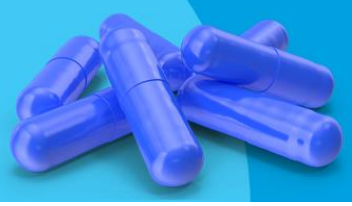
Medicines Management newsletter

Issue 24 - October 2020

NHS
Halton Clinical Commissioning Group



OPIOIDS: RISK OF DEPENDENCE AND ADDICTION

The September 2020 Drug safety update highlights important new recommendations following a review of the risks of dependence and addiction associated with prolonged use of opioid medicines (opioids) for non-cancer pain.

Considerable concern has been raised regarding prescribing rates of opioids in the UK and the awareness of healthcare professionals and patients of the risks of dependence and addiction. This includes Public Health England's evidence review of dependence and withdrawal associated with some prescribed medicines.

In 2019, the Commission on Human Medicines (CHM) convened an Expert Working Group to examine the benefits and risks of opioids in the relief of non-cancer pain, including information available to healthcare professionals and patients about the risks of dependence and addiction. Following this review, CHM has made recommendations to improve information for prescribers and patients about these risks to protect public health.

Advice for Healthcare Professionals:

- Opioid medicines (opioids) provide relief from serious short-term pain; however long-term use in non-cancer pain (longer than 3 months) carries an increased risk of dependence and addiction.
- Discuss with patients that prolonged use of opioids may lead to drug dependence and addiction, even at therapeutic doses – warnings have been added to the labels (packaging) of UK opioid medicines to support patient awareness.
- Before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment.
- Explain the risks of tolerance and potentially fatal unintentional overdose, and counsel patients and caregivers on signs and symptoms of opioid overdose to be aware of (see opioids safety information leaflet plus PDF leaflet).
- Provide regular monitoring and support especially to individuals at increased risk, such as those with current or past history of substance use disorder (including alcohol misuse) or mental health disorder.
- At the end of treatment, taper dosage slowly to reduce the risk of withdrawal effects associated with sudden cessation of opioids; tapering from a high dose may take weeks or months.
- Consider the possibility of hyperalgesia if a patient on long-term opioid therapy presents with increased sensitivity to pain.
- Consult the latest advice and warnings for opioids during pregnancy in the product information and in clinical resources.

To make it clear that a medicine contains an opioid and that there is a risk of addiction (a recognised term by patients) with prolonged use, CHM recommended that the packaging for all opioid medicines in the UK carries the

warnings 'Can cause addiction' and 'Contains opioid'. The CHM also recommended including further information on the risk of tolerance, dependence and addiction in the product information.

Please follow the link for more information on this topic along with useful resources:
https://www.gov.uk/drug-safety-update/opioids-risk-of-dependence-and-addiction

The Royal Collage of General Practitioners (RCGP) have produced a "Top Ten Tips" document of the considerations that should be made prior to the prescribing of Dependence Forming Medications (DFMs).

Top Ten Tips – Dependence Forming Medications

DFMs are mainly opioids, z drugs, benzodiazepines, gabapentin and pregabalin. Dependence is defined as 'the need to continue taking a medicine to maintain a state of normality and avoid symptoms of withdrawal'.

Medicines Management Work Plan 2020/2021

During **October and November 2020** the NHS Halton CCG Medicines Management Team will continue to support with the following COVID-19 related work:

- Medicines support to care Homes.
- Supply of end of life medication.
- Electronic Repeat Dispensing (eRD).
- Medicines supply issues.
- Medication support guidance.

The MMT will also be repeating the STOMP/STAMP audit and supporting with the Q4 2019/20 & Q1 2020/21 Controlled Drug Monitoring in all Halton practices.

Practice Medicine Co-ordinator (PMC) Reviews

The PMCs will be doing the following reviews:

- **Formulation switches** – switch to more cost-effective formulary formulations:
    - Switch of topiramate capsules to tablets for migraine patients
    - Switch of loperamide tablets to capsules, as more cost-effective formulations.
- **Aymes® switch** in Care Homes– Switch of ready-made oral nutritional supplements to equivalent Aymes® powder shakes for care home residents, in line with 1st line formulary choice (joint work project with MMT care homes technicians).
- **MHRA Drug Safety Update (DSU) Reviews** - Methotrexate and denosumab reviews in line with DSU recommendations as detailed under Safety Section.

