Issue 14

Date: 07/01/2019

Controlled Drugs Newsletter

Safe and secure handling of Controlled Drugs

NHS CDAO - East of England

It has been six months since the last CDAO NHS E&I East of England released a newsletter. A lot has happened in that time: NHS England East of England has extended to cover Bedfordshire, Hertfordshire, Milton Keynes and Luton. A lot of work has been undertaken to realign www.cdreporting.co.uk to fit the new regional structures. The Public Health England report "Dependence and withdrawal associated with some prescribed medicines" was published. We also launched the second cycle of high dose opioid prescribing in General Practice.

New NHS England East of England region

In August 2019, NHS England East of England extended. Previously NHS Midlands and East covered Suffolk, Norfolk, Essex, Cambridgeshire and Peterborough formed (East). The East of England CD Team now also covers Bedfordshire, Hertfordshire, Luton and Milton Keynes. The CDAO for the East of England is Sarah Rann, the CD Team can be contacted on england.ea-cdao@nhs.net or 01138250770.

CD Reporting www.cdreporting.co.uk

The CD Reporting Tool www.cdreporting.co.uk will be realigned to fit the new NHS East of England new boundaries.

This website covers:

- Reporting of CD related incidents to the NHS England East of England CDAO. This includes: prescribing errors, dispensing errors, balance discrepancies, lost medication, lost prescriptions and fraudulent attempts to obtain CDs.
- Designated Bodies should use this site to submit Quarterly Occurrence Reports
- Requests for Authorised Witnesses for CD Destructions
- For GPs, Dentists and Private Midwives to complete Annual CD Declarations

PHE: Dependence and withdrawal associated with some prescribed medicines, an evidence review 2019

The PHE report on dependence and withdrawal associated with some prescribed medicines was released in early September 2019. On page 4 of this issue, you can read some of the recommendations made by NHS E&I East of England based on the outcome of the Public Health paper.

Second cycle of high dose opioid prescribing in General Practice

Page 6 of the Controlled Drugs Newsletter winter edition offers a comparison between the year 2018 and 2019 with regards to high dose opioids prescribed in General Practice. Good news 2019 brings: 38% reduction on chronic pain CD prescriptions.

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Polypharmacy in patients who substance misuse

According to https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management, it is estimated that:
-Half of community mental health patients have reported problem drug use of harmful alcohol use in the previous year
-In drug and alcohol treatment services, over 3/4 of patients have been found to have a psychiatric disorder in the past year (mostly depression, anxiety, personality disorder)

GPs may care for with patients with multiple complex morbidities who are also on treatment for drug/alcohol problems. Treatment with methadone represents a particular patient safety risk as it does cause respiratory depression.
Many drug and alcohol services used to, but now do not, have specialist input from a substance misuse psychiatrist, leaving GPs with the responsibility for managing co prescribing and needing to take into account potential drug interactions between methadone, often prescribed by specialist substance misuse services and other medications, prescribed by the GP.
The patient may also be taking a variety of other substances, such as opioids, alcohol, benzodiazepines and increasingly gabapentin/pregabalin, illicitly.
Psychiatric symptoms, and less often psychiatric diagnosis, will create pressure on the GP to prescribe. Although on its own the prescribing by the GP may seem safe, the prescriber must fully take into account what other substances, both prescribed and not prescribed, the patient may be taking. For example, the treatment of anxiety may involve prescribing benzodiazepines, z drugs and gabapentin/pregabalin, all of which interact with opioids, both prescribed and obtained illicitly (more guidance can be found at https://www.rcgp.org.uk/clinical-and-research/resources/a-to-z-clinical-resources/dependence-forming-medications.aspx).
NICE is very clear on how patients with dual diagnosis are managed and their full recommendation can be read at https://www.nice.org.uk/guidance/ng58/chapter/Recommendations#partnership-working-between-specialist-services-health-social-care-and-other-support-services-and .
However, in practice shared care models may be patchy in their implementation, such that NICE is now consulting on guidance on how to ensure 'no wrong door' policies for patients with dual diagnosis are actually being implemented. CD teams need to be particularly aware that toxicology reports on patients taking methadone who have died very often report 'an elevated concentration of Methadone, consistent with either chronic therapeutic use or excessive use depending on the deceased's tolerance and/or dose regime'. This is not the same as the cause of death being methadone over dose and full consideration should be given to co prescribing of other respiratory depressants, some of which are CDs, which may have contributed to the death of the patient.

