GG&C Chronic
Non Malignant Pain
Opioid Prescribing Guideline

Background

Persistent pain is common, affecting around five million people in the UK. For many sufferers, pain can be frustrating and disabling, resulting in functional impairment - physically, emotionally and vocationally. Medications and other treatments that aim to reduce pain intensity play a role in the management of symptoms, but should be provided as part of a wider management plan focused on reducing disability and improving overall quality of life.

Opioids have been increasingly prescribed to treat chronic non-malignant pain. There is evidence from clinical trials that they can be effective, in the short and medium term, in providing symptomatic improvement in somatic, visceral and neuropathic pain. Complete relief of pain is rarely achieved. The goal should be to reduce pain sufficiently to facilitate engagement with rehabilitation and the restoration of useful function. The management of persistent pain focuses not only on reduction in pain intensity but also on improvement in sleep, mood, and physical, vocational, social and emotional wellbeing.

The safety and efficacy of opioids in the long term is uncertain, as is the propensity for these drugs to cause problems of tolerance, dependence and addiction. The benefits of opioid treatment for the patient must be balanced against burdens of long term use as therapy for persistent pain may need to be continued for months or years.

There is no good predictive factor of the analgesic effect of opioids in chronic non-malignant pain. If deemed appropriate, the individual should have **a monitored opioid trial over a period of 6 weeks** to determine the effectiveness of the treatment and the presence of side effects. If the clinical decision is made to continue the prescription of the opioid, there should be ongoing timely reassessment.

Recommendations are made on determining the suitability of an opioid trial, the choice of opioid, the conduct of an opioid trial and long term monitoring of the patient.

The guidelines reviewed included the following;

- The British Pain Society (2010)
- U.S. Department of Veterans Affairs/Department of Defence (2010)
- The Canadian Guidance (2010)
- Guidelines for South Australian GPs (2009)
- American Pain Society-American Academy of Pain Medicine (APS-AAPM) Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain (2009)

A flowchart to support implementation of the Guideline for the prescribing of Opioids to patients with Chronic Non Malignant Pain can be found at the end of this document.

Suggestions for the Safe and Effective Prescribing of Opioids for the Management of Chronic Non-Malignant Pain: initiation, monitoring and tapering

Patients may be managed by the General Practitioner and/or the Pain Specialist. This guideline is to aid primary care and secondary care teams in managing patients, who have chronic pain, with opioids. This guidance should be used in conjunction with local and/or national guidance on the assessment of pain and with reference to British Pain Society Guidelines.

Key Points

- **The aim of using opioids in the short to medium term is to support the rehabilitation and restoration of physical and mental function of patients.**
- **Clinical evidence has demonstrated that opioids can be useful in the management of chronic somatic, visceral and neuropathic pain.**
- **Opioids can also have untoward effects in terms of tolerance, dependence and addiction.**

Before initiating opioids consider the following:

- What is the cause (diagnosis) of persistent pain in your patient?
- Has a biopsychosocial assessment been made?
- Have other appropriate methods of pain management been tried? (e.g. other medications, graded exercises, psychological methods)
- Does your patient have neuropathic pain? (Refer to local neuropathic pain guidelines)
- Would a trial of opioids be suitable for this patient? (see below)

Not Recommended:

•No previous improvement with opioids in the past

•Sleep Apnoea

No Clinical Evidence for Long Term Effectiveness In:

•Headache
•Non Specific Low Back Pain
•Fibromyalgia
•Unexplained Persistent Pain

Potential High Risk/Dependent Patients Requiring Closer Monitoring:

•Mental Health Disorders

•Depression and Anxiety Related to Pain

•Previous or Existing Addiction to Any Substance

•Serious Mental Health Issues or Addiction in the Family

1. There are no chronic pain conditions in which opioids are completely contraindicated, however the boxes to the right are situations where they are not recommended or where closer monitoring would be required. Consideration should be given to using the 'Opioid Risk Tool' (see Appendix 1) to assess for potential high risk/dependent patients. If patients are assessed as moderate to high risk closer monitoring will be required.

2. Initiation of Opioids

Prior to the commencement of opioid therapy, it is essential that appropriate informed consent is obtained from the patient and if necessary family/carers. The discussion should include;
A clear explanation of the advantages and disadvantages of opioid therapy, which should include short term and long term side effects, potential for tolerance and addiction, detrimental impact on quality of life and advice on driving and operating machinery as per the British Pain Society Information Leaflet.
http://www.britishpainsociety.org/book_opioid_patient.pdf

Long Term Effects of Opioids:

•Suppression of the immune system.