Medicines e-learning module - free to all Adult Social Care Providers in Halton

Halton Borough Council (HBC), in partnership with NHS Halton CCG Medicines Management Team, has developed a medicines management theory e-learning module that is free to all adult social care providers in Halton. The comprehensive module can be undertaken on a laptop, tablet or smartphone at a time and place convenient to the learner. Adult social care providers in Halton who would like to take advantage of this free e-learning module should contact HBC via the email address or telephone number below.

To find out more please email
training.reception@halton.gov.uk or telephone 0151 511 7111

NHS Halton Clinical Commissioning Group

HALTON BOROUGH COUNCIL

Safety

The Medicines Management Team would like to highlight some of the recent MHRA Drug Safety Updates relevant to Primary Care:

DENOSUMAB 60MG (PROLIA): INCREASED RISK OF MULTIPLE VERTEBRAL FRACTURES AFTER STOPPING OR DELAYING ONGOING TREATMENT

Advice for Healthcare Professionals:

- An increased risk of multiple vertebral fractures has been reported in patients within 18 months of stopping or delaying ongoing denosumab 60mg treatment for osteoporosis; cases have been reported in patients in the UK.
- Patients with a previous vertebral fracture may be at highest risk.
- Evaluate a patient's individual factors for benefits and risks before initiating treatment with denosumab, particularly in patients at increased risk of vertebral fractures for example those with previous vertebral fracture.
- Patients should not stop denosumab without specialist review.
- The optimal duration of denosumab treatment for osteoporosis has not been established; re-evaluate the need for continued treatment periodically based on the expected benefits and potential risks of denosumab on an individual patient basis, particularly after 5 or more years of use.
- Risks of long-term treatment with denosumab include rare cases of osteonecrosis of the jaw and atypical femoral fractures; osteonecrosis of the external auditory canal has also been reported in association with denosumab.
- NICE rapid guidance (30 April 2020) advises not to postpone ongoing treatment with denosumab during the coronavirus (COVID-19) pandemic.

Advice to give to Patients:

- There have been reports of increased risk of multiple fractures in the spine after stopping or delaying ongoing treatment with denosumab 60mg (Prolia) treatment.
- Do not stop denosumab treatment without talking to your doctor to discuss your individual risk factors.
- If you miss a prescribed dose of denosumab, the missed injection should be administered as soon as possible. After this, your next injection will be scheduled 6 months from the date of your last injection.
- Continue to regularly review your treatments for osteoporosis with your doctor.

https://www.gov.uk/drug-safety-update/denosumab-60mg-prolia-increased-risk-of-multiple-vertebral-fractures-after-stopping-or-delaying-ongoing-treatment

Practice Medicine Co-ordinators plan to support the recommendations of this alert by checking patients currently prescribed denosumab are up to date with their injections and highlighting patients prescribed denosumab for greater than 5 years to the prescriber for referral for specialist review.

EMOLLIENTS AND RISK OF SEVERE AND FATAL BURNS: NEW RESOURCES AVAILABLE

On 29 July 2020, MHRA in partnership with the National Fire Chiefs Council, charities, and organisations from across health and social care launched a campaign to raise awareness of this important risk. A toolkit of resources is now available for health and social care professionals to support the safe use of emollients.
https://www.gov.uk/drug-safety-update/emollients-and-risk-of-severe-and-fatal-burns-new-resources-available

INSULINS (ALL TYPES): RISK OF CUTANEOUS AMYLOIDOSIS AT INJECTION SITE

Advice for Healthcare Professionals:

- Injection of insulin (all types) can lead to deposits of amyloid protein under the skin (cutaneous amyloidosis) at the injection site.
- Cutaneous amyloidosis interferes with insulin absorption, and administration of insulin at an affected site can affect glycaemic control.
- Remind patients to rotate injection sites within the same body region to reduce or prevent the risk of cutaneous amyloidosis and other skin reactions (for example, lipodystrophy).
- Consider cutaneous amyloidosis as a differential diagnosis to lipodystrophy when a patient presents with subcutaneous lumps at an insulin injection site.

