Medicines Safety Newsletter

Issue 7 – December 2024

NHS North East London

Promoting Safe Use of Medicines Across Primary Care

Our aim is to highlight medicines safety concerns and updates raised nationally and locally to support and promote safer use of medicines across North East London (NEL). **Please note this will be the last publication of the NHS NEL medicines safety newsletter. You will find future medicines safety updates in the NEL Prescribing and Medicines Newsletter.** You can access previous medicines safety newsletter editions here.

Contents

National Patient Safety Alert: Safe Use of Valproate

NHS North East London (NEL) has become aware of three women of childbearing potential in our locality whose babies have been exposed to valproate during pregnancy. The NHS NEL Teratogenic Medicines Safety Improvement Group (TMSIG) will be working with colleagues across the NEL to understand more about these patient safety events and aim to put in place additional support to improve the safety of valproate prescribing.

Please could you continue to adhere to the national Patient Safety Alert (NatPSA) introduced in January 2024 to implement new measures to reduce the harms of valproate. In September 2024, due to new evidence of possible harms of valproate in men, the Medicines & Healthcare products Regulatory Agency (MHRA) has issued new safety measures to further support prescribers around the safe use of valproate in men and their partners.

At a minimum all girls and women of childbearing potential prescribed valproate should have:

- Patient and carer education of the risks of valproate when exposed to their babies
- A valid Annual Risk Acknowledgement Form
- Pregnancy Prevention Programme (PPP) also known as, 'PREVENT'
- An annual review with a specialist

At a minimum boys and men of reproductive potential should have:

- Patient and carer education of the risks of valproate
- Advice to patients prescribed valproate, and their partners should use effective contraception
- Where patients are considering starting a family within 1 year, they should be referred to specialist to explore options.
- If newly initiated on valproate, boys and men should have a completed Risk Acknowledgement Form.

Further updates will be provided in subsequent correspondence from the NHS NEL Pharmacy and Medicines Optimisation Team.

Actions for healthcare professionals

- Please read Issue 3 of the Medicines Safety Newsletter for guidance and actions for safely prescribing valproate in girls and women of childbearing potential.
- Please read Issue 6 of the Medicines Safety Newsletter for guidance and actions for safely prescribing valproate in boys and men of reproductive potential.
- Please read the MHRA Valproate safety measures and Valproate use in men

Medicines Safety Improvement Programme (MedSIP) priorities for April 2024 to March 2027

The Medicines Safety Improvement Programme (MedSIP) is one of the National Patient Safety Improvement Programmes which collectively forms the largest safety initiative in the history of the NHS. MedSIP addresses the most important causes of severe harm associated with medicines, most of which have been known about for years, but continue to challenge the health and care systems in England. We are keen to work with colleagues across NEL on these priorities to improve medicines safety for patients and we will update you on developments in future newsletters.

Currently, the key ambitions for MedSIP areas are as follows:

- Improving care for people with persistent pain by reducing opioid analgesic use.
- Improving care for people with epilepsy, bipolar and conditions for which Valproate is prescribed.
- Improving care for people taking anticoagulants.
- Developing the Medication Safety Officer workforce.

From April 2024 to March 2027 the programme will also explore:

- **Psychotropic prescribing in learning disability** Improve care for people with a learning disability by reducing the burden of medications that act on the brain. This will complement the Stopping over medication of people with a learning disability and autistic people (STOMP) and supporting treatment and appropriate medication in paediatrics (STAMP) initiatives. The Health Innovation Networks are currently undertaking some initial scoping work.

- **Medicines optimisation in falls and frailty**: Improve care for people with frailty by optimising their medicines to reduce death and fractures caused by falling. This will support the work of the National Falls Prevention Coordination Group. The Health Innovation Networks are currently undertaking some initial scoping work.

- **Safer use of time critical medicines**: Improve care for people by ensuring that they receive the critical medication they need on time. This will include working with Parkinson's UK in support of their Get It On Time campaign. If you have undertaken any work on safer use of time critical medicines, big or small or if you are experiencing challenges, the Specialist Pharmacy Service (SPS) want to hear from you!

- Please contact them at lnwh-tr.sps-mso@nhs.net

- More information can be found here: Safer use of Time Critical Medicines

Work is also underway to explore how to reduce the incidence of acute kidney injury that is caused by or worsened by medication.