Contributors:
Dr. Ruth Bastable , Medical Adviser NHS E&I
Dr Sarah Rann, NHS CDAO—East of England

Guidance on Epidiolex usage

NICE decision on cannabidiol (Epidiolex), used with clobazam, for refractory childhood epilepsy (Dravet and Lennox Gastaut syndromes) 23 August 2019:

- Cannot recommend it as an efficient use of NHS resources
- Working with GW Pharma to address some of the concerns with the evidence, including:
  - Long-term effectiveness
  - Quality of life
- Final publication due in November 2019 (Technology Appraisals for Dravet syndrome and for Lennox-Gastaut syndrome)

For adult use e.g. chronic pain, chemotherapy nausea, multiple sclerosis – NICE has recommended further research be undertaken as there is currently insufficient for the mostly unlicensed products that are available.

As of October 2019, Epidiolex has been classified Schedule 2 controlled drug.

Contributor: Dr Leonie Prasad, NHS England & NHS Improvement – East of England

How does NHS England decide whether and how to release personal information?

From time to time the police or other government agencies may wish to access personal or sensitive information about patients and may approach NHS England for this information. NHS England has to take into account a number of considerations when deciding whether to release information including various laws and precedents. We must balance the benefit that might be derived from sharing the information with the benefit of confidentiality that patients rely on when giving health care organisations vital information about their health.

Firstly, it may be helpful to know what information NHS England has access to. If a patient is not currently registered with a GP (General Medical Practitioner) we will have access to any old GP records and are known as the "data controller". Patients may not be registered with a GP because they no longer live in the UK, have died or their registration has lapsed for some reason. We do not hold these records ourselves, but they are processed on our behalf by Capita who have the contract for Primary Care Services England (PCSE). They are known as the "data processor". Access to these records would be via Capita's PCSE offices.

If a patient is currently registered with a GP, NHS England has access to the name of the practice where the patient is registered, but the medical notes are the responsibility of the GP practice. They are the "data controller" and the "data processor" so you would need to approach them to decide whether to share information with you, but they should assess any requests in a similar way to NHS England.

When will we release sensitive information?

In general, we can release sensitive information such as medical records where the crime being investigated is considered 'serious' according to NHS definitions. These definitions are not completely transparent and are open to judgment. We can release less sensitive information (such as the name of the GP practice) when the crime is less serious.

The Department of Health defines serious crime as "murder, manslaughter, rape, treason, kidnapping, child abuse or other cases where individuals have suffered serious harm... Serious harm to the security of the state or to public order and crimes that involve substantial financial gain or loss will also generally fall within this category." Another definition sometimes used is whether the crime would attract a prison sentence of 5 years or more.

We also need to know how the information requested will assist your enquiries. If it is not clear that the sensitive information will directly help detect or solve crime then it should not normally be released. You also need to consider if the information could be obtained from other sources where consent is not required. And don't forget that in some cases individuals may be willing to provide consent to access their information, particularly victims of crime.

In summary, we are more likely to be able to share information if you provide as much information about the case as you can and, in particular, its severity and how the information you request will help detect or prevent crime.

More information can be accessed on https://pcse.england.nhs.uk/services/gp-records/accessing-medical-records/.

Contributor:

Dr James Hickling, Deputy Medical Director and Caldicott Guardian, NHS E&I—East of England

Withdrawal and addiction to prescribed medicines

We have received a number of reports of GPs prescribing controlled drugs for patients who report having become addicted by purchasing drugs on the internet. The rationale is harm reduction as drugs purchased on the internet may not be what they say they are.

How would you handle this problem? What might you consider?

Signpost to the substance misuse services. It is worth noting that most of the substance misuse services will not prescribe for patients addicted to prescribed medicines, though may provide the prescribing GP with advice. If you choose to prescribe for the patient, then there will be no access to substance misuse services unless a specialist service is commissioned in your area.

The immediate needs of the patient must be considered, are they showing any signs of withdrawal? Scoring tool. Clinical Opiate Withdrawal Scale https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf

Depending on the score, you may decide to prescribe enough for 24 hours of (xxxxxxxxxx) to manage their symptoms. Be clear this is symptom management, not a withdrawal or substitution regime. The purpose is solely to bridge the few days (up to a week) until the patient can have their first review with the substance misuse service.

If the patient shows no symptoms of withdrawal then they are OK for now, enable them to come back for a quick access appointment (perhaps with a nurse) if they start to experience symptoms.

Do not prescribe based on what the patient tells you they have purchased online or obtained illegally.

Copywright: www.therecoveryvillage.com

Contributor:
Jane Newman,
Senior Pharmacist East of England CDAO Team, NHS England and Improvement

PHE: Dependence and withdrawal associated with some prescribed medicines, an evidence review 2019

Recommendations from the review fall into 5 broad areas:

Increasing the availability and use of data on the prescribing of medicines that can cause dependence or withdrawal to support greater transparency and accountability and help ensure practice is consistent and in line with guidance.

2. Enhancing clinical guidance and the likelihood it will be followed.

3. Improving information for patients and carers on prescribed medicines and other treatments, and increasing informed

choice and shared decision making between clinicians and patients.

