

Quality Prescribing For Chronic Pain A Guide for Improvement 2018 - 2021



Foreword

This guide has been written by Scottish Government and NHS Scotland to promote quality improvement in the prescribing of analgesic medicines and, equally importantly, to integrate this with non-pharmaceutical therapeutic approaches to management of chronic pain. The document is aimed at Primary Care clinicians, General Practice Clusters and NHS teams with responsibility for promoting best practice in medicines prescribing.

For the purposes of this document, chronic pain is defined as *pain which has persisted beyond normal tissue healing time*.¹ Though this document focusses on chronic pain, it should be viewed in the context that most patients with long-term conditions have more than one. Clinicians and managers should consider this document together with the recommendations in *Polypharmacy Guidance*. Chronic Pain affects one in five people in Scotland and is often associated with Polypharmacy.²

The advice is based on existing clinical guidance, in particular <u>SIGN 136</u> - Management of Chronic Pain, which should be considered a companion document to this. Data tables have been included from the <u>National Therapeutic Indicators (NTIs) and Additional Prescribing</u> <u>Measures (APMs)</u>, providing consistency of metrics for Boards.

We are extremely grateful to all those who contributed to the working group and to the review and development of the document.

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¹ International Association for the Study of Pain. Classification of chronic pain. Second edition.

² chronicpainscotland.org/wp-content/uploads/2016/05/Chronic-Pain-in-Scotland-v1-4-Briefing-and-Background-Paper.pdf

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Pills Image courtesy of Piyachok Thawornmat at FreeDigitalPhotos.net

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Introduction

What is the purpose?

The purpose of this document is to promote quality improvement in prescribing for adults with chronic pain across primary care in Scotland, particularly focussing on delivery of safe, person-centred care. In addition, it promotes self-management and non-pharmaceutical management of chronic pain and disseminates prescribing quality indicators that can be used to monitor and review analgesic prescribing and variation in practice across Scotland.

The scope includes review of the pharmaceutical and non-pharmaceutical management for adult patients only. The document is not intended to replace any current clinical guidance and should be used alongside <u>SIGN 136</u>.

What are the benefits to patients?

At a clinician level, this document promotes a focus on analgesic prescribing for chronic pain, leading to structured review of appropriateness, efficacy and tolerability of treatment, and promotion of optimal care. Through consideration of non-pharmaceutical management of chronic pain, there is the potential to reduce medication burden on patients and the associated risk of short and long term adverse effects, as well as better outcomes overall.

At a Board or organisation level, it promotes understanding of population level variation and provides guidance on reducing this, where it is unwarranted.

In line with international evidence, there is a general shift away from a single condition approach to medicines strategy, and it is therefore important to consider this document in the broader context of *Polypharmacy Guidance*, *Many Conditions*, *One Life*, and a holistic approach to care. Furthermore, it is essential that audits and reviews are put in place as part of a prescribing quality improvement programme. It must be accepted that guidelines are written to provide general advice and there are some patients under specialist management who require a more individualised approach. The approach should place an emphasis on *what matters to me* and should involve a partnership with the patient to achieve goals.

What are the benefits to clinicians?

This document provides a practical toolkit and examples of good practice approaches to improvement, including case studies, structure for review and links to additional resources.

What are the benefits for organisations?

Implementation of this document will facilitate improved care for patients with chronic pain and more appropriate prescribing. Included is a suite of data indicators which can help focus resources on areas of prescribing which would benefit from review. Resources such as Prescribing Implementation Guides provide Health Board / HSCP / GP Cluster / Practice level tools to improve management of medicines in this prescribing area. <u>The resource pack is</u> <u>available here.</u> Case studies provide examples of how to implement improvements. Previous national prescribing strategies on <u>Diabetes and Respiratory</u> were linked to a demonstrable improvement in prescribing practice.

Why is this important?

1 in 5 people in Europe suffer from chronic pain which is comparable to the proportion of the population suffering heart disease, diabetes and major depression combined. 1 in 20 people in Scotland suffer severe, disabling chronic pain.³ Prescribing for chronic pain increased by 66% over the ten years from 2006.⁴ <u>Realistic Medicine (2016)</u> is a key driver of strategy for NHS Scotland and talks about goals such as:

- Ensuring high quality care
- Reducing the burden of overtreatment
- Reducing unwarranted variation
- Ensuring value for money
- Combining the expertise of patients and professionals
- Identifying and managing clinical risk

Scotland spends less per capita on analgesic prescribing (BNF Chapter 4.7) than Wales and Northern Ireland, but more than England.



UK Comparative Drug Spend BNF 0407

³ www.sspc.ac.uk/media/media_484727_en.pdf

⁴ PRISMS System NHS Scotland. Based on increase in number of Defined Daily Doses

The box table shows the total annual spend in Scotland for medicines prescribed to manage pain. The central box shows the total for all selected medicines. This is then subdivided to show the total spend by medicine class, then further subdivided by individual medicines.⁵



⁵ ISD 2017 – January to December 2016 Data

The maps below demonstrate change in cost per treated patient since 2012.⁶ There has been an increase in analgesic cost per treated patient for all Boards between 2012 and 2016 with variation in the levels of this change.



Polypharmacy

Medication is by far the most common form of medical intervention, with 300,000 prescriptions issued every day in Scotland. The term polypharmacy itself just means *many medications* and has often been defined to be present when a patient takes five or more medications. However, it is important to note that polypharmacy is not necessarily a bad thing. Polypharmacy can be both rational and required. It is therefore crucial to distinguish appropriate from inappropriate polypharmacy. Inappropriate polypharmacy is present when one or more drugs are prescribed that are not or no longer needed, or where there are dangerous interactions between medicines.⁷

The Scottish Government first published <u>Polypharmacy Guidance</u> in 2012, issuing a revised version in 2015. It is now more common for patients in Scotland to have two or more long term conditions than only one. The chart below indicates the relative co-prevalence of conditions. Chronic pain is one of the most common co-morbidities of other long term, conditions, including heart and respiratory disease, cancer and diabetes.⁸

					who al	so have this c	ondition					
Percentage of patients with this condition	Coronary Heart Disease	Hypertension	Heart Failure	Stroke/TIA	Diabetes	СОРД	Cancer	Painful Condition	Depression	Schizophrenia or Bipolar	Dementia	Any other condition
Coronary Heart Disease		52	14	13	22	13	8	24	17	0	C)	71
Hypertension	18		6	1	18	8	7	19	14	0	۲	61
Heart Failure	59	57		16	23	18	9	23	17	0	4	81
Stroke/TIA	29	61	8		19	12	8	22	21	0	6	63
Diabetes	23	54	6	9		8	6	21	18	۷	۲	63
COPD	19	33	6	8	1		0	23	18	0	۲	70
Cancer	14	34	4	7	1	8		19	14	0	۲	60
Painful Condition	16	36	C)	6	13	1	7	•	31	۲	61	70
Depression	1	23	٠	6	9	7	4	27		4	61	64
Schizophrenia or Bipolar	6	16	٩	4	9	6	CI	15	45		61	75
Dementia	21	41	6	18	13	9	8	19	32	61	•	83
Any other condition	1	27	•)	5	9	7	5	17	17	•)	•)	

Multiple conditions in Scotland 9

⁷ Polypharmacy Guidance 2015, Scottish Government

⁸ Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. The Lancet;380(9836):37-43

⁹ Mercer, Guthrie, Wyke: Scottish School of Primary Care

Recommendations

Clinicians should...

- Ensure patients are properly assessed with a Read code recorded for chronic pain to create a disease register, following guidance in this document and using chronic pain read code 1M52 (Chronic Pain) to facilitate audit and review. Use Read code 66n (Chronic Pain Review) record when a chronic pain review has been undertaken.
- **Develop a clear management plan** collaboratively with patients, including review dates. It is important that patients understand their pain and have realistic expectations. The plan should focus on <u>what matters to me</u>.
- **Pursue non-pharmaceutical approaches** wherever possible, either alone or in conjunction with medicines. Self-management should be encouraged and supported.
- Follow a clinically appropriate approach to initiation of analgesia, discussing expectations, risks and benefits and incorporating agreed criteria for stopping/continuing medication.
- **Review effectiveness, tolerability and compliance** on an ongoing basis. The burden of medicines should be reduced where possible, in line with Polypharmacy guidance.

Boards/HSCPs should...

