NHS England - Midlands Controlled Drugs Summer 23 Newsletter

Local and national CD information to support safe use and handling of controlled drugs

NHS England Midlands

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Information from The Midlands Quality & Safety Newsletter

Reducing Harm from Opioids

The World Health Organisation launched a patient safety challenge in 2017, 'Medications without harm", Medication Without Harm (who.int) with the aim of reducing severe avoidable medication-related harm by half within 5 years. Opioids are a highly effective class of analgesics that offer great benefits for people living with pain. But when the source of long-term pain does not have a cause that can be treated, they can do more harm than good, particularly when they are used at higher doses. This can lead to complications, avoidable hospital admissions and even death.

The national Medication Safety Improvement Programme has suggested that for every 62 people that can be helped to stop (or not start) an opioid, a life can be saved. Within the Midlands, there are over 204,000 people prescribed opioid medication and of these around 161,000 have been receiving them for more than five and a half months. There are 12,060 people that have been prescribed doses equivalent to more than 120mg of oral morphine daily. NHS BSA Opioid Prescribing Comparators Dashboard, suggests that by focussing together on opioid prescribing across the Midlands, we have the opportunity to save up to 3,290 lives. There are lots of supporting resources available to support a whole systems approach to reducing high risk opioid prescribing available through a dedicated FutureNHS workspace FutureNHS Collaboration Platform - FutureNHS Collaboration Platform (requires registration).

Overprescribing of potentially addictive medicines

Optimising personalised care for adults prescribed medicines associated with dependence or withdrawal symptoms: Framework for action for integrated care boards (ICBs) and primary care was published in March 2023. NHS England » Optimising personalised care for adults prescribed medicines associated with dependence or withdrawal symptoms: Framework for action for integrated care boards (ICBs) and primary care.

NICE - Benzodiazepines and Z-drugs

NICE have recently published a patient decision aid on reducing and/or stopping benzodiazepines and Z drugs. This decision aid supports implementation of NICE's guidance on medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults. Link to the document: Should I stop my benzodiazepine or z-drug? Patient decision aid full version (nice.org.uk)

Controlled Drug (CD) Incidents and Concerns involving patients on Opioid Substitution Treatment (OST)

Missed pick-up of OST medicines for three days

The NHS England (NHSE) Midlands CD Team have seen an increasing number of CD incident reports, relating to patients who have missed pick up of methadone or buprenorphine for more than 3 days where the prescriber and/or drug treatment service had not been notified. If a patient has not taken their regular prescribed dose of opioid, there is the possibility that their tolerance to the drug could have reduced, increasing risk of overdose if the usual dose of medication is then taken. Every effort should be made to limit the potentially harmful impact on the patient. The pharmacist and pharmacy team have pivotal roles in the safe and effective delivery of care.

Pharmacists are strongly advised that they or another member of the pharmacy team, must contact the prescriber / key worker / service after the third day is missed to inform them so advice from the prescriber on what action to take can be obtained. A pharmacist should not normally dispense the fourth day's dose unless they have confirmed with the prescriber either to continue to dispense or to ask the patient to attend the prescribing service for an urgent clinical review.

Examples of CD Incidents and Concerns

Pharmacies and Drug and Alcohol Teams (DAAT) should be reporting to the CDAO using the CD Reporting Portal (www.cdreporting.co.uk) -

- Patients missing doses (or receiving extra) due to dispensing, administration or prescribing errors (e.g. no stock or valid prescription)
- Patients receiving incorrect doses due to dispensing, administration or prescribing errors (e.g. incorrect quantity dispensed or prescribed)
- Doses not been given as per prescribers instructions e.g. a patient not supervised despite the prescriber requesting or not in daily doses
- Patients receiving doses from invalid / cancelled prescriptions
- Patients, pharmacy or DAAT losing prescriptions for CDs (this may include prescriptions lost in transit e.g. Royal Mail)
- Patients abusing CDs e.g. fraudulent activity / diversion / theft
- Storage, discrepancies or administration errors by DAAT
- Concerns with professionals or governance in relation to CDs
- Not reporting missed doses during titration phase
- Issues relating to discharge from hospitals / prisons and provisions for OST

