Medicines Safety Newsletter

Issue 4 – April 2024

NHS North East London

Promoting Safe Use of Medicines Across Primary Care

Welcome to the fourth edition of our Medicines Safety Newsletter from the North East London (NEL) Medicines Safety and Quality Group. 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

Contents

Contents

Latest News

FOR MEDICINE SUPPLY SHORTAGES: The Specialist Pharmacy Service (SPS) Medicines Supply Tool offers up-to-date information on Medicines Shortages, provided by Department of Health and Social Care (DHSC) and NHS England and NHS Improvement (NHSE/I). To access Click here

SAFE USE OF VALPROATE- UPDATE: Valproate containing medicines (as sodium valproate or valproic acid) are used in some patients for the treatment of epilepsy, bipolar disorders, and other unlicensed indications. Valproates are contraindicated in women of childbearing potential unless the Pregnancy Prevention Programme (PPP) is in place. Ongoing research has shown limited evidence of risks such as infertility, testicular toxicity and potential neurodevelopmental disorder to men taking valproate.

In compliance with the MHRA NPSA alert, North East London system valproate safety group has developed an action plan for all prescribers to support the implementation of these new legislative safety measures. The purpose is to strengthen the governance around the safe use of valproate in both women and men within North East London.

From 31st January 2024, the 2 new legislation changes are:

A	**All initiations, in women and men, under 55 years must be agreed by two independent specialists with documented evidence that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.**
B	**At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Annual Risk Acknowledgement Form (ARAF), to include a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.**

Action for practices:

Our advice to GPs has been to **not stop** the medication, unless otherwise advised to stop prescribing by a specialist. They have also been requested to reassure the patient and ensure that where appropriate, the patient is on a highly effective contraceptive. General patient-friendly information on contraception methods can be found on the NHS England epilepsy or bipolar-disorder decision tools and NICE has also produced professional guidance on highly effective contraception https://bnf.nice.org.uk/treatment-summaries/contraceptives-hormonal/

Additionally:

- To minimise additional pressure for appointments, please **do not** refer **all** your existing patients into secondary care.
- All secondary, community and mental health care providers within NEL ICS trusts have started the **next scheduled annual specialist reviews** of their eligible female patients of childbearing potential as recommended by the alert. Patients still under the care of a specialist will be invited for this review as a scheduled appointment.
- For patients **who are not recorded as under the care** of a local specialist should be referred to the appropriate specialist using the existing referral pathways
- Please encourage your patients to attend any offered appointments to discuss their treatment plan and to talk to a healthcare professional if they are concerned.
- In terms of the MHRA NPSA alert, men do not need to be referred to secondary care. Annual reviews are anticipated to expand to include men later in the year.
- Prescribe appropriate quantities so that pharmacists can dispense a manufacturer's original full pack which will include all the necessary safety information for the patient.
    - Where it is not in a patient's best interests to prescribe a full original pack, please document the reason in the patient record.
- Further information and educational materials to support the implementation of the new measures for valproate is available from MHRA's collection of valproate safety measures https://www.gov.uk/government/collections/valproate-safety-measures

FLUOROQUINOLONE SAFETY UPDATE:

Following the fluoroquinolone drug safety update published in January 2024, the MHRA has taken additional regulatory action to update the indications and safety information for all systemic fluoroquinolones given by mouth, injection, or inhalation. It states, they **must only be prescribed when other commonly recommended antibiotics are inappropriate**, due to the risk of potentially long-term or irreversible side effects, which, includes more detail about the range of psychiatric symptoms that may occur as part of these reactions. These may include sleep disorders, anxiety, panic attacks, confusion, or depression.

OptimiseRx messages have been updated to reflect the alert. Messages have been uploaded for individual quinolones highlighting the limited range of indications in line with MHRA. Please review in line with the messages.

TACKLING OVERPRESCRIBING (POLYPHARMACY) IN NEL: The NHS NEL Medicines Safety and Quality Group have had a focus on overprescribing and have been aiming to improving understanding and knowledge through a series of webinars.

The second NEL polypharmacy online seminar was delivered as a joint session with North Central London training hub at the end of February and was very well attended. A recording is available here: https://www.ncltraininghub.org/news/event-recap-ncl-and-nel-polypharmacy-masterclass

Further sessions are being developed.

