Medicines Safety Newsletter

NHS North East London

Issue 5 – July 2024

Promoting Safe Use of Medicines Across Primary Care

Welcome to the fifth issue 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

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Latest News

I. **Medicine Supply Shortages and discontinuations:** 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
Register with SPS, free-of-charge, to access.

II. **World Patient Safety Day 2024:** To be observed on ***17th September 2024*** under the theme *"Improving diagnosis for patient safety",* highlighting the critical importance of correct and timely diagnosis in ensuring patient safety and improving health outcomes. Click here for details.

III. Teratogenic Medicines Safety in NEL:

The NEL Medicines Safety and Quality Group (MSQG) is taking a system-wide approach to reduce harm from teratogenic Medicines in line with NHSE's medicines safety programme. We have engaged with key stakeholders across the system, primary and secondary care, and community services to form a NEL Teratogenic Medicines Safety Improvement group. The key aims of this group is to provide oversight for the implementation of all MHRA requirements, improve staff and patient education in relation to the safe use of valproate and topiramate within NEL and to ensure preparedness for forthcoming regulations on these areas of clinical care.

IV. NEW SAFETY MEASURES – PREGNANCY PREVENTION PROGRAMME FOR TOPIRAMATE:

Topiramate is used in some patients for the treatment for epilepsy, migraine and other seizure disorders and migraine. Exposure to topiramate in pregnancy is associated with significant harm to the unborn child, such as an increased risk of congenital malformations, autism spectrum disorders, intellectual disability, and neurodevelopmental disorders.

MHRA has issued new safety measures to further support prescribers around the safe use of topiramate in all women of childbearing potential and in pregnancy.

The use of topiramate is now contraindicated:

1. in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled (for all indications)
2. in pregnancy for prophylaxis of migraine
3. in pregnancy for epilepsy unless there is no other suitable treatment

Safe Use of Topiramate in NEL:
North East London Teratogenic Medicine Safety Improvement group will provide oversight to support providers (primary and secondary care, mental health trusts) with the implementation of these new safety measures. OptimiseRx messages have been updated to reflect this alert. Please review prescriptions and patients in line with the messages.

Action for Practices:

- Do NOT initiate topiramate unless this is formally requested by the relevant specialist in neurology, mental health, or migraine clinics.
- Initiate an EMIS (or SystmOne) search to identify patients in your practice who are prescribed topiramate.
- Continue to prescribe topiramate for existing patients unless you are asked to stop prescribing by the patient's specialist. Provide patients with information and reassurance, when needed.
- To minimise additional pressure for appointments on secondary care, please **do not** initiate new referrals for your existing patients who are known to Consultant Lead Clinics in secondary care. They will be invited for their next **annual specialist reviews** as a scheduled appointment.
- Patients who are not recorded as under the care of a local specialist should be referred to the appropriate specialist using existing referral pathways.
- Ensure the **Pregnancy Prevention Programme** and a **Risk Awareness Form (RAF)** has been completed for all women and girls of child-bearing potential on topiramate.
- Ensure existing women and girls of childbearing potential use a highly effective form of contraception and for at least four weeks after the last dose of topiramate. Guidance on highly effective contraception available at https://bnf.nice.org.uk/treatment-summaries/contraceptives-hormonal/
- Provide a copy of the Patient Guide for Migraine or Epilepsy to all eligible patients (or their guardian or responsible person) who continue to use topiramate-containing medicines.
- 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 is available online via Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme - GOV.UK (www.gov.uk)
- Please continue to report suspected adverse drug reactions to the Yellow Card scheme

V. SAFE MANAGEMENT AND USE OF CONTROLLED DRUGS UPDATE

Useful updates from the Controlled Drugs Team, London Region, NHS England. For more information

- **Reporting of Controlled Drug incidents in primary care:**
  Incident reporting from primary care services in London, including community pharmacies and GP practices, is lower than other regions. This may be due to lack of awareness of the need to report controlled drug (CD) incidents to the London Controlled Drug Accountable Officer (CDAO) team. All CD-related incidents and concerns involving controlled drugs of all schedules , including those in lower schedules such as benzodiazepines, z-drugs, codeine, and dihydrocodeine must be reported to the NHS England London CDAO team via the Controlled Drugs Reporting website
  These reports help identify themes, share learning and intelligence with stakeholders including regulatory bodies and police if needed and ensure appropriate mitigation actions are implemented.

