November 2014

Derbyshire and Nottinghamshire Area Team Controlled Drugs Newsletter

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Occurrence Reports

Just a reminder— designated bodies (organisations that have a CDAO) and provider organisations are due to submit their 14/15 Q2 (July- September) reports to the CDAO or a member of the team by the 14th November 2014. You can also submit via the dedicated in-box at england.nottsderbycontrolleddrugs@nhs.net

Report CD Incidents, concerns & discrepancies to Samantha Travis the CDAO for Derbyshire and Nottinghamshire. Samantha.travis@nhs.net

This is the first edition of the Derbyshire & Nottinghamshire Area Team Controlled Drugs Newsletter which contains local and national CD information. We have a dedicated email in-box so you can contact us with any articles for future editions. england.nottsderbycontrolleddrugs@nhs.net

Drug Safety Update - Accidental exposure to transdermal fentanyl

The Medicines and Healthcare products Regulatory Agency (MHRA) have issued a reminder of the risks of life-threatening harm from accidental exposure to transdermal fentanyl “patches”.

A copy of the letter sent to healthcare professionals in June 2014 can be accessed at http://www.mhra.gov.uk/home/groups/comms-ic/documents/drugsafetymessage/con428394.pdf .

The message from MHRA is to remind all health care professionals of the importance of providing clear information to patients and caregivers regarding the risk of accidental patch transfer and ingestion of patches, and the need for appropriate safe disposal of fentanyl patches.

Children are at risk as they may touch, suck, chew, or swallow a patch that has not been disposed of properly. Also, children have a lower threshold for fentanyl overdose than adults. Two of the three Yellow Card reports MHRA have received concerned children.

All Healthcare professionals are asked to advise patients and caregivers to follow the instructions on the patch carton and in the accompanying leaflet. If a patch is transferred to another person, it should be removed and the individual should get medical help immediately. If a patch is swallowed, the individual should get medical help immediately.
A patch may cause serious harm if it accidentally sticks to somebody else’s skin or is swallowed (e.g. by a toddler).

An Information leaflet is available to give to patients and caregivers http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con437440.pdf

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CD Registers

Some common issues with CD Registers have been found by the Police Controlled Drugs Liaison Officer's (CDLO) during their CD destruction visits to pharmacies.

- The running balance of a controlled drug remaining, **should include out of date stock** (until denatured by an authorised witness). Balances to be calculated and recorded after each transaction and checked at regular intervals – normally each week.
- Transfer correct quantity from old to new register – take extra care when transferring to reduce time identifying discrepancy later.
- Crossings-out, cancellations and alterations are **NOT permitted in the CD register**. Ensure all corrections in the CD register have a foot note and are not crossed through or rubbed out. Remember to always use an indelible pen, do not use pencil and do not use any corrective fluid. If an amendment needs to be made in the CD register, place an asterisk (*) next to the register entry containing the error. Enter details of the amendment as a footnote next to another asterisk (*) at the bottom of the page then sign and date the footnote.
- For CDs received from the wholesaler, include the invoice reference number in the column 'name and address from whom supply received' for audit purposes. It is good practice to also record batch numbers.

Patient returns and destruction of CDs

An authorised person is required to witness the destruction of schedule 2 out of date or obsolete CD stock (also best practice for Sch.3 to be witnessed by an authorised person). This is someone who has been appointed by the CDAO. The Police CD Liaison Officer can also witness destruction.

All CDs in schedules 2, 3 and 4 (part 1) that require destruction need to be rendered irretrievable in an appropriate denaturing kit before disposal in an appropriate manner. Ensure you have denaturing kits available in the pharmacy/practice.

Patient returns do not require witnessing by an authorised person but they should be denatured and witnessed by another member of staff.

When patient returns are received, record details of the person returning the medicines, together with the patient's name and address, as these will be needed if an entry is required in the "Controlled Drugs — destruction register for returned medicines" (or equivalent). If they cannot be destroyed immediately, secure them in a bag, clearly marking 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be

Standard Operating Procedures

Ensure that your practice/pharmacy has adequate and up-to-date Standard Operating Procedures (SOPs) in place for the management and use of Controlled Drugs.
It is good practice for CD SOPs to cover all aspects of risk management, and should highlight the accountabilities and roles of all members of the healthcare team, including reporting CD incidents, discrepancies to the CDAO. They should include audit trails for ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction of CDs, appropriate to the Pharmacy/ GP practice and the team.

Security of Prescriptions

There has been an increasing trend for fraudulent prescriptions to be presented at pharmacies.
GPs and practices should ensure prescription form stock and practice stamps in possession of prescribers are always stored securely when not in use. If prescriptions are stolen report it to NHS England Primary Care Team ASAP so that an alert may be considered. Phoning 101 advises the Police and if a CD prescription is involved report it to the CDAO. The CDAO would advise the CDLOs (Controlled Drugs Liaison Officer). If you have CCTV please ensure it is working and recording; this may provide valuable evidence in identifying the suspect.