Advice to give to Patients:

- That insulin may not work very well if they inject into an affected 'lumpy' area.
- To contact their doctor if they are currently injecting insulin into a 'lumpy' area before changing injection site since a sudden change may result in hypoglycaemia.
- To monitor carefully blood glucose after a change in injection site and that dose adjustment of insulin or other antidiabetic medication may be needed.

https://www.gov.uk/drug-safety-update/insulins-all-types-risk-of-cutaneous-amyloidosis-at-injection-site

METHOTREXATE ONCE WEEKLY FOR AUTOIMMUNE DISEASES: NEW MEASURES TO REDUCE RISK OF FATAL OVERDOSE DUE TO INADVERTENT DAILY INSTEAD OF WEEKLY DOSING.

MHRA continue to receive reports of inadvertent overdose due to more frequent dosing (including daily administration). New measures have been implemented to prompt healthcare professionals to record the day of the week for intake and to remind patients of the dosing schedule and the risks of overdose.

Advice for Prescribers:

- Before prescribing methotrexate, make sure that the patient is able to understand and comply with once-weekly dosing.
- Consider the patient's overall polypharmacy burden when deciding which formulation to prescribe, especially for a patient with a high pill burden.
- Decide with the patient which day of the week they will take their methotrexate and note this day down in full on the prescription.
- Inform the patient and their caregivers of the potentially fatal risk of accidental overdose if methotrexate is taken more frequently than once a week; specifically, that it should not be taken daily.

- Advise patients of the need to promptly seek medical advice if they think they have taken too much.

Advice for Dispensers:

- Remind the patient of the once-weekly dosing and risks of potentially fatal overdose if they take more than has been directed.
- Where applicable, write the day of the week for intake in full in the space provided on the outer package.
- Demonstrate the Patient Card included with the methotrexate packet and encourage patients to:
    - Write the day of the week for intake on the patient card.
    - Carry it with them to alert any healthcare professionals they consult who are not familiar with their methotrexate treatment about their dosing schedule (for example, on hospital admission, change of care).

https://www.gov.uk/drug-safety-update/methotrexate-once-weekly-for-autoimmune-diseases-new-measures-to-reduce-risk-of-fatal-overdose-due-to-inadvertent-daily-instead-of-weekly-dosing

Practice Medicine Co-ordinators plan to support the recommendations of this alert by contacting patients currently prescribed methotrexate to check which day of the week they take this medication and adding it to current drug directions.

TRANSDERMAL FENTANYL PATCHES FOR NON-CANCER PAIN: DO NOT USE IN OPIOID-NAIVE PATIENTS.

Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines (CHM) has recommended that fentanyl transdermal patches are contraindicated in opioid-naive patients in the UK.

Advice for Healthcare Professionals:

- Fentanyl is a potent opioid – a 12 microgram (µg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day.
- Do not use fentanyl patches in opioid-naive patients.
- Use other analgesics and other opioid medicines (opioids) for non-cancer pain before prescribing fentanyl patches.
- If prescribing fentanyl patches, remind patients of the importance of:
    - Not exceeding the prescribed dose.
    - Following the correct frequency of patch application, avoiding touching the adhesive side of patches, and washing hands after application.
    - Not cutting patches and avoiding exposure of patches to heat including via hot water (bath, shower).
    - Ensuring that old patches are removed before applying a new one.
    - Following instructions for safe storage and properly disposing of used patches or patches that are not needed (see advice issued previously); it is particularly important to keep patches out of sight and reach of children at all times.
- Make patients and caregivers aware of the signs and symptoms of fentanyl overdose and advise them to seek medical attention immediately (by dialling 999 and requesting an ambulance) if overdose is suspected.
- Remind patients that long-term use of opioids in non-cancer pain carries an increased risk of dependence and addiction, even at therapeutic doses. Before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment.

https://www.gov.uk/drug-safety-update/transdermal-fentanyl-patches-for-non-cancer-pain-do-not-use-in-opioid-naive-patients