- **Consider the guidance** within this document alongside the data provided on relative prescribing positions and trends. Prioritise analgesic prescribing within prescribing action plans and use this document to drive improvement.
- Nominate local leads (eg. one medical and one within, or with strong links to, the Medicines Management Team, or equivalent) to drive delivery and implementation of the recommendations within this document. Part of this role should be to ensure appropriate links and communication between primary and secondary care clinicians, particularly around hospital discharge and medicines reconciliation. Guidance is available from <u>SIGN 128, the SIGN Discharge Document</u> and on <u>medicines reconciliation</u> from the Scottish Patient Safety Programme.
- Take a whole system approach to delivering improvement, including:
 - Work with third sector organisations to develop capacity for self-management and co-production as part of non-pharmaceutical management of chronic pain.
 - Ensure the primary/secondary care interface is appropriately developed. Given the considerable influence that local secondary care prescribing culture has on primary care clinicians, it is vital to engage with secondary care clinicians.

Clusters can...

• Engage with local Prescribing Support Teams who have a wealth of experience in improving quality of prescribing through use of local and national datasets and tools.

Guidance for clinicians

Key Principles

This document aims to optimise prescribing, while reducing harm and wasteful, unwarranted variation. There are a number of principles which should be considered.

- Chronic pain is a condition which is individual to the patient and any therapeutic management plan needs to place the patient at the centre. The approach should be based on assisting the patient to achieve goals which have been identified in partnership with the prescriber, adopting the <u>what matters to me</u> principle.
- Prescribers should help patients to develop their understanding of the value of selfmanagement and non-pharmaceutical approaches, and support people to access the tools, resources and support available to put these approaches in to practice.
- Prescribers should work with patients to develop their understanding of chronic pain, how it differs from acute pain and the impact this may have on goals of therapy. Difficult and honest conversations may be required to establish an understanding with the patient that it is highly unlikely that the therapeutic management plan will result in full resolution of their pain symptoms (>30%), but it may assist them with coping.
- Patients should be given information on the potential benefits of their medicine as well as risks and reported side effects. This is particularly important regarding drugs which have the potential for misuse, including gabapentinoids and opioids.
- Patients should be aware that non-pharmaceutical options, or those offered along with prescribed medicines, may result in better achievement of goals and result in less harm than medicines alone. This may include referral to physiotherapy, mental health or occupational therapy services. Further information for patients on managing musculoskeletal conditions can be found on <u>NHS Inform</u>.
- Assessment Treatment pathways for chronic pain are available in <u>SIGN 136</u>.
- A robust plan for ongoing review should be at the centre of care for every patient.
- Clinicians should ensure extra care is taken when prescribing in non-healthcare settings, particularly around storage and administration of medicines.
- Prescribers should particularly review patients who are co-prescribed analgesics and other potentially problematic drugs such as benzodiazepines, and those with a history of substance misuse.

The prescribing for people with chronic pain is clearly defined in <u>SIGN 136</u>. NICE have also produced guidelines on management of chronic pain. However, clinicians in NHS Scotland should refer to SIGN in the first instance which remains the only comprehensive evidence based guideline for managing chronic pain in the non-specialist setting. The table overleaf provides a list of principles for prescribing for patients with chronic pain.¹⁰

¹⁰ Table developed in collaboration with NHS GGC Chronic Pain Primary Care Guideline Development Group

Pr	inciples for prescribing for patients with chronic pain
Principle	Detail
Early Assessment	Early assessment and characterisation of pain type is crucial in guiding treatment. Many drugs that are specifically effective in neuropathic pain are ineffective in other types, and vice versa. ¹¹ SIGN 136 pathways are recommended for assessment and management. Consider high risk patient groups and patient risk factors, including misuse/abuse potential.
Planning and Patient Understanding	It is important that patients understand their condition and have appropriate expectations. Medication should be considered as part of the management of chronic pain: patients should understand that medication will not "cure" chronic pain and they need to engage in self-management, for example the <u>pain toolkit</u> . It is vital the short and long term treatment plan, and any changes are discussed with and agreed by the patient along with arrangements for repeat prescribing.
Realistic Aims	It is important to discuss patients' aims for pharmacological treatment. Realistic aims may include pain reduction (≥30%) and/or functional goal improvement. Stepping down should be discussed as part of initiation. Patient understanding can be explored using <u>teach-back</u> .
Record Consumption	Record all analgesic consumption including OTC medication and identify complementary therapies. Recording of the Read code 1M52 is strongly recommended for audit, review and quality improvement. ¹²
Stepped Approach	Apply a stepped approach to pain management and review regularly. Remember that there is both a <i>step up</i> and <i>step down</i> approach and that patients should be empowered to safely reduce their medications where appropriate. NSAIDs (including topical) and adjuvants can be considered at each step.
Early Review	Any drug initiated for chronic pain should be subject to early, frequent and recorded review with the patient. It should be titrated up to a dose which balances maximum clinical efficacy with minimal risk, and gradually stopped if found to be ineffective or if adverse effects outweigh benefits. This particularly applies to medicines with common serious adverse effects or abuse potential, and/or that are expensive to prescribe. ¹³
Ongoing Review	Once the dose is stable and effectiveness has been established, ongoing recorded review should occur at least every six to twelve months - more frequently if needed, for example due to flare-ups. This review should: confirm ongoing need for and effectiveness of medication; screen for side effects; and adjust dose or discontinue prescription as appropriate. A holistic <u>Polypharmacy</u> approach is recommended.
Effective Care	Multimodal analgesia is most effective but requires using medicines with different mechanisms of action to deliver additional or synergistic impact: inappropriate polypharmacy should be avoided. Use the minimum effective or tolerated dose and step up as required. Start low and go slow.

¹¹ Finnerup NB, et al. Lancet Neurology, 2015 ¹² Smith et al, Scottish School of Primary Care, 2016 ¹³ Smith et al, Scottish School of Primary Care, 2016

Non-pharmacological therapies

Healthcare providers should support patients to self-manage their pain. Supported selfmanagement is a recognised intervention for chronic pain. It does not seek to cure, but it helps patients manage their condition and minimise the impact the pain has on their everyday life. Healthcare providers should discuss self-management options with patients, and be able to direct patients to appropriate resources, where they can learn more about pain and what they can do for themselves.

Self-management is a core driver of reform in health and social care in Scotland, including the *National Clinical Strategy*, the Chief Medical Officer's report on *Realistic Medicine* and *Making It Easier* - the national Health Literacy Action Plan. Self-management can be described as a set of approaches which aim to enable people to feel able to live well on their terms with a long term condition(s) or being an unpaid carer, with support from a range of family, peer groups and professionals. It includes a spectrum of support that helps someone to learn about their condition, acknowledge the impact it has on their life, make changes and identify areas where they require support. Support for self-management is designed to enhance these strengths and help people to feel in control and able to manage well in their everyday life. The Health Literacy Place provides a range of information, tools and techniques for health and social care staff to support their health literacy practice.

It is important to explain to patients that it's normal for pain to affect mood and vice-versa, and that relaxation, mindfulness and pleasurable activity can help counter distress. Useful tools include the <u>Pain Toolkit</u> and <u>Scottish Moodjuice</u> website. A leaflet is available for patients from Pain Concern regarding <u>stress and relaxation</u>.

There is evidence that brief education about pain can reduce sick leave and disability.¹⁴ There is strong evidence for the benefits for **physical exercise and activity** as part of the management of chronic pain and this is highlighted within <u>SIGN 136</u>. However, giving advice to exercise without any additional explanation or support is unlikely to be effective. Exercise has one of the strongest recommendations in the SIGN Guideline.¹⁵ A comprehensive overview of pain management is available from <u>National Education Scotland</u>.

NHS Fife have produced a self-help leaflet. This is available for use in other Boards and can be locally customised. It can be downloaded from <u>this link</u>.

There is limited evidence for the use of massage and manual therapy in the treatment of some types of pain. Clinicians should refer to <u>SIGN 136</u>.

A recent Cochrane review of Psychological therapies for the management of chronic pain highlighted the following: "The two main types of psychological treatment are called cognitive behavioural therapy (CBT) and behaviour therapy. Both focus on helping people to

¹⁴ Dobscha SK, et al. Journal of American Medical Association. 2009, 301. 1242

¹⁵ SIGN 136

change behaviour that maintains or worsens pain, disability, distress and catastrophic thinking; CBT also directly addresses the thoughts and feelings that are a problem for people with persistent pain. The effects of these two treatments on pain, disability, mood and catastrophic thinking were tested immediately after the treatment, and six months later.

Small to moderate benefits, more for disability, mood and catastrophic thinking than for pain, were found in trials which compared CBT with no treatment. Some of these were still positive six months later. Behaviour therapy showed few and only brief benefits.