- **CQC annual report (2023) on safe management of controlled drugs**
  The report has been published and can be accessed here

- **Tramadol and Warfarin Interaction- Incident and Cause**:
  A patient's death resulted from intraparenchymal, and subarachnoid haemorrhage caused by an unknown interaction between warfarin and tramadol, leading to excessive blood thinning.
  - **Response Action**:
    - A "prevention of future deaths" report (Regulation 28 letter) was issued.
    - The British National Formulary (BNF) is now updated with details of this severe interaction. ePACT2 Alerts Dashboard now includes a comparator for co-prescribing warfarin and tramadol.

Learning from Patient Safety Events (LFPSE)

Using patient safety events data to keep patients' safe makes the NHS safer for our patients,"
From 30th June 2024, the National Reporting and Learning System (NRLS) was decommissioned and replaced by Learning from Patient Safety Events (LFPSE).
A primary care-specific LFPSE information site that explains how to log onto the system and record an event, with user guides is available via LFPSE webform.
Providers can contact england.patientsafetyhelpdesk@nhs.net for further information and next steps.

While we appreciate that general practice is incredibly busy, recording safety issues on LFPSE offers multiple benefits to practices in addition to improving patient safety.

Please ensure you assign the submitted medicine related incident as a "medication event" on LFPSE

Collected data on LFPSE service helps meet statutory and national policy requirements, ensuring compliance with regulations . Can contribute towards a positive CQC rating

Recording a patient safety event allows for self reflection which contributes towards CPD.

Learning from Incidents across North East London Integrated Care System

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INCIDENT- AMITRIPTYLINE TOXICITY- PREVENTION OF FUTURE DEATHS REPORT

A prevention of future deaths report (Regulation 28 letter) was issued after an inquest concluded that the medical cause death of a resident from amitriptyline toxicity was caused by an overdose of amitriptyline.

The patient, known to have a depressive illness was prescribed a dose of amitriptyline exceeding the maximum recommended by the BNF. Despite warnings in the BNF (and from the practice prescribing software in use) that, amitriptyline is "not recommended for use in depression and has an increased risk of fatality in overdose," the drug continued to be prescribed.

The report noted that following a hospital admission from an overdose incident with amitriptyline, the practice changed the prescription frequency from daily to monthly. This allowed the patient access to 28 days' worth of amitriptyline, thereby further increasing the overdose risk. The inquest also highlighted the need to ensure that medicine related risks are adequately identified, recorded in the medical notes, and communicated with all relevant staff looking after the patient.

Action for practices:

- To review Eclipse Live on a weekly basis to identify and review patients on concomitant use of amitriptyline and other Dependence Forming Medicines (DFM), which includes benzodiazepines, gabapentinoids, opioids and Z- drugs. Initiate a conversation with affected patients with the aim of de-prescribing one or both medicines.
- To support patients with a clear treatment plan on initiation of amitriptyline and Dependence Forming Medicines (DFM), offer patient information- that includes information on potential dependence.
- Incidents or risks should be reported, recorded, communicated, and escalated as appropriate, Including those that arise once patients are discharged from hospital.
- Medical and non-medical prescribers should refer to the most up-to-date online BNF (bnf.nice.org.uk) in addition to reviewing safety alerts offered by the practice's prescribing support software, OptimiseRx
- The practice's prescribing clinical lead (supported by the practice manager) must ensure that all relevant staff are properly trained on the practice's electronic prescribing systems (EMIS/ SystmOne); other prescribing support software - OptimiseRx as well as Eclipse, the medication-based risk stratification tool that highlights patients who are likely to be at higher risk of harm from their medication

MHRA Latest Drug Safety Updates

April – July 2024

MHRA Latest Safety Alerts

- Epimax ointment-and-epimax paraffin free ointment-reports of ocular surface toxicity and ocular chemical injury
- Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme
- Warfarin: be alert to the risk of drug interactions with tramadol
- Topical steroids: introduction of new labelling and a reminder of the possibility of severe side effects, including Topical Steroid Withdrawal Reactions
- Finasteride: reminder of the risk psychiatric side effects and of sexual side effects (which may persist after discontinuation of treatment)
- Montelukast: reminder of the risk of neuropsychiatric reactions

Letters sent to relevant healthcare professionals.

- Letters and medicine recalls sent to healthcare professionals in June 2024 - GOV.UK (www.gov.uk)
- Letters and medicine recalls sent to healthcare professionals in May 2024 - GOV.UK (www.gov.uk)
- Letters and medicine recalls sent to healthcare professionals in April 2024 - GOV.UK (www.gov.uk)

Medicine Recalls and Notifications

Medicine recalls and notifications for the period April to July 2024, can be accessed here: Alerts, recalls and safety information: drugs and medical devices

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