NHS England London

MEDICINES SAFETY NEWSLETTER

From the Medicines Safety Team, London Region, NHS England and our London Medication Safety Officer Network Chair

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Welcome to the fourth London Region Medication Safety Newsletter. We hope you find it useful and informative, and we also hope you have enjoyed the previous editions. This issue contains updates on important Medicines Safety Improvement Programme priorities, spotlights on medication safety roles, and updates on other important alerts which have been published. The aim is for you to take away some of the suggested actions for your organisations for implementation, and to share these with others.

As always, we welcome your feedback and any contributions!

With best wishes, Sarah, NHSE London Region Controlled Drug Accountable Office & Medication Safety Officer and Amandeep, London MSO Network Chair.

Please feedback your comments or send any contributions via Amandeep Setra, London MSO Network Chair (amandeep.setra@nhs.net)

MEDICINES SAFETY WEEK

This week (4th - 10th November) is #MedSafetyWeek.

#MedSafetyWeek is a social media campaign that takes place annually in November each year with a different focus or theme to encourage the reporting of suspected side effects.

This year's theme is: 'the importance of using medicines in the right way to prevent side effects, and to report side effects when they do occur'.

Further information can be found here, including resources that are available from the MHRA.

MEDICINES SAFETY IMPROVEMENT PROGRAMME (MEDSIP) PRIORITIES

The key ambition for the Medicines Safety Improvement Programme remain 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 how to:

- Improve care for people with a learning disability by reducing the burden of medications that act on the brain. This will complement the STOMP/STAMP campaigns, and the Health Innovation Networks are currently undertaking some initial scoping work.
- 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, and the Health Innovation Networks are currently undertaking some initial scoping work.
- 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, 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.

AN UPDATE ON VALPROATE

The September edition of the MHRA Drug Safety Update shared results of a retrospective observational study which indicated a possible association between valproate use by men around the time of conception, and an increased risk of neurodevelopmental disorders in their children.

Advice has been provided on the alert to inform male patients who may father children of this possible increased risk, and to recommend the use of effective contraception (condoms, plus contraception used by the female sexual partner) throughout valproate treatment, and for at least 3 months after stopping valproate.

This information follows information from a previous drug safety update (January 2024) which shared new safety and educational materials which had been introduced for men and women to reduce the harms from valproate.

Actions for all:

- Check who is leading on embedding these actions within your organisation
- Share information with pharmacy colleagues who may need to be aware of this new advice
- Refer to the valproate resources and tools on the NHS Futures site: Medicines Safety Improvement Programme - FutureNHS Collaboration Platform

TOPIRAMATE

In June 2024, MHRA published a Drug Safety Update for topiramate, introducing new safety measures, with actions for general practice, community pharmacy and neurology including paediatric neurology: https://www.gov.uk/drug-safety-update/topiramate-topamax-introduction-of-new-safety-measures-including-a-pregnancy-prevention-programme.

The SPC has been updated in line with MHRA guidance Revised SPC: Topamax (topiramate) products and a number of resources are available as part of the topiramate Pregnancy Prevention Programme, which is aimed at minimising pregnancy exposure during treatment with topiramate and can be found here: Risk minimisation materials for topiramate products: Pregnancy Prevention Programme

This affects around 45,000 patients across England and educational materials for patients include a patient guide, risk awareness form and patient card

Actions to take away:

- Check on what is being done within your ICB to support General practices with this regulatory change to topiramate
- Share information with pharmacy colleagues who may need to be aware of this new advice

TRAMADOL/WARFARIN INTERACTION

The June edition of the MHRA Drug Safety Update highlighted an important but little known drug interaction between warfarin and tramadol.

Taking warfarin and tramadol together can cause harmful drug interactions, which can raise the International Normalised Ratio (INR), and result in severe bruising and bleeding, which in some patients could be fatal.

Actions for all:

- Take note of the advice and the specific points for healthcare professionals
- Please share this with colleagues
- Check what has been done within your organisations to highlight this interaction

CQC CONTROLLED DRUGS ANNUAL REPORT

CQC published their annual update on controlled drugs for the calendar year 2023 in July 2024: The safer management of controlled drugs: Annual update 2023 - Care Quality Commission

Some key points for awareness and actions to take away:

- There are useful section in the report on managing unknown substances in services and use of disposal kits: Key issues in 2023 - Care Quality Commission
- Services need to be aware of the risks of theft and diversion of nitrous oxide from areas where medical gases are used and/or stored.
- CQC have seen a recent increase in incidents relating to the incorrect selection of alfentanil – either in terms of prescribing or physically selecting a vial for administration.
- Ensure ID cards and uniforms are returned, and access cards de-activated when staff change roles or leave employment to minimise opportunities for theft of medicines.
- Nitazenes are synthetic opioids which are often mixed with other street drugs and are sometimes found to be present in counterfeit medicines. Their use can be fatal.