4. Improving the support available from the healthcare system for patients experiencing dependence on, or withdrawal from, prescribed medicines.

5. Further research on the prevention and treatment of dependence on, and withdrawal from, prescribed medicines.

Link to Review: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/829777/PHE_PMR_report.pdf

Ireland: Medical Council found a GP guilty of prescribing drugs irresponsibly

A GP practicing in Ireland was found guilty of prescribing drugs irresponsibly by the Medical Council in Ireland. According to the final report, the GP was prescribing benzodiazepines to patients with addiction problems.

The Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners provides guidance on the responsibilities of doctors in relation to prescribing and referral including clear guidance to doctors on the prescribing of benzodiazepines:
Following the inquiry which was held in public, the practitioner was found guilty of:

1.Prescribing drugs in inappropriate quantities and strengths.

2.Failed to prescribe the most appropriate medication to suite the patient's conditions and/or best interest.

3.Placed undue reliance on the prescribing of drugs.

4.Failed to make any or adequate inquiries as to whether the patient was being treated by another general practitioner or specialist substance misuse practitioner.

5.Failed to take or any adequate history.

6.Failed to carry out any adequate examination and7.Failed to maintain any or adequate medical records.

The Medical Council at its subsequent meeting to decide on sanc-

tion decided to attach conditions to the practitioner's registration: that the practitioner formulate a Professional Development Plan which would include attendance at a professional course approved by the Council that would include areas of deficiency. The Council's decision was subsequently confirmed by the High Court.
Other Guidance from the Guide to Professional Conduct and Ethics for Registered Medical Practitioners relevant to this case includes:
-Your paramount professional responsibility is to act in the best interests of your patients. This takes priority of responsibilities to your colleagues and employers."

-When prescribing medications, you must comply with the misuse of drugs legislation and other relevant regulations and/or guidelines.

-You should ensure you have appropriate training, facilities and support before treating patients with drug dependency or abuse problems. You should refer patients to other services and supports where this is in the patient's best interests.
-You must be aware of the dangers of drug dependency when prescribing benzodiazepines, opiates and other drugs with addictive potential.

-You should refer patients with drug dependency to the appropriate drug treatment services and supports unless you have appropriate training, facilities and support yourself.

-You should not undertake treatment of opiate dependency unless you have been approved under the Methadone Treatment Protocol. You should make reasonable efforts to ensure that patients with drug dependency are not inappropriately obtaining drugs from multiple sources and you should liaise with drug treatment services, other doctors and pharmacists to safeguard the patient's interest in this regard."

(https://medicalcouncil.ie/Information-for-Doctors/Complaints/Inquiry-Notifications/Case-Studies/Allegation-of-prescribing-drugs-irresponsibly.html)

Text taken from the Medical Council Ireland's website

Audit High Dose Opioid prescribing in General Practice

Report post Second 2nd cycle

In January 2018, the Controlled Drugs Accountable Officer team for NHSE East(formed by Cambridgeshire & Peterborough, Norfolk, Suffolk and Essex) offered GPs in the East of England the opportunity to undertake an audit of high dose opioid prescribing using a downloadable, publicly available search (developed by PrescQipp).

The audit was educationally resourced with web links to resources, relevant research, webinars and fact sheets. No incentives were provided. Practices were invited to review patients identified who were prescribed 120mg ME or more (OME), excluding end of life care. 74 practices responded initially.

In May 2019 participating practices were asked to repeat the same search and report back with reflections.

15 completed the 2nd cycle with responses that included:

FINDINGS	Jan 2018	May 2019	
Number of practices	15	15	
Total population surveyed	136,852	146,154	
Number of patients on 120mgME or more for chronic pain	255 (0.18%)	161 (0.11%)	**= 38% reduction**

"What has changed (if anything)" and "What do you think has helped/hindered you to effect any change?".

Practices noted variation in success at reducing the number of patients on high dose opioids;

10 showed a reduction; 2 stayed the same; 3 increased (2 trivially, one significantly).

What has changed?

Having a Pharmacist in the practice to review patients on high doses of Morphine;

'Strict reduction programme with some of our long- term users of opiates particularly those who are using them for pain control'.

The patients who are on high dose opioids for chronic pain have been reviewed by the community pain clinic but no resolution has been found for them

More allocated appointment slots for medication review

More opiate medication reviews are now done by GPs.

High dose prescribing as discussed at GP meeting.

Contributors:
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Dr. Ruth Bastable , Medical Adviser NHS E&I

What has helped/hindered?

