NHS England

Pain Management Formulary for Prisons:

Implementation Guide

Document Title: Pain Management Formulary for Prisons

Subtitle: Implementation Guide

Version number: 1

First published: December 2015

Gateway Number: 04243

Prepared by: Health and Justice Clinical Reference Group NHS England

Classification: OFFICIAL

Contents

Acknowledgements

The Formulary Working Group would like to thank:

- Norfolk CCGs for allowing the use of their CCG formulary template to develop this prison formulary.
- UserVoice and Val Conway for their co-operation in delivering service user forums and interviews to inform this programme.
- Arun Sondhi (Therapeutic Solutions Addictions) and Rosie Ayub (Patient and Public Partnership Account Manager NHS England) for their advice on engaging service users.

1 Executive summary

The NHS makes widespread use of formularies to support clinical decision making and optimising medicines use in all sectors of healthcare practice. Formulary development is underpinned using NICE Medicines Practice Guidelines: (MPG1) Guidelines "Developing and updating local formularies" (updated February 2014).

The Prison Healthcare Board (England) approved a programme of work, hosted by the NHS England Health and Justice Clinical Reference Group, to deliver a recommended national pain management formulary for use in HM Prisons. In prisons there are some medicines where diversion or abuse of medicines is known to be problematic, leading to medication safety incidents some of which result in patient harm[1].

The formulary supports clinicians in the management of acute or persistent pain and neuropathic pain for people in prisons taking account of the specific challenges of prescribing pain medicines in prisons. The formulary does not include the management of pain in palliative care or antispasmodics (including benzodiazepines) and pain management for specific clinical conditions such as gout, rheumatoid arthritis or migraine. When selecting analgesia for these conditions, as advised by clinical guidelines, clinicians can still use the formulary to inform analgesic choices.

The formulary is published as two documents that are available on the NHS England Health and Justice Resources page *(link)*. They should be used together to embed the formulary into practice:

- The Formulary - this document contains the recommended medicines along with advice and clinical guidance links to support these choices.

- The Implementation Guide - this guide provides information about:

    - The scope and development of the formulary and who should use it.
    - How medicines fit into the pain care pathway versus alternative treatment.
    - The patient perspective on their experiences of current pain care in prisons.
    - Prescribing, reviewing and continuing pain care for people coming into prison, during their stay and on release or transfer to another prison.
    - Self-care and supporting self-management of pain by prisoners.
    - How to optimise safety when prescribing and using pain medicines for people in prison.

In addition to these publications, practical implementation tools and examples of good practice in managing pain in prisons will be collated and published in due course.

[1] Review of Unclassified Deaths report NOMS, National Offender Management Service, May 2012 Link

2 Introduction

The NHS makes widespread use of formularies to support clinical decision making in all sectors of healthcare practice. Formulary development is underpinned using NICE Medicines Practice Guidelines: (MPG1) Guidelines "Developing and updating local formularies" (updated February 2014).

Prisons usually use local CCG formularies to support prescribing decisions as this demonstrates parity and equity for prisoners and community-based patients. These CCG formularies have undergone robust processes that ensure formulary inclusions have a clear clinical evidence base and demonstrate value for money that supports positive clinical outcomes.

In prisons there are some medicines where diversion or abuse of medicines is known to be problematic, leading to medication safety incidents some of which result in patient harm[2]. To support clinicians in identifying and taking account of these risks, the Royal College of GPs (RCGP) and Public Health England, in partnership with other organisations, has published two key guidance documents: Safer prescribing in Prisons (2011) and Persistent Pain in Secure Environments (2013).

An audit suggests that 75% of prisons have a prison pain formulary[3] but only 1 in 5 of these formularies is implemented. There is also variation in the selection and use of specific medicines within those formularies. This means that as prisoners move between prisons there are inconsistencies in the medicines they are prescribed within common pain care pathways. There are also differences in how formularies are applied to patients who are started on a medicine for the first time versus a patient who is admitted to the prison already being prescribed it from care in another prison, a community GP or hospital clinician.

In July 2014 the Prison Healthcare Board (a partnership Board between NHS England, Public Health England and the National Offender Management Service (NOMS)), included the development of a national prison pain management formulary within priority 5 of the National Prison Healthcare Partnership Agreement.

The national formulary provides the basis for these benefits/outcomes:

- Greater consistency for patients who will receive medicines for pain that are underpinned by additional safety improvements during their time in prison.
- Improved patient experiences at transfer of care as a common formulary will be used.
- Clinicians can base their decision-making against a formulary that takes account of NICE guidance, current practice and known risks in prisons. They will know that the formulary is being followed by other clinicians who have or will care for the patient whichever prison the patient resides in.
- Clarity for providers and commissioners in expectations of how medicines for pain management are integrated into pain management care pathways.
- Improved interpretation of prescribing patterns as these would shift towards formulary medicines, potentially reducing costs and duplication of effort.

[2] Review of Unclassified Deaths report, National Offender Management Service, May 2012 Link
[3] Audit of pregabalin and gabapentin use in prisons, Specialist Pharmacy Service, 2013 Link

2.1 Holistic approaches to pain management

Medicines should always be used as part of a wider treatment plan including advice on physical activity or physiotherapy, sleep and support in achieving improvements in mental health and quality of life. Medicines don't work for all patients and will not usually make the patient pain free. Medicines can help reduce the intensity of pain sufficiently that patients can do things that would otherwise be difficult.

