Prescribing Policy for the Management of Substance Misuse

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Prescribing Policy for the Management of Substance Misuse

1. INTRODUCTION

The policy is developed to provide a comprehensive, evidence based prescribing policy to be used with NHSL Addictions Service. It is designed to standardise practice whilst providing the evidence base and supporting documents.

2. AIM, PURPOSE AND OUTCOMES

This policy enables prescribers and allied professionals to access prescribing information relating to substance misuse. It will enable prescribers to formulate prescribing interventions in line with best practice and evidence based guidelines and to establish a prescribing governance framework through NHS Lanarkshire.

3. SCOPE

3.1 Who is the Policy intended to Benefit or Affect?

Prescribers and allied professionals working in substance misuse in NHS Lanarkshire
Patients of addiction services

3.2 Who are the Stakeholders?

Staff and patients of addiction services in NHS Lanarkshire
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This prescribing policy is designed to accompany and supplement national guidelines described in:


And

Royal College of General Practitioners guidelines
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For information on specific drugs used as treatment options, including dose, interactions and pharmacology, it is recommended to check with the online data sources:

www.bnf.org or www.medicines.org
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Prescribing Guidelines

There is a full section of prescribing guidelines at the end of this policy. These are continually under review and updated.
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SECTION 4.1

Principles of Good Prescribing (Summary)

- Prescribing should take place within a framework where co-existing physical, emotional, social and legal problems are addressed at the same time.

- Prescribing should take place with a firm harm reduction approach, and within accepted frameworks of the Scottish Government and NHS Lanarkshire.

- The patient should receive a full assessment and have a care plan and prescribing plan before prescribing is undertaken.

- Patients must be screened to confirm substance use before prescribing is initiated.

- Regular monitoring and reviews should occur during treatment, including screening.

- The patients should be reviewed by the prescriber / Locality GPwSI usually on a six monthly basis.

- Continued illicit drug/or alcohol use will lead to a review of the current prescription.

- Patients should be informed about driving regulations and what contact they need to make with the DVLA (appendix 2).

- Pharmacy liaison is very important as the pharmacist is usually the only health care professional who will have daily contact with the patient.

- It is essential that prescriptions are written correctly to ensure continuity of treatment.

- Discontinuation of a prescription is a serious intervention and should ideally be a multi-disciplinary decision.

- Decisions to work outside the prescribing policy should be a multi-disciplinary decision but must ultimately be supported by the prescriber. All decisions should be documented.
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- “On top” use is a complex issue and one that should not be ignored. It can be dealt with through psychological therapy, pharmacological therapy or a mixture of both.

4.1.1 Introduction

In line with guidance from all Governmental addiction agencies, it is recommended that community prescribing only takes place within a context in which the co-existing physical, emotional, social and legal problems are addressed at the same time. Prescribing of pharmacotherapy is a component of a treatment package rather than being a treatment on its own. Community prescribing may comprise:

- Stabilisation or maintenance on substitute opioids, for example methadone or Suboxone.
- Withdrawal from opioids with non-opioid medication, for example lofexedine.
- Stabilisation and withdrawal from sedatives, benzodiazepines and alcohol.
- Relapse prevention prescribing, for example acamprosate and disulfiram.
- Prescribing for stimulant users including symptomatic prescribing and maintenance prescribing.
4.1.2 Aims of Prescribing

- Stabilise the patient\(^1\), where appropriate, on substitute medication to alleviate withdrawal and withdrawal symptoms.
- Reduce or eliminate the use of illicit/non-prescribed drugs.
- Reduce the dangers associated with drug misuse particularly blood borne viruses e.g. reducing injecting and sharing of injecting paraphernalia.
- Reduce criminal activity associated with drug misuse.
- Reduce the risk of prescribed drugs being diverted.
- Improve the patient’s overall functioning from a personal, social, family and community perspective.
- Achieve safe detoxification, minimising adverse events, for example seizures in the case of alcohol and benzodiazepines.
- Engage and retain drug users in their treatment programme in the context of their care plan.

4.1.2 Precursors to prescribing

The following areas should be addressed before prescribing takes place as part of the assessment process:

- In order to receive prescribing interventions, the patient must have signed a confidentiality agreement allowing communication between the relevant agencies involved. It is recommended that patients are registered with a General Practitioner.
- If there is any difficulty obtaining a General Practitioner, the care coordinator may assist the patient in obtaining this.

\(^1\) The term “patient” is used in this policy when referring to service users who have been prescribed medication for their substance misuse.
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- A tier three comprehensive nursing / medical assessment must have been performed before prescribing is initiated.
- Staff undertaking such an assessment must be trained to the appropriate national standards.
- Medical/Physical assessment will be needed before prescribing especially if there are concerns about the physical health of the patient.
- Urine drug of addiction screening must have been taken to confirm substance misuse and a clear and consistent history must have been obtained concerning dependent use.
- Prescribing cannot be initiated until there is an agreement regarding a wider treatment programme that addresses physical, psychological, social and legal needs. This plan can be reviewed during the patient’s time in treatment and may need to be changed by mutual agreement.
- The patient will be provided with a written plan and asked to sign this care plan.
- Before prescribing is initiated the patient and others involved in their care should have made a clear agreement about the nature (maintenance or detoxification) of prescribing and the aims of the treatment package. This will be reviewed regularly and may be changed, with mutual agreement, if circumstances demand it.
- The care plan should include goals of the patient, for example attendance at appointments, providing specimens or avoiding illicit use of drugs within an agreed period, dependent on history.
- Before prescribing is undertaken, the patient must be made clearly aware of service policy regarding missed appointments and non- collection of prescription.
- When written material is provided, levels of literacy will need to be considered.
- It is the prescriber and named nurse’s responsibility to ensure that the patient makes an informed choice about the prescribed treatment and to note that the patient is aware of the side effects and hazards of any of the drugs that are prescribed.
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- It is the care co-ordinator’s responsibility to ensure that an assessment has been undertaken and that at least one toxicological test confirming the presence of the appropriate illicit drug is filed in the notes.

- The prescriber, if they are not the GP, and named nurse has the obligation to inform the GP about any proposed prescribing plan including start date, dosages, supervised consumption and pharmacy.

- It is the named nurse's responsibility to inform the GP of the final dose after titration.

- The named nurse will co-ordinate the monitoring of the patient for any signs of over sedation during titration and treatment. This will be supplemented by the pharmacist, who will withhold doses if the patient presents to the pharmacy intoxicated.

- The GP/GPwSI and named nurse will record the prescription details with start date, pharmacy and details of the prescription in the patient’s case file. A letter confirming these details must be sent to the patient’s GP, even if the prescriber is the patient’s GP.

- The relevant “in-house” form (appendix 1) will be used by the named nurse for requesting or changing agreed prescriptions with the GP/GPwSI. All changes should be recorded in the patient’s case file.

4.1.3 Safety and Good Practice

- All patients treated for drug dependency must be registered with the National Drug Treatment Monitoring System (NDTMS) using the SMR 25. This is the responsibility of the named nurse or the prescriber if they are not supported by a care co-ordinator. Regional funding is dependent upon accurate returns of the SMR information.

- Regular monitoring and reviews should occur during treatment which includes regular, random urine screening.

- This should be in line with Criminal Justice procedures for patients referred via the criminal justice route. For other patients this should never be less than two screens per year, but will be more for patients who are not stable or in early treatment.

- Appropriate dispensing arrangements should be in place in line with guidance in the supervised consumption section. Prescriptions should be posted, delivered to pharmacies or given directly to patients in some...
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circumstances. Pharmacies may also collect prescriptions if this arrangement is in place.

- The patient should be advised on appropriate storage arrangements for their prescription, especially if children live at the same premises.
- Ineffective prescriptions should be reviewed by the multi-disciplinary team and, if necessary, stopped.
- Accurate records must be kept of the prescription including date issued, dates to start, drugs prescribed, dosage and prescription numbers.
- The patient named on the prescription should collect the medication from the pharmacy. This is identified as good practice in Drug Misuse and Dependence – Guidelines and Clinical Management (DoH 2008). If a third party needs to collect the prescription, this must be authorised by the named nurse or the prescriber. This must be in writing for three days or longer (good practice). Pharmacists will also require a “letter of authority” for each collection (Law and Ethics Bulletin RPSGB 1996).

4.1.4 Appointments and Review Procedures

The patient will be reviewed by the prescriber/locality GPwSI, usually on a 6 monthly basis. This requires the agreement of the multi-disciplinary team. For certain patients with complex needs the review appointments with the doctor may need to be more frequent.

Patients must be seen at least monthly by their GP/GPwSI for prescribing and at least three monthly by their care co-ordinator. This is the interval if a patient is completely stable on their prescription. After initiation of prescribing, the patient should be seen at least weekly for the first eight weeks and after this at two or four weekly intervals, depending on the agreement in the care plan, reflecting the patient’s history.

The care co-ordinator should prepare the patient for an appointment with the prescriber by reflecting with the patient on the aspects of the care plan that have been achieved and those that have not and a proposed plan should be brought to the assessment.

If the prescriber is unhappy with the recommendations of the named nurse they should seek advice from the named nurse’s manager and senior members of the medical team. If the prescriber remains unhappy with the
Prescribing Policy for the management of Substance Misuse

advice, the patient will be handed over to either another GPwSI or secondary care specialist as appropriate.

Prescribers and named nurses will follow the policies outlined in this document with regard to prescribing. Any deviation from this must follow the decisions to work outside prescribing policy section 1.13. It is the named nurse’s responsibility to ensure that appointments are booked with the prescriber and that they are informed of any significant change in the patient’s presentation. If the patient misses three consecutive appointments (without good reason) it is a strong indicator for stopping the prescription. Input must be sought from the multi-disciplinary team before reaching such a decision.

It should be noted that continued illicit drug use will lead to a review of the prescription and/or the psychological approach adopted. This is further considered in section 1.17, “monitoring on top use”.

4.1.5 Driving

The Driver and Vehicle Licensing Agency, through their drivers’ medical unit, issues comprehensive guidance on current medical standards of fitness to drive: http://www.dvla.gov.uk. This guidance refers to substance misuse amongst other conditions. It is the duty of the license holder to notify the DVLA of any condition which may affect safe driving; the DVLA is then legally responsible for deciding if a person is medically fit to drive (appendix 2). The General Medical Council has issued guidance to doctors in relation to their responsibilities as follows:

- The person must have it made clear to them that their driving may be impaired and that they have a legal duty to inform the DVLA.

- If they refuse to accept this advice, they may wish to seek a second opinion and appropriate arrangements should be made to enable them to do so. They should be advised not to drive until the second opinion has been obtained.

- If the person continues to drive, every reasonable effort should be made to persuade them to stop. This may include telling their next of kin.

- If it becomes clear that the person is continuing to drive contrary to advice, relevant clinical information should be passed immediately, in confidence to the medical advisor at the DVLA.
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- Before giving information to the DVLA, the person should be informed of the decision to do so. Once the DVLA has been informed the person should have confirmation, in writing, that disclosure has been made.

- Driving may be permitted by the DVLA for some people on a “consultant supervised methadone programme”. Criteria the authority will use to make judgments on capacity include*:
  - A minimum of one year of stability on the treatment programme.
  - Methadone or buprenorphine taken orally/sublingually.
  - Not on an active treatment withdrawal programme. The DVLA view is that withdrawal necessarily implies a degree of instability.
  - Random screens confirm the appropriate use of the treatment prescribed and the absence of drugs of abuse, including cannabis.

*Personal communication, DVLA drivers’ medical development group.

NHS Lanarkshire Alcohol & Drug service practice includes:

- The procedures outlined above are followed in cases when driving continues.

- The provision of advice in relation to alcohol, drugs and the responsibility to inform DVLA of any impairment is provided to all patients. Doctors/nurses should discuss the effects of any drugs prescribed on driving and make a note of this discussion.

- All discussion and/or warnings about drug and alcohol use on the patient’s ability to drive should be recorded in the patient’s notes.

A patient information leaflet is illustrated in appendix 2.

4.1.6 Pharmacy liaison

The important role of the pharmacy cannot be understated as they provide a significant point of contact and have regular (often daily) contact with the patient. When initiating a prescription requiring supervised consumption, the named nurse should help the patient obtain a pharmacy as pharmacies are not obliged to supervise the self-administration of controlled drugs and pharmacies that do may have reached full capacity.
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If the prescription is unsupervised the prescriber/named nurse will still need to make separate contact to confirm the Pharmacy is happy to become involved and liaise regarding start dates and other relevant details. A 4-way agreement (appendix 3) should also be completed and the named nurse should make sure that the appropriate copies of this are distributed. The named nurse should also make contact with the pharmacy and introduce the patient.

The named nurse / care coordinator needs to put a request in writing to the relevant prescriber to obtain a prescription. Any changes to prescriptions require the named nurse to do this in writing to the relevant prescriber; this can be done by using the “tracker” system.

Changes to a prescription may require several days’ notice. However, in exceptional circumstances every effort will be made to accommodate a request. The prescriber will post the prescription or the pharmacy may collect if a local agreement is in place. If an earlier delivery is required, the named nurse will need to assist.

4.1.7 Prescription regulations

Recent changes to the Misuse of Drugs Act Regulations 2001 mean that prescriptions for controlled drugs will no longer need to be “written in ink” and will be valid so long as they are written so as to be indelible. This will permit typewritten prescriptions, and those printed using a computer printer. The prescriptions must be signed by the prescriber with his/her usual signature. The prescription is also required to be dated, but this does not need to be in the handwriting of the prescriber, so a computer generated date is acceptable; however, the prescriber’s signature is still required. The prescription for CD schedules 2 and 3 should also state:

- In the case of a preparation, the form and, where appropriate, the strength of the preparation.
- The total quantity of the preparation, or the number of dose units, in both words and figures.
- The dose.
- Instructions to cover when the pharmacy is closed e.g. Sundays and Bank Holidays

NB It is an offence for a doctor to issue an incomplete prescription and a pharmacist is not allowed to dispense a controlled drug unless all information required by law is given on the prescription. It is in the best interests of all
Prescribing Policy for the management of Substance Misuse

Concerned to ensure that all aspects of the law are complied with before the prescription leaves the practice.

The doctor who signs the prescription carries the ultimate responsibility for prescribing. Starting or changing a prescription is a medical responsibility, which cannot be delegated to other members of the team (unless nurse/pharmacist is a supplementary prescriber), although full discussions with the professionals involved in the case will, of course, be taken. However, the named nurse should recognise they are responsible for ensuring that:

- A full comprehensive nursing assessment has been carried out including drug screening
- The correct information and guidance is provided to the prescriber.
- The patient is monitored and appropriate information is fed back to the prescriber.
- Advice provided to the prescriber is in line with local and national policy.

4.1.8 Lost prescriptions

Wherever possible, prescriptions will be sent by recorded delivery post directly to the pharmacy or the pharmacy will collect if a local agreement exists. In taking charge of a prescription, a patient must be made aware of their responsibility, as lost prescriptions will not be routinely replaced. Local police, the GP, the pharmacy and prescribing team (if the GP is not the prescriber) should be informed of lost, stolen or forged prescriptions. Any forged prescriptions must always be reported to the police. NHS Lanarkshire’s Head Pharmacist Prescribing Team should also be informed.

4.1.9 Recording cancelled prescriptions

When a prescription already issued and held by a pharmacy needs to be changed, the following procedure should be followed:
Prescribing Policy for the management of Substance Misuse

- The named nurse should contact the pharmacy by phone with details of the prescription to be cancelled.

- The cancellation of any prescription and any replacement is recorded in the patient’s prescription record (electronic and paper file).

The named nurse is responsible for informing the prescriber about any prescriptions that are suspended or cancelled. This includes when patients are admitted to hospital. This telephone conversation should be followed up by written confirmation of the change in prescription.

4.1.10 Procedure for the discontinuation of prescriptions

Prescribing may come to an end for a number of reasons. The ideal conclusion is that, following agreement with the patient, all reasonably achievable goals in relation to their substance abuse have been met.

When there is a disagreement between a patient and the team over prescribing issues, the aim is negotiation of a new treatment agreement whenever possible. If agreement cannot be reached, a unilateral decision to reduce or stop a prescription may result. Normally this would apply in the following circumstances:

- Compromised safety, either of the patient or others. In the case of safety to others (for instance if the prescriptions are lost or others gain access to prescribed controlled drugs) the risk can usually be addressed by a return to supervised consumption.

- It may become clear to the team that the patient is using alcohol or additional illicit drugs at a level which, when combined with a regular prescription, puts them at risk of dangerous side effects. Risks of “on top” use become more significant as the dosage of the prescription increases. If the risk is judged to be significantly high when weighed against the risks of continued illicit drug use, the prescription may be reduced.
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or stopped. All cases where there is significant drug use on top of the prescription must be brought to the multi-disciplinary team.

- Where there is lack of progress towards previously agreed and achievable goals. This decision to discontinue a prescription requires multi-disciplinary team discussion and requires the team to consider the best use of resources against the overall demands on the Substance Misuse Service. The team must question whether they continue to attempt to engage with a patient currently unlikely to make progress, or to withdraw/discontinue treatment to enable others to make more productive use of the resource released and re-engage with the patient at a later date. The patient will be informed in writing and still encouraged to access Tier 2 services with harm reduction information.

4.1.11 Discontinuation of prescription

The discontinuation of substitute prescribing is a serious matter. The following steps should be undertaken:

- At initial treatment agreement, the patient should be made aware of the circumstances in which the prescription would be withdrawn.

- When treatment withdrawal is considered, the situation is discussed both with the patient and with the multi-disciplinary team. A reformulation of treatment goals should be considered unless there is a clear safety risk to the patient or to others. Treatment proceeds with the new agreement and if further problems occur the process is repeated.

- The named nurse will discuss the team view with the patient. In certain circumstances it may be appropriate that this is done together with the prescriber. If the patient does not attend relevant appointments, this may have to be done by phone or by letter.

- If a patient does not attend three consecutive appointments, they are informed by letter that if they do not attend a fourth appointment they will be discharged from the service.

It may be appropriate for the patient to spend a period of time in working without a prescription. All decisions to end prescribing should be communicated to the service user’s GP, where they are not the prescriber and the dispensing pharmacy.
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4.1.12 Decisions to work outside the prescribing policy

Although in the majority of cases prescribing should be carried out within the prescribing policy, there are exceptional circumstances where a decision to work outside these guidelines can be beneficial. This is a serious step and should involve discussion at the multi-disciplinary team and have the full agreement of both the manager of the team and the doctor. In exceptional circumstances, a decision may need to be made before a multi-disciplinary team review is possible. In these circumstances, if there is significant risk involved, the full agreement of the relevant manager, consultant, GPwSI and named nurse is needed. If, for any reason, any of these individuals are not available, the person covering for them should be consulted instead. All reasons for the final decision, including varying opinions, should be documented in the case file by the care co-ordinator.

4.1.13 Ongoing care and monitoring

The following information is provided to the patient with the initial written care plan:

- Information on the drug prescribed, its effects and side effects (see appendix 4(A - I)).
- Warnings about overdose and how to manage others who overdose.
- Information regarding help and advice regarding blood borne virus screening, safer injecting and sexual practices.
- Information for those who are Hepatitis B or C positive should be provided with information about alcohol usage.
4.1.14 Named Nurse Role

The named nurse maintains contact with patients and liaises with others involved in the care plan and any relevant outside agencies. One to one sessions should be tailored to the needs of patients but, in general, should initially include weekly meetings during the stabilisation period, followed by at least six sessions within the following six months. The named nurse role also includes:

- Liaison with local pharmacies and other health and social care professionals, ensuring that the care plan addresses psychological and social needs.
- Liaison with other workers from the Mental Health services where the client has a dual diagnosis.
- Ensures that prescribing doctors are made aware of any significant changes to the patient's circumstances, especially in those that may have health or safety implications.

4.1.15 The Care Plan

The care plan forms the basis for the treatment agreement and sets out the expectations of both the service user and the service provider. The care plan should include other agencies and carers, where appropriate. The agreement of the treatment goals is a central feature of care planning. Goals have to be consistent with the patient's circumstances and stage of treatment. They should be specific, measurable, achievable, relevant and time limited (SMART) (see table 1.1).
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<table>
<thead>
<tr>
<th>Treatment goals</th>
<th>Treatment outcome measures</th>
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<tbody>
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<td>Harm reduction</td>
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</tr>
<tr>
<td>Health promotion</td>
<td>Hepatitis B/C /HIV testing Hepatitis A &amp; B vaccination Safer sex</td>
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<td></td>
<td>Increased knowledge of drug use/ harm reduction Aware of overdose prevention and management Engagement with GP re health problems</td>
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<td>Stabilisation of drug use</td>
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</tr>
<tr>
<td>Abstinence</td>
<td>Drug free after 1,3,6 months Completing relapse prevention intervention</td>
</tr>
</tbody>
</table>

Table 1.1: Treatment goals, which would be addressed as part of a care plan

4.1.16 Managing “on top” use

The approach to this problem will depend, among other things, on the treatment aims of the patient, their preparedness to enter into a treatment agreement and the extent of additional drug use. Opiate substitute treatment alone will often be insufficient to address this common and complex issue (Tober 2003).

- Try to ascertain whether use is, indeed, in addition to the prescription. Sometimes the prescription is traded for street drugs.
Reconsider any contingent interval dispensing i.e. three times a week dispensing to daily supervised.

