch 12mcg then STOP

www.hastingsandrotherccg.nhs.uk www.eastbournehailshamandseafordccg.nhs.uk NHS Hastings and Rother Clinical Commissioning Group
Chair – Dr David Warden Chief Officer – Amanda Philpott
NHS Eastbourne, Hailsham and Seaford Clinical Commissioning Group
Chair – Dr Martin Writer Chief Officer – Amanda Philpott



Oxycodone Suggested Dose Reduction Protocol

Opioid reduction plans can take place over a longer period if necessary. Remember to include additional 'when required' doses taken regularly, when calculating the total daily dosage of oxycodone.

Oxycodone MR 10mg BD (Oxycontin/Longtec) – total daily oxycodone dose 20mg

Conversion to morphine followed by dose reduction

	Week 0 convert to morphine sulfate MR caps (Zomorph)	Week 2	Week 4	Week 6
Morning dose	20mg (2 x 10mg) Zomorph	10mg	STOP	STOP
Evening dose	20mg (2 x 10mg) Zomorph	10mg	10mg	STOP

Oxycodone MR 20mg BD (Oxycontin/ Longtec) - total daily oxycodone dose 40mg

Conversion to morphine followed by dose reduction

	Week 0 convert to morphine sulfate MR caps (Zomorph)	Week 2	Week 4	Week 6	Week 8	Week 9
Morning dose	40mg (30mg+10mg) Zomorph	30mg	20mg (2 x 10mg)	10mg	STOP	STOP
Evening dose	40mg (30mg+10mg) Zomorph	30mg	20mg (2 x 10mg)	10mg	10mg	STOP

Oxycodone MR 30mg BD (Oxycontin/ Longtec) - total daily oxycodone dose 60mg.

Conversion to morphine followed by dose reduction

	Week 0 convert to morphine sulphate MR cap (Zomorph)	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 13
Morning dose	60mg Zomorph	50mg (30mg+ 2x10mg)	40mg (30mg+ 10mg)	30mg	20mg (2 x 10mg)	10mg	STOP	STOP
Evening dose	60mg Zomorph	50mg	40mg	30mg	20mg	10mg	10mg	STOP

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Appendix 20 – CQC and NHSE Checklist for safer use of Oxycodone Medicines

1. Oxycodone should **only be used as a second-line strong opioid**, if morphine is not suitable or cannot be tolerated.

The specialist pain or palliative care team **should be consulted** for advice in cases of complex pain management.

- 2. Obtain details of the previous daily dose, and frequency of administration of previous analgesics used by the patient.
 - i. Ensure where a dose increase is intended, that the calculated dose is safe for the patient (for oxycodone in adult patients, not normally more than 50% higher than the previous dose).
 - ii. Where the patient was previously taking another opioid analgesic use a locally or nationally approved dose conversion chart to accurately determine the equivalent daily dose of oxycodone.

Dose conversion charts can be found in the' Prescribing in Palliative Care' section of the British National Formulary (BNF).

3. Confirm the appropriate medicine formulation is being used. There are fast acting short duration (e.g. Oxynorm) and slow acting, long duration (e.g.Oxycontin) oxycodone products.

There are significant risks of overdose when a fast acting product of short duration is used in error for the slow acting, longer duration products.

Where possible prescribe by brand name to reduce confusion.

- 4. Check for therapeutic duplication of strong analgesics by 2 different routes of administration. There may have been an error and the previous route of administration may not have been cancelled.
- 5. Confirm any use of oxycodone concentrate products.

There are significant risks of overdose if a concentrate product is used in error for a normal strength product.

6. Any use of oxycodone medicines 'as required' should have clear guidance on the frequency that the doses can be administered.

Appendix 21 – CQC and NHSE Checklist for safer use of Fentanyl and Buprenorphine CD Transdermal Patches

- 1. CD transdermal fentanyl patches should be restricted to patients that are already receiving regular doses of opioids.
 - i. Do not use for acute pain.
 - ii. Do not use in opiate naïve patients.
- 2. Before using a CD transdermal patch, calculate the total daily dose of all the opioid analgesics that the patient has received previously. This is usually in morphine equivalence.

Use locally or nationally approved dose conversion charts to do this. There are dose conversion charts in the 'Prescribing in Palliative Care' Section of the British National Formulary and in CD transdermal manufacturers guidance (SPC).

3. Determine a new dose of analgesia to be delivered by transdermal CD patch in morphine equivalents. For changes in analgesia, as a 'rule of thumb', the total daily dose should not be increased in steps greater than 50% of the previous daily dose.

Again use a conversion chart to determine the total daily dose of analgesia by CD transdermal patch(es) and where necessary divide by 24 to equate with the micrograms/hour strength of available products.

To deliver the intended dose more than one CD patch may have to be used.

NB - Formally double check the calculations and where possible have the patient's dose independently verified.

4. Ensure only those CD transdermal patches intended for current use are applied.

Patches may be skin coloured or transparent, and so may not be easy to locate.