In prisons, there are unique opportunities where facilities and support are available to provide multidisciplinary care for pain that avoids or complements the use of medicines. Examples include psychological or occupational therapies and access to specialised gym activities.

Partnerships between prison and healthcare teams to deliver these opportunities are essential to providing a holistic approach to pain care that avoids the sole reliance on medicines.

2.2 Formulary structure and scope

The formulary outlines a rational, evidence based approach to the use of pain relief medicines for people in prisons. It is not a comprehensive clinical guideline for pain management, but there are links signposting clinicians to relevant information.

The formulary **excludes pain management for palliative care.** Clinicians should continue to use national palliative care guidance when prescribing pain relief for these patients. Also excluded from the formulary scope are antispasmodics (including benzodiazepines) and pain management for specific clinical conditions such as gout, rheumatoid arthritis or migraine. When selecting analgesia for these conditions, as advised by clinical guidelines, clinicians can still use the formulary to inform analgesic choices.

The formulary consists of three main elements available at *(formulary web-page link)*:

1. The Formulary: This contains the formulary medicines and detailed information about them to support choice. It has two sections:
    - Acute and persistent pain
    - Neuropathic pain

    There are quick reference formats for both sections that can be printed and used locally to promote their use.

2. This Implementation Guide: This document describes the background to the formulary and how to use it.

3. Implementation Resources: This is a collation of practical information and tools that have been shared by providers and partners covering various aspects of formulary use and pain management. This area of the website will be updated as new resources are shared.

2.3 How the formulary was developed

The formulary was developed by the Health and Justice Clinical Reference Group (CRG). A working group of stakeholders was convened to develop and agree the content of the formulary in line with NICE Medicines Practice Guidelines: (MPG1) Guidelines "Developing and updating local formularies" (updated February 2014).

The medicines were selected using a combination of clinical guidance and evidence appraisal, individual expertise and known safety concerns within secure environments.

A formal targeted consultation of the draft formulary selections and information was completed in March 2015. Responses were analysed by the working group and accounted for in the final version of the published formulary.

A series of prisoner forums were undertaken to include a contribution from patients in the implementation guide. This helps clinicians using the formulary to take account of patient experience and individualised care when making clinical decisions with patients about pain medicines.

The formulary working group and wider CRG will review the formulary periodically and provide advice on how the implementation of the formulary can be evaluated.

2.4 Who should use this formulary

The main users of the formulary are clinicians and other practitioners involved in treating people in prison who are in pain. For robust implementation of the formulary all prescribers in prisons must be able to use the formulary when prescribing for pain. Healthcare providers should raise awareness of the formulary and encourage its use by all staff including temporary staff and locums.

As pain is a complex symptom, with known links to mental health well-being, mental health clinicians can use the formulary as a reference when supporting people with pain and mental health diagnoses.

The formulary will be a useful reference for substance misuse clinicians as many medicines in the pain formulary have the potential for dependence and misuse. In addition pain symptoms can arise as people reduce their doses of opioid substitution therapy. The formulary provides advice on this issue and how to safely manage substance misuse treatment in combination with pain relief.

Dentists use the Dental Practitioners' Formulary which includes medicines for dental pain. We have taken account of this when selecting medicines for the formulary.

Additional clinicians who can also use the formulary to support continuity and safe care for people in or recently released from prisons are:

- Primary care prescribers - when reviewing care for released prisoners, the formulary can be used as a reference during care review as it explains the basis of medicines choices for pain made during the patient's time in prison.

- Secondary care prescribers - Prisoners will be a small subgroup of the people seen by secondary care clinicians. However using the prison pain formulary where possible for urgent, medical and surgical treatment (including specialist pain services) and following the principles of prescribing for pain detailed in the formulary, will enable pain medicines to be continued safely when the prisoner is discharged from hospital.

2.5 The patient perspective

During the development of the formulary, UserVoice an organisation led by ex-offenders, delivered focus groups and face to face interviews in four prisons for prisoners who had accessed care for pain or were currently taking medicines for pain. The aim of the sessions was to gain an insight into the patient experience of being treated for pain so that:

- clinicians and prison staff can incorporate the findings into their local formulary implementation plans and pain care pathway reviews.
- healthcare providers can consider how to use patient forums locally to include the patient voice in care planning and feedback.

2.5.1 Key themes arising from prisoner feedback

There were four main themes that prisoners shared:

- Delays in accessing treatment: Prisoners in all prisons reported delays in being able to attend consultations with clinicians. Participants reported delays of days and weeks. However prisoners valued access to specific pain clinics in the prison:

Feedback examples:

"I had a toothache for a whole month." "The waiting list is always long."

"To see a doctor was slightly more difficult [than a nurse] because every time I was in pain I still had to follow the standard procedures which could and did take days."

"They [the pain clinics] got their meds sorted."

"Now I have seen pain clinic they have examined me, seen my hip x-ray and got me decent pain relief."

- Differing experiences patients have with clinicians treating them: Prisoners felt that healthcare staff didn't take their pain seriously and experienced a poor attitude of staff towards them. This was highlighted more by the focus group in a remand prison (a prison that receives people from the community/court):

Feedback examples:

"Non-caring attitude of healthcare staff needs to change."

"What's the point of asking them, they don't listen?"

"Doctors [and] nurses need to understand that we are in jail, so need to be treated properly, not treated like we are caged up."

