Joint Trust Guideline for the Management of: Opiate Dependence in Adults

A clinical guideline recommended for use

In:	Medical and Surgical Wards
By:	All Medical Staff
For:	Opiate dependant patients (adults, including pregnancy)
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If Yes – does the strategy/policy deviate from the recommendations of NICE? If so, why?	No

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document

Quick Reference guide

Refer all patients to the NRP (Norfolk Recovery Partnership) Liaison Nurses

Sean Wood and Marita Isaacs DECT **, Bleep *****
or seek advice from NRP 0300 7900 227 (Mon-Fri 8am-6pm)

History and Examination

- Take brief history
  - Is patient currently receiving prescription for drugs of dependency?
  - Names of drugs used – also ask about alcohol, benzodiazepines
  - Quantity; frequency; duration; route of administration; patterns of use i.e. daily vs. intermittent use
  - When were drugs last used? Are they withdrawing?
- Send urine for drug screen (though results will not help at this stage)
- Look for presence of needle marks, thrombosed veins, cellulitis, abscesses

Are they on prescribed maintenance opiate treatment?

YES

Phone GP, NRP, or Pharmacy to confirm. Cancel community px for duration of admission

For methadone give as divided (BD) dose.

If unable to confirm for:

- Buprenorphine - give as stated but first check no other recent opiate use.
- Methadone - titrate as below.

NO

Observe for opiate withdrawal symptoms 4-hourly using the **Opiate Withdrawal Scale**

Opiate dependent

Mild symptoms or non-dependent use

Symptomatic relief - as needed

metoclopramide buscopan, ibuprofen loperamide diazepam zopiclone

lofexidine 200mcg qds - Monitor pulse and blood pressure before and after dosing

For choice of drug, refer to full guideline

METHADONE TITRATION

- Initial dose of 10mg (mild symptoms) to 40mg (severe symptoms) of methadone
- Observe for intoxication
- Second dose of 10-20mg can be given if withdrawal symptoms persist after 4-6hours
- Max dose on day 1 = 50mg
- Repeat assessment after a further 4 hours
- Use the total dose as stabilisation dose for day 2
- Further increases no more than 5-10mg /day

BUPRENORPHINE TITRATION

- Wait until clear signs of opiate withdrawal
- 1st dose 2-4mg increased if tolerated to max 8mg on day 1
- Observe for intoxication or further

DISCHARGE

Liaise with NRP at least 24hrs prior to discharge to ensure appropriate community prescribing. Weekends may need to be covered by NNUH - discuss with pharmacy before discharge

NB: 1g Heroin = 50-80mg Methadone
Depending on whether it is smoked or injected (rough guide only)

If indicated **opiate analgesia** is required it can be given in the usual dosage and frequency. Patients must be observed for over sedation. Avoid additional methadone for pain relief.

Objective/s

a. To assist in the assessment and treatment of patients who report opiate addiction during an acute admission on a medical or surgical ward.

b. To minimise the risk of patients engaging in risky or drug-taking behaviour in hospital or discharging themselves before their treatment is complete.

Rationale

This guideline has been developed to support appropriate and safe prescribing and treatment of this specific patient group.

Broad recommendations

Always request advice from the NRP Liaison Nurses Sean Wood and Marita Isaacs DECT ****, Bleep ******8am-6pm weekdays.

Assessment

- **History**
    - Names of drugs used (always ask about other drugs such as benzodiazepines and alcohol).
    - Average daily dose.
    - Routes of administration - if IV, ask where they inject.
    - Patterns of use; Intermittent/continuous daily use.
    - Experience of withdrawal symptoms.
    - Duration of use.
    - When were the drugs last used?
    - Is the patient experiencing opiate withdrawal symptoms?
- Some **medical complications** should alert staff to the possibility of underlying drug misuse
    - Cellulitis, abscess, thrombophlebitis, DVT.
    - TB, hepatitis, HIV related conditions.
    - Respiratory infections, endocarditis, septicaemia.
    - False aneurysm.
- On **examination,** look for
    - Evidence of drug use e.g. needle marks, abscesses, bruising and old scars.
    - Signs of **intoxication:**

- Constricted pupils.
- Drowsiness.
- Slurred speech.
- Poor attention / concentration.
- Euphoria / relaxation.
- Feeling of wellbeing.

