Medicines Safety Newsletter

Issue 3 – January 2024

NHS North East London

Promoting Safe Use of Medicines Across Primary Care

Welcome to the third 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

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 NHSE/I (NHS England and NHS Improvement). To access Click here

SAFE USE OF VALPROATE: Valproates (as sodium valproate or valproic acid) is a treatment for epilepsy, bipolar disorders, and other indications. Evidence from the National guidance on valproate-use-by-women-and-girls has shown that, if valproate is taken in pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects. There is also limited evidence of risks to men, and studies on this are ongoing.

MHRA UPDATES

REGULATORY MEASURES FOR VALPROATE PRESCRIBING:
Organisations to prepare for new regulatory measures for oversight of prescribing to all new patients and existing female patients

The MHRA has issued a critical NPSA alert of actions to ensure all prescribers are prepared for new regulatory measures for prescribing valproate to all new patients and existing female patients. An action plan for this implementation is due 31st January 2024.
The 2 new regulatory measures 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.

LEGISLATIVE CHANGE FOR VALPROATE DISPENSING:

From October 2023, legislation changes have been made to ensure all patients (male and female) receive their valproate-containing medicines in the manufacturers original full pack that includes specific warnings with pictograms, a patient information leaflet and card. These documents alert patients to the risks to unborn babies if valproate is used in pregnancy.
There are exceptional cases where the manufacturer's original full pack does not have to be supplied where:

(i) a risk assessment is in place that refers to the need for the patient to be sold or supplied valproate-containing medicines in different packaging from its manufacturer's original full outer packaging (for example, in a monitored dosage system) and
(ii) there are processes in place to make sure that the patient receives the Patient Information Leaflet.

NEL ICB is co-ordinating the implementation of the new regulatory measures in providers (primary and secondary care). A system group has been convened and further updates will be made available from the group.

Action for practices:

- Continue to prescribe valproates for existing patients and provide advice and reassurance when needed unless you are asked to stop prescribing by a specialist.
- Make every contact count (MECC)
  - Use the opportunity to provide patients of childbearing potential with information
  - Ensure existing patients of childbearing potential continue to use a highly effective form of contraception. General patient-friendly information on contraception methods can be found on the 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/
- 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
- A process for identifying patients in primary care without an Annual Risk Assessment Form (ARAF), followed by referral into specialist care is being developed and will be shared once completed

PrescQIPP – ISOTRETINION SAFETY UPDATE

Following the Isotretinoin (Roaccutane▼) drug safety update published in October 2023, PrescQIPP has published a helpful resource for all prescribers regarding the introduction of new safety measures, including additional oversight of the initiation of treatment with Isotretinoin for patients under 18 years of age.
They can be found here Isotretinoin_December.01.pdf

Structured Medication Review Resource

A range of evidenced-based patient information resources (Table 1) has been developed by the Health Innovation Network to support and help prepare people invited for a Structured Medication Review (SMR) with their GP, pharmacist, or other healthcare professional. The national rollout is supported as part of the recommendations from the National Overprescribing Review. The resources are available in a range of community languages to include Arabic, Bengali, Gujarati, Polish, Punjabi Gurmukhi, Punjabi Shamakhi, Romanian, and Urdu. The resources include the following:

- SMR invitation letter,
- ‘Stopping Medicines Safely’ leaflet,
- Patient films and questions, they may want to ask their health professional.

Further information can be found here

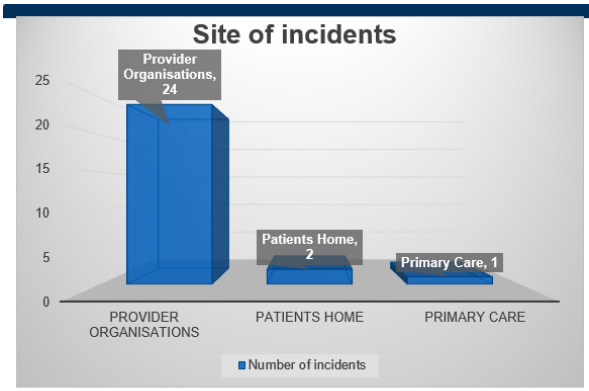
Table 1

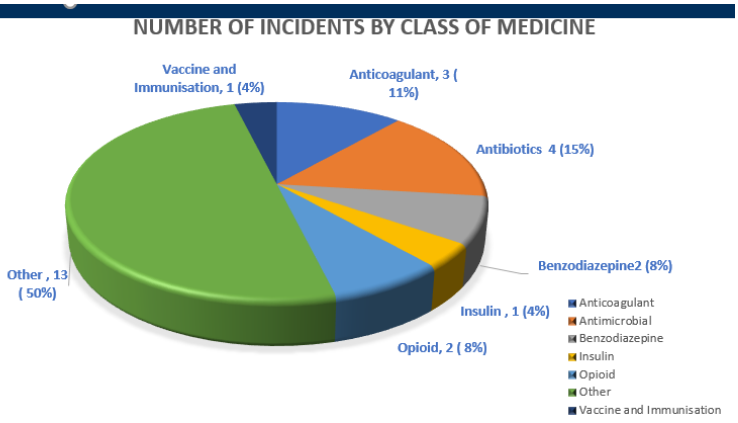
Name of Resource	Description
Patient invitation letter / audio recording	Template letter highlighting to patients the purpose of a medicine review. It includes questions for patients to think about before the appointment that they may wish to ask.
Safely stopping your medicine leaflet / audio recording	Information leaflet to aid the documentation of any medicines that have been stopped.
Me + My Medicines Charter	**Me + My Medicines** is a patient-created, patient-led and health professional supported campaign to help patients get more benefit and greater value from their prescription medicines. The Medicines Communication Charter encourages patients to ask, and clinicians to support people to ask about their medicines, to agree together a shared approach to overcoming any issues around their medicines.
Are Your Medicines Working? audio recording	Patient Checklist
Are Your Medicines Working? audio recording	Symptom tracker
• Download a subtitled version of the animation here to show in your GP practice. • Download a version of the animation without sound	These animations were created to help patients think about their medicines and to prepare for a SMR
Information sheet for healthcare professionals (Are Your Medicines Working? version)	Clinician information and implementation guide. Supporting patients before a medication review: Patient information pack