NATIONAL PATIENT SAFETY ALERT (OXYTOCIN)

A new patient safety alert was published on the 24th September 2024 to highlight the risk of oxytocin overdose during labour and childbirth.

Actions for the alert are to be completed as soon as possible but by no later than 31st March 2025.

Actions to take away:

- If applicable, check how your organisation is implementing this alert, and who is leading on this
- Share alert widely, and ensure maternity, and anaesthetic colleagues are involved where needed in reviewing practices

National Patient Safety Alert | RCOA Royal College of Anaesthetists | Royal College of Midwives | Royal College of Obstetricians & Gynaecologists | NHS

Risk of oxytocin overdose during labour and childbirth

Date of issue:	24 September 2024	Reference no:	NatPSA/2024/010/NHSPS

This alert is for action by: Organisations providing maternity services.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leads in maternity, anaesthetics, theatres, and pharmacy.

Explanation of identified safety issue:

Oxytocin can be given in low dose infusions to induce labour or to augment contractions during labour (intrapartum), and in significantly higher doses following birth (postpartum) to manage a postpartum haemorrhage (PPH).

Midwives need to complete several tasks immediately and simultaneously following birth to ensure the safety of both the mother and baby. To support this, postpartum oxytocin infusions have been prepared in advance of being required.

If a pre-prepared oxytocin infusion is unintentionally given before the baby is born, for example if it is confused with standard fluids or the intrapartum and postpartum infusions are confused, the woman's contractions will increase in frequency and strength. This can lower the baby's oxygen levels and alter their heart rate, increasing the risk of placental abruption (where the placenta prematurely separates from the uterus and deprives the baby of oxygen).

A review of the National Reporting and Learning Systems over a 5 year period identified 25 incidents including one report of a woman receiving a pre-prepared postpartum oxytocin infusion in place of IV fluids while in labour. The baby's heart rate slowed, and the woman required an emergency caesarean section due to a placental abruption. The baby was born in poor condition and admitted to the neonatal intensive care unit (NICU) for close monitoring.

Other reports described:

- postpartum oxytocin regimens accidentally given during labour or in theatre pre caesarean section
- oxytocin infusions and IV fluids being confused, leading to oxytocin infusions running through freely or at a significantly increased rate during labour.

This alert seeks to balance the benefit of ensuring an oxytocin infusion can be started immediately after a woman (at high-risk of PPH) has given birth and mitigate the risk of preparing the oxytocin infusion in advance.

Actions required

Actions to be completed as soon as possible but no later than 31 March 2025

Review and update local clinical procedures (or equivalent documents) to ensure:

1. Oxytocin infusions for any indication are **not** pre-prepared at ward level in any clinical area (including delivery suites and theatres). NOTES A, B, C
2. Post-partum haemorrhage (PPH) kits/ trolleys are immediately available in all clinical areas/theatres where it may be required. NOTE D
3. Where a woman is identified to be at high risk of PPH:
   a. the PPH kit/trolley should be brought into the labour/delivery room/theatre during the second stage of labour
   b. the postpartum oxytocin infusion should be prepared at the time of birth and not before NOTE E
   c. a second midwife should be available to support the administration of the postpartum oxytocin infusion.
4. Roles and responsibilities of staff groups in the labour setting, including theatres, are clearly defined in terms of prescribing, preparation, administration and disposal of oxytocin infusions. NOTE F

   Including:
   - intrapartum oxytocin infusions
   - postpartum oxytocin infusions
   - unused, pre-prepared oxytocin infusions.

For further detail, resources and supporting materials see: https://www.england.nhs.uk/2024/09/national-patient-safety-alert-risk-of-oxytocin-overdose-during-labour-and-childbirth/. For any enquiries about this alert contact: patientsafety.enquiries@nhs.net 1/2

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

NATIONAL PATIENT SAFETY ALERT (KAY-CEE-L, (POTASSIUM CHLORIDE 5MMOL/5ML SYRUP))

An updated NatPSA was issued on 21st October 2024 to advise that potassium chloride 5mmol/5ml syrup will be discontinued from late November 2024 due to manufacturing and commercial issues.