Update on the MedSIP Reducing harm from Opioids in chronic (non-cancer) pain programme

As part of the current MedSIP priorities, NEL has been working in partnership with UCLPartners to reduce harm from prescribing of opioids in chronic non-cancer pain.

To support collaboration, insight into service user experience and shared learning on how to sustain improvements, UCLPartners hosts an Opioids Network. It is made up of pharmacists, GPs, specialist clinicians, third sector employees, service users, and more who are interested in reducing the use of opioids for chronic non-cancer pain.

The Opioid Network affords the opportunity for people with lived experience and people working in different sectors across the healthcare system to come together and discuss challenges, share learning and celebrate successes. Anyone who is interested in this topic is very welcome to attend, and the network meets quarterly. Recordings and slides of previous Opioid Network meetings can be found on the UCLPartners MedSIP page. The most recent meeting was held on **Thursday, December 12th from 12:30 – 1:30 pm**. If you would like to attend, please contact Jess Catone at jessica.catone@uclpartners.com

To support a biopsychosocial approach to chronic (non-cancer) pain management, UCLPartners developed resources to facilitate group education sessions. Materials can be accessed on the UCLPartners website. Please do not hesitate to ask if you have any questions. There is also a webinar about it here. For further information, please contact Jess Catone at jessica.catone@uclpartners.com

NEL Learning from Medicine Patient Safety Events - Incident involving propranolol overdose

Propranolol is used to treat medical conditions including migraine and cardiovascular problems. It is also licensed for relief of anxiety symptoms, although this is not mentioned in NICE guidance.

Following a tragic incident in which a patient at one of our mental health providers sadly passed away after taking an overdose of prescribed propranolol, clinicians across NEL are urged to be aware of the potentially **under-recognised** risk of toxicity of propranolol in overdose.

In 2022-2023 the National Poisons Information Service (NPIS), who maintain the Toxbase database, received 358 enquiries involving intentional propranolol overdose (321 exposures in 318 patients). In 12 cases the overdose resulted in death. The risk of convulsions is higher with propranolol than with other beta-blockers. Delay in treatment for overdose increases the risk of fatality, therefore it is important to seek emergency help as soon as possible following overdose.

NICE does not recommend the use of propranolol in anxiety, nor is there any recommendation in the British National Formulary (BNF) to use propranolol for the treatment of anxiety in isolation. The BNF does provide dose information for the treatment of anxiety with symptoms such as palpitations, sweating and tremor, reflecting the licensed dose for these indications. The BNF has been updated to include the side-effects related to propranolol overdose.

Where propranolol is prescribed for a user of service:

- Consider whether there is a risk of the patient overdosing on medication, and whether they have a history of medication overdoses/self-harming behaviour.
- If a risk of overdose is identified, weigh up the risks and benefits of prescribing propranolol, taking into account the clinical indication it is being prescribed for.
- Ensure you clearly document the rationale for any decision taken regarding the ongoing use of propranolol.
- Consider prescribing smaller quantities of medication if patients are at an increased risk of self-harm.

Learning materials and resources

Propranolol overdose has previously been the subject of a PrescQIPP pack which contains useful background information, patient information leaflets and clinical searches to identify patients at higher risk (log in required): PrescQIPP Hot Topics – Potential under-recognised risk of harm from the use of propranolol 2.0.

The PrescQIPP pack covers the Healthcare Safety Investigation Board (HSIB) report calling for greater awareness of specific groups of patients who may be at an increased risk of using propranolol for self-harm because they have coexisting migraine, depression, or anxiety.

- Under-recognised risk of harm from propranolol - February 2020.pdf
- Attachment 1. Potential under-recognised risk of harm from the use of propranolol audit.xlsx
- Propranolol in at-risk patients 'how-to' guide EMIS Web.pdf
- Under-recognised risk of harm from propranolol - EMIS Web.xml
- Propranolol in at-risk patients SystmOne guide.docx
- Under-recognised risk of harm from propranolol - SystmOne.rpt
- KNOW, CHECK, ASK - propranolol campaign materials - side 1
- KNOW, CHECK, ASK - propranolol campaign materials - side 2

NEL Learning from Medicine Patient Safety Events– Multiple Oral Anticoagulants

Anticoagulants are used to treat and prevent blood clots, while lifesaving medicines, are also classed as high risk with a potential to cause significant harm.