Psychological therapies can help people with chronic pain reduce negative mood (depression and anxiety), disability, catastrophic thinking, and in some cases, pain. Although the overall effect is positive, we do not know enough about exactly which type of treatment is best for which person.^{''16}

Pharmacological therapies

There are a number of pharmacological therapies available for the management of chronic pain - this section provides key guidance. Treatment options are dependent on patient assessment. Many analgesic medicines are used off-label – clinicians should consult local policies and ensure this is properly recorded and discussed with the patient. Clinicians should plan to trial cessation of analgesia at regular intervals, even where treatments is considered effective.

Misuse of medicines

There is increasing evidence that many analgesics, including opioids, gabapentin and pregabalin, have the potential for harm and abuse. Cases of dependency have been described and there are reports of an increasing street value and risk of drug misuse.^{17,18,19} Evidence also highlights that over recent years there has been a significant increase in the number of drug related deaths where both gabapentin and pregabalin have been involved.²⁰

Patients should be given information on the potential benefits of their medicine, and the risks and reported side effects of the drugs. This is particularly important regarding drugs which have the potential for misuse, abuse or dependence including gabapentinoids and opioids. Patients should be told about the potential for such medicines to lead to abuse or dependence.

¹⁶ Williams ACDC, Eccleston C, Morley S. - Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database of Systematic Reviews 2012, Issue 11. Art. No.: CD007407. DOI: 10.1002/14651858.CD007407.pub3.

¹⁷ Public Health England. Advice for prescribers on the risk of the misuse of pregabalin and gabapentin

¹⁸ Willis S. Drugs of Abuse. 2nd ed. London: Pharmaceutical Press; 2005

¹⁹ www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware/clinical-use-of-opioids/crime-survey-findings

²⁰ <u>https://www.nrscotland.gov.uk/files//statistics/drug-related-deaths/drd2016/16-drug-rel-deaths.pdf</u> - Table Y, Page 71

If there are features in the patient's history that increase the likelihood of a medicine being misused, these should be discussed openly with the patient and the rationale for prescribing suggestions and decisions should be discussed fully and documented. Prescribers should evaluate the risks of continued prescribing and make appropriate decisions regarding quantity of drugs prescribed and the intervals at which the patient should be reviewed. Similarly, clinicians should investigate any behaviours or patterns of prescription requests which may indicate an issue such as excessive or early ordering or repeated loss of prescriptions. Care should be taken when co-prescribing opioids, gabapentinoids and other drugs associated with misuse, such as benzodiazepine, z-drugs and sedating agents.

It is important for prescribers to have a complete list of medications (including any over-thecounter products or illicit drugs) that patients are taking so that hazardous drug interactions can be minimised or avoided.²¹

There is growing concern about the rise of prescribed opioid use for chronic pain, both in the UK and internationally, not least because of the risk of dependence and given the very limited evidence for their effectiveness in long term pain conditions. When assessing and managing complex cases involving chronic pain, clinicians need to be fully aware of this evidence in their evaluation of such cases, in providing care and in giving advice to other professionals.

A significant proportion of individuals whose care may benefit from specialist support around addiction and dependence may never receive support of this nature. Early intervention and identification of potential issues by non-specialist primary care physicians may be more effective to prevent future problems

The care of patients within secure settings carries many additional difficulties. The management of pain during imprisonment presents a serious challenge given the misuse potential of opioid analgesics and of high doses of medicines such as pregabalin and gabapentin. Clarity about the need for adequate and appropriate treatment of pain that takes account of both the context and risk of dependence, and the principles underlying pain treatment, is essential.²²

 $^{^{21}} www.gov.uk/government/uploads/system/uploads/attachment_data/file/385791/PHE-interval attachment_data/file/385791/PHE-interval attachment_data/file/3857$

NHS_England_pregabalin_and_gabapentin_advice_Dec_2014.pdf

²² UK Guidelines on clinical management – drug misuse and dependence, 2017

Non-opioid +/- Adjuvant

The following guidance applies to non-opioids.

Paracetamol

The evidence of benefit from paracetamol varies depending on the type of chronic pain present. There is high quality evidence that paracetamol is ineffective in reducing pain and disability or improving quality of life in patients with low back pain and only offers a small but not clinically important benefit for pain and disability reduction in patients with hip or knee osteoarthritis.²³ The combination of paracetamol 1000mg – 4000mg daily plus ibuprofen 400mg has been shown to be significantly superior to paracetamol alone in patients with hip or knee osteoarthritis but is associated with a higher risk of gastro-intestinal bleeding. Paracetamol dosing should be adjusted appropriately in patients weighing less than 50 kilograms.

Oral Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

NSAIDs have an established place in therapy in treatment of rheumatoid arthritis and gout and confer some benefit in chronic low back pain and some forms of osteoarthritis. They are associated with cardiovascular and gastro-intestinal risk factors. Lower risk agents should be prescribed first line at the lowest effective dose for the shortest duration necessary to control symptoms. Ibuprofen in doses up to 1.2g daily or naproxen 0.5 -1g daily, have not been associated with significant thrombotic or cardiovascular risks. Where one drug is ineffective, a switch to a different NSAID may be helpful. Extra caution is required for the use of NSAIDs in frail patients where there is an increased risk of acute kidney injury with dehydrating illness – refer to Polypharmacy <u>sick day guidance</u>.

Topical NSAIDs and rubefacients

Topical NSAIDs are safe, may be effective and should be considered in the treatment of patients with chronic pain from musculoskeletal conditions, particularly in patients who cannot tolerate oral NSAIDs.²⁴

Topical rubefacients are safe, may be effective and should be considered for the treatment of pain in patients with musculoskeletal conditions. These can be purchased over the counter in accordance with self-management goals.²⁵

²³ BMJ 2014;350:h1225. Gustavo C et al

²⁴ SIGN 136 – Management of Chronic Pain

²⁵ SIGN 136 – Management of Chronic Pain

Opioids for mild to moderate pain +/- Non-opioid

The following guidance applies to opioids for mild to moderate pain.

Opioids for mild to moderate pain:

- Co-codamol 30/500mg 1-2 tablets four times daily.
- Codeine* 30-60mg four times daily (max 240mg/day orally)
- Dihydrocodeine* 30mg four times daily (max 120mg/day orally)

* Despite prescribing of single component dihydrocodeine/codeine potentially improving safety where patients are overusing the medicine, this may be less desirable in areas where diversion of prescriptions is an issue. Clinicians should review local formularies and guidance for further information.

The *National Therapeutic Indicators* consider Tramadol as a strong opioid. More information can be found in the section below.

'Starting low' and 'Going slow' is a good strategy for newly prescribed opioids to help minimise side effects. Low dose codeine or dihydrocodeine in combination with paracetamol (e.g. Co-codamol) has a place in therapy for all patients, but particularly those susceptible to opioid side effects to allow tolerance to develop before titrating up to therapeutic doses.

Not only is there a **lack of evidence for efficacy of opioids in the long term treatment of chronic pain** there is also considerable risk, such as increased risk of overdose, fractures, abuse or dependence; this should be explicitly discussed with patients.²⁶ A recent Cochrane reviews found an increased risk of adverse events with opioids vs placebo and vs non-opioid active comparator. There was also an increased risk of serious adverse events vs placebo. The authors noted that "based on the adverse events identified, clinically relevant benefit would need to be clearly demonstrated before long-term use could be considered in people with chronic non-cancer pain in clinical practice".²⁷

Despite limited evidence for use of co-codamol 8/500 mg, a small percentage of patients may not tolerate stronger opioids and co-codamol 8/500 mg may be appropriate in these patients. There may be some risk associated with co-codamol 8/500, such as addiction and constipation, hence a step down to paracetamol alone should be trialled. Patients who are co-prescribed two opioids for mild to moderate pain should be reviewed.

²⁶ Chou, R et al. The Effectiveness and Risks of Long Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop

²⁷ Els, C et al. Adverse events associated with medium- and long-term use of opioids for chronic non-cancer pain: an overview of Cochrane Reviews. Cochrane Database of Systematic Reviews 2017, Issue 10. Art. No.: CD012509. DOI: 10.1002/14651858.CD012509.pub2.

Strong Opioids +/- Non-Opioids

The following guidance applies to Strong opioids.

Actions for Clinicians and Clusters

Across Scotland, the number of patients on morphine equivalent doses of 50mg or above is roughly 6 per 1000 list size. Clinicians should ensure these patients are reviewed at least annually. Tools are highlighted within this document to assist in identifying this patient cohort and optimising care.