- Inconsistencies of care as prisoners move between prisons and on admission: Participants were asked how moving between prisons affects their pain medication. Prisoners stated that moving between prisons means they have to start the process of explaining their issues from the beginning as opposed to information being transferred. Prisoners also felt moving between prisons delays their healthcare, leading to a stressful experience:

Feedback examples:

"When you go to a new jail, they can get your records up but they get you to go through your life story again. They'll say 'well, it's because I care about you, I want to know."

"Sometime it takes [a] long [time for the] medication to catch up with you. It can be stressful."

"Dr on the out[side], gives me what I want and then when I come in here, you lot take it off me so I have to buy it on the wing and then when I get out I go back to my doc and he gives me what I want again."

- Perceptions and dissatisfaction that only simple analgesics will be provided: This theme arose in all prisons and prisoners expressed frustration that stronger analgesics were not prescribed:

Feedback examples:
"I had a broken hand. I've broken that bone twice before, I knew exactly what it was. I got told to wait 48 hours for the swelling to go down. I was given 20 ibuprofen, two days later! I haven't bothered going back, what's the point? I've lost faith in the system."

"We always get something for pain, just that it's generally

Participants were asked if there were any other ways that pain was dealt with in prison other than by medication. They openly shared that they use illicit means to manage their pain - for example they referenced a need to access opioid medicines, such as buprenorphine (Subutex) from people being treated for heroin addiction:

Feedback examples:
"Some prisoners use illegal drugs as the usual paracetamol is not always effective."

"You go down and see the local 'Pablo' [drug dealer] and get something."

2.5.2 Taking account of service user feedback

Overall, participants from both prisons were unhappy with the complications linked with trying to see a healthcare professional such as the long waiting times, perceived inappropriate prescriptions and the treatment and attitude towards patients. The general consensus was after the long waiting time patients found the healthcare professionals were easy to talk to, but most would like to have stronger alternatives available.

Responses regarding the service users moving between prisons highlighted that no system is currently in place to ensure the transfer of care is without complications.

Participants from both prisons felt adjustments needed to be made with the medication available for service users.

Managing pain in prisons is clearly a challenge for prisoners as well as clinicians.

When writing this implementation guide we have valued and taken account of these themes across all the following sections. We encourage healthcare providers, their teams and prison staff colleagues to consider these themes when planning and delivering care for pain in prisons.

2.6 Equality and Diversity

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it.

- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities.

3 Integrating the formulary and pain medicines into pain care

The formulary is only one part of providing high quality pain management services and care. This section describes how the formulary and medicines fit into to the wider pain pathways.

Pain is usually described as **acute** (short term) or **persistent** (long term) pain (usually more than three months). Both types of pain can range from mild or severe with the difference being how long the pain lasts.

Acute pain is usually related to an obvious injury such as dental disease, fracture or surgical procedure. Treatment can be given for a short time while healing of the injury begins. Acute pain is often straightforward to treat with a range of medicines depending on the pain severity.

Persistent pain sometimes begins with an acute injury but the pain does not settle as expected and sometimes it is not clear how a persistent pain has started. Common types of persistent pain include low back pain, arthritis pain and pain related to injury to a nerve or other part of the nervous system (**neuropathic pain**). Persistent pain is usually not a sign of ongoing tissue damage but may relate to changes in the nervous system that occur over time so that the injury signals travelling down nerves (which are usually short lived) become self-sustaining over a prolonged period.

A pain care pathway for persistent pain is underpinned by a comprehensive assessment that includes:

- assessment of the pain symptoms including assessment of how the pain interferes with function,
- past medical history for physical and mental health,
- medication history (linked to a medicines reconciliation – see section 4.1.1),
- physical examination and assessment of mobility,

- supporting tests where indicated (e.g. blood tests, x-rays, scans) but note that these may not identify the cause of persistent pain.

Usually patients will need more than one component of a pain management plan. The treatment of pain necessarily includes management of any underlying medical condition that may be causing pain as a symptom and also includes parallel management of any emotional or mental health problems that the patient may have.

The management of persistent pain usually involves a number of healthcare professionals including doctors (GPs and specialists), physiotherapists, and mental health teams in collaboration with the patient. It is also important to include other people who the patient comes in contact with (e.g. gym staff, officers) in development of the best plan for the patient. Good communication between team members and between the healthcare team and the patient is important and all treatment decisions and discussions should be documented to facilitate the multidisciplinary approach.

3.1 Managing pain symptoms

The sorts of treatments that can provide a useful part of the pain management plan can be divided into medicines and non-medicinal treatments.

Non-medicinal treatments include:

- self-care (see http://www.paintoolkit.org/tools for some examples),
- transcutaneous electrical nerve stimulation (TENS),
- acupuncture,
- individualised or group physical activity programmes (e.g. in partnership with the gym team),
- cognitive behavioural therapy,
- meditation based techniques such as mindfulness.

Medicines play a small role in the treatment of long-term pain. If they are used, medicines should always be part of a wider pain care plan including advice on physical activity or physiotherapy, sleep, general advice about managing pain such as weight loss and exercise and support in achieving improvements in quality of life.

Facilities and services available for people in prisons such as occupational, rehabilitation and gym services provide a unique opportunity to deliver a holistic approach to pain within a single setting.

Medicines don't work for all patients and will not usually make the patient pain free. Medicines may be used to help reduce the intensity of pain so that patients can do things that would otherwise be difficult. It is important to explain to patients that complete relief of symptoms is not necessarily the goal of therapy so they understand the expected outcomes from treatment.