Post-dated prescriptions

Prescriptions for Schedule 2, 3 and 4 CDs are only valid for 28 days. The 28 day period of validity runs from the date the prescription was signed unless the prescriber has specified a start date on the prescription as a date before which the drugs should not be supplied. Any owing balance of prescriptions for Schedule 2, 3 or 4 CDs cannot be dispensed later than 28 days after the appropriate date on the prescription.

Prescribing Monitoring - activities carried out by the Midlands CD Team

Gabapentin

As from 1 April 2019 gabapentin was reclassified as a Schedule 3 controlled drug under the Misuse of Drugs Regulations 2001, and Class C of the Misuse of Drugs Act 1971. The Department of Health and Social Care has issued strong recommendations that the maximum quantity of Schedule 3 drugs prescribed should not routinely exceed 30 days.

The common themes highlighted the following:

- ⇒ Two months' supply was routinely prescribed and not challenged by the GP
- ⇒ Maximum recommended daily dose of 3.6g exceeded, with reports of patients on 4.8g, 5.4g and 6g daily
- ⇒ One prescribing incident where a patient received a quantity of 900 capsules
- ⇒ Post dated prescriptions issued but patients were still able to overorder medication

Recommended actions:

For GP practices: Identify and review all repeat prescriptions for gabapentin taking the following into consideration -

- ♦ Ensure the quantity on the prescription does not routinely exceed 30 days' supply
- ♦ Check patients prescribed gabapentin do not exceed the recommended 3.6g maximum daily dose.
- ♦ Ensure prescriptions include the dose clearly defined and not 'as directed'
- ♦ Systems and processes need to be in place to monitor over ordering

For pharmacies and dispensing GP practices:

- ♦ Communicate with GP practices where the total amount prescribed exceeds 30 days supply
- ♦ Query any gabapentin prescription which exceeds the 3.6g daily dose with the prescriber

CD Destructions in Community Pharmacies and GP surgeries

The Misuse of Drugs Regulations 2001 requires premises to denature Sch 2, 3 and 4 (part 1) CDs prior to safe disposal. Usually, this process requires an appropriate licence, but some premises for can register an exemption without needing to obtain a licence. In England, an exemption is issued by the Environment Agency and is known as the 'T28 exemption'. This exemption needs to be registered and updated every 3 years - Register or renew waste exemptions - GOV.UK (www.gov.uk).

	Is Denaturing Required?	Is An Authorised Witness (AW) Required?	Record Keeping
Patient Returned CDs	Yes For Sch 2, 3 or 4 (part 1)	No. However it is preferable for denaturing to be witnessed by another member of staff familiar with CDs	It is good practice to make a record in a patient returns register
Expired / Obsolete / Unwanted CD Stock	Yes For Sch 2, 3 or 4 (part 1)	Yes - if Sch 2 For Sch 3 and 4 (part 1) it is good practice to have another member of staff witness the destruction	An entry is needed in the CD register for Sch 2 CDs. Good practice would be to maintain a destruction record for other Schedules

Safe custody regulations apply to patient-returned CDs and expired / obsolete / unwanted CD stock until they can be destroyed appropriately. To minimise the risk of supplying these to patients, this stock should be segregated in the CD cabinet from stock which is in use and be clearly marked (e.g. mark the stock as 'patient returns waiting to be destroyed' or 'out of date, waiting authorised witness to destroy', etc). Please note CD stock waiting for destruction should also remain in the running balance and appropriately balance checked regularly until destroyed. Organisations such as GP surgeries and Pharmacies in a chain of less than 5 needing an AW for destruction should submit a request to the NHSE CD Team using the CD Reporting Portal – www.cdreporting.co.uk. If you have any queries please contact the CD Team using the generic inbox email.