Key points for strong opioids

The following key points should be noted with regards to prescription of strong opioids.

- 1. It is crucial that the potential benefits **and** potential risks are discussed with the patient.
- 2. Side effects resulting from continuing use of opioids may include tolerance, withdrawal, weight gain, reduced fertility and irregular periods, erectile dysfunction, hyperalgesia, depression, dependence, addiction, reduced immunity, osteoporosis and constipation.
- 3. There is a variety of evidence regarding misuse of these medicines and this should be considered particularly when prescribing to at risk patients.

Strong opioids include tramadol, morphine, oxycodone, fentanyl and tapentadol. They should be prescribed **instead** of, not alongside, lower strength opioids. They are best used in conjunction with non-opioid analgesic medication to reduce dosing and side-effects. <u>Dose equivalence calculators</u> and tapering guides are available to facilitate switching or discontinuing opioids. However, it is important to point out that equivalent analgesic dose conversions are only estimates and patients may be more sensitive to the new opioid than expected, which may cause, for instance, life threatening over sedation, and/or respiratory suppression. If switching, ensure the dose is reduced on the new agent. The screenshot below demonstrates the tapering tool.

Opioid Tapering							
Deta	ils	Week/ Date	24hr Dose	Reduction Dose			
Mrs Harrison CHI	,	1 01-Oct	120.0	10.0			
123456789		2 08-Oct	110.0	5.0			
Select opioid	Morphine	3 15-Oct	105.0	5.0			
Set Reduction (%)	10	4 22-Oct	100.0	5.0			
Current 24hr Dose	120	5 29-Oct	95.0	5.0			
Target 24hr Dose (<current dose)<="" td=""><td>60</td><td>6 05-Nov</td><td>90.0</td><td>5.0</td></current>	60	6 05-Nov	90.0	5.0			
Start Date	01/10/2017 dd/mm/yyyy	7 12-Nov	85.0	5.0			
Reset F	orm	8 19-Nov	80.0	5.0			

The <u>National Therapeutic Indicators</u> consider Tramadol as a strong opioid. The dose range is 50-100mg every 4–6 hours, maximum 400mg in 24 hours. It is similar in adverse effect profile to codeine and dihydrocodeine but has a greater potential for drug interactions. **It should not be combined with other opioids for mild to moderate pain.** If converting to or from Tramadol and another opioid, be aware of the wide morphine equivalence range. Clinicians should be aware of the potentially serious side effects of prescribing tramadol with an SSRI, such as serotonin syndrome.

Opioids are not effective in every patient and this should be discussed prior to commencing treatment. Opioids are not routinely recommended for managing acute or chronic lower back pain.²⁸ If opioids are deemed appropriate then a realistic aim should be for a minimum of a 30% improvement in pain and/or a significant improvement in functional ability; complete pain relief is rarely achieved with opioids. A one to two-week trial approach is recommended when prescribing opioids, to observe efficacy, tolerability and suitability.

The patient should be reviewed within four weeks of initiation of opioid treatment. 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.

There is evidence to suggest that the majority of patients taking opioids for moderate to severe pain will develop opioid induced constipation; tolerance does not develop to this side effect.²⁹ Refer to local formularies for guidance on specific agents for opioid induced constipation. When a regimen is stable, the patient reports substantial relief of symptoms and additional concerns do not dictate otherwise, opioids should be reviewed at least six monthly.³⁰

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm. Various thresholds are quoted where the risk of harm outweigh the benefits. The US Department of Health suggests reconsidering "the individual benefits and risks when increasing dosage to \geq 50 Morphine Equivalent Dose (MED)/day, and should avoid increasing dosage to \geq 90 MED/day or carefully justify a decision to titrate dosage to \geq 90 MED/day".³¹ The risk of harm substantially increases at doses of \geq 120mg MED/day with no increase in benefit.^{32,33}

²⁸ Nice Low back pain and sciatica in over 16s, November 2016

²⁹ SIGN 136 – Management of Chronic Pain

³⁰ Faculty of pain medicine A structured approach to opioid prescribing

³¹ US Dept of Health – Centres for Disease Control and Prevention – March 2016 – Checklist for Prescribing Opioids for Chronic Pain

³² www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware

The number of deaths where a prescription opioid pain medicine, especially Tramadol, is mentioned as present on the death certificate continues to increase, which largely reflects the increase in prescribing rates. In 2016, there were 64 deaths related to Tramadol in Scotland.³⁴ Tramadol been classified as a controlled drug since 2014.

A patient story which illustrates how opioid prescribing can potential have serious, unintended consequences can be <u>read here</u>. A careful assessment of the benefits and risks of prescribing an opioid should be considered. An opioid risk assessment tool is available in the <u>resource pack</u>.

<u>Opioid Aware</u> is an excellent resource for patients and healthcare professionals to support prescribing of opioid medicines for pain.

³³ UK Guidelines on Clinical Management – Drug misuse and dependence 2017

³⁴ https://www.nrscotland.gov.uk/files//statistics/drug-related-deaths/drd2016/16-drug-rel-deaths.pdf

This case study from NHS Forth Valley explores a specific patient case, and serves to demonstrate how changes to care can have a significant impact at a patient level.

Case Study – NHS Forth Valley

A patient was referred to the pharmacist led pain management clinic. The patient has a diagnosis of Fibromyalgia with all over body pain and low back pain. She had stopped work and was prescribed eight medicines: MST 50mg bd, regular Oramorph, amitriptyline 50mg, pregabalin 150mg bd, mirtazapine 30mg, cetirizine, lansoprazole, letrozole.

The key issue for the patient was waking up at night with restless legs. Following a thorough review, the pharmacist recommended reduction or cessation of one medicine (mirtazapine). After six weeks, the medicine had been fully stopped and the restless leg issue resolved. Further review has allowed another medicine to be stopped (Oramorph) and another reduced (MST). The patient is now returning to work.

Practices in NHS Fife undertook a review of opioid prescribing focussing on safety.

Case Study – NHS Fife

GPs were asked to audit ten patients who were newly initiated on an opioid to ensure compliance with the criteria in the practice prescribing policy, recommended by NHS Fife. Five audit standards were set and the audit was repeated within the year. Comparison between the baseline and follow up data show an improvement across all standards.

The audit standards were:

1) 90% of patients newly initiated on an opioid have an indication document.

2) 90% of newly initiated patient have been given non-pharmacological advice on ways of managing their pain and given advice on side effects of opioids.

3) 90% of all newly initiated opioids are issued on acute prescription – i.e. not a repeat.

4) 90% of patients newly initiated on opioids are prescribed no more than 30 days' supply for initial and subsequent prescriptions.

5) 90% of all newly initiated prescriptions for an opioid have had a review before their next supply, within a maximum of 8 weeks.

% Patients Meeting Standard Data Set 1						% Pa	atients	Meeti	ng Star	ndard D	Data Set	2	
No. patients	Standard 1	Standard 2	Standard 3	Standard 4	Standard 5	All standards	No. patients	Standard 1	Standard 2	Standard 3	Standard 4	Standard 5	All standards
1468	93%	29%	94%	97%	83%	26%	1374	96%	54%	97%	98%	91%	50%
Tools a	re avail	able to	o assist	in un	dertakiı	ng a sir	nilar aud	it with	in the	Resou	irce Pa	ick.	

Opioid Bundle Resource

NHS Scotland colleagues have adapted a resource developed in New Zealand which bundles elements of care into a tool for quality improvement to assist audit and review of patients prescribed opioids. The bundle shares a number of principles with the tools used in NHS Fife (per case study above). The bundle is available within the <u>resource pack</u>.

Neuropathic pain

Actions for Clinicians and Clusters

There are risks of addiction and abuse for gabapentin and pregabalin – these medicines are currently being considered for reclassification as controlled drugs following the reported rise in deaths. Drug related deaths involving gabapentin and pregabalin have risen from 2 in 2009, to 225 in 2016.³⁵ Clinicians should ensure these patients are reviewed at least annually. Tools are highlighted alongside this document to assist in identifying this patient cohort and optimising care.

Lidocaine prescribing should be reviewed. There is no evidence from good quality randomised controlled studies to support the use of topical lidocaine to treat neuropathic pain, although low quality individual studies indicated that it may have a role in pain relief.³⁶

It is important to assess whether there are elements of neuropathic pain. Neuropathic pain has been defined by the International Association for the Study of Pain as pain caused by a lesion or disease of the somatosensory nervous system. <u>SIGN 136</u> recommends first line pharmacological treatment for neuropathic pain as amitriptyline or gabapentin. The drug to use first mainly depends on clinical preference and patient factors. If the response to the first agent is not helpful or is inadequate, the other may be used as a replacement or in combination. Pregabalin is an alternative in patients who have found no benefit from, or not tolerated, amitriptyline or gabapentin.