- Clarify the treatment aims and dosing strategy with the patient (see below). Those who are clearly motivated to cease on top use or who report heroin use to manage withdrawal symptoms may benefit from higher dose regimes. It is likely that those reporting hedonistic use will be less likely to benefit from dose increases (Best et al. 2000). Potential benefit of higher doses has to be traded against additional risk.

- If a high dose strategy fails or is clearly inappropriate consider whether the risk of continued, but lower dose, methadone is worth the harm
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reduction benefits or whether substitute prescribing should be discontinued.

- Concomitant alcohol misuse has been reported in 20-50% of patients in treatment on methadone (Ball & Ross 1991). Whilst methadone maintenance treatment has been shown to significantly reduce the risk of overdose, alcohol misuse contributes to overdose risk and will enhance the respiratory depressant effects of heroin use. The National Treatment Outcome Research Study (NTORS) showed that, whereas treatment improved outcomes overall for drug use, the effect on alcohol consumption was minimal. Evidence suggests that continued prescribing in the face of alcohol misuse should follow a careful appraisal of risks versus benefits together with interventions targeted at alcohol. Refer to Sections 12 and 13.

- Benzodiazepine misuse is a common accompaniment of opiate dependence with reported prevalence as high as 50% (Ball & Ross 1991).

Benzodiazepine use is linked to poorer treatment outcomes, polydrug misuse and overdose risk (Darke 1993, Best & MacAulay 2011). NHS Lanarkshire does not sanction initiation of benzodiazepine prescribing. Continuation of current prescriptions will be on a detoxification regime only. Any exception to this must be approved by the addictions service community prescribers or addiction psychiatrists.

The management of “on-top” use is a complex area and will always need multi-disciplinary discussion. A flow chart demonstrating management of “on-top” use is illustrated in figure 1.1.
Initiate supervised consumption and review in 3–6 months.

Follow "treatment discontinuation Section 12)."

Continue regular treatment package but be aware of risk of lapsing (increased screens???)

Titrate dose upwards to therapeutic dose and review.
Figure 1.1: Management of “On top” use in patients on opiate substitution treatment.
References and Further Reading

Somerset Drug and Alcohol Prescribing Policy.


**SECTION 4.2**

*Methadone Prescribing Policy (Summary)*

- The most effective methadone maintenance programmes aim for an optimal dose of 60mg to 120mg a day.

- Methadone should be prescribed as the standard 1mg/1ml formulation where possible. Sugar free formulations and tablets have a greater potential for injection and evidence suggests sugar-free formulations have no influence on dental hygiene.

- Substitute prescribing with methadone should usually start at 30 mg daily, dependant on initial assessment and tolerance, and the dose should be titrated up by 5 to 10mg daily (every 3 - 4 days, not exceeding 20mg in a week), until withdrawal symptoms are controlled; **start low and go slow. Dose adjustments greater than 20mg per week can only occur after consultation with the Lead Medical Practitioner**

- Steady state plasma levels are reached after 3 - 5 days following the last dose increase.

- Supervised Consumption should be observed for a minimum of 12 weeks.

- Methadone has a clinically significant interaction with benzodiazepines and alcohol. Patients who continue to misuse these drugs should have their treatment assessed and receive supervised consumption until the use of both is stopped.

- Methadone maintenance therapy is the treatment of choice in pregnancy and breast-feeding. This policy draws upon guidelines written by The Royal College of General Practitioners (RCGP) and The British Association of Psychopharmacology (BAP). They should be read in conjunction with the Clinical Guidelines, Drug Misuse and Dependence: Guidelines on Clinical Management, DOH 2007 (Orange Guidelines) and the relevant sections within this prescribing policy.

**4.2.1 Background**

This policy draws upon guidelines written by The Royal College of General Practitioners (RCGP) and The British Association of Psychopharmacology (BAP). They should be read in conjunction with the Clinical Guidelines, Drug Misuse and Dependence: Guidelines on Clinical Management, DOH 2007 (Orange Guidelines) and the relevant sections within this prescribing policy.
4.2.2 Rationale for the use of methadone

Substitute prescribing with methadone is a well established treatment and is supported by a substantial body of research, literature and clinical practice (1, 2, 3).

Methadone Maintenance Treatment (MMT) greatly reduces mortality (4), reduces illicit drug use, reduces transmission of HIV (5,6,7) and attracts and retains more patients in treatment than other treatments (2). There is no evidence that MMT increases length of dependence (1). There is good evidence for success in a wide range of settings and countries (1,7,8,9) and increasing evidence of effectiveness in primary care settings (3,10). There is also evidence that children of drug using parents in methadone treatment do significantly better than those of parents not being treated (11). There is, however, variability in programme effectiveness, particularly related to daily dose and relationship with individual workers (2) and the programme variables are far more significant than patient variables.

Effectiveness may be reduced by departure from optimum methods of delivery, such as reducing the methadone dose and putting pressure on patients to become abstinent from methadone. The most effective programmes are those that provide optimal doses (usually between 60-120mgs) of methadone as part of a comprehensive treatment programme, which will include regular reviews and psychosocial support as required, with maintenance rather than abstinence as the treatment goal.

Given the high morbidity and mortality from opioid dependence, the public health challenge is to deliver safe and effective treatments to as many patients as can benefit from them.

4.2.3 Clinical Pharmacology

Methadone is a long acting, synthetic opioid with full agonist activity at mu opioid receptors. It was originally formulated in 1938 shortly after the discovery of pethidine. It is a lipophilic drug with considerable tissue distribution, resulting in a peripheral reservoir with chronic dosing. Methadone differs from morphine in that it acts as a non-competitive antagonist at the N-methyl-D-aspartate receptor. Methadone is a strong inhibitor of serotonin uptake. Methadone Mixture 1mg/ml is licensed for the treatment of opioid dependency in the UK. It contains 1mg in 1ml of liquid and is licensed for oral consumption.
Relevant properties

- Time to first effect is within 1 hour of dosing.

- Time to peak clinical effects:
  - Two to four hours for first dose
  - Four to five days for methadone tissue and plasma levels to stabilise, though accumulation continues beyond this to finally reach a steady state by ten days (12)

- Methadone metabolism
  - Well absorbed from the gastrointestinal tract into the bloodstream. Oral bioavailability is estimated at approximately 80% (ranging from 40-99%) for doses between 10 and 60mg in opioid dependent individuals (Gourlay et al 1986; Eap et al 2002). Comparisons at higher doses have not been published.
  - Soluble in body fats.
  - Metabolised through the liver primarily by N-demethylation (CYP 3A4) to inactive metabolites. Its metabolism can be greatly affected by disease states or concomitant medications that impact upon the CYP 3A4 system.
  - A small number of people may genuinely need to split the dose due to rapid metabolising of methadone. (13)
  - Injected methadone avoids the immediate CYP mediated metabolism resulting in potentially greater amounts of methadone reaching the brain immediately after i.v. administration.

- Excretion
  - Metabolites, and about 10% of unchanged methadone, are principally excreted in the faeces and urine. The kidneys clear limited amounts, but this may become significant at urinary pH below 6 (Eap 2002). Other drugs affect clearance and metabolism.
• **Equivalence**

  - Direct equivalence to heroin is difficult to estimate as purity of street heroin varies, but 1 gram roughly equates to 50-80mgs oral methadone.

  - When comparing the equivalence to injectable pharmaceutical heroin, half-lives must be taken into consideration. The conversion between heroin to methadone is non-linear and is affected by many other drugs/individual variables. The conversion factor varies between 1:3 to 1:6 (refer to section on diamorphine prescribing in advance prescribing section for more detail).

  - The conversion to buprenorphine is also non-linear. Doses of 50-80mg of methadone are approximately as effective as 12 to 16mg buprenorphine in reducing heroin use and retaining patients in treatment.

• **Tolerance**

  - Develops at different speeds in different individuals and can change in individuals over time.

  - Neuroadaption occurs with long-term use.

  - Intolerance to methadone is rare, but if confirmed, other medication (e.g. Buprenorphine) should be considered.

**Types of methadone**

• **Methadone Mixture 1mg/1ml.**

  Methadone mixture is an oral solution containing either sugar syrup or sorbitol to disguise the bitter flavor of the methadone; it may also contain chloroform water. The energy value of methadone 1mg/ml containing sugar is 1.7 calories per ml (Martindale)

  Sugar free methadone is available but has the potential for injection. Tartrazine (E102), E142, E110 are added to some preparations as colourants. Many patients
and healthcare professionals believe sugar free formulations have a less detrimental effect on dental hygiene than the standard methadone mixture. However, a survey by Dr Ruth Gray, senior clinical dental surgeon in Dublin, in 2002 concluded that methadone, in its sugared or non-sugared formulations, had no significant effect on the person's dental health and methadone was not the main factor leading to dental decay (14). **Sugar free formulations should, therefore, should only be prescribed when there is proven intolerance to the standard formulation or the patient suffers from a recognised medical condition e.g. diabetes.**

Methadone Mixture 1mg/ml is the treatment of choice because:

- It alleviates opioid withdrawals.
- It is easier to titrate to the appropriate dose.
- There is limited euphoria.
- It is less likely to be diverted than shorter acting drugs.
- It is less likely to be injected and has a comparatively low resale value.
- Its clinical effectiveness is supported by research. Methadone 10mg/ml oral solution

This product should only be used for patients prescribed over 150mg methadone daily and in exceptional circumstances. Any prescribing of this strength has to be authorised by the Lead Medical Practitioner for NHS Lanarkshire Drug and Alcohol Services. There must be NO take home of the concentrated methadone solution.

Methadone tablets 5mgs / tablet

- Should not routinely be prescribed as they are not licensed for use in opiate addiction. Special consideration can be given if patients are going on holiday and liquid medication is a practical issue, e.g. flying. The Advisory Council for the Misuse of Drugs (ACMD) advises absolutely against the prescription of methadone tablets in normal circumstances (15)

The Advisory Council for the Misuse of Drugs (ACMD) advises absolutely against the prescription of methadone tablets in normal circumstances (15).
4.2.4 Indications, contraindications, precautions and side effects

- **Indications**

  - Opiate dependency.

- **Contra-indications**

  - Severe liver disease; however in many cases the benefits will outweigh the risks.
  - Non opioid dependent.
  - Under 16 years except on the advice of a specialist.
  - Allergy or proven intolerance to methadone.

- **Cautions**

  - Concurrent use of other sedating drugs or medications; methadone can be associated with sedation, respiratory depression and coma when used in conjunction with CNS depressants, such as alcohol, benzodiazepines, barbiturates, neuroleptics and tricyclic anti-depressants.
  - Medical conditions complicating opioid use; as with other opioids, methadone should be used cautiously in individuals with recent head injury, acute abdominal conditions, or with severe respiratory, hepatic or renal disease. Some authors recommend that doses be reduced by 50% in those with end stage renal disease.
  - It has been suggested that the maintenance dose of methadone need not be changed in chronic stable liver disease, although abrupt changes in hepatic function might result in substantial changes in plasma levels. (Norvick 1981).
  - Infection with hepatitis C may induce CYP enzymes so requiring higher doses than non-infected (Eap 2002).
  - Patients suffering with chronic pain must be given appropriate doses of additional opioid analgesia and may need increased doses.
  - People with severe mental illness, with limited capacity to provide informed consent.
• **Side effects**

Most unwanted effects of methadone are similar to those associated with other opioids, including constipation, reduced libido, headaches, insomnia, nausea/vomiting and sweating. Side effects vary from individual to individual. Many report a “clouding” effect, which is valued by some, but not others. The common complaint of methadone “getting into your bones” has no medical basis and is probably a symptom of withdrawal or the notion that it is hard to Detox from. Methadone can cause respiratory depression, dizziness, dysphoria, pruritis, impaired sexual function, increased pressure in the biliary tract, urinary retention and hypotension.

An area of recent concern has been reports of Torsade de Pointes and QT prolongation in patients with high dose methadone (Krantz et al 2002, Krantz et al 2003), with particular concerns regarding intravenous methadone (Kornick et al 2003), or those taking concomitant medications (Piguet et al 2004). The issue requires continued monitoring and further research. If the patient is assessed as being at high risk of QT prolongation or Torsade de Pointes (e.g. underlying cardiac disease, family history, symptoms of arrhythmias), they should have an ECG conducted and referred to a cardiologist if abnormalities are detected.
4.2.5 Choosing between maintenance and detoxification

**Maintenance** is suitable for patients who want to stop using illicit opioids but are unable to achieve abstinence from all opioids at present. Prescribing is long-term at effective doses individualised for each patient. The goal is harm reduction and stabilisation of life-style.

When comparing detoxification and maintenance treatment with methadone, outcomes are considerably better with long-term maintenance (2, 3, 16, 17).

**Detoxification** can be attempted with patients who wish to detoxify from all opioids. There is a high relapse rate to heroin use unless combined with psychological interventions. Methadone is not the most effective detoxification agent and other medications (e.g. Buprenorphine or lofexidine) should be considered first.
4.2.6 Starting and titration of Methadone

The purpose of titration is to safely establish the patient as quickly as possible on a dose of methadone that prevents opioid withdrawal, reduces the need to take additional illicit opioids, keeps side effects to a minimum and to be prescribed safely to avoid the dangers of overdose and diversion. But from the initial dose it is important that an optimal dose is reached quickly and safely. It is usual to start on a low dose and increase over the course of a few days, until a stabilising dose is reached.

- Assessment
  - It is important that a full assessment be undertaken for patients. Models of Care states that a ‘level 3’ assessment should be completed before the commencement of community prescribing (18).

- Before starting methadone 1mg/1ml mixture for the first time:
  - Carry out urine toxicology to check that there are opioids in the urine.
  - Check for the objective signs of opioid dependence using the appropriate opioid withdrawal scale (appendix 4 – COWS) including dilated pupils when the patient is withdrawing and injecting tracks.
  - Starting methadone is never an emergency.
  - Starting methadone without evidence of opioid dependency should never be done.
  - There should be very clear agreement about the care plan that will accompany the substitute treatment and an approximate timescale that is appropriate for the patient in treatment taking into consideration the patient’s goals. The length of treatment should also reflect the patient’s history.

- If a substitute prescription of methadone mixture is appropriate:
• Usually begin with 10 - 30 mg methadone 1mg/ml mixture daily, based on the assessment of the person's opioid tolerance, the frequency of use and the route of administration, past experience in treatment and the use of other drugs such as benzodiazepines and alcohol.

• If undertaking the induction as an outpatient, it is preferable to see the patient frequently in the first week (if possible) so that the dose can be titrated up in 10mg increments.

• A total weekly increase should not exceed 20mg

• At any dose, use of alcohol, sedatives, and/or short-acting opioids (e.g., heroin, oxycodone, hydrocodone) during induction significantly increases the risk of overdose/death (20, 21, 22).

• Deaths have occurred following the commencement of a daily dose of 40mg methadone.

• Steady plasma levels are reached after 3 -5 days following the last dose increase

Since there is no scientific formula for calculating opioid tolerance, the prudent methadone dosing advice is to **start low and go slow** (21).

### 4.2.6 Stabilisation of methadone dose

Dose stabilisation may take several weeks. It is important that this is achieved as quickly but as safely as possible to prevent patient drop out.

Sleep difficulties must be taken seriously and advice about sleep hygiene should be given.
There is no clear relationship between prior “heavy” misuse of an opioid and the methadone dose ultimately required for stabilisation (21).

Dose adjustments during stabilisation are usually in the 5 to 10 mg/d range – no more frequent than every 3 to 4 days (21).

4.2.7 Methadone maintenance prescribing

After dose induction, research has shown that, on average, the dose range for maintenance which shows the greatest benefits for most patients is between 60-120mg daily (23).

Due to individual patient factors, some require significantly greater or lower doses for treatment success. If higher doses are required a specialist referral may be required which may include serum methadone level testing.

There should be regular reviews of treatment, including care-plans and goals, which should be at least 6 monthly and should include checking for injecting sites. The usual General Medical Services should always be offered (including blood borne virus screening, hepatitis vaccinations (HBV and HAV if injector), smears, etc.).

Patients should be made aware of, and be able to access, a range of social and psychological services within the local environment.

- Frequency of dosing for maintenance
Methadone should normally be prescribed on a **daily** regimen. Patients who have been stable on supervised consumption for 3 months, who have no high-risk drug use (e.g. ongoing use of heroin, other injecting drug use, alcohol or benzodiazepines, frequent intoxicated presentations, recent history of overdose) may be considered for increased take home dosing.

- **Missed doses and lost prescriptions** – see guideline section

Missed doses can lead to loss of tolerance and prescribers should be kept informed of missed doses.

- If a patient on a daily dispensing regimen misses a pickup from the pharmacy, the patient should return the next day as usual for their next dose. The missed dose should not be replaced.
- If a dose is missed for 3 consecutive days then treatment should be suspended and the named nurse, service manager or prescriber contacted. If the patient misses 3 pick ups on a 14 day prescription then the named nurse, service manager or prescriber should also be contacted
- Patients who repeatedly miss doses should have their treatment reviewed. If on less than daily dosing the first step would be to revert to daily dispensing.

- **Supervised Consumption**

Supervised consumption should be used as a therapeutic tool for the beginning of treatment and sometimes used at random times during treatment to check dose and compliance. There is no reason to continue supervised consumption indefinitely except in exceptional circumstances (Section 12).

There may be cases where daily supervised consumption may not be appropriate (work commitments, childcare) and these should be resolved on an individual needs basis.
It should be noted that supervised consumption could be reinstated at any time if there are concerns and ultimately the need for supervision is a clinical decision.

See take home guideline section reference

- Treatment withdrawal

Withdrawal of maintenance treatment is associated with poor outcomes and should only be considered as a last resort, if it is clinically felt that there is not or likely to be any benefit to the patient if it is continued or that it is detrimental. A gradual process leading to cessation is recommended giving the patient ample time to review their options. Written confirmation of the script stopping together with how to re-engage in treatment later is advised.

There will be times when stopping a script is therapeutic to re-enforce the meaning of treatment when the prescription is facilitating continued dependent use.
4.2.8 Detoxification from methadone maintenance

If the patient wishes, methadone can be prescribed in reducing doses as agreed between doctor and patient until final detoxification is achieved. Because of the poor outcomes, this is not the preferred method of opioid detoxification, but some patients may choose it. It is also possible to transfer to buprenorphine, which is reportedly easier to withdraw from – see Section 3 (24).

Detoxification should never be seen as a stand-alone treatment and should always be supported by after-care either in a residential rehabilitation unit, community day programme or community support programme, because of the enormous risk (greater than 95%) of relapse, the loss of tolerance and the risk of overdose and death (28, 25).

4.2.9 Injectable formulation

Should be prescribed very rarely and only by specialist doctors who have the necessary expertise (26). It should only be initiated after consultant assessment. It may be appropriate for some drug users, with a considerable injecting history, who have not adapted to oral medication and for whom injecting itself has become a dependency. A proportion of the total methadone dose will be oral where possible. An injectable prescription should not be continued by a GP.
4.2.10 Drug Interactions

- Benzodiazepines *(clinically important)*:

  Large numbers of opioid drug users also use benzodiazepines (between 40-90%). Most studies show a reduction in using benzodiazepines after several months of using daily methadone. Deaths involving methadone are frequently associated with concomitant use of benzodiazepines and/or alcohol (27). Combined consumption of both increases levels of respiratory depression.

- Alcohol, other sedatives, anti-depressants *(clinically important)*:

  Alcohol intake may impair the metabolism of methadone. Mixing methadone with other opioid agonists, alcohol or other central nervous system depressants can be dangerous. Caution is advised, as are thorough assessment and review procedures. Some anti-depressants including tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs) should be prescribed with caution due to possible sedation. If any significant intake of any of the above compounds is detected then the worker should alert their prescriber. The case should then be reviewed at the multi-disciplinary team. Combined consumption of both increases levels of respiratory depression.

- Opioid antagonists *(clinically important)*:
Opioid withdrawal syndrome can be precipitated by the use of naltrexone and naloxone and, to a lesser extent, buprenorphine.

- HIV medications:
There is no known interaction with HIV combination therapies.

As with other opioids, patients being treated with HIV combination therapies may require dose levels to be adjusted but these adjustments are likely to be minor and, in keeping with titration principles, sufficient to ensure patient comfort (28).

It may be useful to offer prescribing treatment in conjunction with a HIV specialist.

- **HCV medications**

There is good data on interferon/ribavirin and methadone showing that there are no problems. It is likely to be similar with anti-HCV therapy and buprenorphine but further research and experience is required.

**Table Two: Selected drug interactions with methadone** (for comprehensive list of methadone drug interactions refer to [www.atforum.com](http://www.atforum.com)/addiction_resources/Drug_Interactions.pdf.).

### 4.2.11 Methadone and other Medical Conditions

a) **Liver Disease**

Hepatic dysfunction does not seem unduly to disrupt methadone metabolism and it has been suggested that maintenance dosage of methadone need not be changed in stable chronic liver disease, although abrupt changes in hepatic status might result in substantial alterations in methadone metabolism.
requiring dosage adjustments (29). It appears safe in patients who are hepatitis B or C positive or HIV positive, but LFT’s
should be monitored, particularly if the patient’s clinical condition changes. For cirrhosis a reduced platelet count is the best marker and in this situation caution should be exercised and specialist advice sought.

It should always be remembered that the risks from controlled methadone are less significant compared to the risk from street drugs and, therefore, its use should be encouraged.

b) Renal Disease

The urinary excretion of methadone was reduced in renal failure in one study but plasma concentrations were within the usual range and faecal excretion accounted for the majority of the dose (29).