Helpful	Not helpful
Greater awareness of the maximum dose of Morphine	Increasing patient list size and patients with complex care needs
Better awareness of the issues encountered with opiate up titration.	Lots of these prescriptions are 'historic' so difficult to address weaning off
'I think the public awareness of opiates as a problem has helped here. People have been more open to considering reductions and stopping'.	Patient engagement with reducing lacking, much more success in reducing down patients who were at a lower level of opiate use
'It remains the case that the biggest thing in this area is to try to avoid getting patients on to repeat opiates in the first place. Again, public education on this can and does help.	Many are historically on fentanyl patches- more difficult to wean down
Patient awareness of the impact of taking opioids (through media)'	Patient expectation / demand
Better awareness when starting	Patient reluctance to reduce / stop medication
Patient awareness of impact on driving/ operating machinery if taking opioids (through media)	Hospitals / other clinics outside of primary care prescribing
Targeted action plan where appropriate	Too little clinical time to call in each patient individually.
Awareness of risks	
Earlier referral to Pain Clinic	

Emergency supplies and the Community Pharmacy Consultation Service medicines (CPCS)

Emergency supplies of medicines either private or NHS must comply with the regulations, shown below for your reference.

Some top tips for pharmacists:

- Remember **a referral from NHS111** for the CPCS **is not a direction to make a supply**. It is up to the pharmacist to determine if an emergency supply is safe, necessary and appropriate.
- Use all available information sources to determine if a request is genuine and support your decision making
- Check the SCR – in addition to verifying the prescribed medicines the authorising prescriber may put a note on the SCR to enable urgent and emergency services to identify if a patient is seeking additional drugs when under close monitoring by their GP.
- Check the EPS tracker status for current prescriptions and where necessary contact the nominated pharmacy for further information.
- Document any concerns and raise them with the prescriber

Extract from the Human Medicines Regulations 2012 Reg 225

(2) Condition A is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting it and is satisfied—

(a)that there is an immediate need for the prescription only medicine to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay;

(b)that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person requesting it; and

(c)as to the dose which in the circumstances it would be appropriate for that person to take.

3) Condition B is that for a prescription only medicine shown in column 1 of the following table, the quantity of the product that is sold or supplied does not exceed that shown in column 2 for that prescription only medicine—

Prescription only medicine	Maximum quantity
A prescription only medicines that (a) is a preparation of insulin, an aerosol for the relief of asthma, an ointment or cream and (b) Has been made up for sale in a package elsewhere than at the place of sale or supply.	The smallest pack that the pharmacist has available for sale or supply.
An oral contraceptive	A quantity sufficient for a full treatment cycle.
An antibiotic for oral administration in liquid form	The smallest quantity that will provide a full course of treatment.
A controlled drug within the meaning od Schedule 4 or 5 of the Misuse of Drugs Regulations 2001 or Schedule 4 or 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002.	Five days' treatment.
Any other prescription only medicine.	30 days' treatment.

(4) Condition C is that the prescription only medicine—

(a)does not consist of or contain a substance specified in Schedule 18; and

(b)is not a controlled drug, other than a prescription only medicine that—

(i)consists of or contains phenobarbital or phenobarbital sodium, and

(ii)is sold or supplied for use in the treatment of epilepsy.

Contributor:
Jane Newman, Senior Pharmacist East of England CDAO Team, NHS England and Improvement

Private prescribing of Schedule 2&3 controlled drugs

The requirements for prescribing and dispensing controlled drugs (schedule 2 & 3) privately:

 Prescribers must have a private PIN, this is different to their NHS prescriber number. The PIN is obtained by application to the appropriate lead CDAO, in this region please contact england.ea-cdao@nhs.net

 Once a prescriber has a PIN they can order the pink private prescription forms FP10PCD.

 The prescriber must ensure their 6 digit PIN is written or printed on the prescription form otherwise the pharmacist will refuse to dispense it.

 Pharmacies must make appropriate checks* on the validity of the prescription and the prescriber.

 Dispensed prescriptions should be submitted to the NHSBSA at the end of each month. This enables tracking of private CD prescribing in a similar way to NHS prescribing.

 To submit FP10PCD community pharmacies need a private CD submission number, to obtain a number please apply to england.pharmacyeast@nhs.net

 The special submission form can be downloaded from the NHSBSA website.

*Checks:

Is the prescription written on the right form (Pink FP10PCD)

Does it have a private prescriber number (6 digits)

If you do not recognise the prescriber check the GMC website. Some prescribers may have conditions imposed on their practice which restrict prescribing of certain drugs.

Are all the legal requirements met for a CD prescription. Dose, words and figures, expiry date, pharmaceutical form etc.

Note: A private PIN is also required to requisition CDs privately.

N H S C D A O - E a s t o f E n g l a n d

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The address for the East of England CD team is **england.ea-cdao@nhs.net.**

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Telephone number: 01138250770

Report a CD incident, request an Authorised Witness or make an annual declaration at **www.cdreporting.co.uk**