A recent meta-analysis of the pharmacotherapy for neuropathic pain in adults showed that outcomes were relatively modest. Trials were included with treatments lasting longer than 3 weeks' duration and achieved 50% pain relief with the following Numbers Needed to Treat (NNT) and Numbers Needed to Harm (NNH).³⁷ The table overleaf is based on meta-analysis from Finnerup NB et al.

³⁵ https://www.nrscotland.gov.uk/files//statistics/drug-related-deaths/drd2016/16-drug-rel-deaths.pdf)

³⁶ Derry S, Wiffen PJ, Moore RA, Quinlan J. Topical lidocaine for neuropathic pain in adults. Cochrane Database of Systematic Reviews 2014, Issue 7

³⁷ Finnerup NB et al 2015. Pharmacotherapy for neuropathic pain in adults a systematic review and metaanalysis

Drug	Number Needed to	Number Needed to	Quality of final
	Treat	Harm	evidence
Tricyclic antidepressants	3.6 (95% Cl 3.0-4.4)	13·4 (9·3–24·4)	Moderate
(TCA)			
Serotonin-noradrenaline	6.4 (95% CI 5.2-8.4)	11.8 (9.5–15.2)	High
re-uptake inhibitor (SNRI)			
antidepressants			
duloxetine and			
venlafaxine			
Pregabalin	7.7 (95% CI 6.5-9.4)	13·9 (11·6–17·4)	High
Gabapentin	7.2(95% CI 5.0-8.3)	25·6 (15·3–78·6)	High
		and 31.9 for ER	
		preps	
Tramadol	4.7 (3.6–6.7)	12.6 (8.4–25.3)	Moderate
Morphine/oxycodone	4·3 (3·4–5·8)	11.7 (8.4–19.3)	Moderate
Topical lidocaine	No information	No information	Low
Capsacin 8%	10.6 (7.4–19)	No information	High

Results of this meta-analysis showed that the efficacy of systemic drug treatments was generally not dependent on the aetiology of the underlying disorder. Despite low NNTs for tramadol and the opioids the quality of evidence is moderate and therefore the authors of the meta-analysis propose first line use for TCAs, SNRIs, pregabalin and gabapentin in neuropathic pain; a weak recommendation for lidocaine patches, capsaicin patches and tramadol as second line; and a weak recommendation for strong opioids (particularly oxycodone and morphine) as third line. However, there is no consideration of health economics in these recommendations and current acquisition costs would **endorse the SIGN recommendation of amitriptyline or gabapentin first line in neuropathic pain** (excluding trigeminal neuralgia).

The suggested doses are:

- Amitriptyline should be started at a low dose and slowly titrated up from 25mg to 125mg. In many patients it may be helpful to start with only 10mg and titrate upwards.
- Gabapentin usually starts at 300mg at night and titrates upwards usually by 300mg per week. Evidence suggests that a minimum of 1200mg is needed and doses may need to be increased to the maximum of 3600mg.
- Pregabalin usually starts at 75mg twice daily up to a maximum of 300mg twice daily. This would be managed according to side effects and clinical effectiveness.

If pregabalin is replacing gabapentin there are two options for the changeover.³⁸ Changeover should be determined by the individual patient's response to minimise disruption of pain control and withdrawal effects.

Option 1. Gradually reduce and stop gabapentin over a minimum of one week, then start pregabalin.

Option 2. Replace gabapentin with pregabalin equivalent dose as per example below:

- replace gabapentin 300mg three times a day with pregabalin 75mg twice a day
- replace gabapentin 600mg three times a day with pregabalin 150mg twice a day
- replace gabapentin 900mg three times a day with pregabalin 225mg twice a day
- replace gabapentin 1200mg three times a day with pregabalin 300mg twice a day

When changing from pregabalin to gabapentin do the above in reverse.

NB – Patients with renal impairment should have their dose of gabapentin or pregabalin reduced per BNF recommendation below.

eGFR (mLs per minute per 1 73m ²	Total gabapentin dose mg
50-79	1600-1800
30-49	300-900
15-29	150mg ^a - 600mg
<15 ^b	150mg ^a - 300mg

a. To be administered as 300 mg every other day.

b. For patients with creatinine clearance <15 ml/min, the daily dose should be reduced in proportion to creatinine clearance (e.g., patients with a creatinine clearance of 7.5 ml/min should receive one-half the daily dose that patients with a creatinine clearance of 15 ml/min receive).</p>

eGFR (mLs per minute per	Total pregabalin dose				
1.73m ²	Starting dose	Maximum dose			
30-60	75mg	300mg			
15-30	25-50mg	150mg			
<15	25mg	75mg			

Duloxetine has been accepted by the SMC for painful diabetic neuropathy and is restricted to initiation by prescribers experienced in the management of diabetic peripheral neuropathic pain as second or third line therapy. Start with 30mg per day for two weeks and titrate up to a max of 120mg per day.

³⁸ Section developed in collaboration with NHS GGC Chronic Pain Primary Care Neuropathic Guidelines Group

Carbamazepine (can be used as first line treatment for Trigeminal Neuralgia). Initial dose of 100-200mg daily, increasing slowly in increments of 100-200mg at weekly intervals. Usual maintenance dose range 600-1200mg in 24 hours. Maximum dose of 1600mg per day.

Capsaicin 0.075% cream can be used for people with localised neuropathic pain who wish to avoid, or cannot tolerate, oral treatments.

There is no evidence from good quality randomised controlled studies to support the use of topical lidocaine to treat neuropathic pain, although some individual studies (low quality) indicate that it may be effective in pain relief.³⁹ Lidocaine 5% medicated plaster is licensed for use in Postherpetic Neuralgia (PHN). It may be used in patients who have very localised neuropathic pain and who are intolerant of first line therapies, or where these therapies have been ineffective. Lidocaine patches should be worn for 12 hours on and 12 hours off, reviewed after 2 weeks and stopped if ineffective. If the patient has responded to treatment and the plaster has alleviated pain completely then a plaster-free period should be trialled after seven days of plaster use (remove for 24 hours and assess need to restart). Treatment should be reassessed frequently to decide whether the amount of plasters needed to cover the painful area can be reduced, or if the plaster-free period can be extended.

Capsaicin 8% patch is restricted to specialist use in pain management for the treatment of postherpetic neuralgia (PHN) and peripheral neuropathic pain (PNP) in non-diabetic adults who have not achieved adequate pain relief from, or who have not tolerated conventional first and second-line treatments.

³⁹ Derry S, Wiffen PJ, Moore RA, Quinlan J. Topical lidocaine for neuropathic pain in adults. Cochrane Database of Systematic Reviews 2014, Issue 7

All reviews should be undertaken in a holistic manner. The case study below serves as an example.

Patient Details	
70 year old woman	
Current medical history	
 Total knee replacement GI reflux Hypothyroidism Hypertension 	
Results	
 All blood results are normal Normal X ray Normal MRI 	 BMI 23.5 kg/m2 BP 123/74 mmHg Cholesterol of 4.5 mmol/l
Lifestyle	
 Retired cleaner Ex-smoker 20 years Little exercise Alcohol units 20 /week 	
Current Medication	
 Co-codamol 30/500 8 tabs daily Ibuprofen 400mg 1 three times dai Omeprazole 20mg once daily Levothyroxine 25mcg once daily Bendroflumethazide 2.5mg once d Simvastatin 40mg once nightly Previous medication Buprenorphine patch 20mcg/hour. 	ily - prn (3/7 if needed) aily post knee replacement 18 months ago
Current Function	Peee
 A brief Pain Inventory questionnain of 6 and an average interference so No inflammation or swelling of join position for a long time Good range of movement No neuropathic symptoms Some symptoms of postural hypotom 	re was completed showing an average pain score core of 4 hts, some stiffness on remaining in the same ension on standing
Most recent consultations	
 At her most recent consultation he feeling a bit constipated and tired No chronic pain coding - pain estab Dizzy on standing She reported that she has some pa analgesics were working and she w 	r pain management was stable and she was lished over 3 months, code as chronic pain. 1M52 in most of the time, however she didn't feel her as sedated and constipated.