4.2.12 Special Groups

Please refer to the pregnancy and breast-feeding section.

References


SECTION 4.3

_Buprenorphine Prescribing Policy_

- Buprenorphine is a “safer” alternative to methadone due to its partial agonist properties and it appears to have an easier withdrawal phase. In NHSL we will use Suboxone (Buprenorphine/naloxone combination)

- Buprenorphine will provide a blockade effect against other opioids at doses of 12 mg or above.

- Buprenorphine is easily soluble allowing it to be dissolved and injected. Initial supply should be via supervised consumption (minimum 12 weeks).

- Buprenorphine should be initiated when there is clear evidence of withdrawal (at least 6-8 hours after the last heroin dose or 36 to 48 hours after the last dose of methadone). Patients should not routinely be transferred to buprenorphine from methadone until the methadone dose is 30ml or below. However, this can be arranged via the Lead Medical Practitioner.

- Suboxone induction should be via a titration regime, which is commonly 8mg (day one), 16 mg (day 2) and daily increases of 8 mg per day are possible up to a maximum daily dose of 24 mg (day 3 onwards). This will reduce the chance of precipitated withdrawal and allow monitoring of withdrawal symptoms against dose. Only the first dose need be monitored.

- As with methadone, patients who continue to misuse benzodiazepines and alcohol while on a buprenorphine prescription should have their treatment reviewed.

- Patients with liver disease should have their treatment discussed with a specialist or the hepatology department before starting a prescription for buprenorphine.

- Buprenorphine is not a contra-indication in pregnancy but a caution. Patients who are pregnant should have their case discussed with a GPwSI or specialist in the field of substance misuse, and this will be assessed on a risk: benefit discussion and decision.

- Buprenorphine is considerably more expensive than methadone
4.3.1 Background

This policy should be read in conjunction with “Drug Misuse and Dependence: Guidelines on Clinical Management” (1). The policy draws on the Royal College of General Practitioners (RCGP) document “Guidance for the use of buprenorphine for the treatment of opioid dependence in primary care” (2) and the British Association for Psychopharmacology (BAP) document “Evidence-based guidelines for the pharmacological management of substance misuse, addiction and co morbidity: recommendations from the British Association of Psychopharmacology” (3).

4.3.2 Rationale for Use of Buprenorphine

The use of methadone in the treatment of opioid dependence is well established and supported by a substantial body of evidence (4,5,6,7,8,9). However, methadone does not suit every patient and many clinicians welcomed the introduction of a further option to the UK market. Buprenorphine has been licensed in the United Kingdom for substitute therapy in the management (maintenance and detoxification) of opiate dependency since 1999 although it has been used in America and France for some time longer. The Department of Health Guidelines (2008) provides only limited information on buprenorphine compared to methadone but since its introduction into the UK a body of evidence has been developed to support its use including a Cochrane review in 2003 (10).

It is a partial opioid agonist and appears safer in overdose than methadone when used as a single agent i.e. no polydrug use, and it may have an easier withdrawal phase. It is used for maintenance and detoxification.

4.3.3 Clinical Pharmacology

The existence of multiple opioid receptors was reported in 1976 by Martin et al and further pharmacological studies established the existence of three receptor classes referred to as mu, delta and kappa. Animal experiments have established that:

- mu receptor agonists have reinforcing properties
- delta receptor agonists have reinforcing properties although to a lesser extent than mu receptor agonists, and
- kappa receptor agonists have an opposing effect on reward and can produce psychotomimetic effects e.g. dysphoria, analgesia and depersonalisation.
Understanding this basic neuro-pharmacology can help us understand how Buprenorphine exerts its effect. Pharmacologically, Buprenorphine is a partial agonist at the mu (μ) receptor and a weak antagonist at the kappa receptor. Because it binds tightly to, and dissociates slowly from these receptors, Buprenorphine exhibits an agonist ‘ceiling effect’, most noticeably in its respiratory depression effect, which accords the medication a high degree of clinical safety. Its tight binding with slow dissociation from receptors also provides a blockade for the effects of subsequently administered agonists, precipitates withdrawal in patients maintained on a sufficient dose of full agonist, and provides prolonged duration of action with poor reversibility by naloxone. Furthermore, Buprenorphine’s weak antagonist effect at the kappa receptor renders it devoid of psychotomimetic effects (11).

Other relevant pharmacological effects include:

- Time to peak concentration: 90 – 150 minutes after sublingual administration.

- Time to peak clinical effects: 1 – 4 hours post dose.

- Duration of Action:
  - Low Dose (2-4mg): Up to 12 hours.
  - Higher Doses (16-32mg): Can exert effects for up to 48 – 72 hours.

- Elimination half-life: Between 20 and 37 hours.

- Metabolism: Principally in the liver via two hepatic pathways: glucuronide conjugation and N-dealkylation by the CP450 enzyme system. Buprenorphine should be administered sublingually because it has poor oral bioavailability due to high first pass metabolism and inactivation by gastric secretions.

- Excretion: Predominantly unchanged in the faeces with some evidence of enterohepatic recirculation. The renal route excretes approximately 20%; however renal impairment may have little effect on Buprenorphine kinetics. Small amounts are distributed into breast milk.

- Blockade Dose (dose where effects of additional opioids are markedly reduced): Maximal above 12 – 16mg daily.

- Suboxone’s licensed maximum dose is 24mg. Buprenorphine maintenance doses: 8 – 32mg daily.

- Equivalence: Direct equivalence with methadone is difficult to estimate and is not a linear relationship. When comparing the efficacy of maintenance...
doses, 12 to 16mg buprenorphine is approximately as effective as 50 – 80mg methadone in reducing heroin use and retaining patients in treatment (12).

- It is difficult to compare doses above 80mg of methadone and 16mg of buprenorphine because of their different effects. A comparison chart used in Bristol is illustrated in appendix 6.

- Easily Soluble: Buprenorphine does have a misuse potential, as it can be easily dissolved and injected or crushed and snorted which results in a rapid onset euphoria and markedly shorter period of antagonistic action. Buprenorphine administration should be supervised initially for at least 12-weeks in line with NHS Lanarkshire’s Take Home Policy. Any decision outside this policy must be agreed with the multi-disciplinary team prior to initiating a prescription.

- Injecting buprenorphine tablets can be associated with venous damage, thrombosis, pain on injecting, infections, risk of blood borne viruses (BBV) and toxic hepatitis.

4.3.4 Indications, contra-indications, precautions and side-effects

- Buprenorphine is indicated in the treatment of opioid dependence

- Buprenorphine is contra-indicated in acute respiratory depression, children under 16, severe hepatic insufficiency (see later), acute alcoholism or delirium tremens and breast-feeding (13).

- Buprenorphine should be used with caution in the following groups:

  - Respiratory Depression: some cases of death due to respiratory depression have been reported, particularly when used in combination with benzodiazepines
  - Liver Disorders: hepatic necrosis and hepatitis with jaundice, which generally have resolved favourably, have been reported in patients who use buprenorphine (see other medical conditions)
  - Renal insufficiency (20% of the administered dose is eliminated by the renal route; thus, renal elimination may be prolonged). (13)
  - Patients in methadone treatment at doses of greater than 30mg: Transferring to buprenorphine is likely to be associated with precipitated withdrawal (see section 3.5) and should only be attempted after consultation with the Lead Medical Practitioner.
  - Patients with severe mental illness with limited capacity to provide informed consent.
  - Pregnancy: refer to pregnancy section (11).
• Buprenorphine is associated with the following side effects:
  o Buprenorphine may cause drowsiness, particularly when taken together with alcohol or central nervous system depressants. Therefore, patients should be warned against driving or operating machinery.
  o Constipation
  o Headaches
  o Insomnia
  o Asthenia (abnormal loss or lack of bodily strength; weakness or debility)
  o Nausea and vomiting
  o Fainting and dizziness
  o Orthostatic hypotension (sudden fall in blood pressure when standing)
  o Sweating

4.3.5 Precipitated withdrawal

Due to its high affinity, buprenorphine competes with and displaces full opioid agonists such as heroin and methadone from opiate receptors. That and its lower intrinsic activity means it has the potential to cause opiate withdrawal symptoms. Precipitated withdrawal is most likely to occur if the first dose of buprenorphine is given whilst the patient is experiencing the effects of other opiates. Precipitated withdrawal may commence in the first 30-90 minutes, usually peaking within 3 hours and then subsiding (in contrast to under replacement symptoms which characteristically begin later). Less severe symptoms may continue after the second or third dose.

To reduce the risk of precipitated withdrawal the first dose of buprenorphine should be taken when the patient is experiencing features of opioid withdrawal.
This will typically mean at least 8 hours after the last heroin use, or 24 to 48 hours after the last methadone dose. Patients can be assessed using the appropriate opioid withdrawal scale (appendix 8a) to assess first dose suitability. It is essential that the patient understands the concept of the precipitated withdrawal so they know the importance of the timing of the first dose and how to deal with withdrawal symptoms if they are present. A patient leaflet (appendix 4a-i) may help to support this. If the patient
experiences a level of precipitated withdrawal they may be treated with symptomatic medications such as:
- Lofexidine (400-600mcg 8 hourly for 1 to 2 days).
- Loperamide 2mg capsules: two capsules at onset of diarrhoea followed by one capsule with every loose motion.
- Metoclopramide 10mg tablets: one tablet up to three times a day for nausea and vomiting.
- Ibuprofen 400mg tablets: one three times a day for pain (paracetamol 500mg tablets two four times a day if ibuprofen is contra-indicated)
- Zolpidem 10mg tablets one at night when required (short term only).

4.3.6 Choosing between Methadone and Buprenorphine

Current clinical evidence is to be taken into account when deciding the most appropriate prescribed intervention in the management of opiate dependency. This evidence combined with the license terms makes buprenorphine the clear drug of choice for patients under the age of 18, although it should be noted that the license is for patients of 16 years plus. In adult populations there is less clear clinical evidence to inform choice between buprenorphine and methadone. The Royal College of General Practitioners suggests that the decision should be made on an individual basis taking into consideration a variety of factors such as:

- Patient’s preference.
- Previous treatment history e.g. not previously stabilised on methadone or not responding well on an adequate dose of methadone.
- Whether a sedating (methadone) or less sedating opiate (Buprenorphine) would be advantageous. This may be a positive or negative effect for different patients. It has been noted that some patients report a “clearer head” on initiating buprenorphine treatment as opposed to the clouding effect associated with heroin or methadone use.
- Some patients find this a benefit while others may find it uncomfortable and this effect may have a direct bearing on compliance with treatment. Methadone is preferred to buprenorphine if there is a risk of psychological decompensation as seen with histories of severe trauma or mental illness.
- Type of treatment, maintenance, or detoxification?

Buprenorphine is more appropriate for detoxification as withdrawal appears to be easier compared to methadone if used for less than four to six months.
- If Naltrexone is being considered it can be commenced much
sooner if Buprenorphine is used (3-7 days).

- Buprenorphine is less affected by interactions with Anti Convulsants, Rifampacin and Ribavarin.
- Buprenorphine is safer in overdose as a single agent.
The blockade effects of buprenorphine may be better suited to patients who wish to cease using heroin completely.

Buprenorphine should not be continued if patients continue to use illicit opiates on a regular basis (risk of precipitated withdrawal).

It must be recognised that methadone is cheaper than the equivalent doses of buprenorphine. With the limited evidence of the superiority of either medication for particular subgroups, there is a strong argument that under the current pricing arrangements, where there is no patient preference, or other convincing clinical reason to favour buprenorphine, methadone should be used as a first line treatment for opioid maintenance therapy.

4.3.7 Buprenorphine as a Detoxification Agent

I. Evidence Base

A systematic review of studies comparing buprenorphine with other withdrawal regimens considered 37 studies of which only 6 were included in the final review (14). It was concluded that buprenorphine has the potential to ameliorate withdrawal from heroin and possibly methadone, but there was insufficient information to quantify outcomes, and the small number of studies and risk of bias in the studies made it difficult to draw any conclusions regarding appropriate treatment protocols.

A large RCT comparing buprenorphine with clonidine and benzodiazepines (14) concluded that buprenorphine was superior for managing withdrawals in terms of heroin use during withdrawal, completion of withdrawal, alleviation of withdrawal symptoms and retention in treatment after withdrawal.

II. Detoxification Information and Regime

Before initiating a buprenorphine prescription for the management of substance dependency it is essential that illicit drug use be confirmed, therefore drug screening must take place prior to the initiation of the prescription.

Buprenorphine is a useful adjunct to detoxification from opiate dependency, however it is usual for a degree of stability to be achieved before a community detox is considered. The decision to detoxify a patient should be undertaken collaboratively and not dictated by the service. It is important that the regime is flexible and tailored to the patient’s needs. In addition, the goal of detox, in keeping with all treatment goals, should be S.M.A.R.T. (Sustainable,
Measurable, Achievable, Recorded and Timed). Whilst most patients experience minimal physical withdrawal symptoms, it is important that the reduction regime is slowed down or suspended if the patient is experiencing difficulties. It should be noted that if rapid detox is carried out (7 days or less) then the full impact of withdrawal might not be experienced until
after the detox has been completed. A reasonable reduction rate for community detox is suggested below.

- Buprenorphine >16mgs daily reduce at 2mgs twice weekly until
- Buprenorphine >8mgs < 16mgs reduce at 2mg weekly until
- Buprenorphine >2mgs <8mgs reduce at 2mg every 2 weeks then
- Buprenorphine <2mgs reduce a 0.4mg every 1 to 2 weeks.

This functions as a rough guide only and faster or slower regimes may be negotiated between the patient, the named nurse, and the prescriber as required. The multi-disciplinary team approach should be used to discuss any complex presentations and share the experience of colleagues. Other suitable reduction regimes are illustrated in appendix 9.
Additional Medication During Suboxone Detox

In the latter stages of the detox, adjunct medication can be considered if the withdrawal symptoms become difficult to manage.

These may include:
- Buscopan – stomach cramps
- Loperamide – vomiting
- Paracetamol
- Ibuprofen
- Diazepam – anxiety
- Zolpidem – night sedation
- Lofexidine – during 48 hour period prior to commencing Naltrexone

4.3.8 Buprenorphine as a maintenance agent

Evidence Base

The effectiveness of buprenorphine maintenance treatment has been examined in a Cochrane review (10).

In comparison to placebo:
- There is evidence that buprenorphine is superior in terms of retention in treatment at low or moderate doses (four trials) and at a high dose (one trial).
- It is superior in terms of reduction in opioid positive urines at moderate doses (two trials) and high doses (one trial) but not at low doses (two trials).

In comparison to methadone maintenance treatment:
- Higher dose methadone maintenance treatment (> 80mg) appears more effective than buprenorphine.
- Buprenorphine produces comparable outcomes to lower dose (e.g. 40-80mg) methadone.
- There is evidence that buprenorphine is superior to methadone in terms of retention in treatment when methadone is used in low dose <30mgs daily (Mattick et al 2003).
- It has been shown to be superior in the reduction of positive opiate test results; however there is little evidence that it reduces the incidence of
positive tests for cocaine or benzodiazepines in comparison to methadone.

There are few adequate comparisons of higher dose buprenorphine i.e. 16-32mgs daily with high dose methadone treatment and this is an area that needs further research. A summary of the evidence base for the efficacy of buprenorphine compared to methadone is illustrated in table 3.2.

<table>
<thead>
<tr>
<th>For Heroin use and treatment retention in Randomised Controlled Trials (RCT’s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Dose Methadone Maintenance Treatment (MMT) (&gt;$80mg).</td>
</tr>
<tr>
<td>Better than</td>
</tr>
<tr>
<td>Medium Dose MMT (40-80mg) = Medium Dose Buprenorphine Maintenance Treatment (BMT) (8-12mg)</td>
</tr>
<tr>
<td>Better than</td>
</tr>
<tr>
<td>Low Dose MMT (&lt;40mg) = Low Dose BMT (&lt;8mg).</td>
</tr>
</tbody>
</table>

Table 3.2: Efficacy of BMT compared to MMT (Taken from NTA)

Maintenance Information and Regime

Before initiating a Suboxone prescription for the management of substance dependency it is essential that dependency be confirmed, therefore drug screening must take place prior to the initiation of the prescription.

The first stage of maintenance prescribing is induction. The purpose of induction is to safely establish the patient as quickly as possible on a target dose of Suboxone that prevents opioid withdrawal, reduces the need to take additional illicit opioids and keeps side effects to a minimum. When initiating a Suboxone prescription the following factors should be taken into account.

- The patient should be given information about Buprenorphine and should understand how it works and about the possibility of precipitated withdrawal (see patient leaflet; appendix 4b)
- The initial dose should only be taken when the patient demonstrates signs of early opiate withdrawal (as measured on the subjective and clinical opiate withdrawal scales (SOWS and COWS, see appendix 8a-b). This is usually at least 8 hours after the last heroin use, or 24 to 48 hours after last methadone use.
- The initial dose on day one is usually 8 mg.
- The dose is then increased on subsequent days, or later the same day if facilities are available, according to clinical response.
• Dose titration on subsequent days is usually 8 mg.

• Buprenorphine should test positive with drugs of abuse screening between 20-37 hours post dose.

• Opiate blockade takes place (i.e. the effects of additional opiates are markedly reduced) at 12mgs and above.

  A maintenance dose should usually be between 8-16mgs daily, although it is possible to prescribe up to 32mgs; but this is rarely required.

• Steady state blood concentration levels are reached after about 5 to 8 days.

Undoubtedly the most successful titrations are the ones that are carefully monitored and where dose is titrated as required. However in community settings it is often not practical to change prescriptions on a daily basis. Therefore the following regime is popular in the community setting:

<table>
<thead>
<tr>
<th>Day One</th>
<th>8 mg then</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day Two</td>
<td>16 mg for one week</td>
</tr>
<tr>
<td>One week onwards</td>
<td>24 mg depending on patient experience</td>
</tr>
<tr>
<td>Day three can be 24mg and maintain for at least one week</td>
<td></td>
</tr>
<tr>
<td><strong>The adage for Suboxone is “the higher, the faster, the better!”</strong></td>
<td></td>
</tr>
</tbody>
</table>

There are many experienced practitioners within the team, both medical and nursing, who would be able to assist in the development of an appropriate regime and this should be discussed at the multi-disciplinary team meeting.

The specialist prescriber may prescribe an alternate day dosing regime as the long-acting nature of Buprenorphine provides adequate clinical effectiveness in this manner for some individuals. This may be useful in the treatment of the reasonably stable patient who has been on Buprenorphine for at least three months and who has no high-risk drug use and confirmed cessation of illicit drugs. This is not covered under the product licence and therefore should be initiated in discussion with the addiction psychiatrist / Lead GPwSI and full agreement of the multi-disciplinary team. If alternate day prescribing were to be initiated a two-day dispensing regime would consist of 2 x the daily dose up to a maximum of 24 mgs (Suboxone) every two days. A three-day dispensing regime would be 3 x the daily dose up to a daily maximum of 24 mgs every three days.
Transferring to Suboxone from Methadone

When initiating the patient from **methadone** it should be remembered that:

- The dose should be reduced to and stabilised on 30 mg or less.
- The first dose of Buprenorphine should be administered at least 24 to 36 hours after the last use of methadone and with mild to moderate withdrawals.
- Increasing the time interval between the last dose of methadone and the first dose of Buprenorphine reduces the incidence and severity of precipitated withdrawal.
- Dose titration should follow the following schedule as a rough guide:
<table>
<thead>
<tr>
<th>Last methadone dose</th>
<th>Suboxone Day 1</th>
<th>Suboxone Day 2</th>
<th>Suboxone Day 3 onwards</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;30mg</td>
<td>Not recommended in general practice unless experienced practitioner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-30mg</td>
<td>8mg</td>
<td>16 mg</td>
<td></td>
</tr>
<tr>
<td>10-20mg</td>
<td>8mg</td>
<td>16 mg</td>
<td>Daily increases of 8 mg a day are possible up to a maximum of 24 mg</td>
</tr>
<tr>
<td>&lt; 10mg</td>
<td>8 mg</td>
<td>8 mg</td>
<td></td>
</tr>
</tbody>
</table>

Subsequent titration procedures are the same as for the induction from heroin (15).

Transfers can be attempted at doses above 30mg of methadone but this will usually be carried out by the Lead Medical Practitioner; this must be discussed with him first.

**4.3.9 Missed Doses**

Missed doses can lead to loss of tolerance and prescribers should be kept informed of missed doses.

- If a patient on a daily dispensing regimen misses a pickup from the pharmacy, the patient should return the next day as usual for their next dose. The missed dose should not be replaced.

- If a dose is missed for 3 consecutive days then treatment should be suspended and the named nurse, service manager or prescriber contacted. If the patient misses three pick ups on a 14-day prescription then the named nurse, service manager or prescriber should also be contacted.

- Patients who repeatedly miss doses should have their treatment reviewed, in line with NHS Lanarkshire’s Missed Doses Guidelines. If on less than daily dosing the first step would be to revert to daily dispensing.
4.3.10 Drug Interactions
The main drug interactions of Buprenorphine are due to its opioid characteristics and are summarised below:

- **Benzodiazepines:** This interaction is well documented and a combination of Buprenorphine with benzodiazepines and/or alcohol has been known to cause respiratory depression, sedation, coma and death (16). Assessment of the patient must address alcohol and benzodiazepine use (both licit and illicit) and caution advised if there is a risk of poly-drug use with thorough review procedures in place. Patients receiving diazepam prescriptions in excess of 30mgs daily will have their cases discussed with specialist prescribers and the multi-disciplinary team, but will usually not be commenced on Buprenorphine.

