Pharmaceutical services for opioid drug users

Annual Update Briefing. Issue 6 2024-26

Introduction

The aim of this Annual Update Briefing is to:

- Support the pharmacy in meeting the training requirements in the supervised consumption service specification.
- Update staff on the latest national guidance and local practice on substance misuse.
- Compliment the local online training signposted to on the CPNEC website at https://www.cpnec.org.uk/.

Pharmacy service specification 2024-25 training requirements

The contractor should ensure that a lead pharmacist has completed the required mandated training which is to:

- Complete, or refresh every 2 years, the CPPE Declaration of Competence (DoC) for supervision of prescribed medicines at https://www.cppe.ac.uk/services/declaration-of-competence (Appendix 1).

The lead pharmacist should be assured that all staff are competent to deliver the service and will complete the required mandated training which is to:

- Read the service specification.

Non-mandated training:

- View the local online training signposted to on the CPNEC website at https://www.cpnec.org.uk/ which includes this Annual Update Briefing 2024-26.

For 2024 – 25, a PharmOutcomes Declaration needs to be completed for each staff member accessing the claims template.

Local training offer

The quarterly Drug and Alcohol Recovery Service training calendar for online courses includes (signposted on the CPNEC website at https://www.cpnec.org.uk/):

- *Basic Drug Awareness*
  This course aims to provide a basic awareness of the range of drugs currently misused, the appearance and paraphernalia associated with the use of drugs, the different effects and risks associated with their use. We also cover the law surrounding substances and why people use drugs, whether legal or illegal, harm minimisation techniques and signposting to treatment services.
- *Basic Harm Reduction*
  This course will enable a non-specialist to understand risks associated with substance use and feel comfortable offering basic harm reduction advice.
- *BITESIZE - Blood Borne Viruses and Substance Misuse*
  Prevention, detection, and treatment of infections related to substance use, particularly when injecting remains high on the public health agenda in the UK.
- *Understanding Opioids*
  This course takes a look at different opioid drugs, covering heroin use, injecting behaviour and prescription opiates and newer synthetic opiates. We also look at opioid substitute prescribing and harm reduction advice for people who use these drugs.

For a summary of the work of the Drug and Alcohol Recovery Service see short video at https://codurhamdrugalcoholrecovery.co.uk/about-us

National guidance

- Drug misuse and dependence: UK guidelines on clinical management. DHSC. Updated 15/12/17. www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management
- NICE resources:
  1. Drug misuse in over 16s: Opioid detoxification. NICE Guidance CG52. Published 25/07/07. https://www.nice.org.uk/guidance/cg52
  2. Opioid dependence. NICE Clinical Knowledge Summary. Updated Apr 2022. https://cks.nice.org.uk/topics/opioid-dependence/
- Office for Health Improvement and Disparities[1] national guidance at www.gov.uk/government/collections/alcohol-and-drug-misuse-prevention-and-treatment-guidance and https://www.gov.uk/government/collections/preventing-and-reducing-drug-related-harm (see Further Reading).

The *Drug misuse and dependence: UK guidelines on clinical management* (commonly known as the Orange Guide) **is the definitive national guidance.**

Key points in *Chapter 4: Pharmaceutical Interventions* include:

Choice of drug for opioid dependence
There is insufficient evidence to recommend one drug over the other. While there is accumulating evidence that buprenorphine is associated with reduced risk of fatal overdose in the first weeks of treatment initiation, there is also evidence that methadone is more effective in retaining patients in treatment and so may indirectly reduce risks longer term for those patients.
In the first weeks of methadone treatment there is an increased risk of death due to overdose. After around a month in treatment, the risk of death due to opioid overdose during maintenance treatment falls to very low levels.
Dose induction should aim carefully, as soon as possible, for a stable dose of opioid that avoids both intoxication and withdrawal. It may take two to four weeks (or more) to achieve an optimal dose with methadone. It usually takes less time with buprenorphine since induction with buprenorphine may be carried out more rapidly with less risk of overdose.