CD Reporting Portal (CDRP) - Useful Tips

Controlled Drug Reporting

Remember all CD Incidents and Concerns should be reported to the CDAO on the CDRP (www.cdreporting.co.uk) in a timely manner.
The CDRP now has separate Incident and Concern Modules. Below are definitions of Incidents and Concerns, including examples to support reporters in which form to use. The CD Team would advise that if you are unsure which form to use please get in touch using the generic email addresses.

An Incident is defined as: An event or situation arising in the course of work that resulted in or could have resulted in injuries, illnesses, damage to health, or fatalities. "Near miss" or "dangerous occurrence" are also terms for an event that could have caused harm but did not and these may be treated as an "Incident".

Examples of incidents:

- Theft or diversion by healthcare professional
- Wrong dose administration of a controlled drug
- Dispensing error
- Running balance discrepancies
- Spillages / Breakages / Damaged CDS

A Concern is defined as: A matter of interest or importance to the Controlled Drug Accountable Officer on the safe use or management of controlled drugs. Events that are yet to be corroborated or substantiated also constitute a concern. These could include a complaint or a whistleblowing report by a member of the public, healthcare professional or support staff.

Examples of concerns:

- Several reports of discrepancies that all link to one individual
- Numerous low-level events from the same provider
- Allegation - selling or receiving CDs

Messages from the CDRP

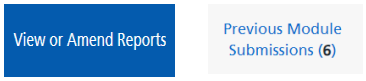
Your local CD team now has the ability to send messages to reporters using the CDRP. You will receive an email notification asking you to log into the CDRP to respond. Once you log in you should be able to navigate to the messages tab to see any notifications needing action.

Anonymous Concerns

The CDRP now has the functionality to submit anonymous concerns relating to CD's to the NHSE CDAO. To do this the reporter must not log in and select 'Report a Concern anonymously' on the log in page.

Accessing old submissions on the CDRP

To view your previously submitted incidents on the CDRP you must log in and first navigate to 'View or Amend Report'. Then select 'Previous Module Submissions'.



Resource Centre

The CDRP has a Resource Centre which includes newsletters, guidance and tutorials from all Regional CD Teams which any user can access.

Resource Centre

We would like to share a Serious Incident Case Study: Infant Morphine Overdose Investigation Summary & Learning which was produced by the North East and Yorkshire CD Team.

A recent Serious Incident has occurred in their region where a 4-week-old baby was administered a dose of morphine sulphate oral solution 20 times higher than the intended dose. The case study has been prepared as a learning tool for you. Please use this case study and learnings / actions taken as an example of good practice to help you review your own processes and professional practice within your own organisation.

Below are details from the case study but you can download a pdf version by logging into the portal, selecting 'Resource Centre' and 'Guidelines'.

Serious Incident Case Study: Infant Morphine Overdose Investigation Summary & Learning

NHS England North East and Yorkshire

July 2023

A 4 week-old baby from the North East and Yorkshire region was recently treated in the Accident & Emergency department following an overdose of **morphine sulphate oral solution,** administered at a dose **20 times higher** than the intended dose.

The parents of the baby were supplied with a bottle of **10mg/5ml oral solution** instead of the **100mcg/ml oral solution.** The **100mcg/ml oral solution** is a **'RED DRUG – HOSPITAL ONLY DRUG' AVAILABLE AS A 'SPECIALS' PRODUCT** on most regional formularies. **RED drugs** should be initiated by specialists only, and the prescribing and dispensing retained within secondary care.

The baby survived following treatment with naloxone. A review of national incident data indicates that this is now the fifth incident where this has occurred since 2018 and in one case it led to the death of a baby.

This special patient safety case study summarises the key findings of the Serious Incident Review to help all our providers and healthcare staff learn from this incident and review their own systems and processes to help prevent a further **morphine sulphate 100mcg/ml oral solution** incident.