- **Alcohol, other sedatives and anti-depressants:** Alcohol intake may impair the metabolism of buprenorphine and potentiate the sedative effects of the drug. Mixing buprenorphine with alcohol or other CNS depressants can be dangerous. Caution is advised, together with thorough assessment and review procedures. Tricyclic antidepressants e.g. amitriptyline, should be prescribed with caution due to increased sedation. MAOI’s should NOT be prescribed with Buprenorphine and for two weeks after stopping the MAOI due to possible CNS excitation or depression (hypertension or hypotension) (17).

- **Other full opioid agonists i.e. opiate analgesia:** Buprenorphine may precipitate opioid withdrawal syndrome when given to those taking full opioid agonists e.g. morphine, pethidine. Buprenorphine will also reduce the effects of other opioids given for analgesia.

- **Cocaine:** To date, no notable interaction has been observed with cocaine.

- **Ketoconazole:** An interaction study of Buprenorphine with ketoconazole (a potent inhibitor of CYP3A4) resulted in increased Cmax and AUC of buprenorphine (approximately 70% and 50% respectively) and, to a lesser extent, of the metabolite, norbuprenorphine. Patients receiving Buprenorphine should be closely monitored and the dose of buprenorphine should be halved when starting treatment with ketoconazole.

- **Enzyme Inducing Drugs:** The interaction of Buprenorphine with CYP 3A4 inducers has not been investigated; therefore it is recommended that patients receiving Buprenorphine should be closely monitored if enzyme inducers (e.g. phenobarbital, carbamazepine, phenytoin, and rifampicin) are co-administered.
Use of these medications may increase the metabolism of Buprenorphine and the dose of Buprenorphine should be increased appropriately if patients
complain of decreased benefit from Buprenorphine or if there is re-emergence of craving for illicit drugs.

- HIV medication and HCV medications: There is no known interaction with Buprenorphine, but further research and experience is needed in this field.

- Naloxone: Very high doses of naloxone (up to 25 x the dose i.e. 10-15mg) are needed to reverse buprenorphine induced respiratory depression in overdose due to buprenorphine’s high affinity for opiate receptors.

### 4.3.11 Buprenorphine and other medical conditions

a) Liver Disease: Buprenorphine appears safe in patients with hepatitis C infection (HCV), as long as the patient has normal liver function and no evidence of cirrhosis. There is some evidence that high-dose Buprenorphine can cause changes in liver function in individuals with a history of liver disease who inject or take an overdose (18). With this in mind The Royal College of General Practitioners recommend:

i. LFT’s are checked at assessment, but waiting for the results should not delay the starting of Buprenorphine if the patient is well.

ii. If LFT’s are normal, monitor periodically (e.g. 6 monthly) through treatment as Buprenorphine can cause an increase in AST and ALT.

iii. If there is evidence of liver disease (e.g. HCV antibody positive, alcohol misuse), take LFT’s BEFORE commencing Buprenorphine treatment (baseline) and monitor LFT’s again after 2 to 3 months.

iv. If there is evidence of marked deterioration in LFT’s refer to a liver specialist for advice.

Initiation of a prescription in this patient group should be discussed with specialist prescribers and the hepatology department.

b) Kidney Disease: There is no significant difference in the kinetics of Buprenorphine when patients with renal failure or renal impairment are compared to controls (19)

### 4.3.12 Special Groups
Please refer to the pregnancy and breast-feeding section.

Pregnancy and Suboxone

- Suboxone is no longer contraindicated in pregnancy.

- If a client suspects that she might be pregnant prior to commencing a Suboxone titration, then confirm with a pregnancy test. If positive, liaise with prescriber and client to amend treatment to methadone or Subutex, as both are licensed in pregnancy.

- If a client suspects that she is pregnant whilst receiving a Suboxone prescription, confirm with pregnancy test. If positive, liaise with the prescriber to determine treatment options, which include converting to Subutex or methadone.

4.3.13 Dispensing Arrangements

Dispensing should be daily and all new prescriptions should be supervised in line with Home Office guidelines (DOH 2008) for a minimum of 12-weeks barring exceptional circumstances agreed by the multi-disciplinary team. The pharmacist should be adequately trained in supervised consumption (attendance at a local training event and completion of CPPE distance learning package: Opiate treatment: Supporting pharmacists for improved patient care) and the following is recommended:

- The patient should be offered a drink of water to speed up the dissolution time

- The tablet should be placed whole under the tongue and the patient told not to chew the tablet

- The patient should be warned about the bitter taste

- Advise the patient to swallow as little saliva as possible

- The patient should be observed for at least 3 minutes in a suitable area

- After the medication has dissolved and only a chalky residue left the patient should be offered a drink of water and engaged in conversation to ensure that the tablet has not been secreted in the mouth.

The patient should remain on supervised consumption until the named nurse and the prescriber are reasonably confident of the stability of the patient’s treatment and the risk of diversion is minimal. In situations where daily-supervised consumption is not viable (work commitments etc) the case must be discussed and agreed by the multi-disciplinary team at caseload discussion.
4.3.14  Crushing of Buprenorphine Tablets

Some pharmacists crush Buprenorphine for the purpose of supervised consumption to speed up the absorption process and help prevent diversion. This is not recommended in this prescribing policy because buprenorphine is not currently licensed to be administered like this and there may be problems with product liability. However, there may be situations where "crushing" is advisable e.g. possible diversion, and all parties agree to this arrangement. Recent guidelines from the Royal Pharmaceutical Society of Great Britain (RPSGB), in conjunction with the National Pharmaceutical Association (NPA), have agreed to indemnify NPA members who provide a “crushing” service provided:

- They comply with a defined protocol (appendix 9)
- Crushing of the tablet should be for the benefit of the patient, rather than the convenience of the pharmacist and the patient should be informed of the risks and benefits associated with crushing
- The prescriber provides consent to the service either in writing or as a direction on the prescription

The decision to provide a “crushing” service to the patient should, therefore, be based on multi-disciplinary discussions and based on the patient’s initial assessment and reviews. When appropriate, there is a template letter to pharmacies authorising crushing of medication.

Suspected Overdose / Intoxication

- If a client appears incapacitated or difficult to rouse, then assess Airway, Breathing and Circulation (ABC), responding accordingly. Alert emergency services as necessary.
References


SECTION 4.4

Benzodiazepine Prescribing Policy (Summary)

- Benzodiazepines should **not** be prescribed routinely in the treatment of substance misuse.
- The benefit of long-term prescribing has not been established and long-term prescribing of more than 30mg of diazepam a day is harmful. Prescribed doses should not exceed 30mg.
- Benzodiazepines should be prescribed on a reducing schedule for substance dependency.
- Due to the “binge” nature of benzodiazepine misuse assessment should identify dependency before a prescription is initiated.
- All benzodiazepines should be converted to an equivalent dose of diazepam which has a long half life and provokes a less severe withdrawal state.
- Caution is advised with the co-prescribing of benzodiazepines with opioids and alcohol.
- Liver disease may necessitate a reduction in dose or a transfer to a benzodiazepine that is not metabolised by the liver e.g. oxazepam. Decision to treat should be made in conjunction with a prescriber from the addictions service and the hepatology department.
- Benzodiazepines should be avoided where possible in pregnancy and breast-feeding.
- Benzodiazepines should be used with care in the elderly due to increased risk of fall and cognitive impairment. Anecdotal evidence suggests this is a route for diversion to the illegal market also.

FOR FULL BENZODIAZEPINE GUIDELINE SEE GUIDELINE SECTION
4.4.1 Background

These guidelines have been formulated taking into account a variety of factors that are specific to Benzodiazepine misuse. These guidelines are fully compliant with the Dept of Health Guidelines (Dept of Health et al 2007) and The National Treatment Agency directives (NTA Research into practice Jan 2003).

Benzodiazepines were first introduced in the 1960’s and primarily replaced barbiturates because they were thought to be reliable, with fewer unwanted effects, be less addictive and safer in overdose. During the 1970’s and 80’s they were widely prescribed by clinicians, although addiction problems were being recognised. It has now become clear that illicit benzodiazepine use is a major problem. Up to 90% of people attending drug treatment centres reported benzodiazepine use in a one-year period and almost half had injected them at some time (1). High doses of prescribed and illicit benzodiazepines are taken and users become extremely tolerant to the sedative effects (2). They are taken primarily to:

- Produce intoxication on their own
- Enhance the effects of methadone (3,4)
- Counter early withdrawal symptoms from other drugs

Methadone maintenance patients using non-prescribed benzodiazepines have been reported to be on higher methadone doses, as well as exhibiting more HIV/HCV risk-taking behaviour, greater poly-drug use, higher levels of psychopathology and social dysfunction (5,6,7). However, attending treatment has been effective in reducing non-prescribed benzodiazepine use (8). Some
prescribers are still more comfortable with prescribing benzodiazepines than methadone to problem drug users, whereas the
reverse should be true. In addition to this, anecdotal evidence suggests that there is diversion of legitimate prescription supply to the black market.

4.4.2 Rationale for Use

There is no “gold standard” treatment for benzodiazepine dependency and little rationale for its use. It should always be remembered that they are not licensed for the management of benzodiazepine dependence and they are licensed only for short-term use for the management of insomnia and anxiety (9). Short term prescribing of benzodiazepines may have some benefit in supporting drug users to control their intake of benzodiazepines and stabilise their lives but the benefit of long term prescribing of benzodiazepines is less certain with increasing evidence that long term prescribing of more than 30mg is harmful (10). Prolonged prescription of benzodiazepines to a person with an illicit benzodiazepines habit rarely results in abstinence and more often ends in long term prescribing, continued illicit use or both. It is therefore of doubtful therapeutic value (11). Benzodiazepines have also been cited as important in combination with methadone and buprenorphine and / or alcohol in drug related deaths.

However, there are possible advantages in prescribing benzodiazepines to some drug users, which include:

- Patients with long-term dependence problems with benzodiazepines may benefit from time-limited substitution prescribing
- Control of existing benzodiazepine usage

NHS Lanarkshire alcohol & drug services have agreed that all benzodiazepine prescriptions for dependency treatment should be on a reducing schedule rather than a maintenance schedule.

The prescribing of benzodiazepines should be the exception rather than the rule and prescribers should only initiate prescriptions where:

- They have had the appropriate training (RCGP Certificate in Substance Misuse Part 2)

In situations where both benzodiazepines and opiate dependency is present, it is appropriate to commence prescribed treatment for the opiate dependency first and stabilise the patient on a specific dose. Alongside this, non-prescribed interventions to reduce the benzodiazepine use should be examined and a benzodiazepine prescription should only be considered when other options
have failed. All benzodiazepine prescriptions for dependency must be discussed and cleared by the multi disciplinary team as part of a case management discussion.
Benzodiazepine Withdrawal Syndrome is a recognised condition (table 4.1), which occurs in at least a third of long-term users on dosage reduction and withdrawal (12). Short-acting drugs such as lorazepam are associated with more problems on withdrawal than longer-acting drugs such as diazepam (13). In the majority, symptoms last no longer than a few weeks, although a minority experience disabling symptoms, which can persist between 10 months and 3 ½ years in a third of drug users (14). Continuing support is required for patients including psychological therapies, self help groups and family support.

### Table 4.1: Problems on withdrawal of benzodiazepines (Petursson H. The benzodiazepine withdrawal syndrome Addiction 1994; 89: 1455-1459)

<table>
<thead>
<tr>
<th>Physical</th>
<th>Psychological</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness</td>
<td>Anxiety / Insomnia</td>
</tr>
<tr>
<td>Weakness</td>
<td>Nightmares</td>
</tr>
<tr>
<td>GI disturbance</td>
<td>Depersonalisation</td>
</tr>
<tr>
<td>Paraesthesia</td>
<td>Decreased memory</td>
</tr>
<tr>
<td>Flu-like symptoms</td>
<td>and concentration</td>
</tr>
<tr>
<td>Visual Disturbances</td>
<td>Delusions and hallucinations</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
</tr>
</tbody>
</table>

4.4.3 Clinical Pharmacology

Where treatment has been agreed, all benzodiazepines should be converted to an equivalent dose of diazepam, which has a long half-life and therefore provokes less severe withdrawal (table 4.2). Diazepam is readily and completely absorbed from the gastrointestinal tract with peak plasma concentrations occurring within about 30 to 90 minutes of oral administration. Diazepam is highly lipid soluble and crosses the blood-brain barrier; it acts promptly on the brain, but its initial effects decrease rapidly as it is redistributed into fat depots and tissues.

Diazepam has a bi-phasic half-life with an initial rapid distribution phase followed by a prolonged terminal elimination phase of 1 or 2 days: its action is further prolonged by the even longer half life of 2 to 5 days of its principle active metabolite, desmethyldiazepam. No simple correlation has been found between plasma concentrations of diazepam or its metabolites and their therapeutic effect.

Diazepam is extensively metabolised in the liver and, in addition to desmethyldiazepam, its active metabolites include oxazepam and temazepam. It is excreted in the urine, mainly in the form of free or conjugated metabolites. Diazepam is 98-99% bound to plasma proteins.

The plasma elimination half-life of diazepam and / or its metabolites is prolonged in neonates, in the elderly and in patients with liver disease. In
addition to crossing the blood-brain barrier, diazepam and its metabolites also cross the placental barrier and are distributed into breast milk.
4.4.4 Indications, contra-indications and precautions

- Diazepam is licensed for short-term use in anxiety or insomnia (two to four weeks only) and as an adjunct in acute alcohol withdrawal.

- It is used in benzodiazepine withdrawal and dependency but these are both outside licensed indication.

- It is contra-indicated in respiratory depression, acute pulmonary insufficiency, sleep apnoea syndrome, severe hepatic impairment and in chronic psychosis. It should not be used alone in depression or in anxiety with depression.

- Extra caution should be exercised in the following circumstances:
  - Respiratory disease
  - Muscle weakness
  - History of drug or alcohol abuse (remember there is a high risk of dependence as they are addictive).
  - Marked personality disorder
  - Pregnancy*
  - Breast feeding*
  - Reduce dose in elderly and debilitated, and in hepatic impairment (avoid if severe)*
  - Renal Impairment
  - Avoid prolonged use and abrupt withdrawal thereafter
  - Porphyria
  - Patient with a history of violence (due to the disinhibiting effects of benzodiazepines).

(*See special groups section 4.8)

4.4.5 Prescribing regimes

Once the conversion to diazepam has been undertaken, the prescriber should aim for the lowest dose that will prevent withdrawal symptoms and work up to a maximum of 30mgs of diazepam. Patients should be encouraged to divide the daily dose so as to avoid being intoxicated or drowsy during the day. All changes should be done working with the patient as lack of prescribing flexibility can reduce success for some patients in this area (15).

Where the patient is also on a methadone or buprenorphine maintenance prescription, this should be held on the current dose, or even increased, whilst the diazepam is reduced. All patients in receipt of a benzodiazepine prescription should be reviewed every three months. For patients being
prescribed both an opiate
substitute and diazepam, the opiate substitute should be consumed under supervision daily and the diazepam should be collected daily, due to the increased risk and instability.

Reduction regimes should be the goal of the majority of care plans and these will be agreed by the multi-disciplinary team before the initiation of the prescription. The rate of reduction is often determined by the individual's capacity to tolerate symptoms. Dept of Health Guidelines (Dept of Health et al 2007) recommend withdrawals in proportions of about one-eighth (range one-tenth to one-quarter) of daily dose every fortnight reducing to 2 to 2.5mg a fortnight in therapeutic dose dependence.

If patients are experiencing a high level of distress during a benzodiazepine detoxification, as long as the patient is otherwise engaging well in the care plan, it is appropriate to suspend the reduction for up to a month or slow the rate of reduction following discussion with the prescriber. Discussion with the multi-disciplinary team is essential if the period of stabilisation is to take place for greater than a month.

Adjuvant therapy should generally be avoided although a beta-blocker may be given for prominent sympathetic over activity and an antidepressant for clinical depression (see later under 4.6). Antipsychotic drugs may aggravate withdrawal symptoms and should be avoided (17).

**Cessation of Diazepam following non compliance**

In situations where there is non-compliance with the care plan the decision may be made to stop treatment. This may be due to non-attendance of more than two appointments or for inappropriate behaviours.

In this situation, it would not be appropriate to immediately stop the diazepam prescription due to the risk of severe withdrawal symptoms. The care co-ordinator and the prescriber, taking into account the following factors, decide the rate of reduction.

1. If there is chaotic drug and or alcohol use and the prescription represents only a small percentage of drugs/alcohol used, the prescription should be stopped immediately.

2. If the patient has been reasonably stable on the prescription before the decision to stop, the prescription should reduce as follows; If the prescription is 30mgs or less, the reduction should be 5mgs every 3 days until 10mgs, then reduce 2mgs every two days to zero. (see Appendix 11)

3. In certain situations (co morbidity with severe mental health problems etc.), either the prescriber or the named nurse may wish to consider
an alternative regime in order to minimise risk. It is essential that this be discussed with the Consultant. If severe mental health problems are
Involved, a psychiatrist needs to be involved in the prescribing / care plan interventions.

4.4.6 Drug Interactions

In the management of substance dependency, it is important to be aware of the interaction between illicit drugs/alcohol and benzodiazepines. Opiates (including methadone and buprenorphine), alcohol and other sedative drugs combined with benzodiazepines will greatly increase the risk of respiratory depression and suppression of the gag reflex. This is a major factor in drug related death (17). Other clinically significant interactions include:

- Metabolism of diazepam is possibly inhibited by esomeprazole and omeprazole (increased plasma concentration).
- Metabolism of diazepam is accelerated by rifampicin (reduced plasma concentration).
- Metabolism of diazepam is inhibited by isoniazid.
- Diazepam increases or decreases the plasma concentration of phenytoin.
- Diazepam increases the plasma concentration of zotepine.
- Increased risk of prolonged sedation and respiratory depression when diazepam (and other benzodiazepines) is given with amprenavir.
- Plasma concentration of diazepam (and other benzodiazepines) possibly increased by ritonavir (risk of extreme sedation and respiratory depression). Avoid concomitant use.

(Refer to BNF, latest available edition for full list of interactions).

4.4.7 Benzodiazepines And Other Medical Conditions

a) Anxiolytic Action: Benzodiazepines reduce pathological anxiety, agitation and tension. Although useful in the emergency management of anxiety, their use should be restricted to no more than one month, in line with current guidelines (18). It should be re-iterated at this point that benzodiazepines should be avoided, if possible, in patients with a history of substance misuse.

b) Depression: Occasionally in the management of benzodiazepine withdrawal, depressive illness will be identified. This depression may be a direct result of the withdrawal process or part of the underlying cause. Regardless of the cause, an assessment of the level of depression should take place and, if indicated, an antidepressant commenced. Only a skilled professional, with experience in this field should undertake the recommendation and implementation of anti-depressant therapy. Benzodiazepines are not a
treatment for major depressive illness. The National Service Framework for Mental Health highlights this point and NICE found no evidence to support the use of benzodiazepines alongside antidepressants in the initial treatment of depression (19). When an anti-depressant is indicated prescribing should be in line with national and local guidelines.

c) Insomnia: **Benzodiazepines should NOT be used** as hypnotics in this group of patients due to their potential for abuse. Where depression has been diagnosed in the clinician may consider using a more sedating anti-depressant. However, treating the underlying depression could result in an improved sleep pattern so matching the antidepressant to the patient would be the main clinical priority. Alternatively a sedating anti-histamine such as promethazine may be useful on a short-term basis. Non-pharmacological interventions into sleep hygiene should **always** be initiated. The Good Sleep guide (appendix 12a) is an excellent tool to facilitate this process.

d) Liver Disease: Studies of the pharmacokinetics of diazepam in patients with liver disorders suggest that oxidative metabolism is impaired, resulting in a prolonged half-life and reduced clearance. A reduction in dosage is generally required (20). An alternative approach would be to prescribe a benzodiazepine with a shorter half-life, which does not rely on hepatic enzymes for their metabolism, to reduce accumulation of the drug (e.g. lorazepam or oxazepam). The decision to treat in these situations must be made at Consultant level with input from the hepatology department if this is appropriate.

### 4.4.8 Special Groups

Pregnancy: Please refer to the pregnancy and breast-feeding section (11).

Breast Feeding: Please refer to the pregnancy and breast-feeding section (11).

Older People: All benzodiazepines should be used with care in the elderly, as side effects are likely to be enhanced. Enhanced side effects include sedation, disturbances in gait, daytime drowsiness, cognitive impairment, hypotension, memory impairment and reduced psycho-motor performance. The use of benzodiazepines in the elderly has been associated with at least a 50% increase in the risk of hip fracture (21). Anecdotal evidence suggests that diversion from legal sources to the illegal market may also be an issue in this patient group.
4.4.9 Dispensing Arrangements

All Diazepam prescriptions must be initiated on daily collection. However, if there is good compliance with the care plan and demonstrated stability and no co-prescribing of an opiate substitute, in exceptional circumstances dispensing may be less frequent. It is essential that the multi-disciplinary team be in agreement with any alternative dispensing arrangements.

4.4.10 Alternative Non-Prescribed Supportive Interventions In Benzodiazepine Withdrawal

There are varieties of non-prescribed interventions that can assist with the withdrawal from Benzodiazepines. Cognitive Behavioural Therapy has been shown to be extremely useful in dealing with anxiety, panic attacks and phobias. There are trained practitioners within the teams that can offer advice concerning possible interventions.