Signs of opiate withdrawal include

- Coughing, sneezing, runny nose, watering eyes
- Raised blood pressure, increased pulse
- Yawning, dilated pupils, cool and clammy skin, fine muscle tremor
- Diarrhoea, nausea
- Restlessness, irritability, anxiety

Methadone toxicity and risk of overdose
All staff working with service users who are taking methadone should be aware that there is a risk of death in early methadone treatment. This can be due to excessive initial doses, failing to recognise symptoms of cumulative effects, impaired liver function (due to chronic

[1] Previously Public Health England

hepatitis), or failing to inform patients of the dangers of overdose if they are using other drugs (particularly benzodiazepines and alcohol) at the same time (since opioids induce respiratory depression, and sedative drugs potentiate this effect).
Signs and symptoms of methadone toxicity include:

- Drowsiness, slurred speech
- Slow and/or shallow breathing
- Constricted (pinpoint) pupils
- Disorientation/ confusion, dizziness/ feeling faint, balance/ coordination problems.

With methadone, toxicity is delayed at least several hours after exposure, and this may only become apparent after several days of treatment. The reason for the delayed toxicity is methadone's long but variable half-life, of between 13 and 50 hours with chronic administration. It takes five half-lives, or 3-10 days, for patients on a stable dose of methadone to reach steady-state blood levels. During these 3-10 days, blood levels progressively rise even if patients remain on the same daily dose. A daily dose tolerated on day one may become a toxic dose on day three. Patients must therefore be carefully inducted on to methadone and then monitored, and if necessary, the dosage adjusted during this accumulation period.

Risk factors for buprenorphine
Buprenorphine is widely considered to cause less respiratory depression than methadone. At low doses, buprenorphine is a potent opioid agonist, producing morphine-like effects. However, due to its mixed agonist-antagonist properties, increasing doses become self-limiting and do not produce more intense opioid effects. This may be one reason some patients prefer methadone.
Precipitated withdrawal occurs when buprenorphine is first administered to an opiate-dependent person with circulating opioid agonist drugs present. In this situation, buprenorphine can inhibit the opioid actions of the full agonist without adequately replacing them, leading to the appearance of withdrawal signs and symptoms. Precipitated withdrawal can be very unpleasant and may deter patients from continuing participation in treatment.
There are three measures to minimise precipitated withdrawal:

- Administer the first dose of buprenorphine when the patient is exhibiting signs of withdrawal.
- If withdrawal is difficult for the patient to tolerate, delay the administration of buprenorphine until at least 6-12 hours after the last use of heroin (or other short-acting opioid), or 24-48 hours after the last dose of low-dose methadone.
- Provide the anticipated day's doses, for the first day or two, in divided doses (typically using 2mg tablets) so that the speed of the induction can be managed.

Methadone dosing
In general, the initial daily dose will be in the range of 10-30mg.

- *First 7 days*: Where doses need to be increased during the first 7 days, the increment should be no more than 5-10mg on one day. In any event, a total weekly increase should not usually exceed 30mg above the starting day's dose. Patients should be alerted to the risk of over-sedation and the risks with ongoing illicit use.
- *Subsequent optimisation*: Following the first 7 days, doses can continue to be increased incrementally. A total target dose of 60-120mg a day, and occasionally more, may be required.

Buprenorphine sublingual dosing
Most dosing regimens involve starting with a low dose (4-8mg) that is rapidly increased. Effective maintenance treatment with buprenorphine involves doses in the range of 12-16mg for most patients dependent on heroin, with some needing up to 32mg. It makes sense to work towards this dose rapidly, so long as this does not produce side-effects or precipitated withdrawal. A cautious approach is to initiate treatment with 4mg on day one, then 8-16mg on day two and thereafter.

Key points in *Chapter 2: Essential elements of treatment provision* include:

2.2.2 Assessment
The Clinical Opiate Withdrawl Scale (COWS) Opiate withdrawal scale is used along with physical observations.[2]
The COWS rates the common signs and symptoms of opiate withdrawal to help clinicians determine the stage or severity of opiate withdrawal and assess the level of physical dependence on opioids.