N.B. Selecting medicines from this formulary means that prescribing choices take account of the latest clinical evidence and the safety of pain medicines in the prison environment.

Some pain medicines are also used for other indications. Clinicians assessing and treating prisoners for pain symptoms will need to take account of other care pathways that prisoners have accessed where pain medicines could have been prescribed.

3.2 Over the Counter (OTC) medicines

For minor pain, whether for acute or minor persistent pain, prisoners can usually access over the counter pain medicines such as paracetamol or ibuprofen.

As for people in the community, prisoners should be encouraged to self-manage their health for minor ailments including mild pain symptoms.

Healthcare providers in prisons have used a variety of ways for prisoners to access pain medicines for self-care. These include:

- Including paracetamol in the list of items that can be purchased from the prison canteen list - this is supported by links with the canteen list administrators that limits the supply purchased and feeds back information about purchases to healthcare teams.

- Setting up the equivalent of a pharmacy “shop” or healthcare-based OTC access that includes self-care pain medicines. The items can be accessed directly from the pharmacy or nursing staff and prisoners pay for these using their prison-based accounts.

- Some prisons have arranged for access to paracetamol or ibuprofen outside healthcare service hours. They use robust protocols where there is a principle of self-assessment and access by the prisoner, facilitated by prison staff. Healthcare follow-up this access the following day so that a record can be made of the supply and any further clinical action taken.

In all cases, the access of pain medicines for self-care should be documented in the clinical record so repeated or prolonged access can considered for further clinical assessment.

3.3 Pain medicines for minor ailments

Minor ailment clinics or “special sick” arrangements in some prisons enable the supply of paracetamol or ibuprofen by nurses or pharmacy staff using a formal protocol. Where these supplies enable the supply of pharmacy medicines (i.e. pack sizes or formulations only available under the supervision of a pharmacist) or prescription only medicines, a Patient Group Direction is used. Further examples of these will be available within the implementation resources for this formulary.

4 Prescribing pain medicines - general principles

This section describes a common set of principles that apply to all decisions to prescribe a pain medicine, whether

- it is for an acute or long term medicine,
- it is the first time it has been prescribed,
- it is being reviewed or is continuing care started by a previous prescriber.

As with any medicine, the General Medical Council "Good practice in prescribing and managing medicines and devices" (2013) and Medicines Optimisation NICE Guideline (NG 5, 2015) underpin safe and effective prescribing to get the best outcomes for individual patients.

In prisons there are additional risks of demand, patient expectations, bullying for and illicit trading of medicines, and a high prevalence of drug dependence. These influence the safety of prescribing medicines for pain relief. The following points contribute to improving prescribing safety:

- Complete a thorough assessment of the patient's pain with a documented indication or diagnosis when a pain medicine is prescribed.

- Consider diagnoses and treatment especially substance misuse and mental health diagnoses. Close working with clinicians treating the patient for these is needed to maximise outcomes for the patient. This also minimises the risk of adverse effects, drug-drug interactions and the risk of developing dependence on pain medicines. Delaying prescribing or providing very short term initial prescriptions in some cases will facilitate this multidisciplinary approach to pain management.

- Some medicines e.g. pregabalin and opioid drugs are associated with particular risks in prisons. Given the risks to the patient of prescribing these drugs, following a full assessment of the patient's pain and other co-morbidities, prescribing may be delayed in order for all of the healthcare team to discuss the patient and make a safe prescribing plan. This approach will facilitate this multidisciplinary approach to pain management

- Select formulary medicines for their licenced indications unless the formulary advises specific, commonly used off-label use. Local unlicensed medicines policies will need to be updated to incorporate these choices.

- Use a sequential approach to medicines choices as detailed in the main formulary.

- Prescribe appropriate quantities: in prisons prescription lengths are usually for a maximum of 28 days. Shorter durations are likely to be needed for:

  - Newly prescribed medicines (on admission or for new diagnoses): This allows time for verification of previous prescriptions or to assess the efficacy of the medicine before prescribing larger amounts.

  - Acute pain indications or post-operative/post-hospital care.

- For long term pain medicines, link prescribing to a documented pain management plan.

- Regularly review **the diagnosis and prescribed pain medicines**, with more frequent reviews after the first prescription prescribed in prison. A maximum review period of six months for all pain medicines is recommended.

- Repeat prescriptions: as with other long-term care, repeat prescribing can be used for pain medicines except for Schedule 2 and 3 controlled drugs (CDs) (see box 1).

Box 1: Repeat CD prescribing

"It is clear under the current legislation that repeat prescribing of CDs in Schedule 2 and 3 is not permitted. However, management systems which allow the patient to receive a prescription without a consultation is not subject to legislation, but is a clinical decision made on a case by case basis. It is good practice that patients should be reviewed before prescribing Schedule 2 and 3 CDs."

NPC, 2009, A guide to good practice in the management of controlled drugs in primary care.

- Use medicines adherence information and non-clinical information to support prescribing decisions. For example:
  - Functional assessments before and during treatment. These involve receiving activity assessments from other aspects of the patient's day to day life (such as gym use, work activities, sport) and are a useful contribution to the patient consultation and review.

  - Use the e-medication or manual drug chart that shows whether the medicines have been supplied or administered as expected.