There are a large number of self-help publications with which patients can be encouraged to develop better coping strategies. In addition, complementary medicine techniques such as acupuncture, massage and reflexology may be useful for certain individuals.

Exercise such as jogging, swimming and pilates are proven in various studies to be very useful in dealing with these symptoms. Simple interventions such as reducing caffeine intake, sleep diaries and basic advice on ways to establish healthy sleep patterns are often very useful. In addition, there are whole ranges of psychotherapeutic interventions that will help to reduce the occurrence of these symptoms. These include Person Centred Counselling, Relaxation Therapy and Psychotherapy.
References


17. British National Formulary


SECTION 4.5

Community Alcohol Detoxification Prescribing Policy (Summary)

- Prescribing should be an adjunct to psychological therapy rather than an intervention in its own right.

- Successive episodes of alcohol detoxification are associated with increased withdrawal severity and rate of complications and with cognitive impairment.

- Chlordiazepoxide is the drug of choice for alcohol withdrawal.

- Chlormethiazole should not be used.

- Thiamine should be used to reduce the risk of Wernicke’s encephalopathy (WE). Patients should also receive vitamin B co strong tablets.

- Treatment with chlordiazepoxide should be individually tailored; regimes of up to a week are typical.

- An alcohol withdrawal syndrome (AWS) will occur in about 40% of patients.

- Delirium Tremens (DTs) will develop in about 5% of cases with a mortality rate of 1-2%.

- For patients with severe hepatic insufficiency a lower dose of chlordiazepoxide could be used. Alternatively, a benzodiazepine with a shorter half life or one that is not metabolised by the liver could be used (e.g. lorazepam or oxazepam). Specialist Consultant guidance should be sought in these cases.

4.5.1 Background

It is recognised that compared to the misuse of illicit drugs, alcohol has the potential to cause greater harm. This is not only because more people use alcohol than illicit drugs, but it also poses greater risks for both physical and psychological health than many other forms of substance misuse. It is accepted that alcohol detoxification in the community, in line with The National Treatment Agency’s (NTA) recommendations, is in many incidents an effective and safe intervention. However detoxification and related prescribing alone are not adequate:
“In UK policy, it is recommended that community prescribing takes place within a context in which the co-existing physical, emotional, social and legal problems are addressed as far as possible. Prescribing therefore must also be complemented by counselling or structured psychotherapy.

Other services sometimes referred to as 'ancillary' or 'wrap around' are also provided, and include welfare advice, help with housing, employment, vocational agencies and so forth" (1).

Prescribing, or pharmacotherapy, is therefore an enhancement of psychological therapy, rather than an intervention on its own. (2)

These guidelines are to enable a safe and effective approach to community alcohol detoxification, taking into account that patients need to be selected carefully. Not all will benefit or indeed be safe with this type of intervention.

4.5.2 Rationale for Use

Many alcohol withdrawal episodes take place without any medical or pharmaceutical interventions. However, some patients will need both psychosocial and pharmacological support to achieve detoxification. When it is improperly managed, alcohol withdrawal is associated with significant morbidity and mortality and successive episodes are associated with increased withdrawal severity and rate of complications with cognitive impairment (3).

Several meta-analyses and systematic reviews have concluded that benzodiazepines are better than placebo as the treatment of choice for alcohol withdrawal as assessed by severity of withdrawal, reduction in incidence of delirium and seizures, adverse effects of medication, completion of detoxification and entrance into rehabilitation (3). They are cross-tolerant with alcohol and have anticonvulsant properties. Chlordiazepoxide is the benzodiazepine of choice. Its longer acting nature makes it more effective against withdrawal seizures and provides a smoother withdrawal profile. (4)

Chlormethiazole (Heminevrin) should not be used due to greater risk of respiratory depression if alcohol is drunk, as well as other concerns including its variable bio-availability, addictive potential and street value (3)

Vitamin deficiency in alcohol dependency is common and there is a particular need for thiamine stores to be replenished due to its critical role as a co-factor for metabolic enzymes. Thiamine deficiency causes Wernicke’s encephalopathy (WE) and is most commonly seen in heavy drinkers with a poor diet. Classical signs of WE include:

a) Ataxia (failure of muscular co-ordination, irregular movement, tremor).

b) Confusion.
c) Ophthalmoplegia (nystagmus: paralysis of eyeball, or involuntary, rapid rhythmic movement). These are rarely all present (about 10% of cases).

WE is initially reversible but, if left untreated or with inadequate thiamine replenishment, can result in irreversible brain damage (Korsakoff’s syndrome: KS) in 84% of survivors and is associated with significant mortality (Death in up to 20%) (5).

The lack of controlled trials and different empirical practices means that different practitioners will prescribe different doses of thiamine and this can complicate treatment. Guidelines are available from the Royal College of Physicians (6).

4.5.3 Clinical Pharmacology

- Chlordiazepoxide (See benzodiazepine section 4) for general guidance

Absorption of chlordiazepoxide is almost complete following oral administration. It is extensively bound (96%) to plasma proteins. Reported values for elimination half-life range from 5 to 30 hours, but its main active metabolite desmethyldiazepam has a half-life of several days. Chlordiazepoxide passes into the cerebrospinal fluid (CSF) and breast milk and crosses the placenta. Unchanged drug and metabolites are excreted in the urine, mainly as conjugated metabolites (7).

- Thiamine

Small amounts of thiamine are well absorbed from the GI tract following oral administration, but the absorption of doses larger than about 5mg is limited. It is widely distributed to most body tissues, and appears in breast milk. Thiamine is not stored to any appreciable effect in the body and amounts in excess of the body’s requirements are excreted in the urine as unchanged thiamine or as metabolites (8).

4.5.4 Indications, Contra-Indications, Precautions and Side Effects

- Chlordiazepoxide (See benzodiazepine section (4) for general guidance)

- Thiamine
Adverse effects seldom occur via the oral route, however, hypersensitivity reactions have occurred following parenteral administration. These reactions have ranged in severity from very mild to, very rarely, fatal anaphylactic shock. The Committee of Safety in Medicine (CSM) advise that parenteral administration of B vitamins should be restricted to essential treatment, should be administered slowly (IV over 10 minutes) and facilities should be available for treating anaphylaxis (9). Parenteral treatment should only occur in an in-patient setting. IM administration is currently carried out in a community setting following the NHS Lanarkshire PGD guidance.

4.5.5 Aims of Prescribing In Alcohol Detoxification

a) To provide pharmacological cover for the relief of alcohol withdrawal symptoms during detoxification from alcohol.

b) To provide adequate and appropriate vitamin supplementation.

4.5.6 Limitations of Prescribing In Alcohol Detoxification

Current best practice informs us that in addition to pharmacological interventions treatment options should be delivered in the context of therapeutic working relationships between the patient and the named nurse/care coordinator. Therefore, no prescribing intervention should be undertaken without a Care Plan offering structured counselling, CBT, or other appropriate psychological or social intervention delivered either individually or in a group setting. The aim of offering this additional service is:

a) To develop alternative coping strategies

b) Maintenance of abstinence

c) Relapse prevention

d) Preparation for the introduction of controlled drinking, if appropriate, after an agreed period of abstinence.

4.5.7 Choosing Patients for a Detoxification Regime

An assessment of a patient's suitability for a community detoxification must be undertaken before prescribing takes place. This will be in conjunction with guidance from the specialist Consultant or GP. This assessment should take into account a variety of factors that will identify both the indicators of likely success and any risk factors (see inclusion and exclusion factors below). Preparatory work will be offered to the patient, either through group work, or structured counselling to fully prepare the patient for detoxification and to ensure they are aware of what is involved.
Patients will need to see their General Practitioner for a medical assessment as to their suitability for a detoxification. Blood tests will include; full blood
count (FBC), liver function test (LFT) and urea and electrolytes(U&E) Test. The General Practitioner will be kept informed of the proposed care plan.

**Assessment will include completion of:**

a) Comprehensive assessment forms  
b) Risk assessment  
c) CISS / SADQ assessment forms (appendix 15 a, b)  
d) Signature on consent to share care form. (Appendix 16)  

- Inclusion Criteria - Consideration for a Community Detoxification  
  a) Physical dependence on alcohol  
  b) Clear desire by the patient to stop drinking  
  c) Adequate home support/supervision available  
  d) Patient has previously shown responsibility with prescribed drugs  
  e) Previous absence of severe withdrawal symptoms, fits, Delirium Tremens (DTs), violence  
  f) No evidence of mental illness or severe ill health  
  g) SADQ score of 30 or under  

- Exclusion Factors - Consideration for In-patient Detoxification  
  If there is evidence of poor physical health including:  
  a) Dehydration  
  b) Cirrhosis of the liver  
  c) Severe malnutrition  
  d) Presence of severe acute infection especially pulmonary  
  e) Wernicke's encephalopathy (WE)  
  f) Presence of severe lung disease (Increased risk of benzodiazepine induced respiratory depression)
g) Diabetes

h) Cardiovascular problems

i) Convulsions

j) Other significant physical health problems

k) History of withdrawal seizures/delirium tremens (DT's)

l) Older patients

Also if there is evidence of acute mental health problems including:

a) History of mental health problems, including self-harm

b) Severe depression

c) Suicide risk

d) Confused state

e) Memory impairment (beyond that to be expected in dependent drinkers)

f) Hallucinations

Other factors that may be considered when assessing patients:

a) Is the patient living alone or is there a lack of supervision or daily observation (poor social support)

b) History of repeated drug misuse

c) Poor motivation and co-operation of the patient

d) History of violence

e) Unstable living conditions

f) Consider the needs of the family/affected others

g) SADQ score of over 30

h) History of failed community detoxification
4.5.8 Alcohol Withdrawal Effects

Patients admitting to over ten units of alcohol per day are likely to experience withdrawal symptoms. Although Delirium Tremens (DTs) are rare at consumption of less than 15 units per day in a person (male) of normal body build (10). A ready reckoner for calculating units is illustrated in appendix 17.

The Department of Health recommends the following guidelines for weekly alcohol consumption:

<table>
<thead>
<tr>
<th></th>
<th>Low Risk</th>
<th>Hazardous</th>
<th>Harmful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>14 units</td>
<td>15-30</td>
<td>35 +</td>
</tr>
<tr>
<td>Men</td>
<td>21 units</td>
<td>22-50</td>
<td>50 +</td>
</tr>
</tbody>
</table>

Note. For pregnant women either abstinence or no more than 1-2 units, once or twice weekly" although there is no established "safe" level in pregnancy. (*Source: Royal College of Psychiatrists 1986; Royal College of General Practitioners 1986; Royal College of Physicians 1987.)

In alcohol-dependent individuals, the central nervous system has adjusted to the constant inhibitory presence of alcohol in the body. When the blood alcohol concentration (BAC) is suddenly lowered in dependent drinkers the brain is left in a hyperactive and hyper excited state causing the alcohol withdrawal syndrome (AWS). This is not a uniform entity and varies significantly in clinical manifestations and severity, affecting about 40% of patients. Symptoms can range from mild insomnia to DT’s and convulsions.

The first symptoms and signs occur within hours of the last drink and peak within 24-48 hours. They include:

- Restlessness
- Tremor
- Sweating
- Anxiety
- Nausea
- Vomiting
- Loss of appetite
- Insomnia
- Tachycardia
- Systolic hypertension
- Generalised Seizures (rare and usually within 24 hours of cessation)

DTs present as confusion, disorientation, agitation, tachycardia, hypertension, fever, visual and auditory hallucinations and paranoid ideation. DT’s will develop in about 5% of cases with a mortality rate of 1-2% (11). If diagnosed the patient should be transferred to a general medical setting for treatment.

4.5.9 Dose Regimes

Detoxification should commence at the beginning of the week so that a patient’s response can be monitored and medication adjusted if appropriate. Starting detoxification mid-week or later results in patients being at highest risk of complications at the weekend when monitoring and input is limited.

The patient should be given information about the detoxification process and the expectations placed on them. Appropriate literature should be provided for both the patient and carer(s). The patient should be asked to read and sign the consent form/care plan for home detoxification (appendix 16). The patient will also be given information on the medication they will be prescribed, including side effects and contra-indications.

The patient should be asked and encouraged to plan ahead for the detoxification and post-detoxification period to maximise the benefits and outcome of the intervention. After care arrangements post detoxification should be clearly identified with the patient. Care plans should include patient participating in pre-detoxification work and relapse prevention post-detoxification work.

An individual care plan will be negotiated with the patient and copies will be given to the patient, patient’s GP and carer, if appropriate.

The named nurse/care coordinator, or appropriately trained worker, should visit the patient at their home on at least the first three days of the programme. Baseline observations should be taken of the patient prior to detoxification, including the pulse and blood pressure. This must be recorded in the patient’s records.

Patients should be breathalysed prior to, and during, detoxification. Most patients will breathalyse positive and can still safely be given chlordiazepoxide to start detoxification (see below). Patients should be breathalysed on each visit.

The drink drive limit of 0.35mg/l breath alcohol level (note: breathalyser may be calibrated to read blood alcohol level) can serve as a guide to assess how much
alcohol a patient has in their system.

This may aid clinical assessment to inform prescribing decisions:

- If a patient has a high reading and appears intoxicated, it is advisable to delay detoxification.

- Re-breathalyse them in one hour’s time to see if their alcohol level is reducing. If it is, start the detoxification, adjusting dose of chlordiazepoxide depending on their clinical state

- If a patient has a low reading and is showing signs of clinical withdrawal, chlordiazepoxide should be commenced immediately.

The named nurse/ care co-ordinator will visit on the first three days, visiting twice on day one (or once plus a phone call) then daily on days two and three. Blood pressure and pulse should be checked during the first three days. Changes on both systolic and diastolic pressures can reflect withdrawal severity. Changes from baseline of +/- 20mmHg systolic or +/- 20mmHg diastolic should prompt discussion with the medical team.

After day three, other members of the team may monitor the patient. The patient should be seen on day 4 and 5, unless they are managing well independently, when just a monitoring phone call will suffice.

Alcohol withdrawal severity varies widely and the amount of chlordiazepoxide required for symptom amelioration can also vary. There is no fixed, standardised dose for all patients, but a typical regimen for covering uncomplicated withdrawal is illustrated in table 9.1. It should be noted that a treatment regime of 5 to 7 days is usually adequate and longer treatment is rarely helpful or necessary. Additional titration using “when required” (prn) up to 20 mg a day to achieve complete symptom suppression in the first two days can also be used.

<table>
<thead>
<tr>
<th>Day</th>
<th>Dose</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>20 mg x 4</td>
</tr>
<tr>
<td>2</td>
<td>15 mg x 4</td>
</tr>
<tr>
<td>3</td>
<td>10 mg x 4</td>
</tr>
<tr>
<td>4</td>
<td>5 mg x 4</td>
</tr>
<tr>
<td>5</td>
<td>5 mg x 3</td>
</tr>
<tr>
<td>6</td>
<td>5 mg x 2</td>
</tr>
<tr>
<td>7</td>
<td>5 mg at night</td>
</tr>
</tbody>
</table>

**Table 9.1: Typical chlordiazepoxide reduction regime for alcohol detoxification**

- Thiamine

Patients undergoing alcohol detoxification in the community should receive an oral dose of thiamine of 200mg four times a day for 30 days then 300mg daily
for the following three months, or continued indefinitely if there is poor nutrition or still drinking. Following detoxification both medications could be
continued if there is evidence of cognitive impairment (thiamine 50mg qds) or poor diet (vitamin B co strong 30mg a day). Compliance is an important aspect to consider when initiating this regime. Also refer to NHS Lanarkshire PGD for IM Thiamine administration in a community setting.

4.5.10 Drug Interactions

- Chlordiazepoxide (See benzodiazepine section (4) for general guidance)
- Thiamine

No relevant drug interactions are listed for oral thiamine.

4.5.11 Alcohol Detoxification And Other Medical Conditions

a) Liver Disease: Patients with evidence of severe hepatic insufficiency (usually alcoholic cirrhosis) may require substantially lower doses of chlordiazepoxide. An alternative approach would be to prescribe a benzodiazepine with a shorter half-life, which does not rely on hepatic enzymes for their metabolism to reduce accumulation of the drug (e.g. lorazepam or oxazepam) (4). Specialist advice and guidance from the Hepatology Department should always be obtained prior to commencing detoxification in these cases.

b) Renal Disease: No special considerations are needed other than general monitoring of renal function following baseline assessment.

4.5.12 Special Groups

Please refer to pregnancy and breast-feeding section (11). Detoxification would generally only be recommended on an in-patient basis for patients who are pregnant.

4.5.13 Dispensing Arrangements

The patient may be given a week’s supply of medication at a time and will be advised as to when to take their medication. They will also be advised as to how to store the medication safely. On the daily visits the named nurse will undertake an assessment of the severity of alcohol withdrawals the patient is experiencing and, if required, will arrange extra medication (only up to 20mg a day in line with the PGD). If the withdrawal is not well controlled after the extra 20 mgs then medical advice will be obtained (see below)

The named nurse may advise the patient’s GP to arrange daily collection from community pharmacies in the area if there are concerns about medication storage and diversion.
4.5.14 Contingencies

In the event of the patient experiencing significant physical withdrawal symptoms, a medical review should be sought, to assess the suitability of continuing with the home/community detoxification, or a further plan will be discussed and agreed. In certain situations e.g. acute DT’s, or alcohol withdrawal seizures, an urgent medical assessment will be required and hospital admission may be necessary.

If the patient is not at home for a planned visit every effort should be made to contact them. However, if no contact can be made then the detoxification will be terminated, the patient will be made aware of this before detoxification is commenced. Contact with the patient will be sought as soon as possible to discuss a suitable medication regime.

If a patient consumes a significant amount of alcohol during a detoxification programme, as indicated by breath/alcohol reading, or self-admission, then the detoxification will also be terminated. The patient will be offered a review, and a further care plan will be discussed and agreed, incorporating a suitable medication regime. The patient should be informed of the risks associated with combined alcohol and benzodiazepine use.

If a patient expresses suicidal ideation or intent during the detoxification, the named nurse/care co-ordinator will discuss this with the medical team, and other team members, and the ongoing management of the patient may be reviewed. Consideration will be given to whether a formal risk assessment should be completed. In addition a decision will be made concerning the continuation or cessation of the detoxification.

4.5.15 Driving

See Section 1.

4.5.16 Symptomatic Pharmacotherapy

- Dehydration: Ensure adequate fluid intake in order to maintain hydration and electrolyte balance. Dehydration can lead to cardiac arrhythmia and death
- Pain: Paracetamol tablets (two tablets four times a day or prn)
- Nausea and Vomiting: Metoclopramide 10mg three times a day
- Diarrhoea: Loperamide capsules prn up to eight a day
- Skin Itching: Antihistamines.
4.5.17 Completion of Detoxification

On completion of the detoxification, the patient will be offered a follow up appointment with their named nurse/care co-ordinator, and attendance at the relapse prevention group.

The patient’s General Practitioner will be informed of the outcome.

A SADQ form should be completed. If considered appropriate, relapse prevention medication should be started as soon after detoxification as possible (12). Specific guidelines for the maintenance of abstinence through pharmacotherapy are available in section ten.
References


Recommended Reading


SECTION 4.6

Pharmacotherapy for the Maintenance of Abstinence in Alcohol Dependency (Summary)

- All pharmacotherapy should be used as an adjunct to psychosocial therapy.
- Acamprosate has been shown to reduce the amount and frequency of alcohol consumed compared to placebo by approximately 50%.
- Acamprosate is contra-indicated in pregnancy and breast-feeding.
- Acamprosate should be started with or soon after detoxification.
- Good practice indicates prescribing should take place for 6-12 months.
- Disulfiram has a weaker evidence base than acamprosate.
- Supervision should take place, where possible, with disulfiram to improve efficacy.
- Patients should always be made aware of the disulfiram-alcohol reaction (DAR) and be given literature to support this.
- Disulfiram is contra-indicated in pregnancy and breast-feeding.
- Disulfiram should only be initiated by a specialist Consultant with support from the alcohol & drug service.
- Naltrexone has been used in this field but it is NOT licensed in the UK for the maintenance of abstinence in alcohol dependence.

4.6.1 Background

The use of pharmacotherapies for the promotion and maintenance of abstinence should only be used as an adjunct to psychosocial interventions in the alcohol dependent patient. The three main treatments are acamprosate, disulfiram and naltrexone (not licensed) and it is these interventions that this policy will discuss. As with other forms of drug treatment, it is important to establish clear goals at this stage of treatment. The guidelines from the British Association of Psychopharmacology (1) and The Mendip / South Somerset Guidelines: Alcohol Misuse (2) and the Scottish Intercollegiate Guidelines (SIGN) (3) were used to develop this policy.
4.6.2 Acamprosate

a) Rationale for Use

A number of meta-analyses and systematic reviews of double blind, placebo-controlled trials have found acamprosate to be better than placebo (4). Rates of abstinence range from approximately 25% to 50% at 3, 6 and 12 months and are generally about twice that seen with placebo. Chick et al (5) established that acamprosate reduced the amount and frequency of alcohol consumed compared with placebo by approximately 50%.

b) Clinical Pharmacology

Acamprosate is believed to act by modulating disturbance in the gamma-aminobutyric acid/glutamate system associated with alcohol dependence, reducing the risk of relapse during the post withdrawal period. It is thought to have an action in suppressing the biochemical based craving which occurs in response to learned cues. (Berton 1998, Dahchour 1999, Littleton 1995; Naassila 1998, Schaffer 1998; Wilde and Wagstaff, 1997)

Acamprosate absorption across the gastrointestinal tract is moderate, slow and sustained and varies substantially from person to person. Food reduces the oral absorption of acamprosate. Steady state levels of acamprosate are achieved by the seventh day of dosing. Acamprosate is not protein bound. Oral absorption shows considerable variability and is usually less than 10% of the ingested drug in the first 24 hours. The drug is excreted in the urine and is not metabolised significantly. There is a linear relationship between creatinine clearance values and total apparent plasma clearance, renal clearance and plasma half-life of acamprosate.

c) Indications, Contra-indications and Precautions

Acamprosate is indicated for the maintenance of abstinence in alcohol dependence. Acamprosate has only been shown to be effective as an adjunct in the presence of psychosocial interventions.