Formally record the anatomical position of currently applied patches so that this information is readily available to inform future decisions and actions.

5. Prescribe by brand and ensure patients using CD transdermal patches have adequate prescriptions and supplies to minimise interruption and omission of therapy.

Transdermal CD patches must be removed and replaced in accordance with the manufactures guidance (SPC).

6. Consider that patients may exhibit symptoms of opioid withdrawal when a CD transdermal patch has been omitted.

The cause of these symptoms may not be recognised and patients may be treated with benzodiazepines for these symptoms, rather than have opioid therapy for their analgesia re-instated, if necessary at a reduced dose.

Appendix 22 - MHRA Fentanyl Skin Patches Patient Information Leaflet



Fentanyl skin patches: importance of safe use and disposal July 2014

Key messages

- Fentanyl skin ('transdermal') patches are safe and effective for relieving pain when used according to instructions. Always read the leaflet to learn about safe use and possible side effects
- A patch may cause serious harm if it accidentally sticks to somebody else's skin or is swallowed (eg, by a toddler)
- To reduce this risk, please use and dispose of the patch safely:



- when applying the patch, choose the application site carefully (see instructions on the labelling and in the leaflet that came with the patch). Check that the patch is stuck on securely, especially the edges
- when disposing of the patch, fold it as soon as it is removed so that the sticky side sticks firmly to itself. Dispose of the folded patch safely so that it is not picked up by others (especially children)
- If a patch is transferred to another person, remove it and get medical help immediately
- If a patch is swallowed, get medical help immediately

What are fentanyl skin patches and what do they do?

Fentanyl skin ('transdermal') patches contain a strong painkiller called fentanyl. The patches are prescribed to help relieve severe, long-lasting pain.

The prescriber carefully considers if a fentanyl patch is suitable for an individual. But if the patch accidentally sticks to somebody else's skin or if somebody (eg, a toddler) swallows it, the medicine can cause serious harm.

What is the new safety information on transdermal fentanyl?

There have been reports of patches accidentally sticking to the skin of people (including children) who were not prescribed them.

Reporting side effects

Please report any suspected side effects to any medicine or vaccine to the Yellow Card Scheme via the website (<u>www.mhra.gov.uk/yellowcard</u>) or by calling the free phone line (0800 731 6789). By reporting side effects you can help provide more information on the safety of medicines.

Medicines and Healthcare Products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates.

Appendix 23 – Preparation for Dose Reduction

Factors in deciding whether to wean opioids, and how far to reduce the dose, include:

- Evidence that opioids are not helping patient's complaints of pain; patient's function; reports from patient's family or associates
- Risk of side effects or complications of opioids
- Risk of drug theft or diversion
- Patient's ability to cope with the effects of dose reduction
- Risk of patient procuring more dangerous opioids from alternative sources
- Physical co-morbidities
- Mental health co-morbidities including significant emotional trauma

Before weaning discuss the following with the patient:

- Explain the rationale for stopping opioids including the potential benefits of opioid reduction (avoidance of long term harms and improvement in ability to engage in self-management strategies)
- agreed outcomes of opioid tapering
- monitoring of pain during taper
- symptoms and signs of opioid withdrawal
- choice of opioid reduction scheme and timing of weaning steps
- incremental taper of existing drug
- defining the role of drug and alcohol services to support dose reduction
- close collaboration between the patient, his or her carers and all members of the patient's health care team
- arrangements for follow-up including agreed prescribing responsibilities
- distraction strategies, social support, help in reducing temptation to relapse
- GP or other healthcare support and monitoring during the wean

References

BNF 74 September 2017-March 2018

https://bnf.nice.org.uk/

British Medical Association. Chronic pain: supporting safer prescribing of analgesics. 2017:

https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-

health/analgesics-use

e-PAIN on-line learning:

https://www.rcoa.ac.uk/faculty-of-pain-medicine/e-pain

Faculty of Pain Management and Public Health England. Opioid aware website:

https://www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware

Opioid equivalence table:

https .sps.nhs.uk p-content uploads 2018 06 Dose-equivalence-and-s itchingbet een-opioids.pdf

Live well with pain website:

http://livewellwithpain.co.uk/

NICE Controlled drugs: safe use and management (NG46)

https://www.nice.org.uk/guidance/ng46

NICE Headaches in over 12s: diagnosis and management (CG150)

https://www.nice.org.uk/guidance/cg150

NICE Low back pain and sciatica in over 16s: assessment and management (NG59)

https://www.nice.org.uk/guidance/NG59

NICE Neuropathic pain in adults: pharmacological management in non-specialist settings

(CG173)

https://www.nice.org.uk/guidance/cg173

NICE Osteoarthritis: care and management (CG177)

https://www.nice.org.uk/guidance/cg177

NICE Rheumatoid arthritis in adults: management (NG100)

https://www.nice.org.uk/guidance/ng100

Opioid Management Plan: Treatment Agreement based on NHS Cornwall and Isles of

Scilly document

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