Provider	What actually happened?	Actions taken to prevent the incident and or learning opportunities
	• Handwritten hospital discharge summary was sent to the baby's General Practice • The discharge summary requested the GP to prescribe: **Oramorph 50mcgs/kg/per dose = 190mcg every 4 hours** • Despite classification of this product being a 'RED' drug in this Trust and ICB, it did not prevent the error from occurring	* Issue electronic discharge summaries; the Trust are now introducing an electronic record system in maternity and neonates to allow modification of the contents of discharge summaries to support patient safety * Discharge summaries should contain the full drug name, formulation, strength, clear dose instructions with consideration of daily maximum doses for PRN (when required) medication. For liquids, ensure dose instructions are in both quantity and volume (e.g. **mg/mcg and ml)** * Opportunity for the hospital pharmacist reviewing the discharge summary to identify the 'RED' drug and to not request the GP to continue to supply * Review current process of discharging patients on a 'RED' drug and what actions should be taken to prevent potential harm from communication breakdown during transfer of care * For the management and use 'RED' drugs, Trusts should ensure they have the necessary governance and assurance systems in place * The Trust informatics Pharmacist is investigating whether 'RED' drugs can be flagged more clearly on the prescribing and electronic systems * The Trust has planned education sessions for the medical staff to raise awareness of this incident, the availability of the special product and general understanding of 'RED' drugs * Share this incident alert with all relevant staff across the organisation to help prevent a reoccurrence * This patient would have benefited from the community pharmacy Discharge Medicines Service (DMS) and Trusts should review current progress with implementation of the DMS across the Trust * Where appropriate, Trusts and ICB Area Prescribing Committees to review classification of morphine sulphate 100mcg/ml oral solution

Provider	What actually happened?	Actions taken to prevent the incident and or learning opportunities
	• The GP Practice received a request from the baby's family for a prescription for morphine sulphate a few days after discharge • The lead GP for the baby issued an EPS prescription as per the hospital neonatal discharge summary • GP reviewing the discharge letter was unaware that a **100mcg/ml** product was available • The brand name 'Oramorph' mentioned in the discharge letter, directed the GP to issue the **10mg/5ml** morphine oral solution • The GP calculated the dose needed would be 200mcg based on the baby's current weight, which was correct as per British National Formulary (BNF) and sent a prescription as follows: **Morphine Sulphate 10mg/5mls Oral Solution** **200mcg every 4 hours PRN** **Weight: 4050grams** • The GP when preparing the prescription followed the discharge summary and stated the dose in micrograms only and did not specify dose in volume of the 10mg/5ml oral solution • In essence the error followed through from the discharge summary • An initial enquiry was raised by the community pharmacist to the GP practice, this was relayed to the GP by an inhouse Pharmacy Technician and reception team	* Conduct a face to face medicines reconciliation and ask parents to bring in current medicines supplied by the hospital. This could have helped identify that the **100mcg/ml** preparation is not available to prescribe on the GP system * The dose should have been calculated into volume of the **10mg/5ml** preparation, this would have meant administering a dose of **0.1ml** * Communication between the surgery and pharmacy when dealing with very complex medication issues may require direct clinician to clinician conversations * Adding weight and date of weighing on paediatric prescriptions will help pharmacists complete their clinical assessment of the prescription and reduce the need to further contact the prescriber / parents * The practice has implemented a 'gold' register for babies and children with complex conditions who can have improved access to named GP and clear handover arrangements with others in the surgery in the absence of the named GP
	• The Community Pharmacy received the prescription via EPS and two pharmacists were involved with the dispensing and supply over two days (Friday and Saturday) • The initial pharmacist who received the prescription from the GP practice queried how the discharge summary was written. The pharmacist had highlighted that the prescription would translate to **0.1ml** needing to be given at each dose, which would be a difficult volume to administer • This discussion with the GP practice occurred through the Pharmacy Technician via the reception team and not direct communication with the prescriber • Pharmacist handover notes had limited information to give the context to why the prescription was being queried • Both pharmacists were unaware of the **100mcg/ml** strength being available as a **specials product** • Pharmacy support staff transcribed the dose from the prescription directly on to the dispensing label without any additional information describing the dose volume to be administered • The pharmacy dispensing label included the medical abbreviation from the prescriber 'PRN' and was not changed to as and when required • Pharmacist on duty was inappropriately reassured by the parents that they had previous experience of the dose and verbally mentioned that they would need to give a **0.1ml** dose • No syringe was provided to the parents to enable them to measure a **0.1ml** dose	* Check with the parents how they are measuring the current dose of **0.1ml**; this would have been difficult to measure using a 5ml oral syringe commonly supplied and could have helped identify the error earlier as the parents were giving a dose of **1.9ml of the 100mcg/ml specials product** * Pharmacists could have asked the parents to bring in their current bottle with the hospital pharmacy dispensing label on it to check against * Pharmacy team should have calculated and added the volume to be administered at each dose on the pharmacy dispensing label * Pharmacist at the point of supply, should have used this opportunity to counsel the parents, show them the medication bottle and clarify the dose and volume to be administered using a 1ml syringe * Speaking directly to the prescriber for medication queries with high risk drugs / or patients with complex conditions * Ensure you leave clear and thorough handover notes for prescriptions with queries * Ensure you are keeping paper / electronic records of any significant intervention you make * Document any key counselling points on the patients medication record * Ensure you have in stock 1ml oral medicine syringes to support patients with small volumes and during counselling demonstrate the markings on the syringe
Parents 	• Parents were unaware of the difference in strength and in the absence of any clear instructions, continued to give the same volume of **1.9ml** every four hours when required • The infant was getting **3.8mg** instead of **190mcg** and a single dose was administered before requiring emergency treatment	* When counselling, ask patients to summarise and recall main points back to you to check their understanding * Patient counselling across all settings on the dose to be taken / given and the importance of checking the medicine supplied; if ever in doubt to contact the dispensing pharmacy for confirmation