It is contra-indicated in the following groups:
• With known hypersensitivity to the drug
• Pregnant or lactating
• With renal insufficiency (serum creatinine > 120mm/L)
• With severe hepatic failure (Childs-Pugh Classification C)

Acamprosate does not prevent the harmful effects of continuous alcohol use. Continued alcohol abuse negates the therapeutic benefit; therefore acamprosate treatment should only be initiated after weaning therapy, once the patient is abstinent from alcohol.

d) Side Effects

Mostly mild and transient; they include gastrointestinal (abdominal pain, diarrhoea,
nausea, vomiting), dermatological (bullous skin reactions, maculopapular rash, pruritus) (Lipan, 1995; Wilde 1998) and changes in libido
e) **Drug Interactions.**

No significant drug interactions are listed for acamprosate.

f) **Dose and Duration of Treatment**

The dose for acamprosate in Adults 18 – 65 years:

- 60 kg and over: 666mg (2 tablets) three times a day
- Less than 60 kg: 666mg at breakfast, 333mg (1 tablet) at midday and 333mg at night

The manufacturer’s recommendation is to start acamprosate as soon after detoxification as possible and maintain if the patient relapses (spc). Koob et al (6) suggest that acamprosate may be neuroprotective, which supports the principle that it should be started with or soon after detoxification. Where it appears to be effective, good practice suggests prescribing for 6 – 12 months (7).

There is no clear evidence to suggest which type of patient may benefit from acamprosate, but it has been suggested that a classical, primary type of alcohol-dependent patient appears more likely to benefit than one with a psychiatric or organic disorder or with social problems, or one that is an episodic drinker (4).

4.6.3 **Disulfiram**

a) **Rationale for Use**

Despite a long and widespread use in alcohol dependence treatment, there are few controlled trials with disulfiram. In a recent review disulfiram was reported to reduce the number of drinking days and reduce the quantity of alcohol consumed, but not increase abstinence (8). It was also noted that diversity in the subjects and methodologies used made it difficult to make comparisons and recommendations. Supervision of the dose is important in its efficacy and when prescribed with no supervision it is no better than basic support (8).

b) **Clinical Pharmacology**

The effect of Disulfiram is primarily due to irreversible inactivation of liver ALDH. In the absence of this enzyme, the metabolism of ethanol is blocked and the intracellular acetaldehyde concentration rises. The symptoms of the Disulfiram- alcohol reaction (DAR) are due partly to the high levels of acetaldehyde. The conversion of dopamine to noradrenaline is also inhibited and the depletion of noradrenaline in the heart and blood vessels allows acetaldehyde to act directly on these tissues to cause flushing, tachycardia and hypotension.
Following oral administration, absorption is variable; distribution is primarily to the kidney, pancreas, liver, intestines and fat. Disulfiram is rapidly metabolised to diethylthiocarbamic acid (DDC), is conjugated with glucuronic acid, oxidised to sulphate, methylated and decomposed to diethylamine and carbon disulphide. Excretion is primarily through the kidneys.

c) Indications, Contra-indications and Precautions

Disulfiram is indicated as an adjuvant in the treatment of carefully selected and co-operative patients with drinking problems. Its use must be accompanied by appropriate supportive treatment.

Disulfiram is contra-indicated in the following situations:

- Presence of cardiac failure
- Coronary artery disease
- Previous history of Cerebro-vascular accident
- Hypertension
- Severe personality disorder
- Suicidal risk or psychosis
- Pregnancy
- Breast-feeding

Caution should be exercised in renal failure, hepatic disease (bilirubin ≥ 25 micromol/l or transaminase 3 times normal), respiratory disease, diabetes mellitus and epilepsy.

Alcohol should not be consumed for at least 24 hours before starting disulfiram and not for a week after stopping. Patients and carers should be warned about the DAR and its unpredictable and occasionally severe nature. They should also be provided with the appropriate disulfiram information sheet (appendix 4i). Reactions can occur within 10 minutes and last several hours. Patients and carers should also be warned of the possible presence of alcohol in liquid medicines, remedies, tonics, foods and toiletries.

d) Side-effects

During initial treatment, drowsiness and fatigue may occur; nausea, vomiting, halitosis and reduction in libido have been reported. If side effects are marked the dosage may be reduced. Psychotic reactions, including depression, paranoia, schizophrenia and mania occur rarely in patients receiving Disulfiram. Allergic dermatitis, peripheral neuritis and hepatic cell damage have also been reported.
e) Drug Interactions
- Disulfiram inhibits the metabolism of theophylline, phenytoin and paraldehyde increasing the risk of toxicity
- Anxiolytics, hypnotics and antidepressants: there is an increased disulfiram reaction with alcohol reported with concomitant Amitriptyline. Disulfiram inhibits the metabolism of tricyclics and benzodiazepines (increased plasma concentration and sedative effect)
- Disulfiram enhances the anti-coagulant effect of coumarins
- Psychotic reaction has been reported with Metronidazole

f) Dose and duration of treatment

It is recommended that treatment with Disulfiram should be initiated only in a hospital or specialised clinic and by physicians experienced in its use.

On the first day of treatment, the patient should be given no more than 4 tablets of Disulfiram in one dose (800 mg). The next day the patient should take 3 tablets followed on the third day by 2 tablets and on the fourth and fifth days by 1 tablet. Subsequently, daily dosing should continue at 1 or half a tablet daily for as long as advised by the physician but no longer than six months without review.

The aversion therapy nature of Disulfiram treatment means it should be supervised to increase the likelihood that the medication is taken even at times of ambivalence. There is also evidence of better outcomes when consumption is supervised or witnessed, ideally in the context of a secure supportive relationship (Azrin 1982).

Patients likely to benefit most from disulfiram therapy are those who:

- Accept they have a drinking problem and are committed to treatment.
- Have no serious underlying psychiatric or medical conditions.
- Are aware of the consequence of consuming alcohol while on disulfiram therapy.
- Are willing to undergo adjunctive counselling as part of their overall treatment.
- Have a stable home environment
- Have a family history of problem use of alcohol.
- Have a spouse, close friend or professional colleague who can help supervise or witness their treatment and offer support.
4.6.4 **Naltrexone**

Naltrexone is not licensed in the UK for the maintenance of abstinence in alcohol dependence. It is used by some specialist services and has a supportive evidence base. It has been shown to be superior to placebo in the following outcomes: abstinence, relapse rates, time to first drink, reduction in number of drinking days, reduction in craving and improvement in GGT (9). However, a Cochrane review in 2003 concluded that 50mg of naltrexone was effective in the short-term treatment of alcohol dependence in improving drinking outcomes, but there was no evidence to support its use over acamprosate or disulfiram (10). Kranzler and Van Kirk (11) also conducted a meta-analysis comparing acamprosate and naltrexone and found no differences between the drugs on a number of different outcomes (% abstinent, % retention).

Naltrexone may be helpful in clients dependent on both alcohol and opiates (10), where the primary indication is to prevent relapse into opiates. However, due to its licensed indication, its lack of superior evidence compared to acamprosate and its cost cannot be recommended as a primary treatment for maintenance of abstinence in alcohol dependence.

For further information on naltrexone the reader is referred to the Advanced Prescribing Guideline.

**References**


3. Scottish Intercollegiate Guidelines Network (SIGN). The management of harmful drinking and alcohol dependence in primary care. 74; September 2003. (available at [www.sign.ac.uk](http://www.sign.ac.uk)).


SECTION 4.7

Prescribing in Pregnancy and Breast Feeding (Summary)

- Early engagement and retention of pregnant substance misusers is important for the outcome of both mother and baby.
- The treatment programme for pregnant substance misusers should be coordinated by, or have input from, a medical prescriber working in the field of substance misuse. Consider consultation with specialist midwives.
- Monitoring needs to be more frequent in pregnant substance misusers.
- Methadone Maintenance Treatment (MMT) has the most robust evidence base and results in improved maternal and foetal health.
- Buprenorphine should be used with caution in pregnancy due to the lack of evidence base (but more evidence is being presented and developed). Discussions with an experienced practitioner and establishing the risk: benefit ratio for treating should be established and discussed with the patient.
- Benzodiazepines are best avoided in pregnancy and breast feeding.
- Lofexidine and naltrexone should be used with caution in pregnancy and breast-feeding.
- Stimulants are best avoided in pregnancy and breast-feeding.
- Alcohol is best avoided in pregnancy and breast feeding, but drinking in moderation i.e. one or two units once or twice a week, has not been shown to harm the unborn baby. However, there is no definite “safe level” of drinking during pregnancy.
- If not immune, pregnant women should be offered a course of hepatitis B vaccination. Screening should also take place for other BBV’s. All babies should be routinely immunised against hepatitis B, regardless of the mother’s hepatitis B status.

4.7.1 Background

Substance misuse during pregnancy adversely affects outcomes both medically and socially and can result in potentially high-risk pregnancies. In many cases pregnant substance misusers may also present late to both antenatal and drug services. This late presentation can be multi-factorial in nature and can include:
- Lack of awareness of pregnancy due to menstrual disturbances and amenorrhoea.

- Lack of motivation.

- Difficulty in accessing and/or attending services.

- Perceived attitude of service providers.

- Feeling of guilt about the pregnancy.

To ensure the best outcome for the mother and baby it is important to engage and retain pregnant drug users in treatment. This will involve addressing these issues and will often involve a prescribing intervention.

The disadvantaged background of many pregnant women presenting along with polydrug use means it is not possible to study the direct effects of individual drugs on a pregnancy in a controlled manner. The lack of controlled clinical trials in this field due to the obvious ethical considerations also means it is difficult to develop firm policies. However, a wealth of clinical experience and observational studies have provided clinicians with guidance on how to develop treatment strategies for the pregnant substance misuser.

The treatment programme for the pregnant substance misuser should be co-ordinated by, or have input from, a GPwSI or Consultant working in the field of substance misuse.

4.7.2 Prescribing In Pregnancy

a) Opiate Substitution Prescribing

i. Rationale

Opiate use during pregnancy, particularly dependent heroin use, is associated with a wide range of problems, affecting both obstetric and neonatal health and pregnancy outcomes. These risks include reduction of foetal growth, resulting in low birth weight, prematurity and foetal and neonatal death (1). Opiates also increase the likelihood of antepartum haemorrhage (2).

ii. Treatment goals

The primary aim of management is stability rather than abstinence and objectives should be developed to address this. Stability is usually driven through maintenance treatment to achieve the following goals:

- Prevent withdrawal syndrome and toxic opioid levels with their associated risks to the foetus.

- Improve the health of patients.
• To facilitate an improvement in social functioning.
• Help reduce the spread of blood-borne communicable diseases associated with injecting opioid use.

Furthermore, provision of a daily dose of a substitute can facilitate critical antenatal care rather than insisting on abstinence and risking loss of contact provided there are no significant concerns for safety/ increase of dependent use. Engagement of the partner is an important aspect of enabling the pregnant woman to achieve progress at the earliest stage.

iii. Methadone Maintenance Treatment (MMT)

MMT has the most robust evidence base and results in improved maternal and foetal health (3). Generally, pregnant patients should be maintained on the dose that they are comfortable on and sufficient to get the positive benefits of MMT (4). Pregnant patients already maintained on methadone should be maintained on the same level. In the third trimester, an increase in dose may be needed to maintain pre-pregnancy blood levels due to increase in blood volume in pregnancy, increased liver metabolism and increased glomerular filtration rate. This should be judged on signs of withdrawal with small incremental increases introduced if necessary. Pregnant patients may also benefit from split dosing in the third trimester (4).

Neonatal Abstinence Syndrome (NAS) occurs when babies demonstrate withdrawal symptoms from substances on which they have become physically dependent due to in-utero exposure. It is characterised by irritability, poor feeding, hyper tonicity, vomiting, diarrhoea, tachypnoea, high-pitched crying and seizures. NAS is dependent on the methadone dose, with higher doses being associated with a higher likelihood of NAS (5). However, the dose used for MMT and any decision to increase the dose should be based on the mother’s withdrawal signs rather than the risk of NAS.

A review of methadone use in pregnancy found there was no evidence showing that methadone has adverse effects; indeed, birth weights were higher with methadone than heroin even though 90% on MMT continued other drug use (3).

The general principles of prescribing as documented in the methadone prescribing protocol should be followed, but monitoring needs to be more frequent with medical review every 6 weeks and named nurse review every 1-2 weeks.

iv. Methadone Reduction

In general, stability on a prescription is more important than reduction, but in some cases women strongly prefer to detoxify. Detoxification should be avoided in the first trimester (due to risk of miscarriage) and is preferred in the second trimester at a rate of no more than 2.5-5mg methadone weekly, fortnightly or monthly (6) or 1mg/day (5).
Detoxification can be used with caution in the third trimester (risk of foetal stress and premature labour), but only after informed consent has been obtained regarding the lack of clear guidance around this.

v. Buprenorphine

Pregnancy is not a contraindication under the UK MHRA license; rather it is a special warning. However, its use in pregnancy is becoming more widespread by clinicians in the field of substance misuse. A recent review by Johnson et al (2003) examined the use of buprenorphine in pregnancy (3). A range of buprenorphine doses were used (0.4mg-24mg) and there were low rates of prematurity, and NAS was similar or less than that following methadone exposure. The evidence is still far less robust than for methadone maintenance and therefore buprenorphine should not be considered as a first line treatment in pregnancy. It may be appropriate to consider continuing buprenorphine in patients doing well on established treatment, but this necessitates informed consent from the client and a wish not to transfer to methadone. Due to its partial agonist action, buprenorphine may interfere with opioid analgesia in labour.

b) Benzodiazepines

First-trimester exposure to benzodiazepines appears to be associated with an increased risk of oral clefts in newborns, although there is debate about the magnitude of this risk. Third-trimester use is commonly associated with neonatal difficulties (floppy baby syndrome) (7). The UK Committee on safety of medicines (CSM) has also recommended that women of child bearing potential should be advised to contact the physician regarding discontinuation of the drug if they intend to become, or suspect that they are, pregnant (8). Benzodiazepines are, therefore, best avoided in pregnancy and antenatal detoxification carried out using a controlled reduction schedule (appendix 11). Guidelines from the British Association of Psychopharmacology (BAP) suggest that detoxification should be avoided in the first trimester, preferred in the second and used with caution in the third. A decision to continue a patient on benzodiazepine or initiation of a reduction schedule should be discussed with a GPwSI or consultant working in the field of substance misuse.

c) Alcohol

Drinking seven or more drinks per week or more than five on one day has been linked to an increased risk of an alcohol-affected infant. Rates for foetal alcohol syndrome range from 0.05% to 0.3% of births and for alcohol-related birth defects by as much as 0.5% (9). The standard advice is to avoid all alcohol during pregnancy or at maximum no more than 1-2 units, once or twice weekly (Royal College of Psychiatrists 1986; Royal College of General Practitioners 1986; Royal College of Physicians 1987.)

Psychosocial interventions should be offered and be the mainstay of treatment.
Patients with symptomatic withdrawal should be offered benzodiazepine withdrawal, ideally as an inpatient. The amount of benzodiazepines given should be kept to a minimum to reduce potential teratogenicity.

Medication to sustain abstinence i.e. Acamprosate (Campral EC) and Disulfiram (Antabuse) should not be given in pregnancy or breast-feeding as they are both contra-indicated.

d) Lofexidine

The manufacturers recommend caution in the use of lofexidine in pregnancy. Data on file for lofexidine reveals four pregnant patients who have received the drug during pregnancy. Three patients delivered healthy babies at full term; the fourth patient gave birth to a premature baby with a foramen ovale, which resolved spontaneously and was unlikely to be as a result of lofexidine treatment (10). An assessment of risk-benefit should be undertaken before prescribing lofexidine to a pregnant patient.

e) Naltrexone

The manufacturers of naltrexone recommend caution in the use of naltrexone in pregnancy. Animal studies do not suggest a teratogenic effect and data on file for naltrexone reports nine deliveries of healthy babies for pregnant patients taking naltrexone (11). An assessment of risk-benefit should be undertaken before prescribing naltrexone to pregnant patients.

f) Stimulants e.g. Cocaine

There is quite a lot of information in this area, but most of it is of limited value and can be conflicting. However, there is a risk, especially compared to opiates in pregnancy, and sufficient reason for concern (12). Therefore the only recommendation that can be made is for the patient to stop. Substitution prescribing is not indicated.

4.7.3 Breast-Feeding

a) Methadone

Methadone does pass across to the breast milk but breast feeding should be encouraged because of the usual advantages it confers and the reduction in severity of any withdrawals the baby is experiencing.

b) Buprenorphine
Buprenorphine does pass into the mother’s breast milk but the British National Formulary (BNF 50) states the amount is too small to be harmful (13). However, the manufacturer lists breast-feeding as a contra-indication in the SPC.

In clinical practice, specialists in the field of substance misuse will encourage the mother to breastfeed to obtain the advantages conferred from breastfeeding to babies who are often preterm, of low birth weight and have an increased risk of sudden infant death. The presence of the drug in the breast milk will also reduce the risk or degree of NAS.

c) Benzodiazepines

Diazepam is excreted in breast milk with infant serum levels varying from undetectable to nearly 14% of the maternal serum levels (14). The CSM have also recommended that benzodiazepines should not be given to lactating mothers (15). A decision to continue a patient on benzodiazepine should only be made in conjunction with a GPwSI or Consultant working in the field of substance misuse. Any infant exposed to benzodiazepines in breast milk should be monitored for CNS depression and apnoea.

d) Alcohol

Occasional light drinking, such as one or two units once or twice a week, has not been shown to harm the breast-feeding baby. Moderate to heavy drinking is not advisable as it can interfere with the mother’s “let down” reflex and/or cause drowsiness in the infant, resulting in the baby taking in less milk. As the alcohol clears from a mother's blood, it clears from her milk at the rate of approximately one unit every two hours. Some mothers may choose to allow alcohol to clear from their system before breastfeeding or plan ahead and express milk for special occasions when they know they will be drinking alcohol.

e) Lofexidine

It is not known whether lofexidine is excreted in human milk but clonidine (a
structurally related drug) does in levels up to 6.8% of the original dose (10). Caution should therefore be exercised when it is prescribed to nursing mothers with an assessment of benefit-risk undertaken.

f) **Naltrexone**
One case study on file indicates the total relative infant dose estimated for a complete 24-hour dose interval was 1.06% for naltrexone i.e. 0.53mg based on a dose of 50mg a day. The 6-week old breastfed infant was healthy, achieved expected milestones and showed no adverse effects (11). Because of absence of other documented clinical experience Naltrexone should only be given to breast-feeding women when, in the judgement of the attending physician, the potential benefits outweigh the possible risks.

g) Stimulants e.g. cocaine

Mothers should be encouraged to stop stimulant use when breast-feeding. However, if use continues and the mother wishes to breastfeed then breastfeeding should be encouraged since the more vulnerable babies have more to gain from it. The mother should be warned about the danger of continued stimulant use including possible delay in cognitive development, risk of seizure or stroke, cerebral palsy, mental retardation, vision and hearing impairment, urinary tract abnormalities and autism (12).

4.7.4 Blood Borne Viruses (BBV)

All pregnant women need information about, and should be offered screening for, HIV and Hepatitis B and C. If not immune, a complete course of Hepatitis B vaccination can, and should, be given during pregnancy. All babies born to drug using women should be routinely immunised regardless of their mother’s HBV status. Women infected with HIV should be offered interventions to reduce vertical transmission and managed according to national guidelines. Breast-feeding will increase the risk of vertical transmission of HIV but there is no evidence that this is the case with HCV infection and it is irrelevant with HBV infection since immunisation of the neonate will prevent transmission in almost all cases (16).
References


SECTION 4.8

Supervised Consumption Policy (Summary)

- Supervised consumption should occur for a minimum of three months at the start of treatment unless there are exceptional circumstances.
- Supervised consumption should also be started if a patient restarts a prescription after a break, receives an increase in their dose or transfers to daily collection from three, two or once a week pick-up arrangements.
- Certain patient groups should remain in supervised consumption during their treatment programme, e.g. those on diazepam and opiate substitutes.

See Take Home Guideline within guidelines section
SECTION 4.9

Holiday Prescription Guidelines (Summary)

- Patients deserve the right to a holiday and this can be beneficial in the patient’s treatment programme.

- The patient should give at least seven days notice if a holiday prescription is required for UK travel and fourteen days for international travel.

- The prescribing of controlled drugs in larger than usual quantities should be subject to a risk assessment.

- Where possible the original arrangements already in place should be maintained by using a suitable chemist at the holiday location (if in mainland UK).

- If a bulk prescription is necessary it should not usually exceed two weeks supply.