  - Outcomes from physical adherence checks (i.e. cell searches) and incidents or issues recorded about medicines use. These provide further evidence of how the medicines are contributing to clinical benefits and will identify potential risks of illicit use or self-harm.

4.1 Continuing prescribed pain medicines on admission

One of the main dilemmas facing prescribers in prisons is how to manage a patient when they first come into prison. This is particularly the case where the patient only provides a verbal medication history of pain medicines use and there is little or no documented information to support this from other care settings.
It is important that the healthcare professional who first meets the patient on arrival in prison, determines the need for a prompt expert pain management assessment.

Whilst waiting for further information or in the absence of this information, prescribers make clinical decisions that result in:

- continuing the pain medicines (sometimes with a low quantity of initial supply),
- stopping the medicine in the short-term or long term,
- prescribing an alternative.

There is no general rule that can be applied for this decision and so each case has to be considered on an individual patient basis. However the principles of prescribing shown above and in section 4.2 can support clinicians in handling this issue along with the use of a formal medicines reconciliation process. Clinicians should review the diagnosis when prisoners are transferred into prison and transferred between prisons.

4.1.1 Medicines Reconciliation

Medicines reconciliation (see box 2) can be a useful process for verifying previous and current pain medicines used by a patient. The use of medicines reconciliation (Meds Rec) to increase the safety of transfer of care in any setting is recommended by the Medicines Optimisation NICE Guideline (NG 5, 2015).

Box 2: Medicines Reconciliation

"The collection and accurate identification of a patient's current list of medicines prior to [hospital] admission PLUS the identification AND recording of any discrepancies compared with the list of medicines prescribed since the [hospital] admission. Resolution of any discrepancies identified should occur as soon as possible using clinical judgement to ensure safe and effective patient care."

Introducing a formal Meds Rec process for prisoners either at reception or between reception and the second health assessment will provide clinicians with consistent and verified information about medicines, including those for pain, taken by prisoners prior to custody.

Several prisons have already implemented Meds Rec using nursing and pharmacy staff to deliver it dependent on the local workforce. A toolkit for the implementation of Meds Rec has been published by the Specialist Pharmacy Service and this can

provide practical information about how to embed Meds Rec into prison healthcare practice.

4.2 Reviewing pain medicines

Reviewing any medicine is defined by NICE as "a structured, critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste". The Medicines Optimisation NICE Guideline (NG 5, 2015) provides additional guidance about delivering effective reviews.

In prisons, reviewing pain medicines to inform and increase the potential for safe care and better clinical outcomes for the patient needs to include several elements. This means that consultations for pain medication review may need to be longer than other routine appointments, or that clinicians need to gather information prior to the review (e.g. using a multidisciplinary approach) before seeing the patient.

It is important that the use of the formulary does not distract from individualising care. Changing the medicines prescribed from non-formulary to formulary medicines should be to improve or maintain clinical outcomes (see box 3).

Box 3: Switching to formulary medicines

The use of wholesale switching policies for pain medicines (e.g. where a person is currently prescribed a non-formulary medicine) is not recommended. However the review of the person's pain provides an opportunity to prescribe a formulary medicine or non-medication intervention if clinically appropriate.

Here are some tips for completing a pain medication review:

- Choose an appropriate time period between reviews. This will usually be maximum of 6 months, but much shorter periods will be appropriate when:
  - Initiating pain medicines for new diagnoses.
  - After adjusting doses or medicines so that the effectiveness of this change can be considered sooner.
  - Continuing pain medicines on admission or transfer - a shorter time for review can support the consideration of additional clinical information received after the initial consultation.
  - Uncertainty exists about the extent of the pain or if adherence suggests unexpected over or under use of medicines.
  - Pain medicines have been prescribed by secondary care. The review can identify whether the pain relief can be reduced or discontinued or if advice from or referral back to the specialist is needed.
  - There is evidence that the prescribed medicine may have been diverted recently or the patient has a past history of medicines diversion.

  - There is a risk of dependence arising with pain medicines based on their medical history or current/historical substance misuse.

- Use a holistic multidisciplinary approach to the review **that reviews the diagnosis as well as the medicines**. As in the general principles described earlier, the consideration of feedback and records made by other clinical and non-clinical staff about adherence, general day to day activities and medication safety incidents can create a team-based approach to the review.

- Document outcomes to the review clearly showing outcome and medication changes (including using a common read code to facilitate clinical audit) and revise the clinical management plan agreed with the patient.

- Follow advice in the main formulary and associated national guidance and Summaries of Product Characteristics (SPCs) on how to monitor, increase or reduce pain medicines. There are well documented safety concerns with certain pain medicines such as opioids and interactions with other medicines, especially those used for mental health disorders and substance misuse.

- Handle shared care arrangements with secondary care safely. It is common for prescribers in secondary care to initiate pain medicines for acute or persistent pain. The prison GP monitors and continues to prescribe these medicines until the next review is undertaken by the specialist or until the acute course of treatment is finished. It is advisable for the prison prescriber to complete a regular review using the elements described in this section and referring the patient back to a specialist if any concerns or outcomes suggest a review by the specialist is needed (see box 4).

Box 4: GPs managing pain care in prisons

Prescribers working in prisons are specialists in their own right due to the special challenges of providing safe care. It is appropriate for them to make decisions about ongoing prescribing and feel confident in over-riding decisions of prescribing made in secondary care settings when this improves the safety of care in the prison.