Domain	Steps	Process	Patient details
Aims	What matters to the patient?	 Review diagnoses and identify therapeutic objectives with respect to: Identify objectives of drug therapy Management of existing health problems. Prevention of future health problems 	 Manage pain Minimise GI symptoms Manage hypertension – requires review
	Identify 2 essential drug therapy	 Identify essential drugs (not to be stopped without specialist advice) Drugs that have essential replacement function (e.g. thyroxine) Drugs to prevent rapid symptomatic decline (e.g. drugs for Parkinson's disease, heart failure) 	 Levothyroxine 25mcg od for hypothyroidism
Need	Does the patient take unnecessary drug therapy?	 Identify and review the (continued) need for drugs What is medication for? with temporary indications with higher than usual maintenance doses with limited benefit/evidence of its use in general with limited benefit in the patient under review, see Drug efficacy (NNT) table 	 Does she need an NSAID? Try stopping and review Is hypertension still an issue? Consider stopping bendroflumethazide Does she need a statin ? No indication recorded and appears to have been started for primary prevention
Effectiveness	Are therapeutic objectives being achieved?	 Identify the need for adding/intensifying drug therapy in order to achieve therapeutic objectives to achieve symptom control to achieve biochemical/clinical targets to prevent disease progression/exacerbation is there a more appropriate medication that would help achieve goals? 	 Pain was relatively well controlled and not interfering with function too much and she felt she was coping well. Realistic expectation of pain control discussed as well as self-management. Is ibuprofen required?
Safety	Does the patient have ADR/ Side effects or is at risk of ADRs/ side effects?	 Identify patient safety risks by checking for if the targets set for the individual appropriate ? drug-disease interactions drug-drug interactions (see <i>Cumulative Toxicity</i> tool) monitoring mechanisms for high-risk drugs risk of accidental overdosing 	 Co-codamol causing sedation and constipation. Try reduction ibuprofen causing GI s/e – consider stopping Antihypertensive causing postural hypotension. Consider stopping NSAID- older patient/ pre- existing GI risk

	Does the patient know what to do if they're ill?	 Identify adverse drug effects by checking for specific symptoms/laboratory markers (e.g. hypokalaemia) cumulative adverse drug effects (see <i>Cumulative Toxicity</i> Tool) drugs that may be used to treat side effects caused by other drugs 	
Cost- effectiveness	Is drug therapy cost- effective?	 Identify unnecessarily costly drug therapy by Consider more cost-effective alternatives (but balance against effectiveness, safety, convenience) 	
Patient centeredness	Is the patient willing and able to take drug therapy as intended?	 Does the patient understand the outcomes of the review? Consider Teach back Ensure drug therapy changes are tailored to patient preferences by Is the medication in a form the patient can take? Is the dosing schedule convenient? Consider what assistance the patient might have and when this is available Is the patient able to take medicines as intended? Agree and communicate plan Discuss with the patient/carer/welfare proxy therapeutic objectives and treatment priorities Decide with the patient/ carer/ welfare proxies what medicines have an effect of sufficient magnitude to consider continuation or discontinuation Inform relevant healthcare and social care carers, changes in treatments across the care interfaces 	 Patient keen to reduce tablet burden and try alternatives to medication. Keen to stop co-codamol 30/500mg because of side effects, risks and limited effectiveness. Also keen to reduce ibuprofen as she felt it was making her indigestion worse Discuss options- potential benefits/risks of reducing medication Shared decision making Agreed plan Co-codamol 30m/500mg reduced from 2 qid to 1 qid with paracetamol added 1qid with plan to review and further reduce if possible. Flexibility for increased dose during flare up Antihypertensive stopped and review 1/12 Statin stopped NSAID stopped Plan to review GI s/e and stop omeprazole at next consultation

Key Concepts in this case

- Importance of ongoing review of need, efficacy and side effects of medication.
- Self-management options, to include pacing, increasing activity
- A what matters to me approach, person-centered goals and a plan for what to do in flare ups. For example: patient's wish was to reduce her medication burden and attend the local walking group and the local *Pain Concern* patient education class

Guidance for Boards

Delivery and Resources

Actions for Boards

- Nominate a local lead for analgesic prescribing.
- Develop and implement an action plan for improving analgesic prescribing, identifying targeted areas informed by the *National Therapeutic Indicators, Additional Prescribing Measures*, and this document. It is likely that a multi-disciplinary approach will be of benefit.
- Consider further development of the local primary/secondary care interface.
- Boards should ensure that local plans are in place to support prescribers working in nonhealthcare settings, particularly around storage and administration of medicines.

A number of Boards have developed Prescribing Indicator Implementation Guides (PIIGs), or similar, which have been designed to support implementation of cost effective, evidence based interventions that underpin the NTIs and APMs. Analgesic PIIGs suggest cohorts of patients that can be prioritised for review; provide tools such as letters, audit templates and prescriber discussion/facilitation aids; and provide a framework for therapeutic review. Your local Prescribing Support Team would represent the first point of contact to discuss these. Boards who wish to share or consult on PIIGs should discuss this with their Scottish Practice Pharmacy and Prescribing Advisors Association (SP₃AA) member.

The Scottish Therapeutics Utility (STU) is a software programme aimed at improving the quality of prescribing. A number of searches are being developed for STU based on the NTIs and APMs. These will enable clinicians to quickly identify patients who may benefit from a review of their chronic pain medicines. Boards will be notified through their SP₃AA member(s) when the searches are available.

A template for the EMIS system has been developed to facilitate structured review. This is available within the <u>resources pack</u> alongside bundles to assist with improvement in neuropathic analgesic prescribing and opioid prescribing. PrescQIPP resources (Prescribing Checklist and a Patient Leaflet on decision making for new medicines) are also included.

Supported self-management is a key strategy for management of long term conditions. Some areas may have provision in place – where this is not the case Boards should work towards providing appropriate supporting resources to clinicians, for instance:

- Information Help to navigate, understand condition, plans and tools
- Pathways/ rapid access Right support at right time
- Emotional and psychological support Peer support, counselling at key stages
- Support around employment Guidance for employers, support to stay in work
- Access to online support Online chat, access to results, input symptoms

Boards have made use of a range of channels to deliver improved quality of care. An example of this comes from NHS Fife, who worked in partnership with Community Pharmacy to undertake reviews of analgesic prescribing.

Case Study - NHS Fife

Background

NHS Fife worked in partnership with community pharmacy. Up-skilling of community pharmacist prescribers via NHS Education for Scotland (NES) *Teach & Treat* process has allowed initial stages of review of patients on high risk pain medications as well as an exit strategy for patients from the pain service requiring further medication input. The initiative was based on a recognition that patients with chronic pain can require intensive input and this need could not be met by GPs and the pain service alone. There is also recognition that community pharmacists are often the first port of call for many patients with chronic pain who no longer regularly see their GP or have access to specialist services, and independent prescribing status can improve the quality of patient care.

The Key Components

Specific funding was made available from NES to train and up-skill the community pharmacists and fund a co-ordinator (one session per week) to drive the training. Engagement and support from the multi-disciplinary team in the pain service was crucial to allow shadowing and training. Work was undertaken with the local lead pharmacist for development of community pharmacy services and prescribing clinics. Additional funding was provided by Scottish Government to fund prescribing clinics in community pharmacies. The team developed initial project protocols to help target specific patient groups and build confidence. Patients have 30-45 minute initial appointment, which gives time to properly engage the patient in self-management and the role of medication as well as taking a full pain medication history. Qualified prescribers implement change and review, reducing the need for GP appointment times.

The Benefits

Patients can be seen closer to home and have access to appointments with enough time to fully discuss fears and beliefs which may be hindering safe and effective use of analgesics. Follow up appointments allow the implementation of plans - any changes to pain medication may require adjustment and regular reviews to achieve the optimum combination. Patient feedback has been very positive. Ultimately, patients who do not regularly attend their GP or specialist services can have their pain medication reviewed. Patient surveys confirmed these benefits. NHS Greater Glasgow and Clyde delivered benefits from a whole system approach.

Case Study - NHS GGC

Background

NHS GGC piloted an integrated approach to empower people to self-manage chronic pain and improve quality of life. A group of pharmacists, physiotherapists, GPs, pain consultant, psychologist, health improvement and patient representatives collaborated with the local HSCP, the Chronic Pain Managed Clinical Network and the community pharmacy development team to promote supported self-management of chronic pain.