- Named Nurse/Care coordinators should be aware that export licenses are required for certain drugs when prescribed above certain levels (appendix 21).

- Certain countries will also not allow the import of certain drugs into their country. The patient should check this requirement with the appropriate consulate (http://www.drugs.gov.uk/publication- search/drug-licences/embassy-list for contact details).

- It is good practice to obtain a letter of authority from the prescribing doctor detailing the medication the patient is carrying.

4.9.1 Policy Guidelines for the Issue of Prescriptions in Excess of Normal Dispensing Arrangements (Holiday Prescriptions)

It is accepted that patients deserve rights to holidays! As an agency we would support patients in going away from time to time. In fact, on occasions, we would see this as a part of the therapeutic process. In particular, contact with other family members can often be beneficial in helping patients to move away from a drug-based lifestyle. For the purposes of this document, all extended period prescriptions are
termed holiday prescriptions and the drugs worker referred to as the named nurse/care co-ordinator.

Whilst we support patients in going away from time to time, it is important in a situation involving the prescribing of controlled drugs that a detailed and adequate assessment of the risks associated with this prescription be carried out prior to a holiday prescription being issued. It is essential that all holiday prescriptions that do not fit into the requirements of this policy be discussed within a multi-disciplinary meeting. Many issues are raised when a holiday prescription is requested. Firstly, this will generally entail dispensing in amounts far greater than would normally be supplied. This is particularly relevant for people who are travelling overseas where dispensing may not be available. In addition, if the prescription is for a holiday as opposed to just a time away from the area for other reasons, it is accepted that risk taking behaviours may well increase during a holiday period particularly with use of alcohol and illicit drugs.

In order to process prescription changes, seven days' notice is usually required for all changes relating to travel within the United Kingdom. Fourteen days notice will be required if travel abroad is planned. The named nurse/care co-ordinator should establish with all holiday prescriptions that the patient has the ability to maintain safe storage of any medication throughout the travelling period and, indeed, at all other times.

A holiday prescription can be negotiated between the named nurse/care co-ordinator and Prescriber without recourse to the multi-disciplinary team if all the following criteria are met:

a) The patient has achieved demonstrable stability on the prescription; defined as regular attendance at appointments, compliance with the care plan, provision of drugs of abuse screens showing positive only for the medication being prescribed, non-problematic alcohol use and have been known to the named nurse/care-coordinator and/or prescriber for more than three months.

b) Holiday length does not exceed two weeks.

c) Dispensing arrangements are largely unchanged from normal i.e. where there is a dispensing pharmacy in the holiday destination prepared to dispense in line with the existing established regime.

d) There are no significant changes to any supervised consumption arrangements. There will be occasions when this arrangement is not available in pharmacies at their holiday destination. In this situation, as long as there are no significant risks identified by either the prescriber or the named nurse/care coordinator, the holiday prescription may be issued.
The patient’s named nurse/care coordinator should contact the local ADP (www.lanarkshireadp.org) to find a list of local pharmacies that are prepared to dispense for the patient and whether supervised consumption facilities are available. If the pharmacy is prepared to provide supervised consumption facilities and they are part of the local enhanced service in the area they can claim for providing this facility from NHS Lanarkshire for a period of up to two weeks. The named nurse/care co-ordinator is responsible for contacting the local pharmacy to arrange this.

If overseas travel is planned and local dispensing is not available, a holiday prescription can be authorised between the prescriber and the named nurse/care co-ordinator. This will only take place when all the above criteria are met and the prescriber and/or named nurse/care coordinator has known the patient for a minimum of six months. If the patient has had arrangements previously cleared by the multi-disciplinary team and the patient has demonstrated responsibility with the holiday prescription and has continued stability, then the supply can be approved directly by the prescriber.

In situations where the above criteria are not met, it is essential that the case be brought to caseload discussion with the multi-disciplinary team. The team will then make a detailed assessment of the potential risks and make a joint decision whether to support the request or to make suggestions for alternative acceptable holiday prescribing arrangements. A written decision will be placed in the patient’s notes.

Where patients have to travel for more than two weeks, detailed discussion will be required by the multi-disciplinary team taking into account recent history of stability, total dose of the prescription to be issued and circumstances that are relevant to the prescription. It would be in very rare circumstances that prescriptions in excess of two weeks would be issued and in no situations would a prescription in excess of four weeks ever be issued. This is because regular contact with patients is required in order to ensure safe prescribing. It should be noted that high volumes of dispensed medication present particular risks to the patient or a third party. An exception to this may be made if patient monitoring can be arranged through another appropriate agency at the holiday destination and the prescription collected from a local pharmacy in acceptable amounts.

If benzodiazepines are prescribed the high risk attached to the binge use of these drugs needs be taken into account in the assessment of risk. The decision to proceed without recourse to the multi disciplinary team discussion in this situation should only be made if the named nurse/care co-ordinator and the prescriber are confident that the patient will use the prescription appropriately and safely during the holiday period.

Rarely, changes to the prescription in terms of the medicine prescribed may need to be made. For instance, a change from diamorphine to methadone is required, in order that the patient can take their medication into a country where diamorphine is not permitted or available. In these situations the patient will need to be stabilised on the alternative prescription prior to the period of
travel. The period of titration and stabilisation should last a minimum of one week.

Named nurses/care coordinators should be familiar with Home Office procedures for the export of medication as stated within the Home Office Drug Misuse Dependency Guidelines (appendix 21). It must be remembered that a Home Office license or a letter of clarification from the prescribing doctor only permits exportation of controlled drugs from this country. There are many regional and national variations related to the importation of drugs to other countries. The Care co-ordinator should ensure that the patient has established what the appropriate regulations for the importation of drugs into their planned destinations are, and that they are aware of the implications should they not follow these regulations. This information can be obtained from the relevant department at the national embassy of the destination country (http://www.drugs.gov.uk/publication-search/drug-licences/embassy-list). The patient should be encouraged to establish what the regional regulations are, as it is usually a time consuming procedure and not the responsibility of the named nurse/care co-ordinator.

If a patient is leaving the country for more than the period covered by prescription, it is essential that they be subject to reassessment and drug screening on their return, and prior to the initiation of a new prescription.

The ACMD has advised against the prescribing of methadone tablets (see methadone section) but they may be considered for the very stable patient after a suitable risk assessment within the multi-disciplinary team.

Supply of large quantities of medication should also be supported with advice regarding storage in relation to child safety and the supply should be made in an appropriate child safety container.
Appendix 1

NHS Lanarkshire Alcohol and Drug Service

Patient Information Leaflet: Alcohol / Drugs and Driving

Alcohol and or drug misuse may lead to revocation of your driving licence.

As a driver you have a legal responsibility to inform the DVLA of any condition likely to affect your driving ability. Contact Drivers Medical Unit, Swansea SA99 1TU.

You are required to inform your insurance company of any condition which might affect your ability to drive.

If we are aware that you are under the influence of alcohol or drugs and have driven to your appointment, we may be obliged to inform the statutory authorities if you insist on driving.

Please speak to Alcohol and Drug Service staff if you have any queries in relation to driving.

Current Medical Standards of Fitness to Drive (DVLA March 2001).

Re: Alcohol

Alcohol misuse:"Persistent alcohol misuse confirmed by medical inquiry and/or evidence of otherwise unexplained abnormal blood markers, requires licence revocation or refusal until a minimum six month period of abstinence…"

Alcohol dependency: “. requires revocation or refusal until a one year period free from alcohol problems has been attained"

Re: Cannabis, Amphetamines, Ecstasy, LSD, Heroin, Cocaine, illicit Methadone” Benzodiazepines and other psychoactive substances

“Persistent use of, or dependency on these substances, confirmed by medical inquiry, will lead to licence refusal or revocation for a minimum one year period free of such use…. Independent medical assessment and urine screen arranged by DVLA may be required…"

“Applicants complying fully with a consultant supervised oral Methadone maintenance programme may be licensed subject to annual medical review…”
Appendix 2

NHS Lanarkshire 4 Way Agreement

This signed statement is drawn up to help you and your team develop an effective treatment plan. This involves you, your pharmacy, your named nurse, key worker and your prescribing doctor working together in a respectful way.

To avoid any confusion later the following points are raised:
- Each client is personally responsible for collecting their own "script" at a suitable time arranged with the pharmacy. It is best to come alone.
- If you miss or lose a dose, this may not be replaced later.
- Your "script" cannot be released to anyone else without authorisation from your named nurse or prescribing doctor.
- To help locum pharmacists you may be asked to supply a photo which will be kept safe and confidential at the pharmacy.
- It is the pharmacist's job to check if someone is fit to take medication.

Please remember that your "script" may be stopped if:

- You do not collect your treatment
- You behave unacceptably
- You don't attend appointments with your named nurse, key worker or doctor
- Your team decide it is not safe to let it continue

We hope this will never happen and look forward to working in a helpful way together as many have done already.

Any concerns you have about the service will be taken seriously and we welcome suggestions for improvements.

Summary

<table>
<thead>
<tr>
<th>Name</th>
<th>D.O.B</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td></td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Prescriber</td>
<td>Supervised</td>
<td>Y/N</td>
</tr>
<tr>
<td>Named Nurse</td>
<td>Special Instructions</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature: ........................................ Date: ....................

Witnessed By: ........................................ Date: .................

This information is confidential to the above parties
Appendix 3

**Opioid Conversion Chart**

Conversion table for various opioids to methadone equivalents (Drug Misuse and Dependence – Guidelines on Clinical Management 1999 page 121)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Methadone Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Heroin</td>
<td>Cannot accurately be estimated because street drugs vary in purity, though 1g of street heroin is roughly equivalent to 50-80mg of oral methadone. Titrate against withdrawal symptoms.</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Heroin</td>
<td>10mg tablet</td>
<td>20mg</td>
</tr>
<tr>
<td></td>
<td>30mg ampoule</td>
<td>60mg</td>
</tr>
<tr>
<td>Morphine</td>
<td>10mg ampoule</td>
<td>10mg</td>
</tr>
<tr>
<td>Dipipanone (diconal)</td>
<td>10mg tablet</td>
<td>4mg</td>
</tr>
<tr>
<td>Dihydrocodeine (DF 118)</td>
<td>30mg tablet</td>
<td>3mg</td>
</tr>
<tr>
<td>Pethidine</td>
<td>50mg tablet</td>
<td>5mg</td>
</tr>
<tr>
<td></td>
<td>50mg ampoule</td>
<td>5mg</td>
</tr>
<tr>
<td>Buprenorphine hydrochloride (Temgesic or Subutex)</td>
<td>200mcg</td>
<td>5mg</td>
</tr>
<tr>
<td></td>
<td>400mcg</td>
<td>10mg</td>
</tr>
<tr>
<td></td>
<td>300mcg</td>
<td>8mg</td>
</tr>
<tr>
<td></td>
<td>2mg and 8mg sublingual tablets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methadone equivalents are not available</td>
<td></td>
</tr>
<tr>
<td>Pentazocine</td>
<td>50mg capsule</td>
<td>4mg</td>
</tr>
<tr>
<td></td>
<td>25mg tablet</td>
<td>2mg</td>
</tr>
<tr>
<td>Codeine Linctus 100ml</td>
<td>300mg codeine phosphate</td>
<td>20mg</td>
</tr>
<tr>
<td>Codeine phosphate</td>
<td>15mg tablet</td>
<td>1mg</td>
</tr>
<tr>
<td></td>
<td>30mg tablet</td>
<td>2mg</td>
</tr>
<tr>
<td></td>
<td>60mg tablet</td>
<td>4mg</td>
</tr>
<tr>
<td>Gee’s Linctus 100ml</td>
<td>16mg anhydrous morphine</td>
<td>10mg</td>
</tr>
<tr>
<td>J Collis Brown 100ml</td>
<td>10mg extract of opium</td>
<td>10mg</td>
</tr>
</tbody>
</table>
Appendix 4

Clinical Opiate Withdrawal Scale (COWS)

For each item, write in the number that best describes the patient’s signs or symptom. Rate solely on the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

<table>
<thead>
<tr>
<th>Patient’s Name: ___________________________</th>
<th>Date: ________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Times: _______ _______ _______ _______ _______</td>
<td></td>
</tr>
</tbody>
</table>

| Resting Pulse Rate: (record beats per minute) Measured after patient is sitting or lying for one minute 0 pulse rate 80 or below |
|-------------------------------------------|-------------------|
| 1 pulse rate 81-100                       |                   |
| 2 pulse rate 101-120                      |                   |

| Sweating: over past ½ hour not accounted for by room temperature or patient activity. |
|-----------------------------------------|-------------------|
| 0 no report of chills or flushing       |                   |
| 1 subjective report of chills or flushing |                 |
| 2 flushed or observable moistness on face | 3 beads of sweat on brow |

| Restlessness Observation during assessment 0 able to sit still |
|---------------------------------------------------------------|-----------------|
| 1 reports difficulty sitting still, but is able to do so         |                 |
| 3 frequent shifting or extraneous movements of legs/arms |                 |

<table>
<thead>
<tr>
<th>Pupil size</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 pupils pinned or normal size for room light</td>
</tr>
<tr>
<td>1 pupils possibly larger than normal for room light 2 pupils moderately dilated</td>
</tr>
<tr>
<td>5 pupils so dilated that only the rim of the iris is visible</td>
</tr>
</tbody>
</table>

| Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 0 not present                                                                                                                 |                 |
| 1 mild diffuse discomfort                                                                                                      |                 |
| 2 patient reports severe diffuse aching of joints/ muscles                                                                       |                 |
### Runny nose or tearing

Not accounted for by cold symptoms or allergies

0 not present
1 nasal stuffiness or unusually moist eyes
2 nose running or

### GI Upset: over last ½ hour

0 no GI symptoms
1 stomach cramps

### Tremor

Observation of outstretched hands

0 No tremor
1 tremor can be felt, but not observed
2 slight tremor observable

### Yawning

Observation during assessment

0 no yawning
1 yawning once or twice during assessment
2 yawning three or more times during

### Anxiety or Irritability

0 none
1 patient reports increasing irritability or anxiousness
2 patient obviously irritable anxious

### Gooseflesh skin

0 skin is smooth
3 piloerrection of skin can be felt or hairs standing up on arms
5 prominent piloerrection

### Total scores

with observer’s initials

### Score:

5-12 = mild;
13-24 = moderate;
25-36 = moderately severe;
More than 36 = severe withdrawal
Appendix 5

Client Name: ..........................  Date: ..........................

The Short Opiate Withdrawal Scale (SOWS)

Please put a check mark (✓) in the appropriate box if you have suffered from any of the following conditions in the last 24 hours:

<table>
<thead>
<tr>
<th>Feeling Sick</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Stomach Cramps</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Muscle Spasms/Twitching</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Feelings of Coldness</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>---------------------------</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Heart Pounding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscular Tension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aches and Pains</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yawning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Runny Eyes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insomnia/Problems</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleeping</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Place completed procedure record and accompanying documents in the patient’s notes. (This questionnaire is published in Addictive Behaviours 1990, 15, 487-490. The development of a short opiate withdrawal scale by Michael Gossop)
Sleep is something we take for granted and yet we spend almost a third of our lives asleep. We hardly ever think about it unless we can’t get to sleep. Sleep is very beneficial, and without it our mental and physical capabilities are reduced. We use sleep to rest and to help our brain file away all the information and experiences we have accumulated over the past day.

During the evening

- Worry brought on by bad news or an unpleasant experience received during the day or a difficult task to cope with in the future can cause stress. This is not particularly helpful in dealing with the here and now and can upset sleep patterns leading to more stress. Try to break up this cycle by not dwelling on past events and concentrate on tasks that need to be accomplished now, rather than problems that might (or might not!) arise at some time in the future.

- Put the day to rest. Think it through. Tie up "loose ends" in your mind and plan ahead rather than worry about the future. A notebook may help.

- Take some light exercise early in the evening or afternoon. Avoid vigorous activity just before bedtime. Generally try to keep yourself fit.

- Wind down during the course of the evening. Do not do anything that is mentally demanding within 90 minutes of bedtime.

- Do not sleep or doze in the armchair. Keep your sleep for bedtime.

- Do not drink too much coffee or tea. The caffeine from these can persist for a long time and restricting these drinks after lunch can help. Soft drinks containing caffeine should also be avoided.

- Do not drink alcohol to aid your sleep; it usually upsets sleep. You also have to get up to use the toilet.

- Make sure your bed and bedroom are comfortable. On average, beds are not recommended to last for more than 10 years, so it may be worthwhile getting a new bed. Be sure to try several before buying and do not choose by colour or price. Make sure the room temperature is not too cold and not too warm.

- If necessary, sound proof the bedroom.
At bedtime

- Go to bed when you are "sleepy tired" and not before.
- Do not read or watch TV in bed. Keep these activities for another room. Reading or watching something stimulating just before bedtime is not a good idea.
- Set the alarm for the same time every day, seven days a week, at least until your sleep pattern settles down. You can develop a healthy sleep routine by keeping to set times for waking and sleeping.
- Put the light out when you get into bed.
- Let yourself relax and tell yourself that "sleep will come when it's ready". Enjoy relaxing even if you don't, at first, fall asleep.
- Do not try to fall asleep. Sleep is not something you can switch on deliberately but if you try to switch it on you can switch it off!

If you have problems getting to sleep

- Remember that sleep problems are quite common and they are not as damaging as you might think. Try not to get upset or frustrated.
- If you are awake in bed for more than 20 minutes then get up and go into another room.
- Do something relaxing for a while and don't worry about tomorrow. People usually cope quite well even after a sleepless night.
- Go back to bed when you feel "sleepy tired".
- Remember the tips from the section above and use them again.
- A good sleep pattern may take a number of weeks to establish. Be confident that you will achieve this in the end.
The Good Relaxation Guide

Dealing with physical tension

- Value times of relaxation. Think of them as essentials, not extras. Give relaxation some of your best time not just what's left over.

- Build relaxing things into your lifestyle every day and take your time. Don't rush. Don't try too hard.

- Learn a relaxation routine, but don't expect to learn without practice.

- There are many relaxation routines available, especially on audio tape. These help you to reduce muscle tension and to learn how to use your breathing to help you relax.

- Tension can show in many different ways eg aches, stiffness, heart racing, perspiration, stomach churning etc. Don't be worried about this.

- Keep fit. Physical exercise, such as a regular brisk walk or a swim, can help to relieve tension.

Dealing with worry

- Accept that worry can be normal and that it can be useful. Some people worry more than others, but everyone worries sometimes.

- Write down your concerns. Decide which ones are more important by rating each out of ten.

- Work out a plan of action for each problem.

- Share your worries. Your friends or your general practitioner can give you helpful advice.

- Doing crosswords, reading, taking up a hobby or an interest can all keep your mind active and positive. You can block out worrying thoughts by mentally repeating a comforting phrase.

- Practice enjoying quiet moments, e.g. sitting listening to relaxing music. Allow your mind to wander and try to picture yourself in pleasant, enjoyable situations.
Dealing with difficult situations

- Try to build up your confidence. Try not to avoid circumstances where you feel more anxious. A step by step approach is best to help you face things and places which make you feel tense. Regular practice will help you to overcome your anxiety.

- Make a written plan and decide how you are going to deal with difficult situations.

- Reward yourself for your successes. Tell others. We all need encouragement.

- Your symptoms may return as you face up to difficult situations. Keep trying and they should become less troublesome as your confidence grows.

- Everyone has good days and bad days. Expect to have more good days as time goes on.

- Try to put together a programme based on all of the elements in "The Good Relaxation Guide" that will meet the needs of your particular situation. Remember that expert guidance and advice is available if you need further help.
Appendix 8  
Christo Inventory for Substance Misuse Services

☐ 1998 George Christo Ph.D., Psych.D.

<table>
<thead>
<tr>
<th>Assessor</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Client</th>
<th>DOB</th>
<th>Intake assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drugs of choice</th>
<th>Follow-up assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Residence</th>
<th>(e.g., hostel, prison, residential treatment, home, hospital, NFA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service Provision</th>
<th>Name</th>
<th>Date in</th>
<th>Date out</th>
<th>Reason left</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

This form is for evaluation / clinical audit purposes only and is a rough indicator of professional impression of recent drug / alcohol related problems in the past month. Specific situations / behaviours are listed only as guiding examples and may not reflect the exact situations / behaviours of the client. (Please ring a number under each heading)

**Social functioning**

0... e.g., client has a stable place to live and supportive friends or relatives who are drug / alcohol free

1... e.g., client's living situation may not be stable......, or they may associate with drug users / heavy drinkers....... (Tick one)

2... e.g., living situation not stable, and they either claim to have no friends or their friends are drug users / heavy drinkers

**General health**

0... e.g., client has reported no significant health problems
Prescribing Policy for the management of Substance Misuse

1... moderate health problems e.g., teeth/sleep problems, occasional stomach pain, collapsed vein, asymptomatic Hep B / C / HIV

2... major problems e.g., extreme weight loss, jaundice, abscesses/infection coughing up blood, fever, overdoses, blackouts, seizures, significant memory loss, neurological damage, HIV symptoms

Sexual / injecting risk behaviour

0... e.g., client claims not to inject, or have unsafe sex (except in monogamous relationship with longstanding partner, spouse).

1... e.g., may admit to occasional "unsafe" sexual encounters, or suspected to be injecting but denies sharing injecting equipment.

2... e.g., client may admit to regular "unsafe" sexual encounters, or has recently been injecting and sharing injecting equipment.