5 Patient-centred care

Patient experience and the contribution of patients in the development of NHS services and policy are at the heart of how services and medicines optimisation should be delivered. The development and use of formularies within care pathways is no exception to this. This section provides information to support clinicians in improving the patient experience and patient engagement with pain management when implementing the prison pain formulary locally.

5.1 Non-formulary medicines

The purpose of the formulary is to improve the consistency, safety and patient outcomes of pain management for people in prisons. The medicines in the formulary take into account the additional safety factors in prisons that contribute to the risks of patient harm so using medicines in the formulary is recommended when initiating or changing pain medicines.

However there may be people that clinicians assess and review that have a justifiable reason where a non-formulary medicine is needed. As for other sectors of practice, it is recommended that a formal process for agreeing and documenting the decision to prescribe a non-formulary medicine is in place locally. This forms part of the local medicines policy and formulary implementation.

A multidisciplinary process for agreeing the need for the non-formulary medicine is recommended.

A formal approach supports formulary implementation and the patient's experience by:

- Incorporating clear information about the reasons for a non-formulary medicine being used. This supports continuity of care, clinical audit, clinical review of pain care and informs prescribing trend analysis.
- Informing procedures agreed with pharmacists who raise queries with prescribers when a non-formulary medicine is prescribed.
- Providing subsequent clinicians in the same or different care settings with a clear steer on the basis of the decision to prescribe the non-formulary medicine and the associated patient outcomes.

5.2 Use of patient compacts to support care

It is common for prison healthcare providers to obtain patient agreement about how they will use medicines safely whilst they are in prison. This often is a "compact" that sets out ground rules about patient responsibilities in keeping medicines in their possession or accessing medicines that require dose supervision.

Some pain medicines are associated with a higher risk of patient harm if not taken as prescribed or are diverted or traded. The compact can provide an opportunity to explain to people about specific risks of pain medicines and how to keep themselves and their pain medicines safe. This can include advice about how people access support in the event that they experience bullying for their pain medicines.

The NPC in-possession guidance (see section 6.1) includes some points to consider that are relevant to pain medicines use too. These are shown in box 5.

Box 5: Points to consider for inclusion in a patient medicines compact

- **Medication supplied in-possession to a patient is only for his / her own use, and the consequences of finding it in the possession of another prisoner / patient.**
- **The patient's responsibility for ensuring the medication is kept securely at all times, and consequences of failing to do so.**
- **Ensuring the patient is given sufficient information and understands the implications, benefits and risks.**
- **The consequences if medication is lost, e.g. investigate, not automatically replaced, in-possession status reviewed.**
- **The need for patients to attend a medication review, and consequences of failing to do so.**
- **Attempts to obtain medication by deception are not acceptable, and the consequences.**
- **Full explanations are given to patients about any changes to, or withdrawal of, medication.**
- **Attempt to store or accumulate medication is not acceptable, and the consequences.**
- **Medication is only to be kept in the container in which it was issued.**

5.3 Patient information and support

Along with the patient compact, the use of patient information about managing pain and using particular pain medicines provide additional support to help people manage their pain.

NICE Medicines Optimisation guidance recommends the use of self-management plans for people with long term conditions and this is relevant for people with persistent pain. This self-management can be integral to the pain care plan held by clinicians.

Some prisons also use peer support (i.e. using other prisoners to support people and signpost them to care and advice) to complement healthcare-led information.

There are a variety of resources available at the pain toolkit web-site http://www.paintoolkit.org/tools. These resources have been developed by patients and healthcare professionals to support people with pain to manage their pain.

In addition, the Implementation Resources on the formulary website will provide additional examples of patient information and other strategies developed by prisons to support pain management in prisons.

6 Optimising the safe use of pain medicines

Prescribing and reviewing patients prescribed the medicines in this formulary represents one part of the medicines pathway for medicines[4]. We know from national reports on deaths in custody that pain medicines have been associated with some deaths[5].

This section provides information about how the safety of pain medicines can be optimised in addition to using the formulary itself.

6.1 In-possession versus not in-possession

As recommended in "A Pharmacy Service for Prisoners" in 2003, the aim is to move towards patients being responsible for holding and using their own medicines (see box 6).

Box 6: In-possession medication

"Medicines in use, together with associated monitoring and administration devices, should normally, as a matter of principle, be held in the possession of prisoners.

Each prison should have a policy and risk assessment criteria, developed through the Drug and Therapeutics Committee (D&TC), for determining on an individual basis when medicines and related devices may not be held in possession of a prisoner."

DH, A Pharmacy Service for Prisoners, 2003

The local policy developed for medication in-possession (IP) should take account, and link with, other relevant prison health care and security policies. For example medicines management policies, clinical governance, security policies, harm reduction etc. The National Prescribing Centre published some guidance on how to develop and implement IP medication and this is available here.

While the recommendation is that IP becomes the norm for prisoners, it is not appropriate for all medicines. It is a clear expectation in prison policy that Controlled Drugs (CDs) should be administered under direct supervision[6]. This includes tramadol which is now a Schedule 3 CD[7].

[4] The Safe and Secure Handling of Medicines: a team approach (Royal Pharmaceutical Society) March 2005
[5] National Offender Management Service, Review of unclassified deaths report, May 2012
[6] Prison Service Order PSO 3550
[7] NHS England Guidance on the handling of tramadol in health and justice residential sites, 2014

For other pain medicines in the formulary, local policies should be agreed based on:

- Patient-related factors - there may be groups of patients based on concurrent treatment (such as substance misuse and mental health) or resident in certain areas where the IP of specific pain medicines is different to other patients in the prison. The prison population type as a whole may also be a factor.