The Overprescribing working group are keen to hear about any practices or PCNs who are currently involved in any projects around overprescribing.
Please reply using the secure generic email: **nelondonicb.prescribingqueries@nhs.net**

POLYPHARMACY ACTION LEARNING SET TRAINING:

The Health Innovation Network Polypharmacy Programme are inviting GPs and prescribers to join the NHS England funded Polypharmacy Action Learning Sets. The aim of this evidence-based learning model is to help GPs, Pharmacists and other professionals who undertake prescribing, medication reviews and de-prescribing to understand the complex issues surrounding stopping inappropriate medicines safely. This online interactive course is held over three half-days starting 17 April (9.30am –12.15pm) for a period of one month. Please let us know if someone from your GP practice registers for the course**.**

PRESCRIPTION DURATIONS FOR CONTROLLED DRUGS

Prescribers are strongly advised to limit the quantity of prescriptions for Schedule 2, 3, and 4 Controlled Drugs (CDs), to the quantity necessary, for a maximum of 30 days' treatment.
In cases where the prescriber believes that a prescription should be issued for a longer period, they must be able to justify and document in patient records that, there is a clinical need and that it would not cause an unacceptable risk.

Clinicians should prescribe CDs using electronic prescribing systems (EPS) and only use printed or written prescriptions if this is not possible or is an adverse risk to the patient.

Repeat Dispensing (batch prescriptions) and CDs:

- Schedule 2 and 3 CDs **cannot** be prescribed on repeat dispensing prescriptions.
- Schedule 4 CDs must be dispensed for the first time within 28 days of the date on the prescription. After the first dispensing, the repeats are legally valid within the normal periods of validity of the repeatable prescription.
- Schedule 5 CDs must be dispensed for the first time within six months of the date on the prescription. After the first dispensing, the repeats are legally valid within the normal periods of validity of the repeatable prescription.

Action for practices:

For GP practices:

When reviewing repeat prescriptions for all controlled drugs including opioids, ADHD medicines, gabapentinoids, z- drugs and benzodiazepines:

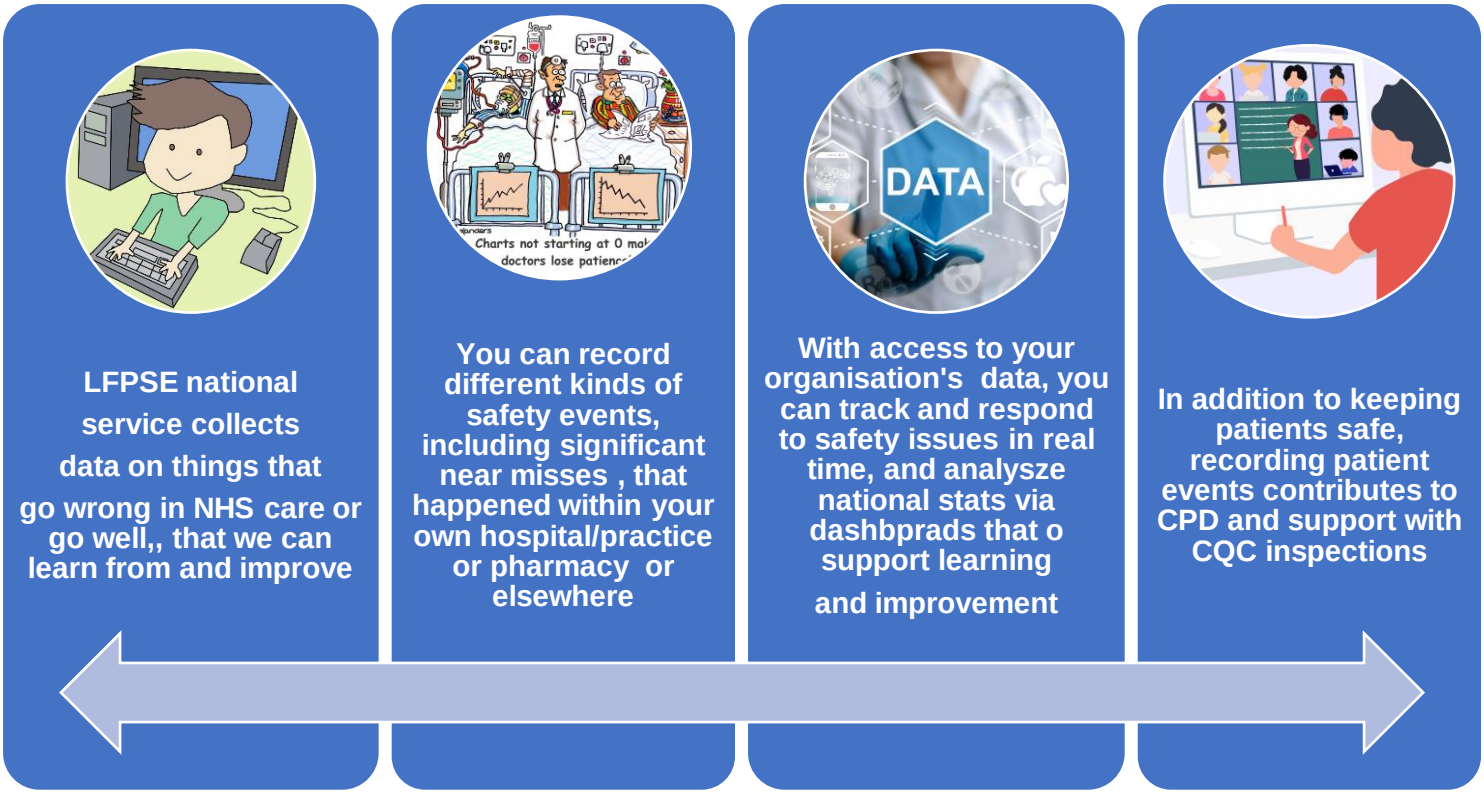
- Ensure the quantity on the prescription does not exceed 30 days' supply.
- Ensure prescriptions include a clearly defined dose, full administration details and not labelled 'as directed'.
- Ensure all patients have regular medication review for repeat prescriptions to ensure the drug and dose is still necessary, and to consider step down and stopping where appropriate.
- Systems and processes need to be in place to monitor concordance, and over-ordering, risks of dependence and misuse.