Learning from Patient Safety Events (LFPSE)

MEDICATION SAFETY SERIOUS INCIDENT THEMES

A report of a thematic review into medication related Serious Incidents (SIs) reported across North East London (NEL) in 2022-2023 to identify patterns and areas of concern to help inform the medicine Safety and Quality Group (MSQG) workstreams and quality improvement programmes. The data included is based on medication related SI reports extracted from the Serious Incident Framework (SIF) by the NEL Patient Safety and Quality.





The identified patterns and themes were:

- 24 out of 26 medication incidents were reported in Acute and Mental health Trusts
- 1 out of these 26 incidents (Administration of medication by the wrong route) was a Never Event
- The top 5 classes of high-risk medicines involved in medication incidents meeting SI criteria were, antibiotics, anticoagulants, opioids, benzodiazepine, and insulin
- The highest number of incidents in a single cause group was Administration and Prescribing errors.
- The top 5 incident categories were wrong route, wrong dose or strength, drug prescribed inappropriately (e.g. contraindication, duplicated, not discontinued, drug omitted on discharge) and failure of Adequate Medicines Security

Action for practices:

- Increase the number of reported patient safety events and/or incidents via LFPSE across NEL
- Encourage reporting from incidents for the purpose of shared learning
- Low reporting reduces shared learning and quality improvement opportunities
- Conduct regular structured medication reviews (SMR) for patients on high risk medicines to prompt early identification of errors e.g. unintentional omission of VTE prophylaxis for stroke prevention
- Increase number of referrals via the NHS Discharge Medicines Service particularly for patients prescribed high risk or complex medications regimes
- Ensure clear communication as patients move across settings from secondary care.

.

Incident –Morphine Toxicity:

A case following a medical certification of cause of death from Oramorph toxicity in an 81year old male. He had a medical history of anxiety, low mood, osteoarthritis, and previous attempt of overdose. Drug history included Lofepramine 70mg Once Daily (requested to wean off by Older Adult services), amitriptyline 10mg, Oramorph 5-10ml when required, Gabapentin 300mg Three times a day, Atorvastatin 40mg and Ramipril 10mg Once Daily.

A review of the case found system issues that led to missed opportunities to risk assess the patient, including follow up of clinic appointments, review of medication, assessment of adverse effects, and communication between services.

Some of the findings relevant for primary care include:

- Patient prescribed 500ml bottles of Oramorph
- Unclear from record notes whether patient was being weaned off Lofepramine
- Regular medication review

Action for practices:

•Prescribing quantities

- Ensure appropriate quantities are prescribed with full administration details.
- Ensure the patient has been counselled on how much they can take for PRN medicines. Where maximum quantities are required, this should be made clear to the patient
- Ensure appropriate pack sizes have been prescribed e.g. 100ml bottles not 500ml
- Where there is concern about high quantities, ensure practices review

•Clear Documentation in notes:

- Ensure clear and complete documentation in patients records
    - Include details of counselling, risk assessments undertaken
    - Where requests to wean anti-depressants have been made, document whether this is in process and any difficulties encountered or any re-starts
    - If require support to wean off – consult local mental health trusts for advice
- May be helpful to have registers of patients with previous history of attempted suicide so appropriate consideration can be given when making changes to medicines

•Medication review

- Ensure patients at risk have their medication reviews and process is in place to prevent on-going repeat prescribing of such patients

•Promote use of Eclipse to proactively identify patients for medication review

MHRA Latest Drug Safety

MHRA Latest Safety Alert – September -11th December 2023

- Ozempic (semaglutide) and Saxenda (liraglutide) vigilance required due to potentially harmful falsified products
- Nirmatrelvir, ritonavir (Paxlovid): be alert to the risk of drug interactions with ritonavir
- E-cigarette use or vaping reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the yellow card scheme
- Isotretinoin (Roaccutane) introduction of new safety measures including additional oversight of the initiation of treatment for patients under 18 years of age
- Valproate: dispense full packs of valproate containing medicines
- Statins very infrequent reports of myasthenia gravis
- Fluoroquinolone antibiotics: suicidal thoughts and behaviour
- Medicines defect information Strandhaven ltd Somex Pharma Clarithromycin 250mg and 500mg film coated tablets
- Medicines defect information Strandhaven ltd Somex pharma Tramadol hydrochloride 50mg capsules hard
- Medicines notification Teva UK ltd Caramet 25/100mg CR tablets
- Medicines recall AstraZeneca UK ltd Fluenz Tetra nasal spray suspension
- National Patient Safety Alert Valproate organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients
- Specific brands of carbomer eye gel recall of Aacarb eye gel Aacomer eye gel and Puroptics eye gel potential risk of infection
- Medicines defect information max remedies ltd max healthcare paracetamol 500mg capsules
- Medicines recall Chiesi ltd dot Trimbow-87/5/9mcg pressurised inhalation solution
- Medicines recall Theramex HQ UK ltd, Evorel Sequi

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 click here
- **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