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Drugs and Driving

The Department for Transport is introducing a new driving offence which is likely to come into force on 2nd March 2015; driving with certain drugs above specified limits in the blood. Anyone found to have any of these drugs in their blood above the specified limits will be guilty of an offence, whether their driving was impaired or not. To identify the drug taken a blood sample will be taken at a police station and sent for forensic test. However, there is a medical defence for people taking the drugs for medical reasons, **if their ability to drive was not impaired**. The conditions are:

- The medicine was prescribed, supplied or sold to treat a medical or dental problem and
- It was taken according to the instructions given by the prescriber or the information provided with the medicine

Drugs included in the new offence that might be used for medicinal purposes are: Cannabis (tetrahydrocannabinol, THC), Cocaine, Morphine, Diamorphine, Methadone, Ketamine, Clonazepam, Diazepam, Lorazepam, Oxazepam, Temazepam. Amphetamine (expected to be included), and Flunitrazepam (not licensed in the UK).

Healthcare professionals should advise patients to:

- continue taking their medicines as prescribed
- check the leaflet that comes with the medicine
- not to drive until they know how the medicine affects them (just starting or changing dose)
- not to drive if they feel affects such as being sleepy, dizzy or are unable to concentrate or have blurred vision.

Remind them it is against the law to drive if their driving ability is impaired.
It may be helpful for them to have evidence of they are taking prescription medicine in case they are stopped by the police, such as the medicine's patient information leaflet (PIL) or the tear off section of their prescription.
An information leaflet is available to give to patients
http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con437439.pdf

Guidance document from the Department for Transport is available at
https://www.gov.uk/government/collections/drug-driving

Penalties for anyone convicted of drug driving could get, a minimum 1 year driving ban, a fine of up to £5,000, a criminal record. Their driving licence will also show they have been convicted for drug driving.

Re-scheduled CDs in 2014

You will be aware that since the 10th June 2014 Zopiclone has been reclassified as CD schedule 4 (part 1) and that Tramadol is now reclassified as CD schedule 3.

Tramadol re-scheduling provides an opportunity for a full clinical review of patients prescribed tramadol. Consider what the risks of tramadol use are:
Serotonin syndrome, drug interactions, lowering of seizure threshold, psychiatric reactions, tolerance, dependence and potential for misuse.
What about Tramacet? Published studies have shown Tramacet (tramadol plus paracetamol) to be no more effective than co-codamol (30mg/300mg) or ibuprofen.

Midazolam Pre-filled Oral Syringes

When prescribing: Ensure the strength and dose are appropriate for the age of the child, with no instructions to administer partial/ half doses e.g. 7.5mg (1.5ml) from a 10mg pre-filled oral syringe.

•Buccolam® is licensed for use in children and is available in 2.5mg, 5mg, 7.5mg and 10mg strengths. Other unlicensed formulations are also available and may have different doses.

•To prevent the risk of accidental overdose care should be taken in prescribing. If you are uncertain of the appropriate dose and/ or strength contact the initiating prescriber (if applicable)/ check BNFC.

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Instalment dispensing

Many pharmacists are not informing the prescriber / drug treatment service when a patient misses 3 doses. There can be significant harm if the patient then receives the normal dose.

Pharmacists – inform the prescriber/ key worker when a patient misses 3 doses, before dispensing the next dose.

Prescribers - discuss with your local pharmacist especially if you have chaotic patients, as the pharmacist can better manage the care of the patient if they are aware in advance.

Errors in start & finish dates especially when prescribing for closed days such as Bank Holidays are common. Remember even if you provide a prescription to cover the supply retrospectively, an illegal supply would have been made.

Disposing of spent Methadone bottles

The Department of Health has produced guidance about empty medicine containers.

It is recommended that liquid controlled drug containers should be emptied as far as possible (during the dispensing process) and any excess liquid such as patient returns denatured. The container should then be placed into a waste container for incineration.

Patient Safety Incidents involving Community Pharmacies /GP practices in Derbyshire & Nottinghamshire

Incorrectly prescribed and dispensed to the patient with potentially serious consequences.
A patient new to opiates was admitted to hospital with confusion, sedation and hallucinations after he had taken prescribed Zomorph 200mg twice a day. The prescriber had intended a dose of 20mg twice a day. The dispenser did not highlight to the pharmacist that the patient was new to opiates and the pharmacist did not check the dose with the prescriber or the patient. The NPSA issued a Rapid Response Alert in 2008 which is still appropriate to use today. The alert highlights risks to patients receiving unsafe opiate doses. Please make time to read the rapid response report and supporting information and have available in your practice/pharmacy.
Opiate rapid response alert can be found at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888

Self Checking
Some of the CD dispensing errors that have been reported are due to pharmacists self-checking.
These may have been prevented by ensuring a second check when dispensing. If as the Pharmacist you find yourself in a situation when you have to self-check always take a mental break and follow accuracy SOPs

Key Messages

- **Risk of accidental harm especially to children, give out safe disposal messages**
- **Make sure CD Registers meet statutory requirements**
- **CD destructions and patient returns**
- **Ensure adequate up to date SOPs are in place**
- **Security of prescriptions**
- **Drugs and Driving advise patients**
- **Tramadol and Zopiclone CD reschedule**
- **Safer midazolam prescribing**
- **Safe Instalment dispensing and disposal of methadone bottles**
- **If as the Pharmacist you find yourself in a situation when you have to self check always take a mental break and follow accuracy checking SOP's**
- **Ensure all staff are aware of the NPSA Opiate Rapid Response report**
- **Report all CD Incidents, however minor, to the CDAO**