Signs of opiate withdrawal

Mild - moderate	**Severe**
Sniffing	Running nose
Eyes watery	Eyes streaming/wiping eyes
Fidgeting	Agitated (can't sit still)
Clammy skin	Beads of sweat
Goose flesh barely palpable	Readily palpable goose flesh
Mild abdominal cramps	Marked cramps+/- diarrhoea
No vomiting	Vomiting
No shivering	Shivering
Yawning 3-5/10mins	Yawning (>6/10mins)
Pulse (80-100)	Pulse (>100)
Dilated pupils (4-6mm)	Dilated pupils (>6mm)
Mild increase in respiratory rate	Marked increase in respiratory rate

- **Investigations**
    - Send urine sample for full drug screen to confirm drugs of abuse.

Treatment

Treatment is necessary if the patient is opiate dependent to avoid unnecessary discomfort, premature self-discharge and / or risky self medication on the ward.

- **If patient is known to the Norfolk Recovery Partnership (NRP) or is prescribed by their GP**
    - Confirm prescription from NRP, GP or Pharmacy.
    - Prescribe accordingly but initially in divided doses for methadone - twice a day in the morning and at tea time. Avoid night-time dosing as this increases the risk of failing to notice over-sedation and respiratory depression.
    - Cancel community prescription while patient is admitted (ensure reinstatement on discharge).
- **If patient is not engaged with the Drug service then**

- Observe for mild/moderate or severe opiate withdrawal symptoms as above using the Opiate Withdrawal scale (OWS). See Appendix 1 & 2.
- Options are symptomatic relief (detoxification) or opiate maintenance therapy with methadone or sublingual buprenorphine (Subutex).
- Consider titration on to opiate maintenance therapy only if the clinical assessment is that the patient is opiate dependent.
- NB if there is established dependence then initiating detoxification without the patient's full agreement and/or adequate after care may increase mortality rates as the reduced opiate tolerance puts the patient at risk of overdose if they relapse on discharge. It is mandatory therefore to discuss the risks of reduced tolerance and means to reduce the risk if relapse occurs. Unless the degree of opiate dependence is felt to be very low or uncertain initiation of maintenance therapy is usually a safer option.

Opiate Maintenance Therapy

Opiate Maintenance Therapy reduces the harm associated with opiate dependence because it replaces the drug of choice (usually heroin) with one which:

- Has a safer route of administration.
- Is less intoxicating (less rewarding).
- Requires less frequent dosing (reduces habit).
- Has a regular legal supply (allowing behaviour change).
- Provides an incentive for engagement with services.

There is a large body of evidence demonstrating that opiate maintenance therapy [1,2,3,9]

REDUCES	and	IMPROVES
• Illicit opiate use • Use of other illicit drugs • Criminal behaviour • HIV risk behaviours • Mortality rate		• Quality of life • Physical health • Mental health • Employment • Perinatal outcome

Methadone

Methadone is a long acting full opiate agonist. The half-life of methadone varies greatly between individuals with a range of 13-50 hours. It takes 3-10 days to reach steady state. Therefore even at the same dose blood levels will continue to rise within this time frame so rapid induction can lead to fatal respiratory depression several days later[4,5].

Although available in tablet form this is not licensed for maintenance treatment and methadone should therefore always be prescribed as methadone mixture 1mg in 1mL. Always specify the strength of the mixture and prescribe in mg. not mL. as more concentrated forms are available.

Methadone also increases the QTc interval and an ECG is recommended if the dose is above 100mg or if it is prescribed in combination with other drugs which increase the QTc

interval e.g. tricyclic antidepressants and antipsychotic medicines. Other side effects include sedation, constipation and sweating.

Risk factors for respiratory depression during induction are[4]:

- Low opiate tolerance.
- Concomitant use of CNS depressant drugs (e.g. benzodiazepines, alcohol).
- High starting dose.
- Rapid dose increase.
- Slow methadone metabolism – this can be affected by drug interactions see below (this is not a complete list – check BNF).

Drugs which Increase Blood Levels of Methadone or Buprenorphine by Inhibition of the Enzyme CYP3A4	**Drugs which Decrease Blood Levels of Methadone or Buprenorphine by Induction of the Enzyme CYP3A4**
Cimetidine	Anticonvulsants (e.g. barbiturates, carbamazepine, phenytoin)
Ciprofloxacin	HIV medicines (e.g. efavirenz, nevirapine)
Erythromycin	Rifampicin
Clarithromycin	Spironolactone
Fluconazole	St John's Wort
Ketoconazole	
Fluvoxamine and possibly other SSRIs	

Buprenorphine

Buprenorphine is a partial agonist with high affinity but low intrinsic activity at the Mu opiate receptor and high affinity but no activity at the kappa receptor. Importantly this results in a ceiling effect on respiratory depression giving a better safety profile[5]. The risks of overdose are however increased where the drug is combined with other

sedatives such as alcohol and benzodiazepines, both of which are commonly used by opiate dependent individuals.