Actions to take away:

- NatPSA_2024_011_DHSC (3).pdf supersedes NatPSA/2024/008/DHSC

National Patient Safety Alert

Department of Health & Social Care

NHS England

UPDATE: Discontinuation of Kay-Cee-L® (potassium chloride 375mg/5ml) (potassium chloride 5mmol/5ml) syrup

Date of issue:	21-Oct-24	Reference no:	NatPSA/2024/011/DHSC

This alert is for action by: All organisations involved in prescribing, dispensing and administering Kay-Cee-L® (potassium chloride 375mg/5ml) (potassium chloride 5mmol/5ml) syrup.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in paediatrics, GP practices and pharmacy services in all sectors.

Explanation of identified safety issue:

This NatPSA supersedes NatPSA/2024/008/DHSC
***Material updates in bold.**

Kay-Cee-L® (potassium chloride 5mmol/5ml) syrup will be discontinued from late November 2024 due to manufacturing and commercial issues.

Sando-K® (potassium bicarbonate 400mg and potassium chloride 600mg) effervescent tablets remain available and can support a full increase in demand. One effervescent tablet contains 12mmol potassium.

Unlicensed potassium chloride oral solutions manufactured within the UK are available via Specials manufacturers, lead times vary. NOTE A

Care is needed to ensure selection of the most appropriate oral potassium supplement and delivery of the correct dosage.

Actions required ⚠

Actions to be completed by 31/10/2024.

Primary and Secondary care providers MUST:

1. Not initiate new patients on Kay-Cee-L® syrup.
2. Proactively review all patients currently prescribed Kay-Cee-L® syrup to establish if potassium supplementation is still required, and switch to an alternative treatment, if considered necessary, ensuring no intolerance of excipients. NOTE E
3. Patients requiring doses of less than 12mmol of potassium should be prescribed:
   a. A UK manufactured Special potassium chloride oral solution NOTES A & D
   b. **Part-dosing of Sando-K® effervescent tablets is not routinely recommended but can be done if unlicensed specials are not available.** NOTES A-D
4. Patients requiring doses of 12mmol potassium or more should be prescribed:
   a. Sando-K® effervescent tablets, where the dose can be rounded to the nearest whole tablet NOTE C or
   b. A UK manufactured Special potassium chloride oral solution, if Sando-K® is not suitable. NOTE A
5. When patients are discharged from secondary care, clinicians should ensure any switch is clearly documented. Secondary care teams should notify primary care of any amendments to the patient's prescribed regimen. NOTES A & D

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk 1/2

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

SPECIAL FEATURE

A DAY IN THE LIFE OF A LONDON AMBULANCE SERVICE MSO

No two days are the same in the London Ambulance Service NHS Trust. It's the busiest ambulance service in the world, and we have a workforce of more than 10,000 covering a variety of roles. With some 6,340 patient-facing staff, and approximately 4.2 million emergency calls made every year in the London area, it's an immense machine, and my week is always different.

I am an Advanced Paramedic Practitioner (APP) with a background in pharmaceuticals, and I work in a unique and challenging environment. My job is always interesting, often intense, but never boring.

Take this week, for instance. Like many of my NHS colleagues, the diary has been filled with matters relating to corporate and clinical governance, regulatory matters, patient safety, innovation and business development, and continuity.

There were governance meetings, such as the Trust Risk Compliance meeting where all directorates come together to discuss the Trust's risk register. The monthly Medicines Management Group also took place this week, and I report to this Group on all aspects of medicines safety, including overviews on incident data, development work, monitoring on governance around formularies and much more.

A big feature this week has been meeting with Directors of each directorate in the Trust to develop their teams' system improvement plans following the findings of a thematic review on medication errors across the Trust, which I recently completed. This is an opportunity to demonstrate to each directorate the roles they play in the system safety and designing out of risk relating to medication and patient safety. Elsewhere, I have undertaken specialist reviews of medication safety incidents related to two critically unwell patients.

Due to the nature of our work, I have been involved in providing evidence in relation to fitness to practice proceedings, and - as a panel member on an employment hearing - I also provided subject matter expert input. On the business development front, I have been involved in scoping work for digitising a paper system and supporting our medicines packing unit with a redesign of their operational rotas. A current pilot of e-prescribing in the pre-hospital setting for APPs is nearing completion and it has entailed some work around medicines safety oversight and governance. Soon, it will begin to expand its impact on what our clinicians bring to the patient's doorstep.