•Suppression of pituitary hormones leading to hypogonadism.

•Low bone mass and risk of fractures.

•Possible effect on cognitive function

- Agreeing achievable patient specific goals. This may include an agreed expected reduction in pain score (30%), improvement in sleep pattern and functional ability.
- An explanation of the concept of an Opioid Trial and what circumstances would surround the discontinuation of opioid medication.
- Complete the 1st page of the 'Progress Note' Pain Assessment & Documentation Tool (PADT) to record baseline levels of the pain score and functional ability.
  http://www.healthinsight.org/Internal/assets/SMART/PADT.pdf

3. Opioid Trial : Anticipated length of trial would be 6 weeks.

Expectation: 30% improvement in pain and/or significant improvement in functional ability.

- Discontinue all Step 2 analgesia and replace with Step 3 during the trial however continue with Step 1 analgesia such as paracetamol/NSAIDs.

Step 2 and Step 3 Analgesia

Stop All STEP 2 Analgesia

Single or combination analgesics containing:
Codeine
Dihydrocodeine
Tramadol
Low Dose Buprenorphine Patches
(This is Non SMC approved and its use is subject to approval via the Individual Patient Treatment Request Process)

Commence Step 3 analgesia

		Starting Dose	Titration	Maximum Dose
1st Line	**Morphine Sulfate Sustained Release**	**10mg BD**	**Increase by 10-20mg BD Every 2 weeks**	**60mg BD**
2nd Line	Oxycodone Sustained Release	5mg BD	Increase by 5 – 10mg BD every 2 weeks	30mg BD
If there are issues with swallowing consider alternative oral slow release preparations e.g. suspension.				
3rd Line or if issues with GI absorption	Fentanyl	12mcg/hr (Equivalent to 45mg morphine in 24 hours)	Increase by 12mcg/hr every 2 weeks	25mcg/hr (Equivalent to ~80mg morphine in 24 hours)

- Use a single agent by the oral route, using sustained release preparations. If no contraindication, first line choice is sustained release Morphine Sulfate SR 10mg BD in opioid naïve patients. For patients already on reasonable dose step 2 analgesics, convert using opioid conversion chart see Appendix 2, then reduce total daily dose by 25% as a safety precaution.

- If Morphine Sulfate SR is not tolerated **despite treatment of side effects**, recommence trial using sustained release Oxycodone SR.

- Oral route is preferred, however if the patient has problems with swallowing or GI absorption, Transdermal Fentanyl preparations should be used, recognizing that titration will take longer than oral preparations.

- Increase dose every 2 weeks until required pain relief has been achieved or side effects are intolerable or until 60mg BD Morphine Sulfate SR or equivalent is reached. Consider referral to the Pain Specialist Clinic.

- Reassess the patient 1-2 weekly.

- Drug specific Patient Information Leaflets can be found at **http://www.knowledge.scot.nhs.uk/pain/nhs-boards/nhs-greater-glasgow-and-clyde/for-professionals.aspx**

- **Ensure most cost effective brands are used as identified from local formularies**

4. Regular Assessment

Use PADT tool for ongoing assessment (http://www.healthinsight.org/Internal/assets/SMART/PADT.pdf)

Assessment should include;

Ongoing Efficacy – carry out recordings of pain score and functional assessment.

If the opioid trial is not successful, discontinue opioid by tapering dose, reducing by 10-20mg of morphine/day or equivalent every 2 weeks.

There are no high quality randomized controlled trials to suggest that one opioid is more effective than another. If there is NO clinical benefit with a full trial of one opioid, we would not encourage further opioid trials in primary care – seek opinion of Pain Specialist If opioid trial is successful, continue with monitoring of dose, pain score, function and side effects every 3 months initially until does is stable, then every 6 months. Consider weaning opioids every 6 months to see if dose is still optimal.