Recently the NHS NEL Integrated Care Board (ICB) Pharmacy and Medicines Optimisation team were provided with data from NHSBSA where patients appeared to have been supplied with two or more oral anticoagulants concurrently. Practices were asked to review their patients and update NEL ICB of their findings and actions

Practices with potential duplicate prescribing were asked to investigate. Seven patients were identified in NEL who may have been on two oral anticoagulants. In five of the patients, it was confirmed that the patient was being switched from one medication to another and was not taken at the same time.

The outcome of the review identified one patient is still outstanding and the practice has been contacted for an update. In the final case the patient was taking apixaban and warfarin concomitantly. The practice reviewed the incident. It was identified that the practice had prescribed bridging therapy, which is not usually prescribed in primary care. There were two further contributory factors that led to a delay identifying the error. Firstly, subsequent prescriptions were issued by two pharmacists working at the surgery. Secondly, the patient's hospital follow-up appointment was delayed, thus the incident was not identified by the hospital team.

Learning materials and resources

As additional support to practices to reduce the risk of prescribing of multiple oral anticoagulants, Eclipse Live have added a monitoring metric on their Vista Pathways dashboard at the request of the ICB.

Safer use of controlled drugs: Harms of concurrent opioid and gabapentinoid prescribing

The NHS NEL Pharmacy and Medicines Optimisation Team review data every three months on a rolling programme to satisfy the regulatory and statutory requirements for controlled drug monitoring. We would like to invite everyone across NEL to join us in making CD prescribing safer. NEL prescribing data shows that the number of unique patients prescribed both a gabapentinoid and an opioid in the same month has been steadily increasing month on month (Data source: August 2024 ePACT-2).

Gabapentinoids are a class of medicines that include pregabalin and gabapentin commonly used to manage nerve pain and less commonly used to manage epilepsy and anxiety. They are Class C controlled substances (under the Misuse of Drugs Act 1971) and Schedule 3 under the Misuse of Drugs Regulations 2001. Opioids such as morphine, fentanyl and codeine are super strength medications for acute pain which can be highly addictive. They have minimal benefit in chronic (non-cancer) pain. They can be Class A or Class B substances (under the Misuse of Drugs Act 1971) and Schedule 2 under the Misuse of Drugs Regulations 2001.

Risks and outcomes of co-prescribing gabapentinoids and opioids

Co-prescription of gabapentin or pregabalin with opioids was associated with a 50% and 68% increase in the risk of opioid-related death respectively, after adjusting for co-morbidities and other prescriptions. [1,2]

Research has shown that gabapentinoids produce minimal improvements in chronic lower back pain - patients have a poorer response than other analgesic medications, and are not effective as an adjunct to opioids.[3]

Use of pregabalin with opioid medicines or other central nervous system (CNS) depressant medicines has been previously associated with reports of respiratory failure, coma, and death. Studies show use of high doses of pregabalin (over 300mg a day) alongside opioid medicines are particularly associated with an increased risk of opioid-related death.

There have been two MHRA alerts published concerning gabapentin and pregabalin which gave advice to healthcare professionals to be aware of the risks of CNS depression. The MHRA also published an alert about the risk of addiction and dependence for opioids prescribed in chronic (non-cancer pain).

When prescribing gabapentin or pregabalin in patients who require concomitant treatment with opioid medicines, patients should be carefully observed for signs of CNS depression, such as somnolence, sedation, and respiratory depression, and the dose of either the gabapentinoid or the opioid should be reduced appropriately.

Actions for healthcare professionals

- Evaluate patients carefully for a history of drug abuse before prescribing and observe patients for development of signs and risks associated with addiction and dependence.
- Regularly review patients prescribed concomitant opioids and gabapentinoids especially patients at higher risk of respiratory depression to consider whether dose adjustments might be necessary in patients at higher risk of respiratory depression including those:
    - with compromised respiratory function or respiratory disease
    - with neurological disease
    - with renal impairment
    - using concomitant CNS depressants
    - elderly people older than 65 years
- Withdraw appropriately when either or both medicines are no longer beneficial to the patient, or the risks outweigh the benefits of continuing treatment to improve patient safety.