2.4 Drug testing
Drug testing can be used for:

- initial assessment and confirmation of drug use (although testing does not confirm dependence or tolerance and should be used alongside other methods of assessment)
- confirming treatment compliance – that a patient is taking prescribed medication
- monitoring illicit drug use, including as a drug-specific treatment goal (for example, as part of a psychosocial intervention)

Urine remains the most versatile biological fluid for drug testing and has the advantage of indicating drug use over the past several days. As well as being physically non-invasive, drugs are present in relatively high concentrations and large samples can quickly and safely be collected.
Oral fluid has the advantage of being easier to collect and harder to switch or adulterate samples, although drugs are present in lower concentrations and the sample size is usually much smaller than for urine.
The detection window for oral fluid testing is normally 24-48 hours for most drugs, so only very recent drug use can be detected.

The NICE Opioid Dependence Clinical Knowledge Summary at https://cks.nice.org.uk/topics/opioid-dependence/ also provides extremely useful summaries of assessment and treatment.

[2] https://nida.nih.gov/sites/default/files/ClinicalOpiateWithdrawalScale.pdf.

Supervised consumption service – key points

All daily doses of methadone should be dispensed in separate containers.

Medication should be withheld, and the Service contacted (via email on PharmOutcomes) if the client misses 3 or more doses consecutively. If a client has missed 3 or more consecutive days of medication, they are likely to require a re-titration appointment with the Service before any further medication is issued.

In the event of any pharmacy service disruption, the pharmacy should contact the local Recovery Centre (see pharmacy mobile numbers below), and ring all affected clients to make suitable alternative arrangements e.g. asking clients to attend the pharmacy at a time when a pharmacist will be available. Pharmacies are required to confirm clients' telephone numbers once a month.

For urgent enquiries to the Service telephone the daily duty workers on:
•Horden / Peterlee: 07974 861000
•Bishop Auckland: 07974 861058
•Durham: 07974 861001

The fee per supervision is per client supervision (i.e. one supervision claim per client visit to the pharmacy) and not, for example, for each different strength of buprenorphine given to a client to make up a specific dose - therefore if a client has more than one prescription for buprenorphine (to make up a specific dose) only one of those prescriptions should then be entered onto PharmOutcomes in order to claim the supervision fee for that occasion.

Further reading

Useful resources in *Alcohol and drug misuse prevention and treatment guidance* at www.gov.uk/government/collections/alcohol-and-drug-misuse-prevention-and-treatment-guidance include:

- *Misuse of illicit drugs and medicines: Applying All Our Health*. Evidence and guidance to help health professionals identify, prevent or reduce drug-related harm. OHID. 23/02/22. https://www.gov.uk/government/publications/misuse-of-illicit-drugs-and-medicines-applying-all-our-health
- Opioid substitution treatment good practice resources. For example:
    1. *The Best practice in Optimising Opioid Substitution Treatment (BOOST)* elearning programme at https://www.e-lfh.org.uk/programmes/best-practice-in-optimising-opioid-substitution-treatment-boost/ which aims to provide drug treatment and recovery professionals with the information they need to deliver good quality opioid substitution treatment to service users.
    2. *Opioid substitution treatment: Guide for keyworkers*. PHE. 21/07/21. https://www.gov.uk/government/publications/opioid-substitution-treatment-guide-for-keyworkers

Useful resources in *Preventing and reducing drug-related harm* at https://www.gov.uk/government/collections/preventing-and-reducing-drug-related-harm include:

- Potent synthetic opioids: preparing for a future threat. OHID. 31/07/23. https://www.gov.uk/government/publications/fentanyl-preparing-for-a-future-threat
- Widening the availability of naloxone. PHE, DHSC, MHRA. Updated 18/02/19. www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone

Appendix 1: The CPPE Declaration of Competence (DoC)
This is supported for use across England by Health Education England and is endorsed by NHS England and UKHSA (https://www.cppe.ac.uk/services/commissioners#navTop).
Moving towards the completion of CPPE DoCs across the ICB region will support the mobile pharmacy workforce and service continuity.
Where required, the pharmacy contractor must ensure that the relevant DoC is completed by the relevant pharmacists / registered pharmacy technicians every 2 years.