7 Actions

to help prevent another Morphine 100mcg/ml oral solution incident

NHS England North East and Yorkshire

1. Share this alert with all relevant staff, including locum / agency workers within your organisation so they all know that Morphine sulphate oral solution **100mcg/ml** is available as a '**SPECIALS**' product for use in / supply from Secondary Care only. It is classed as a **'RED'** drug on many regional formularies, so should **NOT** be prescribed in Primary Care settings. Chief Pharmacists to cascade to all relevant specialities across the trust, including junior doctors.

2. Review / audit current process of discharging patients prescribed this preparation and whether any improvements are needed to help prevent a similar incident.

3. Brand names (e.g., 'Oramorph') should **NOT** be used in communications either written or verbal, unless it is prescribed as a branded product with the strength of the preparation clearly stated on any communication.

4. Ensure **ALL** communications (**discharge summaries** / **prescriptions** / **dispensing labels**) specify the strength of the product intended, as well as the dose expressed in **both volume** (e.g., ml) and **quantity** (e.g., mg/mcg) e.g., 'Morphine Sulphate **100mcg/ml** oral solution — **'Take 2ml (200mcg) every four hours when required'**.

5. Do **NOT** assume that other clinicians or carers (including parents) involved, have got it right and always clarify any concerns you may have before making any supplies. Communication between the GP practice and pharmacy when dealing with very complex and high risk medication queries may require direct clinician to clinician conversations.

6. If a new high risk product is issued for the first time in a community pharmacy, take the time to ask the patient / parents / carer what dose they were giving before or are expecting to administer, then compare this to the prescription issued and query if necessary. Where appropriate ask the patient / parents / carer to bring any current supplies to the pharmacy to help you review the current prescription before dispensing.

7. The dispensing pharmacist **MUST** counsel and demonstrate the dose volume to the parent / carer, even if it is believed that they already know. Ensure you have in stock 1ml oral medicine syringes.