CLOZAPINE AND OTHER ANTIPSYCHOTICS: MONITORING BLOOD CONCENTRATIONS FOR TOXICITY

Monitoring blood concentrations of clozapine for toxicity is now advised in certain clinical situations.
Blood level monitoring of other antipsychotics for toxicity may also be helpful in certain circumstances, where testing and reference values are available. At the time of publication, MHRA drug safety update states - assays and suggested reference values for therapeutic blood concentrations are known to be available for amisulpride, aripiprazole, olanzapine, quetiapine, risperidone and sulpiride, although availability of testing may vary locally.

As Clozapine is RED on Pan Mersey formulary all prescribing should be in a specialist setting. Further information for healthcare professionals regarding blood monitoring for other antipsychotics can be found at:
https://www.gov.uk/drug-safety-update/clozapine-and-other-antipsychotics-monitoring-blood-concentrations-for-toxicity

BARICITINIB (OLUMIANT▼): INCREASED RISK OF DIVERTICULITIS, PARTICULARLY IN PATIENTS WITH RISK FACTORS

Advice for Healthcare Professionals includes the following:

- Cases of diverticulitis and gastrointestinal perforation have been reported in patients taking baricitinib.
- Most, but not all, cases of diverticulitis occurred in patients who were concomitantly taking medicines associated with an increased risk of diverticulitis.
- Advise patients on baricitinib to seek immediate medical care if they experience severe abdominal pain especially accompanied with fever, nausea and vomiting or other symptoms of diverticulitis.
- Ensure prompt evaluation of any patients on baricitinib who present with new-onset abdominal signs and symptoms to identify early diverticulitis or gastrointestinal perforation.

As baricitinib is **RED** on Pan Mersey formulary all prescribing should be in a specialist setting. Further advice for healthcare professionals can be found at:
https://www.gov.uk/drug-safety-update/baricitinib-olumiant-increased-risk-of-diverticulitis-particularly-in-patients-with-risk-factors

ISOTRETINOIN (ROACCUTANE▼): REMINDER OF IMPORTANT RISKS AND PRECAUTIONS

Advice for Healthcare Professionals includes the following:

- Isotretinoin has important risks (including teratogenicity) requiring specialist oversight and therefore must not be used outside of the authorised terms of use.
- Isotretinoin is a powerful teratogen associated with a high frequency of severe and life-threatening birth defects if there is exposure in utero; women of childbearing potential must be under a Pregnancy Prevention Programme.
- Counsel patients fully on the potential risks of isotretinoin, including what to do if they feel their mental health is affected or worsening.
- Be vigilant for serious side effects such as sexual dysfunction in patients taking isotretinoin.

As isotretinoin capsules are **RED** on Pan Mersey formulary all prescribing should be in a specialist setting as described above. Further advice for healthcare professionals can be found at:
https://www.gov.uk/drug-safety-update/isotretinoin-roaccutane-reminder-of-important-risks-and-precautions

Antimicrobial Update: October 2020

WORLD ANTIBIOTIC AWARENESS WEEK 2020: 18TH-24TH NOVEMBER 2020

Antibiotic Resistance continues to be one of the biggest threats facing us today.

Call to action:

Choose one simple pledge about how you'll make better use of antibiotics and help save these vital medicines from becoming obsolete.

Make your pledge today at https://antibioticguardian.com/

Please note that PHE will not be sending out 'Keep antibiotics working' campaign resource packs to GP practices or community pharmacies this year. If necessary, any of the 'Keep Antibiotic Working' campaign resources can be ordered or downloaded free of charge directly from the PHE campaign resource centre.

Local AMR Contact - **Jessica Mellor**, NHS Halton CCG Medicines Management Pharmacist (Jessica.mellor@nhs.net)

Becky Birchall Medicines Management Senior Pharmacist 01928 593010 becky.birchall@nhs.net	Lucy Reid Head of Medicines Management 01928 593452 lucy.reid2@nhs.net	Nathan O'Brien Medicines Management Pharmacist 01928 593010 nathan.obrien@nhs.net