- **Avoid using short acting opioids for breakthrough pain.**
- Keep daily dose of long acting opioid as low as possible.
- Measure sex hormones if patient reporting symptoms of hypogonadism and if abnormal seek advice from local endocrine clinic.
- Observe for signs of drug abuse. Refer to British Pain Society advice; http://www.britishpainsociety.org/book_drug_misuse_main.pdf

Referral to a pain specialist is recommended for:

- **Patients with previous mental health problems, dependency or addiction**
- **Difficulty tapering or problem drug use**
- **Patients with opioid sensitive pain who require dose higher than 60mg Morphine Sulfate Tablets SR BD or equivalent.**
- **Opioid insensitive problematic pain**
- **Diagnostic difficulties**

5. Treatment of Side Effects – further information

Constipation

The majority of patients taking opioids for moderate to severe pain will develop opioid induced constipation; tolerance does not develop to this side effect.[1] Guidelines suggest that the best prophylactic treatment for opioid induced constipation is a combination of a stimulant laxative and a stool softener.[1] Refer to local formularies

Nausea/Vomiting

Nausea and vomiting are common when starting on opioids but generally tolerance develops after 5-10 days.[1] It is recommended that patients commencing on an opioid for moderate to severe pain should have access to prophylactic antiemetics to be taken if required.[1] Refer to local formularies for treatment of choice.

Itch

Opioid induced itch occurs in around 1% of those who receive a systemic opioid. It is thought to be caused by a central mechanism rather than by histamine release, therefore in some cases antihistamines are not effective.[4] Emollients should be used liberally if the patient has dry skin. Trial of a sedating antihistamine such as chlorphenamine or hydroxyzine is suggested, if this is not effective after a few days it should be stopped.[6]

6. Renal Impaired patients

For those patients with renal impairment, the likelihood of opioid toxicity with any opioid increases and the following guiding principles should be followed when prescribing opioids;

- Use the smallest effective dose/frequency.
- Titrate carefully and monitor for adverse effects.
- It should be noted there is no advantage in using Oxycodone over Morphine in Stage 1-3 renal impaired patients.
- In patients with stage 4/5 kidney disease consult with the patients local renal specialist before commencing opioid treatment. General advice would be to avoid long acting preparations and where they are used, delay their introduction until the patient's dose requirements are fully established.
- If there are clinical concerns consult local renal specialists.

NB: ***Treatment of very frail older people with chronic non cancer pain should be guided by individual circumstances and co-morbidities and need not follow guideline recommendations***

References

1. Scottish Intercollegiate Guidelines Network. SIGN Guideline 106. Control of Pain in Adults with Cancer. November 2008. http://www.sign.ac.uk/pdf/SIGN106.pdf
2. NHS Greater Glasgow and Clyde. Theraputics. A Handbook for Prescribing in Adults. August 2011. http://www.ggcprescribing.org.uk/media/uploads/handbooks_and_formularies/therapeutic_handbook_2011.pdf
3. NHS Lothian. Palliative Care Guidelines: Constipation. August 2010. http://www.palliativecareguidelines.scot.nhs.uk/documents/Constipationfinal.pdf
4. Twycross R, Wilcock A. Palliative Care Formulary. 4th Edition. 2011. Palliativedrugs.com Ltd. Nottingham
5. NHS Lothian. Palliative Care Guidelines: Nausea/Vomiting (version 2). August 2010. http://www.palliativecareguidelines.scot.nhs.uk/documents/NauseaVomiting.pdf
6. NHS Lothian. Palliative Care Guidelines: Itch in Palliative Care. August 2010. http://www.palliativecareguidelines.scot.nhs.uk/documents/itch.pdf

Opioid Equivalent Doses*

Oral morphine (mg/24 hrs)	10	15	20	30	40	45	60	80	120
Codeine/Dihydrocodeine (mg/24hrs)	120		240						
Tramadol (mg/24hrs)			200		400				
Oxycontin(mg/24hrs)	5		10	15	20		30		60
Transdermal Buprenorphine (µg/hr)	5		**10**		**20**	20	**35**	35	**52.5**
Transdermal Fentanyl (µg/hr)				**12**	**12**	**12**	**25**	25	**50**

***These figures are taken from a number of sources/dose ranges and are an approximation.**
See BNF for up-to-date equivalence charts for individual opioids.
After an opioid conversion reduce the dose by 25% as a safety precaution

You may also wish to use our online conversion tool:
http://www.jet5.com/pain/calculator.php