- Clinical and medicine related factors - whether the medicine is a CD; the frequency of doses (e.g. sustained release formulations may enable a medicine to be given not-IP); timing of doses needed and how this fits in with access times for medicines collection; local medication safety incidents may influence the default IP status of certain medicines.

- Environmental factors - medicines storage facilities; the extent of movement within the prison and the capacity for prison staff to supervise prisoners receiving medicines under direct observation once or more times a day, every day.

Taking the above factors into account, the following policies are the norm in the majority of prisons:

- Simple analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) are given as full IP where there are no individual patient safety risks. Some limitations on quantities given IP exist for paracetamol and this varies between prisons.

- First-line opioids such as co-codamol are either not-IP or a maximum of weekly IP.

- Medicines in the neuropathic pain formulary are either not-IP or a maximum of weekly IP.

- Controlled Drugs Schedules 2 and 3 are not-IP.

For pain medicines that are given in-possession but have a risk of diversion or misuse, other mechanisms to monitor medicines adherence or detect potential misuse are used. These include:

- Sharing the outcomes of mandatory drug tests between prison teams and healthcare teams.
- Conducting medicines adherence checks as part of cell searches.
- Checking the medicines administration or supply record to identify omitted doses or unusual medicines collection patterns.

If these are used, clear clinical review and non-clinical processes, need to be in place to follow-up any incidents identified. This ensures consistent actions are taken that are open and transparent to prisoners. Examples of non-clinical processes include:

- Submitting and sharing intelligence reports and/or reporting issues as patient safety incidents.

- Issuing prison-led warning letters to prisoners and other formal disciplinary actions where diversion or misuse has been identified.

6.2 Overall governance for local formulary implementation

The implementation of the formulary should be under the umbrella of a robust medicines governance framework. The policies, care pathways and procedures for handling pain medicines, including this formulary should be led by a prison Medicines Management Committee (MMC) as recommended by "A Pharmacy Service for Prisoners". This multidisciplinary MMC, with formal Terms of Reference, is usually responsible for developing and ratifying formularies with additional organisational ratification as needed. Membership and active contributions from a range of clinical and non-clinical stakeholders is needed to oversee the safety of medicines. Examples include:

- The lead pharmacist with overall responsibility for medicines governance.
- Prescribers and lead clinicians from general and mental healthcare.
- A senior healthcare manager.
- A senior prison security lead and/or prison governor representative.

The activities undertaken by the MMC to support implementation of the pain formulary include:

- Analysis of pain medicine prescribing trends to inform the MMC on formulary medicines use and overall pain medicines prescribing.
- Completion of clinical audit of patients receiving pain medicines to inform the MMC on clinical outcomes and care pathway elements.
- Collation and summary reports of patient safety incidents for pain medicines to support the MMC in identifying evolving new safety concerns and revising policies to minimise them.
- Agreement of how to support new and temporary prescribers to maintain the pain management care pathways and safe prescribing.

6.3 Reporting and managing incidents with pain medicines

Some pain medicines have a high misuse potential and may also have a high currency value in prisons, so the risk associated with providing them is also high. Even though the medicines in the formulary have been selected on safety as well as clinical grounds, and the local IP policy supports safe care, the risk remains that both not-IP and IP pain medicines will be misused or diverted.

To identify current and new risks and embed a collaborative approach to the safety of pain medicines use, incidents from both healthcare and prison activities should be shared, documented and handled in partnership, with individual organisations continuing to use their incident reporting policies. This results in a holistic approach to reducing the risks of pain medicines use.

Health and prison staff who identify incidents should be encouraged to report these and share concerns about safety or misuse. A multidisciplinary approach to reviewing incidents embeds the safety of medicines use across all staff working in the prison.

The MMC collates and acts on:

- Intelligence Reports (IRs): These are prison-based incidents that are reported through the prison security team. Reports relating to medicines can usually be identified, although the specific medicine may not always be known.

- Medication safety incidents: These are a subgroup of the patient safety incidents reported via healthcare within the organisation and to the National Reporting and Learning System (NRLS). Healthcare organisations will have reporting strategies and policies and most prison healthcare providers should have a Medication Safety Officer who oversees medication safety.

- Controlled drug incidents: In addition to the reporting mechanisms above, CDs have specific reporting requirements via NHS Controlled Drug Accountable Officers. Local CD Intelligence Networks (CD LINs) will provide prisons with CD incident information from across their geography, including other prisons. Engagement with CD LINs can help prisons identify potential CD risks that have not been identified locally but may trigger local actions. Further information is available on the CQC website.

6.4 Maximising the use of clinical IT systems

The introduction of electronic prescribing and electronic administration improves the assessment made by clinicians when prescribing and reviewing pain medicines. Reduction in the use of paper-based medication record charts streamlines access to information at any time about prescriptions and medicines collected or administered.

Planned integration of future IT systems with the NHS Summary Care Record (SCR) using the NHS number will enhance this for prisoners transferred from the community.

Engaging fully with these developments and using the IT system as a central point of access of clinical information for all healthcare staff and to record or review pain care plans, will significantly minimise the risks of prescribing high risk medicines and improve continuity of care.

The functionality of the clinical IT system includes provision for individual formularies to be published and used within the system. Including the medicines in this pain formulary within the IT formulary function is a key part of successful and consistent implementation across the prison.