For pharmacies:

- Communicate and challenge prescriptions with the prescriber, where the total amount prescribed exceeds 30 days' supply.

Learning from Patient Safety Events (LFPSE UPDATES)

Using patient safety events data to keep patients' safe makes NHS care safer for our patients.



(adapted from NHSE introduction of the Learn from Patient Safety Events (LFPSE) service for primary care).

Action for practices:

- Staff can register either via **locally-connected reporting software**, or directly through an **online log-on**.
- Recording a medication incident in North East London? Ensure you assign the submitted incident as a "medication event" on LFPSE.
- Ensure you are familiar with guidance on how LFPSE can support with **CQC** inspections
- Further information to support recording primary care patient safety events on LFPSE is available here: **primary-care-information**
- To know more, please **watch the video**

Learning from Incidents across North East London Integrated Care System

As part of our key agenda, the NEL Medicine Safety and Quality Group (MSQG) supports the sharing and learning from medicines safety incidents that occur across the ICS to raise awareness of avoidable medicines safety issues and reduce the risks of unintended harm from medicines use.

INCIDENT- COMMUNITY ANTICOAGULANT SERVICE:

A case relating to a patient with a mechanical mitral valve who had a sub-therapeutic INR over a 5-week period.

Patients with mechanical mitral valves are at increased risk of valve thrombosis when their INR is sub-therapeutic. Such patients should be assessed by a clinician, experienced in anticoagulation, and bridging with low molecular weight heparin (LMWH) should be considered until INR is therapeutic. The patient may also be given an increased dose of warfarin and should be brought back to clinic to re-check INR within 3-4 days.

In this case the patient (target INR 2.5-3.5) was seen by an HCA and the sub-therapeutic INR of 1.5 was not escalated to a clinician experienced in anticoagulation. The dosing guidance generated from the Clinical Decision Support System (CDSS), INRstar, was overridden by the HCA and the patient was asked to return to clinic in three weeks. At three weeks the INR was still 1.5. The HCA increased the dose as advised from the dosing guidance generated from INRstar, but the suggested review date of 7 days was overridden, and the patient was asked to return in 21 days. Again, this was not escalated to a clinician, since, the patient was still unstable, not bridged with LMWH and suggested review date from INRstar guidance was again overridden. Two weeks later the patient returned for an INR check and had a therapeutic INR.