The Key Components

The aim of the project was to improve primary care chronic pain pathways and deliver integrated patient-care by April 2016. In addition, to provide support and enable people in the community to better manage and cope with their chronic pain by delivering:

- 1. Pharmacist-led pain clinics delivered in collaboration with GPs.
- 2. Up-skilled Musculoskeletal (MSK) physiotherapists to deliver a better service for their patients attending with chronic pain, with a focus on supported self-management.
- 3. Early intervention in the form of peer-led, local patient education sessions delivering evidenced-based self-management strategies. These were developed and run in collaboration with the charity Pain Concern.
- 4. A community pharmacist pilot to encourage chronic pain medication review.
- 5. An overarching professional education and training session to all GPs, practice staff, pharmacists and MSK physiotherapists involved in the project, to raise awareness of person specific, chronic pain information management strategies.

The Benefits

For Patients:

- 1. Improved access to information and education on self-management of chronic pain.
- 2. Improved pain severity scores.
- 3. Clearer and better integrated primary care pathways for chronic pain management.

For GPs:

- 1. GP consultations regarding chronic pain issues halved from 3.5 per patient in the practice pre-pilot to 1.7 per patient after the pilot, over a six month period.
- 2. Improved professional satisfaction from utilising core skills to deliver better care for patients, in addition to working more collaboratively with other members of the team.

For Boards:

- 1. Small reductions in analgesic utilisation with associated reductions in drug expenditure.
- 2. Increased capacity of NHS GGC to provide supported self-management through collaborative working between NHS GGC and the third sector.

NHS Dumfries & Galloway delivered a patient centred improvement through a Local Enhanced Service (LES).

Case Study - NHS Dumfries & Galloway

In 2014/15 NHS Dumfries & Galloway introduced a Chronic Pain LES for GP practices as part of a Pain Improvement Programme. This involved a series of actions designed to improve practices' prescribing for the management of chronic non-cancer pain. Dumfries and Galloway had the highest expenditure per patient (weighted and un-weighted) on analgesics of all Scottish Boards.

Key Components

- 1. Prescribers (GPs, GP Trainees and nurse prescribers) undertook a learning module.
- 2. All non-cancer patients on high dose opiates were identified. A face to face consultation was offered for full pain review.
- 3. All non-cancer chronic pain patients on pregabalin were reviewed with consideration given to stopping or switching to gabapentin if not tried previously. Where stopping or switching was not appropriate, optimisation was undertaken.
- 4. All non-cancer chronic pain patients on a combination of codeine/dihydrocodeine and tramadol were reviewed and the prescribing restricted to one opiate where possible. A face to face or telephone review was offered to targeted patients.
- 5. All non-cancer chronic pain patients on co-codamol strengths other than 30/500 were reviewed to assess whether treatment was both clinically appropriate and cost-effective, with particular emphasis on the over-65 population.

Practices were given additional support. Lists of patients who met the criteria were checked for exclusions and discussed with the practice. Interventions were allocated to Prescribing Support Pharmacists or GPs on a case by case basis which varied between practices.

Benefits

- 1) Better understanding of chronic pain management by GPs, practice nurses and pharmacists.
- 2) Better adherence to SIGN guidance.
- 3) Better use of opiates as demonstrated in a follow up audit.
- 4) Patient feedback was positive. Patients felt they that had a better understanding of how to take their pain medication to gain maximum benefit especially in a flare up situation.

NHS Lanarkshire delivered significant improvements in lidocaine prescribing.

Case Study – NHS Lanarkshire

Background

Lidocaine 5% medicated plasters are indicated as an option for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults. There is limited comparative clinical effectiveness data available for lidocaine plasters. Despite the limited place in therapy, lidocaine plaster prescribing has been rising.

Key Components

NHS Lanarkshire have been reviewing lidocaine patch prescribing for a number of years with limited success. However in 2015-2016 NHS Lanarkshire introduced a new style incentive scheme for the GPs. Patients on lidocaine patches were invited in for a face to face review with their GP to ensure therapy was appropriate and effective. Patients receiving regular treatment were encouraged to have a plaster free trial as per guidelines. Prescribing out with the licensed indications was particularly targeted. To be counted as a successful review cycle, at least 50% of patients reviewed required to have their therapy stopped.

The aim of the scheme was to promote prescribing for the treatment of neuropathic pain in line with NHS Lanarkshire formulary guidelines and to reduce inappropriate use of lidocaine 5% medicated plasters without compromising patient safety or care by delivering:

- GP face to face review of patients prescribed lidocaine patches.
- Each Practice agreeing and applying a policy of prescribing formulary first line choices for neuropathic pain.

The Benefits

- 1. Patients had an opportunity for a GP face to face review of their lidocaine therapy.
- 2. More appropriate use of lidocaine patches.
- 3. Better understanding of the indications and evidence for lidocaine patches.
- 4. Improved formulary adherence.
- 5. Reductions in lidocaine patch utilisation with associated reductions in drug expenditure.

A resource to support improvement in this area is available in the <u>resource pack</u>.

NHS Fife undertook work to develop the primary/secondary care interface.

Case Study NHS Fife Working across the interface

Morphine is the 1st line choice strong opioid in the NHS Fife Formulary. GPs were raising concerns that many patients were being discharged from the acute setting on oxycodone and without clear review guidance, resulting in some patients being prescribed it long term.

To help identify the directorates involved, a primary care pharmacist met with a senior hospital based pharmacist and reviewed a month's discharge letters. Through this, a particular directorate was highlighted as higher users of oxycodone.

The Primary Care Pharmacist met with the Lead Clinician for the service to understand the rationale behind the prescribing and discuss the potential use of Morphine. The Acute Based Pain Nurse and Clinical Pharmacist, were able to influence change through education, intervention and by being on site regularly, to challenge any prescribing which did not follow the new agreed protocols.

The outcome is decreased use of oxycodone in the specific directorate, increased use of morphine first line and all patients discharged on strong opioids from this service now have a clear review plan as part of discharge. Further work continues to understand and address oxycodone use in other directorates. This example highlights the benefits of primary and secondary care clinicians working together to improve prescribing.

Prescribing Data on Chronic Pain

There follows a series of Board level data charts relating to prescribing for chronic pain. Within the data, the boxplot charts should be interpreted as follows:

- Median GP practices in NHS Board- dark grey bar
- Interquartile range or middle 50% of GP practices in NHS Board blue box
- Maximum and minimum whiskers, unless greater than 1.5 of interquartile range
- Outliers (°) GP practice value greater than 1.5 but less than 3.0 of interquartile range
- Extreme outliers (•) GP practice value greater than 3.0 of interquartile range

The three year charts utilise the mean position of the Board, each year.

The data provided must be considered within the context of local populations and local healthcare arrangements, and provides an indicator of clinical practice. Due to the complex nature of the prescribing being analysed it is not possible to provide advice on *what good looks like*.

Gabapentinoids: pregabalin and gabapentin DDDs per 1,000 LS per day

Prescribers should aim to reduce gabapentinoids prescribing where possible without detriment to patient relief or quality of life. There is published evidence that both gabapentin and pregabalin are subject to abuse. Aim for a lower median value with a short interquartile range



Gabapentinoid DDDs per 1,000 list size per day April to June of 2015 to 2017



NB: Weighted population data is available on request

Morphine as a % of all Morphine, Oxycodone, Fentanyl, Tapentadol and Hydromorphone Morphine is a well-established opioid. SIGN 136 reports that there is no evidence of different pain control between opioids, including morphine. However, if opioid prescribing is required, then morphine is the preferred option for cost effectiveness reasons. Aim for higher a median value with a short interquartile range.

Morphine as a percentage of all Morphine, Oxycodone, Fentanyl, Tapentadol and

Hydromorphone (DDDs) April to June 2017 Morphine as a percentage of Strong Opioids 100% 0 0 80% 60% 40% 20% 0 0 0% 0 0 ISLES ARRAN GLASGOW & CLYDE AYRSHIRE & FORTH VALLEY GRAMPIAN SCOTLAND LOTHIAN TAYSIDE SHETLAND WESTERN HIGHLAND BORDERS LANARKSHIRE DUMFRIES & FIFE GREATER GALLOWAY ORKNEY

Morphine as a percentage of all Morphine, Oxycodone, Fentanyl, Tapentadol and Hydromorphone (DDDs) April to June of 2015 to 2017



O April 2015 to June 2015

April 2016 to June 2016
 April 2017 to June 2017

Number of patients prescribed equivalent to ≥120mg per day of morphine as a % of patients prescribed step 2 and strong opioids

Opioids can provide symptomatic benefits, however growing evidence demonstrates increased risk associated with long term use such as overdose, abuse, fractures, myocardial infarction, and markers of sexual dysfunction.⁴⁰ The risk of harm substantially increases at doses of ≥120mg MED/day with no increase in benefit.^{41,42} Prescribers should aim to reduce opioid prescribing using the lowest dose where possible without detriment to patient relief or quality of life. Aim for a lower median value with a short interquartile range.