The high affinity of buprenorphine for opiate receptors confers a more effective opiate blockade and there is some evidence that this leads to reduced illicit opiate use. As a partial agonist buprenorphine confers reduced subjective effects of intoxication such as sedation and is perceived as easier than methadone to withdraw from.

Due to its high affinity for opiate receptors and low activity it can precipitate withdrawal symptoms if it displaces more potent opiates (e.g. heroin). To avoid this it is important to wait until there are signs of opiate withdrawal to administer the first dose. The necessity of experiencing even mild withdrawal at induction is off-putting to some. There is a risk of individuals crushing and injecting the tablets, a practice which increases both the risk of over dose and of hepatic toxicity in addition to the inherent risks of injecting a crushed tablet[6].

Buprenorphine is available as a sublingual tablet in 400mcg, 2mg and 8mg strengths.

Both drugs are recommended by NICE for maintenance treatment. The choice of drug is based on an assessment of:

- Level of opioid use - clinical experience suggests that those using 1 gram or more of heroin are more easily titrated on to methadone.
- Safety and overdose risk - risk of injecting with sublingual buprenorphine vs. increased risk of overdose with methadone.
- Patient preference and experience with both illicit and prescribed medications, treatment history and response - most local opiate dependent individuals have knowledge of both drugs and many have strong views as to their preferred option[7].
- Retention and treatment compliance - strong evidence that methadone retains more people in treatment. (Cochrane)
- Analgesia requirements – buprenorphine will block the effects of other opiates so if strong analgesia is likely to be required use methadone.
- The prescriber's experience with different medications.

Symptomatic relief (detoxification)

Lofexidine

Lofexidine is an α2 noradrenalin agonist which reduces symptoms of opiate withdrawal by reducing noradrenergic activity. It can reduce the pulse and blood pressure therefore monitoring before and after dosing is required

<u>Dose Regime of Lofexidine</u>

- Treatment should be initiated with 200 mcg 2 to 4 times a day.
- The dose should be increased in steps of 200mcg 2 to 4 times daily to a maximum of 2.4 mg daily (usual dose 200 to 400 micrograms qds).

- Treatment should continue at this level for 7 to 10 days.
- The dose should be gradually reduced over a period of 2 to 4 days.

Monitoring of Pulse and BP during Lofexidine detoxification

BP should be taken and recorded with every dose of lofexidine.

- Lofexidine should be omitted if there is a significant drop in BP or pulse (systolic less than 90 mmHg or 30 mmHg below baseline, or pulse below 55)[9]
- Lofexidine dose should be reviewed and reduced if the fall in systolic BP is < 30 mmHg or pulse between 55-60bpm.

Adjunctive Medication Used In Opioid Detoxification

Below is a suggested list of adjunctive medications that can be considered during inpatient detoxification.

Only one medication for any symptom should be prescribed at a time

Diazepam	Maximum: 20mg / day prn (for irritability & anxiety)
Nitrazepam	Maximum: 10mg nocte (for sleep)
Zopiclone	Maximum: 15mg nocte (for sleep)
Chloral Hydrate Liquid (143.3 mg/5 mL)	15-30mL nocte (for sleep)
Hyoscine Butylbromide	10mg qds prn (for abdominal cramps)
Loperamide	2mg qds prn (for diarrhoea)
Domperidone	10 mg qds prn (for nausea and vomiting)
Metoclopramide	10 mg tds prn (for nausea and vomiting)
Ibuprofen	400 mg tds prn (for aches and muscle pains)

- Adjunctive medication should be prescribed on a PRN basis as far as possible.
- The decision about the type of adjunctive medication and its dose should be determined by assessing withdrawal symptoms and individualized.
- In patients who have been vomiting prior to admission, assess the likelihood of other medication having been poorly absorbed. Consider that overdosing may occur when the vomiting rapidly resolves during the detoxification.

Methadone titration[4]

Ensure there is immediate access to naloxone. A dose of 30mg of methadone can cause fatal respiratory depression.