This patient was not managed according to the agreed anticoagulation guidelines and as a result was put at unnecessary risk of thrombosis over a five-week period.

Action for community anticoagulation centres:

- Ensure all staff working in anticoagulation clinics are familiar with the agreed Anticoagulation Guidelines. This includes guidelines on bridging of mechanical heart valve patients with LMWH when INR is sub-therapeutic.
- Ensure all staff working in anticoagulation clinics have an appropriate level of access to INRstar.
- Anticoagulation service providers should ensure that all staff members with level 3 access to INRstar have been assessed as being competent to hold clinical responsibility to override dose recommendations from the INRstar system. All other staff undertaking clinics should escalate out of range INRs to a GP/lead clinical nurse/pharmacist.
- A few anticoagulation sites in NEL do not use INRstar, these anticoagulation sites are reminded to adhere to the roles and recommendations of the relevant anticoagulation decision support software.
- Ensure formal reporting of sub-therapeutic INRs, which require LMWH bridging, to the anticoagulation provider.

MHRA Latest Drug Safety

MHRA Latest Safety Alerts/Recalls and Updates – Jan – 10th April 2024

- Medicines Recall: Accord-UK Ltd, Co-Codamol 8/500mg Effervescent Tablets (Key Pharmaceuticals Livery)
- 0.9% Sodium Chloride Solutions for Irrigation, Inhalation and Eyewash: recall from manufacturer Legency Remedies
- Counterfeits and unbranded copies of LifeVac anti-choking devices may fail to work correctly or worsen choking incidents if used
- Recall: Besins Healthcare (UK) Ltd, Oestrogel Pump-Pack 750 micrograms /actuation Gel (estradiol)
- Medicines Defect Information Orifarm UK Ltd, Concerta XL 18mg & 36mg prolonged release tablets
- Medicines Recall: Torrent Pharma (UK) Limited, Ramipril 1.25mg tablets
- Medicines Defect Information: Eexeltis UK Limited, Gepretix 100mg Capsules
- Medicines Defect Information Cadila Pharmaceuticals (UK) Limited Pantoprazole 40mg Gastro-Resistant Tablets
- Medicines Defect Information: Quadrant Pharmaceuticals Ltd Cozaar 100mg film- coated tablets
- Medicines Recall Biocon Pharma UK Ltd., Posaconazole Biocon 100mg gastro-resistant tablets
- Medicines Defect Information: Atnahs Pharma UK Limited, Clobazam Atnahs 5mg/5ml and 10mg/5ml Oral suspension

Letters sent to HCP.

- Oral valproate-containing medicines: Restriction of indication for male and female patients aged under 55 years; use revised educational materials
- Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000 mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors
- Lagevrio® (molnupiravir) 200 mg hard capsules ▼ – Extended Use Beyond Labelled Expiry Date
- Artiss 2ml Fibrin Sealant [Human] (product code: 5500649): Interim supply of Nordic Stock (Norway/Denmark) to Mitigate Supply Disruption
- EXKIVITY▼ (mobocertinib) 40 mg hard capsules – Conditional Marketing Authorisation Withdrawal
- Veltassa 16.8 g powder for oral suspension (Patiromer): Interim Supply of Northern Ireland Stock to Mitigate Supply Disruption
- ADAKVEO (crizanlizumab) ▼: revocation of UK marketing authorisation due to lack of therapeutic efficacy as determined by MHRA
- Plasma-Lyte 148 and Glucose 5% w/v Discolouration
- Tostran (Testosterone, 2% gel): priming instructions in the current PIL require updating
- Tamiflu® (oseltamivir) 45 mg Hard Capsules: Different colour ink used on blister pack

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** – **Medication Safety Updates** collating the latest medication safety communications and publications to inform, support and inspire medication safety improvements. For updates, click here ,**Jan, Feb** and **March** 2024
- **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**

For NHS use only – the information in this newsletter is **not suitable to be shared with patients / public**.
Every effort has been made to ensure that the information included in this newsletter is correct at the time of publication. The external links have been provided to improve access to further information and we cannot accept responsibility for their content.
We have no control over the availability of the linked pages, therefore, cannot guarantee that these links will work all the time.
For information or comments on this newsletter, please contact the Medicines Safety & Quality Group**:**
nelondonicb.medicinessafety@nhs.net