The DoC ensures that individual pharmacists and registered pharmacy technicians become personally responsible for considering their training and development needs (i.e. self-assessing their own competence), undertaking these needs (e.g. by shadowing a colleague; considering sources of training signposted to in the CPPE DoC; reading this local Annual Update Briefing 2024-26 and viewing the local online training signposted to on the CPNEC website at https://www.cpnec.org.uk/), and then declaring themselves competent by completion of the relevant DoC every 2 years. This in turn provides assurance to the pharmacy contractor and to the service commissioner that staff are competent to deliver a service.

The CPPE DoC for the supervision of prescribed medicines
Completion of the CPPE DoC for the supervision of prescribed medicine at https://www.cppe.ac.uk/services/declaration-of-competence every 2 years by the lead pharmacist. DoC requirements include:

Core competencies
1. Do you meet the Consultation Skills for Pharmacy Practice: Practice Standards for England, as determined by Health Education England?
   Suggested learning could include: Consultation skills for pharmacy practice: taking a person-centred approach (https://www.cppe.ac.uk/programmes/l/consult-p-02) and Consultation skills: what good practice looks like (https://www.cppe.ac.uk/programmes/l/wgll-e-01).
2. Do you meet the competencies expected of all healthcare professionals with regard to safeguarding children and vulnerable adults?
   Suggested learning could include: CPPE Safeguarding children and adults (Level 2) (https://www.cppe.ac.uk/gateway/safegrding).

Service specific competencies
1. Do you understand the terminology and definitions of substance misuse, drug dependence and the theories of these; and the concept and practice of harm reduction and recovery?
2. Do you understand the terminology; nomenclature of both official and 'street' names for commonly used drugs and definitions of drug dependence?
3. Do you understand the management of substance misuse, including multidisciplinary team working, assessment and care planning, pharmacotherapeutic and non-pharmacotherapeutic options?
4. Are you able to communicate appropriately and sensitively with the client group and their peers, using discretion, privacy, respect and a non-judgmental approach, and treating them with dignity whilst applying conflict resolution skills when appropriate?
5. Are you able to advise clients about substance misuse and enable them to take their medication as prescribed and advise on safe storage?

6. Are you able to recognise the various symptoms and signs potentially displayed by this client group which may adversely affect their treatment and what actions to take (e.g. intoxication)?
7. Are you able to advise clients on how to obtain naloxone and the benefits of having ready access to this to reduce the risk of death from opioid overdose?
8. Do you know how and when to refer/signpost clients regarding problems relating to their substance misuse management, missed doses and general health and social problems?
9. Do you understand the legislation, ethics, duty of care and professional judgement for this client group and know how and when to ask for support and advice?
10. Are you aware of the management, planning, and delivery of pharmacy services for clients, including how to train and monitor staff to deliver these services to the required standard?
11. Are you able to support and develop the pharmacy team in the provision of a safe and effective service?

Suggested learning could include:

- CPPE Substance use and misuse e-course (Units 1, 2, 3 and 4) and e-assessment (https://www.cppe.ac.uk/programmes/l/substance-e-02). Note: Low volume pharmacies or registered pharmacy technicians could consider completing Unit 3 only of this training which focuses on recovery and treatment with non-pharmacological support provided by the wider multidisciplinary team, a detailed look at pharmacological treatments, and supervised consumption of opioid substitute treatments.
- Local sources of training: Annual Update Briefing 2024-26 and local online training signposted to on the CPNEC website at https://www.cpnec.org.uk/.

Commissioner requirements

1. Have a working knowledge of the most recent service documents relating to provision of the service, including: the service specification; administration and claims procedures.
2. Review and/or develop relevant SOPs and policies in your practice.