Learning materials and resources

- PrescQIPP bulletin 353 Dependence-forming medicines found here (registration needed, this is free) contains key recommendations, patient letters/texts, clinical system searches, audits
- NICE NG 215 "Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults".
- The PrescQIPP Improving Medicines and Polypharmacy Appropriateness Clinical Tool (IMPACT) provides information on withdrawing/tapering and lifestyle.
- Tapering plans for opioids are available from the Opioids Aware website
- Gabapentinoid tapering plans are available from NHS Scotland
- Please read the Winter 2024 newsletter from the NHS England London Region Controlled Drug Accountable Office (CDAO) team. You can also access this newsletter and previous copies via the Resource Centre on the CD Reporting website

Co-danthramer Suspension prescribing in primary care

Co-danthramer is a stimulant laxative used for the treatment and prevention of constipation of terminally ill patients. It has been identified that in 2023/24, five NEL GP practices were prescribing co-danthramer suspension long term. This suggests that prescribing may be taking place outside of terminally ill patients. NHS NEL ICB are aiming to launch the netformulary gastrointestinal chapter very soon to advise on the NEL wide status of prescribing, however the primary care legacy formularies advise:

- City and Hackney (specialist knowledge/initiation)
- Tower Hamlets (non-formulary)
- Waltham Forest and Newham (non-formulary)
- Barking, Havering and Redbridge (on formulary)

Please note the following before prescribing:

- It is not generally recommended due to the risk of dantron burns and control is usually achieved with alternative laxatives. Avoid in patients with urine or faecal incontinence – prolonged contact can cause a dantron burn e.g. an erythematous rash with a sharply demarcated border.
- Co-danthramer suspension is available. This is only licensed for use in terminally ill patients due to potential carcinogenic risk. The suspension is expensive, costing upwards of £245 per 300ml bottle.
- Co-danthramer and Co-danthramer Strong Capsules have been discontinued.

Actions for healthcare professionals

- Review your practices prescribing co-danthramer suspension, if the patient does not have a terminal diagnosis please switch to an alternative laxative or seek specialist gastroenterology advice.
- Prescribers may find the PrescQIPP bulletin on constipation useful, please find here

MHRA Latest Drug Safety Updates

October – December 2024

Serious Shortage Protocol (SSP)

- Creon® 25000 and Creon® 10000 for pancreatic enzyme replacement
- Isosorbide Mononitrate Monomil XL 60mg to prevent angina and treat heart failure
- Ceflalexin 125mg/5ml and 250mg/5mL for treatment of acute diverticulitis, lower, recurrent and catheter-associated urinary tract infection in pregnancy and children

MHRA Latest Safety Updates

- MedSafetyWeek November 2024: your Yellow Card report helps prevent future harm to others and improves patient safety
- GLP-1 receptor agonists: reminder of the potential side effects and to be aware of the potential for misuse
- Insulin pumps and continuous glucose monitoring (CGM) equipment: guidance for users on reporting suspected adverse incidents and safety concerns to the MHRA's Yellow Card scheme
- Bromocriptine: monitor blood pressure when prescribing bromocriptine for prevention or inhibition of post-partum physiological lactation

MHRA Drug Safety Updates can be accessed here: Monthly PDF editions of the Drug Safety Update newsletter from MHRA and its independent advisor, the Commission on Human Medicines

Letters sent to relevant healthcare professionals

- Letters and medicine recalls sent to healthcare professionals in September 2024
- Letters and medicine recalls sent to healthcare professionals in October 2024

Medicine Recalls and notifications

All medicine recalls and notifications for the period October to December 2024, can be accessed here: Alerts, recalls and safety information: drugs and medical devices.

Additional Medicines Safety Resources

- **MHRA** - for all MHRA updates on alerts, recalls and safety information on drugs and medical devices, click here
- **Specialist Pharmacy Service (SPS)** – for Medication Safety Updates collating the latest medication safety communications and publications to inform, support and inspire medication safety improvements. For updates, click here July August September 2024
- **SPS - Medicine Supply Shortages and discontinuations –** for updates on medicines shortages and guidance, access SPS medicines tools (register here with SPS free-of-charge to access).
- **PrescQIPP** - for medicines safety tools and resources, click here
- Report suspected adverse effects with medicines, devices, or COVID-19 vaccines via the Yellow Card scheme or Coronavirus Yellow Card reporting site
- **Learning from Patient Safety Events (LFPSE)** – for reporting medicine patient safety events, near misses and good examples to prevent harm from medicines via the LFPSE
  Reporting of Controlled Drug incidents in primary care – for reporting incidents or concerns related to controlled drugs (including loss or theft) via the online Controlled Drugs Reporting website

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For information or comments on this newsletter, please contact the Medicines Safety & Quality Group**:**
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