6.5 Using the workforce effectively

Medicines optimisation[8] is “everybody’s business” and to deliver this for pain medicines involves the whole workforce in prisons as well as the patient themselves.

To achieve optimisation of the workforce for implementing the formulary it is recommended that:

- Providers include the formulary and related pain pathway and medicines management processes as part of the induction of new members of staff. **This includes locum or agency staff that may only be working in the prison for a short period.**

- A multi-professional approach is used when implementing the formulary and associated pain care pathways. This will prevent prescribers from being clinically isolated when treating people with pain but instead be prescribing pain medicines within a wider collaborative approach.

- Clinicians and provider organisations should pro-actively encourage access to education, training and networking events relating to pain management. Specific training and networks available include:

    - Events and workshops run by professional bodies such as the Royal College of GP Secure Environments Group and Secure Environment Pharmacists Group.
    - Formal training is available from the Royal College of Anaesthetists, Faculty of Pain Management: Pain in secure environments.

- Prison staff (both at operational and managerial levels) are key partners in supporting the safe use of pain medicines. Collaboration with the prison workforce is especially important in:
    - Sharing information about security risks relating to medicines.
    - Accessing and supervising pain medicines administered under observation (not-IP).
    - Including the risks of medicines abuse and diversion as part of prison officer training, supported by the healthcare team.
    - An effective MMC with active membership from a senior prison representative. This can significantly contribute to the development of collaborative medicines policies and procedures and managing medicines risk.

[8] RPS 2013 Medicines Optimisation Helping patients to make the most of medicines

7 Optimising continuity of care

Transfer of care into, between and from prisons needs additional safeguards that makes sure pain relief continues safely and seamlessly.

The Medicines Optimisation NICE Guideline (NG 5, 2015) and the Royal Pharmaceutical Society's publications on getting the medicines right on transfer of care give advice on principles and information provision that underpin safe practice. The principles apply to pain medicines (see box 7) and Appendix 1 lists the information that is needed.

The prison IT system can facilitate accessing and sharing this information consistently and in a timely manner. Additional information that supports continuity or use of pain medicines for prisoners between clinicians include:

- When referring or transferring a prisoner into hospital, provide information for the receiving clinician about the risks of pain medicines being taken by prisoners. This advises them about medicines that should be avoided, using the formulary as a reference and can request information they should include when then they transfer the patient back to prison. Examples of this will be available in the Implementation Resources on the formulary website.

- When a prisoner is received back into the prison after hospital treatment, protocols should be in place to ensure that the prisoner can continue to receive pain relief prescribed by the hospital. This pain relief can be reviewed by the prison-based clinicians as described in section 4.2.

Box 7: Principles for getting the medicines right on transfer of care

1. **Health care professionals transferring a patient should ensure that all necessary information about the patient's medicines is accurately recorded and transferred with the patient, and that responsibility for ongoing prescribing is clear.**

2. **When taking over the care of a patient, the healthcare professional responsible should check that information about the patient's medicines has been accurately received, recorded and acted upon.**

3. **Patients (or their parents, carers or advocates) should be encouraged to be active partners in managing their medicines when they move, and know in plain terms why, when and what medicines they are taking.**

4. **Information about patient's medicines should be communicated in a way which is timely, clear, unambiguous and legible; ideally generated and/or transferred electronically.**

Royal Pharmaceutical Society, Keeping patients safe when they transfer between care providers – getting the medicines right, 2011.

- On release into primary care, a copy of the pain management care plan in addition to the general information provided on release can encourage the GP to review pain care against the care plan. This prevents the inappropriate re-prescribing of pain medicines that were ineffective or misused.

- Pain medicines need to be transferred with the prisoner or given to them on release to avoid delays in taking the next dose. As some medicines may not be held in-possession by the prisoner, supplies may need to be prescribed and dispensed for supply on transfer. Release and transfer protocols need to take account of the time needed for the dispensed medicine to be provided.

  N.B. Controlled drugs can be transferred by the prison escort staff along with the person's other property. Specific documentation is needed to enable a clear audit trail for the CD.

- In the event of an unplanned release or if a prisoner is transferred into a prison without pain medicines which are not available in the prison, FP10 prescriptions can be used by the prison[9]. These are dispensed by the local community pharmacy and provide a way of getting pain medicines promptly.

[9] NHS BSA Prescription Pricing Division information on FP10 access for prisons Link

8 Appendix 1: Information provided on transfer or release

The NICE Medicines Optimisation Guideline recommends:

Health and social care practitioners should share relevant information about the person and their medicines when a person transfers from one care setting to another. This should include, but is not limited to, all of the following:

- contact details of the person and their GP details of other relevant contacts identified by the person and their family members or carers where appropriate – for example, their nominated community pharmacy.

- known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced.

- details of the medicines the person is currently taking (including prescribed, over-the counter and complementary medicines) – name, strength, form, dose, timing, frequency and duration, how the medicines are taken and what they are being taken for.

- changes to medicines, including medicines started or stopped, or dosage changes, and reason for the change.

- date and time of the last dose or prescription, such as for weekly or monthly medicines, including injections.

- what information has been given to the person, and their family members or carers where appropriate.

- any other information needed – for example, when the medicines should be reviewed, ongoing monitoring needs and any support the person needs to carry on taking the medicines. Additional information may be needed for specific groups of people, such as children.