Number of patients prescribed equivalent to ≥120mg per day of Morphine as a percentage of patients prescribed Step 2 and Strong Opioids





⁴⁰ Chou R, I, et al. Ann Intern Med. 2015;162:276-286. doi:10.7326/M14-2559

⁴¹ US Dept of Health – March 2016 – Checklist for Prescribing Opioids for Chronic Pain

⁴² www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware

Number of patients prescribed equivalent to ≥50mg per day of morphine as a % of patients prescribed step 2 and strong opioids

Opioids can provide symptomatic benefits, however growing evidence demonstrates increased risk associated with long term use such as overdose, abuse, fractures, myocardial infarction, and markers of sexual dysfunction.⁴³ Risks and benefits should be reconsidered when increasing dosage to ≥50mg per day of morphine. Prescribers should aim to reduce opioid prescribing using the lowest dose where possible without detriment to patient relief or quality of life. Aim for a lower median value with a short interquartile range.





Number of patients prescribed equivalent to ≥50mg per day of Morphine as a percentage of patients prescribed Step 2 and Strong Opioids January to June of 2015 to 2017



⁴³ Chou R, Turner JA, Devine EB, Hansen RN, Sullivan SD, Blazina I, et al. Ann Intern Med. 2015;162:276-286. doi:10.7326/M14-2559

Number of patients prescribed strong opioids (inc tramadol) long term (>2 years) as % of patients prescribed strong opioids

Growing evidence demonstrates increased risk associated with long term opioid therapy such as overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction. Prescribers should aim to reduce opioid prescribing where possible without detriment to patient relief or quality of life. Aim for a lower median value with a short interquartile range.





Number of patients prescribed Strong Opioids (inc Tramadol) long term (>2 years) as a percentage of patients prescribed Strong Opioids July 2013 - June 2015 to July 2015 - June 2017



40

Step 2 opioids (other than strong opioids)

Opioids can provide symptomatic benefits for chronic non-cancer pain, however, repeated administration may cause problems of tolerance, dependence and addiction. Prescribers should aim to reduce opioid prescribing where possible without detriment to patient relief or quality of life. Aim for a lower median value with a short interquartile range.



Step 2 Opioids (other than Strong Opioids) DDDs per 1,000 list size per day April to June 2017

Step 2 Opioids (other than Strong Opioids) DDDs per 1,000 list size per day April to June of 2015 to 2017



April 2016 to June 2016
 April 2017 to June 2017

Lidocaine Patch Gross Ingredient Cost per 1,000 weighted list size

There is no evidence from good quality randomised controlled studies to support the use of topical lidocaine to treat neuropathic pain, although some individual studies (low quality) indicate that may be effective for relief of pain.⁴⁴ Lidocaine prescribing should be reviewed regularly to ensure efficacy. Aim for a lower median value with a short interquartile range.









⁴⁴ Derry S, Wiffen PJ, Moore RA, Quinlan J. Topical lidocaine for neuropathic pain in adults. Cochrane Database of Systematic Reviews 2014, Issue 7

The Polypharmacy Review Process

The '7-Steps' approach to medication review

The following seven steps are intended as a guide to structure the review process.

Step 1: What matters to the patient. Identify aims and objectives of drug therapy by asking the patient *what matters to you*. Before embarking on a clinical medication review it is helpful to establish the aims and objectives of drug therapy on the basis of the information available, i.e. patient demographics, medical and drug history, laboratory markers, social situation. Based on this information, likely treatment objectives can often be identified, and will require agreement with the patient (see step 7).

Step 2: Identify essential drug therapy. A rational first step of the medication review is to separate the list of drugs the patient is currently taking into those that are essential and should usually not be stopped from those that could potentially be stopped. Essential drugs in this respect are those that have a replacement function or may cause rapid symptomatic decline or loss of disease control if stopped, and should only be stopped on specialist advice.

Step 3: Does the patient take unnecessary drug therapy? For the remaining drugs, it should be verified that each has a function in achieving the above defined therapeutic objectives and whether their use is supported by a sufficient up to date evidence base. In addition to stopping drug therapy with expired indications, the continued need for prophylactic treatments in patients with a short life expectancy should be considered.

Step 4: Are therapeutic objectives being achieved? The next step is to check whether the remaining drugs are the most effective for the indication they are used for and whether they are actually achieving what they are intended to achieve. If this is not the case, the possibility of patient non-adherence should be investigated as a potential explanation. Otherwise, the need for intensifying doses or adding or replacing drugs may also be considered.

Step 5: Is the patient at risk of ADRs or suffers actual ADRs? The presence of ADRs can sometimes be identified from laboratory data (e.g. hypokalaemia from diuretic use), or the patient reports such symptoms. However, ADR identification often requires a more pro-active approach of identifying ADR *risks* (including drug-drug and drug-disease interactions, but also the patient's ability to self-medicate) and asking the patient specific questions (e.g. about the presence of anticholinergic symptoms, dizziness or drowsiness).

Step 6: Is drug therapy cost-effective? Opportunities for cost minimisation should be explored, but changing drugs for cost reasons should only be considered if effectiveness, safety or adherence are not comprised.

Step 7: Is the patient willing and able to take drug therapy as intended? Assessment of adherence has been mentioned in steps 4 and 5 as a way to explain drug therapy failure or identify drug therapy risks, but this steps aims at optimising the drug regimen so that adherence is as easy as possible. In order to maximise their involvement and cooperation, patients should be explicitly asked what they hope to achieve from drug therapy and be empowered to make decisions regarding effectiveness versus safety as well as symptom control versus longevity.

An overview of the '7-Steps'

Domain	Steps	Process	
Aims	1. What mathematical What mathematical What mathematical with the particular sector with the particular sector with the particular sector with the particular sector sec	Atters atters atient Atters Prevention of future health problems Atters	
Need	Identify 2. essential therapy	 Identify essential drugs (not to be stopped without specialist advice) Drugs that have essential replacement functions (e.g. thyroxine) Drugs to prevent rapid symptomatic decline (e.g. drugs fo Parkinson's disease, heart failure) 	: r
Need	Does the patient t unneces drug the	 Identify and review the (continued) need for drugs with temporary indications with higher than usual maintenance doses with limited benefit in general for the indication they are for with limited benefit in the patient under review 	used
Effectiveness	4. Are thera objective achieved	apeutic es being i?	ler to
Safety	Does the patient P ADR or is of ADRs 5. Does the patient k what to they're il	Identify patient safety risks by checking for• drug-disease interactions• drug-drug interactions• orbustness of monitoring mechanisms for high-risk drugs• orbustness of monitoring mechanisms for high-risk drugs• drug-drug and drug-disease interactions• risk of accidental overdosingIdentify adverse drug effects by checking for• specific symptoms/laboratory markers (e.g. hypokalaemia• drugs that may be used to treat ADRs caused by other druSick Day Rule guidance	a) a
Cost- effectiveness	6. Is drug th cost-effe	 herapy identify unnecessarily costly drug therapy by Consider more cost-effective alternatives (but balance agaeffectiveness, safety, convenience) 	ainst
Patient centeredness	Is the pa willing an to take of therapy intended	 Identify risks to patient non-adherence by considering Is the medicine in a form that the patient can take? Is the dosing schedule convenient? Is the patient able to take medicines as intended? Might the patient benefit from the Chronic Medication Se (CMS)? Is the patient's pharmacist informed of changes to regime as the patient benefit from the chronic to patient preferent by Discuss with the patient/carer/welfare proxy therapeutic objectives and treatment priorities Decide with the patient/carer/welfare proxies what medinave an effect of sufficient magnitude to consider continuation or discontinuation 	ervice en? nces cines

Glossary

Chronic Pain - Pain lasting longer than 12 weeks or which has persisted beyond normal tissue healing time

- Polypharmacy The use of more than one medicine by a patient
- SIGN Scottish Intercollegiate Guidelines Network
- NTI National Therapeutic Indicator
- APM Additional Prescribing Measure
- **BNF** British National Formulary
- Cluster A group of GP practices within a Health Board
- HSCP Health and Social Care Partnership
- Read Code A code within primary care IT systems to indicate particular information
- OTC Over the Counter Medication
- NSAIDs Non-Steroidal Anti-Inflammatory Drugs
- Formulary A list of medicines recommended for use within a Health Board
- NNT Number Needed to Treat
- NNH Number Needed to Harm
- MED Morphine Equivalent Dose