- Give 10 to 40mg methadone mixture **1mg in 1mL** orally according to the severity of withdrawals (mild 10mg – severe 40mg) and observe for signs of intoxication.
- A second dose of 10 to 20mg can be repeated if withdrawal symptoms persist after 2-6 hours.
- Do not give second dose after 6pm as night-time dosing increases the risk of failing to notice over-sedation and respiratory depression.
- The total dosage in the first 24 hours should not exceed 30mg in those with mild / moderate withdrawal and 50mg in those with severe withdrawal.
- The total dosage needed to suppress withdrawal (but not cause intoxication or over-sedation) in the first 24 hours is the **stabilisation dose**. This dose can be given on a daily basis thereafter in divided doses.
- If necessary further increases can be made over subsequent days by no more than 5 to 10mg per day.
- Doses should be prescribed with instructions to omit if there is evidence of over-sedation.
- In patients who have been vomiting prior to admission, assess the likelihood of other medication having been poorly absorbed. Consider that overdosing may occur when the vomiting resolves.

Buprenorphine titration[4]

Buprenorphine should not be used in those requiring opiate analgaesia due to its blockade of the opiate receptors.

The main risk with buprenorphine titration is of precipitating withdrawal symptoms. Withholding the first dose until opiate withdrawal symptoms are clearly evident reduces the risk. This would normally be at least 6-12 hours after the last use of short acting opiates (e.g. heroin) and 24-48 hours after the last use of long acting opiates (e.g. methadone).

- First dose 2 to 4mg.
- If no precipitation of withdrawal symptoms after 1-2 hours further doses can be given up to a total dose of 8mg in the first 24 hours.
- The dose can be increased on subsequent days as required up to a maximum of 32mg.
- In patients who have been vomiting prior to admission, assess the likelihood of other medication having been poorly absorbed. Consider that overdosing may occur when the vomiting rapidly resolves following buprenorphine administration.

Analgesic Requirements

- Patients maintained on methadone because of their addiction are tolerant to that dose. Therefore they will require additional analgesia for pain depending on their medical or surgical condition.

- If indicated opiate analgesia in the usual dosage and frequency can be given and the patient carefully observed for signs of over sedation.
- Buprenorphine should be avoided due to its mixed agonist/antagonist effects.

Pregnancy

- Opiate withdrawal during pregnancy may induce foetal distress and lead to intrauterine death or premature labour. It is therefore important to prevent pregnant patients from developing a withdrawal state.
- Titration onto opiate maintenance therapy is the preferred management strategy. This can be achieved by following the above guidance as for non-pregnant patients, with **methadone** being the usual drug of choice. Opiate detoxes should **not** be initiated in pregnant patients.
- Patients presenting with opiate dependence during pregnancy may have poor nutritional status, social issues relating to chaotic lifestyles (for example, housing problems, domestic violence, sex-working) and may have not attended prenatal appointments/scans etc. In addition to reducing the risks associated with continued heroin use, stabilisation onto methadone maintenance allows the opportunity for such issues to be addressed.
- Following stabilisation, it may be possible for some pregnant patients to reduce their dose during the 2nd trimester. This should be supervised by their NRP key-worker, and undertaken at a pace that does not induce withdrawal or risk return to on-top illicit opiate use.
- It is not uncommon for methadone requirement to increase during the 3rd trimester due to increased metabolism. Split dosing can sometimes help overcome mild discomfort associated with this, but in others a dose increase may become necessary.
- Babies born to opioid dependent mothers require monitoring for the development of neonatal withdrawal syndrome.

Discharge

When planning discharge involve the Substance Misuse Liaison Nurses (Sean Wood and Marita Isaacs DECT 6489, Bleep 0439) or contact the Duty Worker at the Norfolk Recovery Partnership (0300 7900 227) during office hours who will be able to advise on management and link with follow-up agencies.

If the patient has been started on opiate maintenance therapy and wishes to continue with this a community prescription with appropriate dispensing arrangements (e.g. daily supervised consumption) must be arranged **prior to discharge** with NRP. This will avoid patients going home with large quantities of controlled drugs as prescriptions can usually be arranged to start on the day after discharge (except at weekends).

Clinical Audit Standards derived from guideline

a) All Opiate misusers should have a drug history documented in their medical notes.

b) Urine drug screens should be done routinely in all patients with a history of drug use.

c) The Opiate Withdrawal Scale (OWS) should always be used to monitor symptoms of opiate withdrawal (see Appendix 1&2).

d) Titration onto opiate substitution should conform to UK guidelines.

Summary of development and consultation process undertaken before registration and dissemination

The authors of the original guideline were Julia France, Substance Misuse Liaison Nurse and Dr O. Ugochukwu, Consultant psychiatrist. An update was requested in 2009 and completed by Dr. Hayley Pinto, Consultant Psychiatrist TADS with reference to the TADS.

inpatient protocols originally drafted by Dr. A Wagle, Consultant Psychiatrist and Lead Clinician NRP. During its development it has been circulated for comment to:

The membership of the NRP service governance committee and the NWMHFT Pharmacy Advisory Committee.