APPENDIX 1

Opioid Risk Tool

Item	Mark each box that applies	Item score if female	Item score if male
1. Family History of Substance Abuse:			
Alcohol	[ ]	1	3
Illegal Drugs	[ ]	2	3
Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse:			
Alcohol	[ ]	3	3
Illegal Drugs	[ ]	4	4
Prescription Drugs	[ ]	5	5
3. Age (mark box if 16-45)	[ ]	1	1
4. History of Preadolescent Sexual Abuse	[ ]	3	0
5. Psychological Disease			
Attention Deficit Disorder, Obsessive-Compulsive Disorder, or Bipolar, Schizophrenia	[ ]	2	2
Depression	[ ]	1	1
Total		____	____
Total Score Risk Category: Low Risk: 0 to 3 Moderate Risk: 4 to 7 High Risk: 8 and above			

Printed with permission from LifeSource Not-for-Profit on behalf of Dr Lynn Webster (@LynnRWebsterMD).

Reference

Webster LR, Webster R, Predicting aberrant behaviours in Opioid treated patients: preliminary validation of the Opioid Risk Tool. Pain Medicine. 2005; 6(6):432

APPENDIX 2

GG&C Chronic Non Malignant Pain Opioid Prescribing Guideline

Suggested Areas Where Opioids Are Not Recommended

- No previous improvement with opioids
- Sleep Apnoea

No Clinical Evidence of Long Term Effectiveness In:

- Headache
- Non Specific Low Back Pain
- Fibromyalgia
- Unexplained Persistent Pain

BEFORE INITIATING OPIOIDS CONSIDER

What is the cause of persistent pain?
Biopsychosocial aspects considered?
Have other appropriate methods of pain management been tried?
Is there neuropathic pain?
(Refer to local neuropathic pain guidelines)
Is a trial of opioids appropriate for this patient?

Long Term Effects of Opioids

- Immunosuppression.
- Suppression of pituitary hormones leading to hypogonadism, possible suppression of adrenal function, low bone mass.
- Possible effect on cognitive function

Closer Monitoring Required for Patients With:

- Mental Health Disorders
- Depression and Anxiety Related to Pain
- Previous or Existing Addiction to Any Substance
- Serious Mental Health Issues or Addiction in the Family

Complete Opioid Risk Tool to Assess Risk and Consider Referring to Local Pain Clinic

Commence Opioid Trial (Duration – 6 weeks)

Aim
30% Improvement in Pain And/or Significant Improvement in Functional Ability see PADT tool – see PA

Prior to Initiation
Explain advantages and disadvantages
Explain the concept of the trial and reasons for discontinuation
•Agree patient specific goals
Record baseline levels of pain score and functional ability using the PADT tool

Initiation

Discontinue all Step 2 Analgesia i.e.
•Single or combination analgesics containing:
—Codeine/Dihydrocodeine/Tramadol
—Low Dose Buprenorphine Patches*
*(Non SMC Approved)

Commence Oral Morphine Sulfate SR

•10mg BD for Opioid Naïve patients & increase by 10-20mg BD every 2 weeks.
•Alternatively use Opioid Conversion Chart to transfer from Step 2 analgesia minus 25% of total daily dose for safety.

Assess patient every 1-2 weeks
Increase dose every 2 weeks until pain relief achieved or other agreed objective or maximum dose of 60mg BD is reached. Treat side effects as per local formularies.

If there is NO clinical benefit gained with a *full trial* of one opioid, there are **no** randomised controlled trials that suggest that one opioid is more effective than another. Refer to pain specialist

If Morphine is not tolerated

- Recommence trial using Oxycodone SR 5mg BD
- •If problems with swallowing consider alternative oral slow release preparations e.g. suspension
- If issues with GI absorption use Fentanyl 12mcg/hr

Review: If trial unsuccessful, reduce dose by 10-20mg Morphine or equivalent every 2 weeks until discontinued

Regular Assessment

Use PADT tool to regularly assess pain score and functional ability

Measure sex hormones if patient reporting symptoms of hypogonadism eg impotence, /oligoamenorrhoea and if abnormal seek advice from local endocrine clinic.

If trial is successful initially monitor every 3 months, then six monthly

Consider weaning opioids every 6 months to see if dose is still optimal. Observe for signs of drug abuse. Avoid using short acting opioids for breakthrough pain.

Consider Referral to a Pain Specialist for:

- **Patients with previous mental health problems, dependency or addiction.**
- **Difficulty tapering or problem drug use**
- **Patients with opioid sensitive pain who require dose higher than 60mg Morphine Sulfate Tablets BD or equivalent.**
- **Opioid insensitive problematic pain**
- **Diagnostic difficulties**