In between all this, I have also worked with an acute trust on prepping for their #MedSafetyWeek, as well as reviewing clinical education queries and completing reviews of PGDs and drug monographs/ guidelines.
It's a busy schedule, a varied set of MSO shifts, and to finish off the week I'll be spending Sunday in an APP car, responding to patients across London.

Feel free to drop me an email at gavin.mooney@nhs.net if you would like to connect or discuss any matters in relation to medication safety in ambulance services.

LEARNING FROM INCIDENTS

We have been notified of a potential near miss incident from the community where an entire vial of insulin was inadvertently delivered whilst re-filling an insulin pump. This is currently being investigated, and the patient came to no harm.

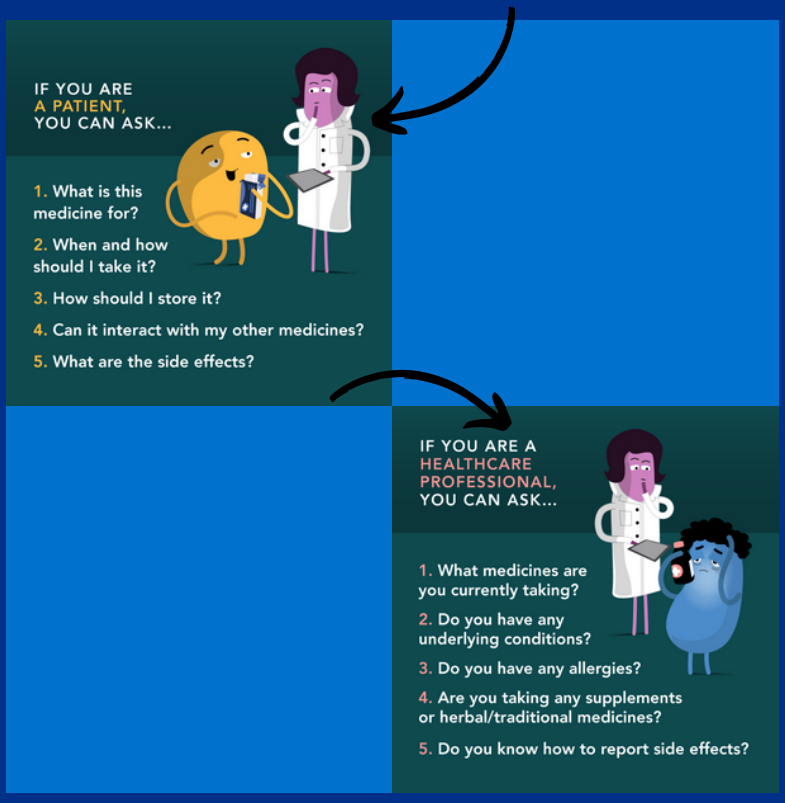
The MHRA Drug Safety Update issued in October highlights the fact that insulin pumps and continuous glucose monitoring devices are complex devices with the potential to result in serious harm in the event of error. To aid the MHRA in early identification of safety concerns associated with these devices, users of the equipment need to know how to report safety issues to the MHRA.

Further information can be found here: Report safety concerns with insulin pumps and continuous glucose monitoring equipment - GOV.UK (www.gov.uk)

LEARNING AND DEVELOPMENT

You may not be aware, but HSIB run courses which are currently available free of charge to NHS staff in England, with a focus on those with patient safety and investigation roles. Their flagship programme, the CPD accredited 'A systems approach to investigating and learning from patient safety incidents', is on-demand learning and they can accommodate large numbers of leaners in each cohort. They also provide other courses which are delivered online to small groups. They release new dates for NHS courses on a regular basis. Please subscribe to their mailing list to be notified of new dates.

#MEDSAFETYWEEK



USEFUL LINKS

Primary care patient safety strategy

NHS England » Medication safety

ALERTS

All alerts can be accessed via the Central Alerting System

SUPPLY ISSUES AND SHORTAGES

The latest information on supply issues, actions to take alternatives to use and expected resolution dates can be found on the Medicines Supply Tool on the SPS website.

DATES FOR YOUR DIARY

London MSO Network:

- Monday 15th January 2025

HOW DO I GET INCLUDED?

For those of you who are newly into a Medication Safety Officer role: You need to provide your contact details to the MHRA's Central Alerting System (CAS) team and once signed up, you will be invited to a national Medication Safety Officer monthly webinar which is held from 1-2pm on the last Wednesday of the month. Previous webinar resources are kept in an MSO workspace on FutureNHS. You may also find it helpful to access the SPS website where you will find many helpful pieces of guidance and resources. For the London MSO Network, please contact Amandeep Setra, **amandeep.setra@nhs.net**