This version has been endorsed by the Clinical Guidelines Assessment Panel.

Distribution list/ dissemination method

Trust intranet

References/ source documents

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8. NICE TA114 Methadone and buprenorphine for managing opioid dependence January 2007

Information for Appendix 1 and 2 (adapted from *Norfolk and Waveney Mental Health NHS Foundation Trust, C103 Opioid Detoxification and Stabilization on to Substitute Medication. Version 1[R2] Page 10 of 14)*

Titration on to Methadone

- The patient should not be given any methadone until clinical observation reveals symptoms and signs of heroin withdrawal. Use SOWS and OOWS to quantify clinical findings.
- The initial dose given will depend upon the reported level of opiate use and the clinical assessment of opiate withdrawal symptoms.
- Methadone should normally be prescribed as a 1 mg in 1 ml oral solution. Methadone tablets are not licensed for the treatment of drug dependence and should not normally be prescribed due to the increased potential for diversion[16].
- Methadone levels continue to rise for 3-5 days after initial dosing leading to risk of toxicity. There is no uniquely fatal dose of methadone and deaths have occurred following doses as little as 20 mg. The initial dose would therefore be in the range of 10-30mg; 10-20mg if tolerance is low or uncertain and up to 40mg in those with known heavy dependence[16].
- *Below is given a guide to determine initial dose of Methadone[14]. This is an example and the actual prescribed dose may be different.*

Withdrawal	**Methadone Dose**
No physical signs (OOWS score 0-1)	No Methadone
Mild withdrawals (OOWS score 2-5)	5-10 mg
Moderate withdrawals (OOWS score 6-10)	15-25 mg
Severe withdrawal (OOWS score 11-14)	30-40 mg

- The patient should be observed after one hour for the evidence of Methadone intoxication. Record BP and TPR.
- The patient should be assessed again after 3-4 hours for the presence of withdrawal symptoms as well as intoxication. If in withdrawals (quantified by SOWS and OOWS) a 'top up' dose of methadone can be given.
- *Below is given a guide to determine the 'top up' dose of Methadone[14]. This is an example and the actual prescribed dose may be different.*

Withdrawal	**Methadone Dose**
No physical signs (OOWS score 0-1)	No Methadone
Mild withdrawals (OOWS score 2-5)	5-10 mg
Moderate withdrawals (OOWS score 6-10)	15-25 mg
Severe withdrawal (OOWS score 11-14)	25-30 mg

- If a 'top up' dose is administered, the patient should be observed after one hour for the evidence of Methadone intoxication. Record BP and TPR.

- The stabilization dose should be such that it suppresses withdrawal symptoms without producing intoxication.
- Stabilization in the inpatient setting should be achieved within 2 - 3 days[9]
- The stabilization dose reached at the end of titration period is the baseline dose. This dose can be divided between two doses per day if necessary[17]

Titration on to Buprenorphine

The process and principles of titration and stabilization for buprenorphine are as described above as the first stage of detoxification using buprenorphine

General Support

- Ensure adequate nutrition.
- Ensure adequate fluid intake to maintain hydration and electrolyte balance.
- Encourage engagement in activities

Appendix I

Subjective Opiate Withdrawal Scale (SOW)

SUBJECTIVE:	none = 0 mild = 1 moderate = 2 severe = 3

SYMPTOMS	Date		Date..... ...		Date.....		Date.....		Date..... ...	
Feeling sick										
Stomach cramps										
Muscle spasms/ twitching										
Feelings of coldness										
Heart pounding										
Muscular tension										
Aches and pains										
Runny eyes										
Sweating										
Yawning										
TOTALS (Max. 30)										
Time of Onset										

Appendix II

Objective Opiate Withdrawal Scale (OOW)

OBJECTIVE	Assessed over 10 minutes									
Lactorrhoea: 1 = Eyes watery 2 = Eyes streaming										
Rhinorrhoea 1 = Sniffing 2 = Profuse										
Agitation: 1 = Fidgeting 2 = Highly aroused										
Perspiration 1 = Clammy skin 2 = Beads of sweat										
Gooseflesh: 1 = Barely palpable 2 = Readily palpable										
Pulse rate 1 = 80 – 100 2 = > 100										
Vomiting 1 = Moderate 2 =Severe										
Shivering 1 = Moderate 2 = Severe										
Yawning 1= 3-5 yawns 2 = > 6 yawns										
Pupils 1 = Dilated 2 = Widely dilated										
TOTALS (Max.20)										
PULSE										