Psychological

0... e.g., client appears well adjusted and relatively satisfied with the way their life is going.

1... e.g., client may have low self-esteem, general anxiety, poor sleep, may be unhappy or dissatisfied with their lot.

2... client has a neurotic disorder e.g., panic attacks, phobias, OCD, bulimia, recently attempted or seriously considered suicide, self-harm, overdose or may be clinically depressed. Or client may have psychotic disorders, paranoia (e.g., everybody is plotting against them), deluded beliefs or hallucinations (e.g. hearing voices).

Occupation

0... client is in full time occupation e.g., homemaker, parent, employed, or student.

1... e.g., client has some part time parenting, occupation or voluntary work.

2... e.g., client is largely unoccupied with any socially acceptable pastime.

Criminal involvement

0... e.g., no criminal involvement (apart from possible possession of illicit drugs for personal use)

1... e.g., client suspected of irregular criminal involvement, perhaps petty fraud, petty theft, drunk driving, small scale dealing.

2... e.g., suspected of regular criminal involvement, or breaking and entering, car theft, robbery, violence, assault.
Prescribing Policy for the management of Substance Misuse

Drug/alcohol use

0... e.g., no recent drug / alcohol use.

1... e.g., client suspected of periodic drug / alcohol use, or else may be socially using drugs that are not considered a problem, or may be on prescribed drugs but not supplementing from other sources.

2... e.g., client suspected of bingeing or regular drug / alcohol use.

Ongoing support

0... e.g., regular attendance of AA / NA, drug free drop in centre, day centre, counselling, or treatment aftercare.

1... e.g., patchy attendance i.e., less than once a week contact with at least one of the above.

2... e.g., client not known to be using any type of structured support.

Compliance

0... e.g., attends all appointments and meetings on time, follows suggestions, or complies with treatment requirements.

1... e.g., not very reliable, or may have been reported as having an "attitude" problem or other difficulty with staff.

2... e.g., chaotic, may have left treatment against staff advice or been ejected for non-compliance e.g. drug use, attitude problem.

Working Relationship

0... relatively easy going e.g., interviews easily, not time consuming or stressful to work with.

1... moderately challenging e.g., a bit demanding or time consuming, but not excessively so.

2... quite challenging e.g., very demanding, hard work, time consuming, emotionally draining or stressful to see.
Prescribing Policy for the management of Substance Misuse

CISS Total Score =

Tips on interpreting items

All injectors score at least 1 on ‘sexual / injecting risk’. Some alcohol users when disinhibited have been known to have unsafe sex with casual partners.

Child care is an ‘occupation’ (you decide if full or part time).

Irregular petty crime (e.g., shoplifting) scores 1 on 'criminal involvement' unless it occurs on a regular basis (e.g., 2+ times a week), in which case it scores 2. Any instance of a more serious crime (e.g., violence) scores 2 regardless.

All methadone or benzodiazepine prescribed (scripted) clients score at least 1 on ‘drug use’, score 2 if using other drugs on top. Only drug free clients score 0.

Alcohol users who regularly binge still score 2 on ‘drug use’ even if they do not drink daily.

Prescribed medication drugs like SSRI’s or neuroleptics need not be classified as ‘drug use’. Prescribed drugs with potential for abuse; like methadone, benzodiazepines or dextedrine, are classified as drug use.

Clinic attendance classifies as ‘ongoing support’. All clients should score 1 or less, unless they were assessed at intake for the month before coming to your clinic.

‘Working relationships’ for clients with a lot of external professional involvement or issues (e.g., lawyers or child care & Social Services, reports that need writing) are unusually time consuming. They score 2 even if the client is not stressful to see.

1998 George Christo PhD, PsychD.
Severity of Alcohol Dependence Questionnaire Form

Name:

Sex:  M / F  DOB:  Age:

Have you drunk any alcohol in the past six months?  YES / NO

If YES, please answer the following questions by ticking the most appropriate response.

**SECTION A – ICQ**

<table>
<thead>
<tr>
<th></th>
<th>Never/Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Nearly Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>After having just one or two drinks, I felt like having a few more</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>After having two or three drinks, I could stop drinking if I had other things to do</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>When I started drinking alcohol, I found it hard to stop until I was fairly drunk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>When I went drinking, I planned to have at least six drinks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>When I went drinking, I planned to have no more than two or three drinks</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SECTION B – SADQ Form C**

<table>
<thead>
<tr>
<th></th>
<th>Never/Almost never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Nearly always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The day after drinking alcohol, I woke up feeling sweaty</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>The day after drinking alcohol, my hands shook first thing in the morning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Prescribing Policy for the management of Substance Misuse

<table>
<thead>
<tr>
<th></th>
<th>Never/Almost never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Nearly always</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>The day after drinking alcohol, I woke up absolutely drenched in sweat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>The day after drinking alcohol, my whole body shook violently first thing in the morning if I didn’t have a drink</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>The day after drinking alcohol, I dread waking up in the morning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>The day after drinking alcohol, I was frightened of meeting people first thing in the morning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>The day after drinking alcohol, I felt at the edge of despair when I awoke</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>The day after drinking alcohol, I felt very frightened when I awoke</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>The day after drinking alcohol, I liked to have a morning drink</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>The day after drinking alcohol, in the morning I always gulped my first few alcoholic drinks down as quickly as possible</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>The day after drinking alcohol, I drank more alcohol in the morning to get rid of the shakes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>The day after drinking alcohol, I had a very strong craving for an alcoholic drink when I awoke</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I drank more than a quarter of a bottle of spirits in a day (or 1 bottle of wine or 7 middies of beer)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Prescribing Policy for the management of Substance Misuse

<table>
<thead>
<tr>
<th></th>
<th>Never/Almost never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Nearly always</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>I drank more than half a bottle of spirits in a day (or 2 bottles of wine or 15 middies of beer)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>I drank more than one bottle of spirits per day (or 4 bottles of wine or 30 middies of beer)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>I drank more than two bottles of spirits per day (or 8 bottles of wine or 60 middies of beer)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION C – SADQ Form C  Imagine the following situation:

1. You have hardly drunk any alcohol for a few weeks.
2. You then drink very heavily for two days.

How would you feel the morning after those two days of heavy drinking?

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I would start to sweat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>My hands would shake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>My body would shake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>I would be craving for a drink</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Scoring:

Items 1,3 and 4 of the ICQ (Section A) is scored on a 4 point scale ranging from 0 (never or almost never) to 3 (nearly always). Items 2 and 5 are scored in reverse with a score of 0 (nearly always) to a score of 3 (never or almost never).

The 20 items of the SADQ are all scored as follows:

0 = never or almost never; not at all
1 = sometimes; slightly
2 = often; moderately
3 = nearly always; quite a lot

Scores from 1 – 20 can be considered indicative of mild alcohol dependence

Scores from 21 – 40 can be considered indicative of moderate alcohol dependence
Scores of over 40 indicate severe alcohol dependence
Consent Form for Alcohol Home Detoxification

Client Name:

Please sign and date this sheet as a statement that you wish to undergo detoxification at home and will agree to the following conditions:

1. That you will not take alcohol during the agreed period of detoxification and will agree to regular examinations by the treatment team. They will visit your home as arranged to supervise detoxification and check your medical condition.

2. You agree to use an alcohol test meter when required by staff.

3. You agree to your GP taking blood and liver function tests now and also in two months time.

4. You will keep your case notes safely for the use of yourself and the treatment team.

5. Should you resume drinking, community detoxification will be discontinued and you will allow the treatment team to retain any remaining medication.

6. The medication used to facilitate your detoxification has been discussed with you.

Signed ........................................ Date.........................

Relative/Carer:

Please sign below if you agree to the following conditions of this home detoxification:

1. I have read and understood the information provided about alcohol withdrawal.

2. I am willing to take responsibility for the medication prescribed by the doctor / prescriber.

3. Should any drinking take place I will return the medication to the doctor/prescriber or the treatment team.

4. I will keep safe the daily record of medication.

Signed................................. Date.........................
I ……………………………………………………… [the PATIENT] agree that in order to abstain from alcohol, I will take Disulfiram as prescribed by my Doctor.

If necessary, the tablets may be dissolved in water and swallowed by me in the presence of a sponsor. I understand that side-effects are few and rare, but if any should occur, I will not stop taking the tablets unless absolutely necessary, and will instead contact the Addiction Team.

I will take Disulfiram continually from the agreement date for one year, and will then seek advice from the Addiction Team as to whether to continue this medication, or not.

I understand that taking any form of alcohol, whilst taking Disulfiram, can result in immediate and severe illness, and that this illness may be most severe in those with pre-existing heart, circulatory, lung, and blood pressure problems. Death can rarely occur. If female, I understand that I need to take precautions against pregnancy whilst I am taking Disulfiram.

I can confirm that I have read and understood any written information provided, as has any proposed sponsor. I agree to carry a Disulfiram warning card with me at all times, in case of an accident.

I agree that should I default in taking Disulfiram, without medical agreement, this does imply that I may wish to continue drinking, regardless of the consequences. I understand that a relapse to alcohol use (or other unsafe practices during treatment) may result in discharge from the “protective medication” clinic, and discontinuation of the Disulfiram prescription.

Signed [Patient]: …………………………………………………………….
Signed [Sponsor]: .................................................................
Signed [Staff Member]: ............................................................
Date: ..................................................................................

(Review date June 2015)
Appendix 12
Home office rules for the export of drugs

If you are taking controlled drugs abroad there are rules set out by the Home Office available on the internet at

http://drugs.homeoffice.gov.uk/drugs-laws/licensing/personal/

These are updated regularly and if you have a patient who falls into this criteria, you should refer to the above website for the most up to date regulations.
## Appendix 13
### Guideline list

Current list of guidelines for use in NHS Lanarkshire

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Version</th>
<th>Date</th>
<th>Review date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quick reference prescribing</td>
<td>2.0</td>
<td>August 2013</td>
<td>August 2015</td>
</tr>
<tr>
<td>Excess Consumption</td>
<td>2.0</td>
<td>February 2015</td>
<td>February 2017</td>
</tr>
<tr>
<td>Missed Doses</td>
<td>2.0</td>
<td>February 2015</td>
<td>February 2017</td>
</tr>
<tr>
<td>Take Home</td>
<td>1.0</td>
<td>November 2013</td>
<td>November 2015</td>
</tr>
<tr>
<td>Benzodiazepine</td>
<td>3.0</td>
<td>February 2015</td>
<td>February 2017</td>
</tr>
</tbody>
</table>
Guideline for patients who have consumed more than prescribed dose

As all substitute medication has the potential to cause the serious complications of overdose if more than the regular prescribed dose is consumed, this guideline sets out to establish a clear pathway to be followed in terms of dose and frequency of collection. Ultimately, response should always be determined by professional judgement.

Where excess consumed

Provide overdose awareness advice
(include warnings on the consumption of other medication/drugs, particularly benzodiazepines and alcohol, that may depress respiration)
Symptoms can be prolonged AND delayed - client should be observed by a responsible person for at least 6 hours after ingestion.
Present at A&E if becoming very sedated or breathing slows
If un-rousable or the patient starts snoring heavily, seek urgent medical assistance. Administer naloxone if available
Consider altering the dose for the next day (as below)

If 50% or more of the normal prescribed dose taken

Cancel prescription at pharmacy
No dose for next 24 hours
Script prepared for recommencing treatment
Dose for second day at 50% usual dose
Return to 100% usual dose on third day
Decide on frequency of supervision

Decision on frequency of collection will depend on the source of the error / consumption and the following is recommended:

Source of error

Pharmacy error
continue with previous dispensing / supervision frequency

Patient attempting to get extra supply
return to 6 ddus

Remember other factors may need to be considered that can affect collection frequency such as child care, employment and education.
Prescribing Policy for the management of Substance Misuse

**Prescribing guideline for missed opiate substitution doses**

The policy is different depending on the opiate substitute prescribed due to the different actions, reduction in tolerance and risks of overdose of each preparation.

The reason for the missed doses should be established. Generally, if for hospital or custodial reasons, supply will have been provided in the interim period.

The presentation of the patient and possible examination by a medical prescriber should be taken into consideration, as should the reason for the missed doses and any substances that may have been taken in the interim.

**Methadone**

Due to the higher risk of respiratory depression the approach is more cautious.

Patients who have missed two or more doses (i.e. appearing on the third day or later) and are attending the pharmacy either intoxicated or with any other worrying presentation should be examined before treatment is issued at an appropriate level. If there are no concerns over intoxication or presentation, the pharmacist should call the case worker to discuss and confirm the dose is to be supplied.

Generally if a patient has missed 3 doses – either 50% of the normal daily dose should be prescribed or recommence at 30ml. The patient will need to return to the team for a consultation with worker/prescriber and a new prescription issued. Remember to cancel existing prescription at pharmacy to prevent 2 prescriptions in circulation.

If 4 doses have been missed treatment should be recommenced at 30ml. The patient will need to return to the team for a consultation with worker/prescriber and a new prescription issued. Remember to cancel existing prescription at pharmacy to prevent 2 prescriptions in circulation.

If more than 4 days are missed, treatment may be restarted following a medical assessment unless the patient has been in police custody/prison or hospital and doses have been maintained in the interim period. The assessment can be done by a nurse, but authorisation to restart treatment must be given by a doctor after discussion with the nurse.

**Buprenorphine (Suboxone or Subutex)**

As there is less respiratory depression associated with buprenorphine, a higher dose can be given even after a longer period of missed doses. It is important that if a patient has missed more than 3 doses they must be in withdrawal before recommencing treatment to avoid precipitated withdrawal (use SOWS).
Prescribing Policy for the management of Substance Misuse

Patients who have missed three or more doses (i.e. appearing on the fourth day or later) and are attending the pharmacy either intoxicated or with any other worrying presentation should be examined before treatment is issued at an appropriate level. If there are no concerns over intoxication or presentation, the pharmacist should call the case worker to discuss and confirm the dose to be supplied. This is mainly to prevent precipitated withdrawal on continuing treatment.

Prescribing guideline for missed opiate substitution doses

The guideline is different depending on the opiate substitute prescribed due to the different actions, reduction in tolerance and risks of overdose of each preparation.

The use of a formal review should be considered if necessary, and if appropriate this process should be followed.

The reason for the missed doses should be established, generally if for hospital or custodial reasons supply will have been provided in the interim period.

The presentation of the patient and possible examination by a medical prescriber should be taken into consideration, as should the reason for the missed doses and any substances that may have been taken in the interim.

Methadone

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Buprenorphine (Suboxone or Subutex)

As there is less respiratory depression associated with buprenorphine, a higher dose can be given even after a longer period of missed doses. It is important that if a patient has missed more than 3 doses they must be in withdrawal before recommencing treatment to avoid precipitated withdrawal (use the Short Opioid Withdrawal Scale (SOWS) assessment).

Patients who have missed three consecutive doses (i.e. appearing on the fourth day) and are attending the pharmacy either intoxicated or worrying presentation should be examined before treatment is issued at an appropriate level. If there are no concerns over intoxication or presentation, the pharmacist should call the case worker to discuss and confirm the dose is to be supplied. This is mainly to prevent precipitated withdrawal on continuing treatment.

If 4 or more doses have been missed, patient should be examined before allowing treatment to continue. If continuing, reduce dose to 50% of usual dose or 8mg, and titrate to normal dose. The patient will need to return to the team for a consultation with worker / prescriber and a new prescription issued. Remember to cancel existing prescription at pharmacy to prevent 2 prescriptions in circulation.

If more than 7 days are missed, treatment should be restarted following a medical assessment unless the patient has been in police custody/ prison or hospital and doses have been maintained in the interim period. The assessment can be done by a nurse, but authorisation to restart treatment must be given by a doctor after discussion with the nurse.

N.B. This document is a guideline and any deviations from the suggested practice should be fully documented in patient notes.
Guidance for increased take home doses for patients receiving Opioid Substitution Therapy (OST).

Dispensing and supervision regimens are critical to the success of a substitute prescribing programme.
The use of various regimens should be closely audited by each part of the organisation.
This is to be part of the medical review.
Although there is some room for differences in practice this must be clearly documented in
the patient notes and follow local guidance.
The guidance has been agreed with the Clinical Leadership Group (CLG) and clinical
governance groups.
Patients should agree and sign the “Agreement for Take Home Medication” (Appendix A) and
be given a copy to take home and a copy retained in the patients notes.
Patients who are going on holiday or are incapacitated and unable to collect their medication
need to sign the “Increased takeaway agreement for OST” (Appendix B) and be given a copy
to take home and a copy retained in the patients notes.

Advantages of a “take away” policy

- National policy favours flexible dispensing.
- Reduces dependence on daily pharmacy contact.
- Provides incentive to stabilise drug use
- Normalises lifestyle, less stigmatising.
- Reduces barriers to moving on towards recovery
- Part of the Recovery Strategy.
- Reduces cost to NHS.
- Motivation to increase take-home doses for patients doing well
- Increased patient responsibility

Risks / disadvantages of a “take away” policy

- Loss of stability not being identified quickly
- Potential increase in risk of overdose
- Diversion of substitution therapy (including dealing), and the creation of a “grey market” in substitution therapies.
- Risks to family members (particularly children) associated with storage of medication at home.
- Conflict and anger if existing “takeaway” privileges have to be reduced or withdrawn.
- Cost and inconvenience of increased urinalysis and its perception by the client as
demeaning or punitive.

General Principles governing “take away” arrangements

1. Decision on dispensing regimen is a team decision: - client, carer (if appropriate),
   prescriber, social worker (if relevant) and worker should all be involved. This protects any one
   individual. However the final decision (and responsibility) rests with the prescriber.

2. Clients must sign a formal written “take away” agreement with prescribers and
workers. (this needs reviewed too and signed by all on increased take home)

3. The only strength of methadone to be supplied as “take away” is 1mg/ml

4. For clients on a “takeaway” regime, frequency of urine screening should be at least twice annually.

5. Reasons for allowing take away doses should be clearly documented in the client’s case notes.

6. Clients receiving “take away” OST may have supervised consumption of their dose on the day of collection, at the agreed and current dispensing frequency as determined by the prescriber / key worker.

7. Clients should normally have at least three months on each dosing schedule before moving to a more relaxed schedule. If progression is more rapid, the clinical reason for this should be clearly documented in the case notes. Normally, progression should be:
   i. 5 days per week (the unsupervised days must not be 2 consecutive days)
   ii. alternate days
   iii. twice weekly
   iv. weekly

8. Arrangements should be in place to distribute the dispensing load evenly over the week, to avoid clustering of clients in pharmacies on particular days. It is hoped that regular liaison with pharmacies will enable addiction staff to stagger dispensing days accordingly (there will of course be exceptions due to some clients’ personal circumstances but this can be accommodated).

9. There should be clear pathways for communication with the pharmacies. Pharmacies should be provided with written information about prescriber, worker and contact details.

10. If a client is found to be unable to adhere to their “takeaway” agreement due to any of the factors listed above, or if there is reasonable suspicion of treatment diversion, a prompt review of prescribing arrangements will take place (including the decision to continue prescribing). This will be a multidisciplinary review and will include the prescriber, who is responsible for the final decision.

Indications to consider commencing “take away” arrangements

Clinical judgement should be used and recorded in patient notes.

The following are recommended:

• Stable on current dose for at least 12 weeks
• At least two clean urinalysis reports available in last 12 weeks.
• No problem use of alcohol
• No persistent illicit drug use (excluding Cannabis)
• Safe medicine storage available and utilised.
• Plan agreed by signing prescriber.
• If Methadone, must be prescribed as a concentration of 1mg/ml only

The following should weigh in favour of granting “takeaway” privileges

• Highly motivated to move on to higher treatment goals.
• Working or attending training/education.
• Genuine practical or physical problems with daily attendance at pharmacy.
• Responsible person (for example, non drug using parent or partner) willing and able to supervise doses.
• If opiate dependent partner is ready for similar regimen.

Reasons to review / reduce “take away” arrangements:

• Suspicion of diversion
• Reduction of stability: in terms of any of the following:
  Illicit drug use (including use of Benzodiazepines)
  Notification of a non-fatal overdose
  Homelessness; resulting in unstable lifestyle.
  Relationship instability (especially if a drug using partner relapses).
  Serious forensic issues.
  Deteriorating mental or physical health.
  Poor relationship with pharmacy / services.
• Child safety fears relating to safe storage
• Problem drinking
• Dose increase required
• Prescriber/worker concern.

Appendix A
Agreement on take home Opioid Substitution Therapy

Client Name______________________________________________________

Key worker_______________________________________________________

Proposed review date_______________________________________________

Dispensing days____________________________________________________

Since you have been on your medication, the arrangement has been for your medication to be dispensed on a daily basis except Sundays, to be taken in the pharmacy under supervision. This has been to help you control your dosage and change your routine and to help staff monitor your progress and motivation.

As a result of the progress you have made in stabilising your drug use and lifestyle, a decision has been made to allow you to have take home medication as discussed with your key worker. This is a further step along the way to full sustained recovery.

To make this change to your programme, you are required to enter into this signed agreement. If you are willing to keep to the conditions that follow, your new dispensing arrangements can begin. If you are unclear about the reasons for any of the conditions below, your key worker will explain them.

Agreement
1. I will not make my medication available to anyone other than myself.
2. Any lost, spilled or stolen doses may not be replaced.
3. I am fully aware that my medication must be stored safely and if possible in a locked cupboard.
4. I will discuss any changes in my drug or alcohol use with my key worker.
5. I agree to undergo urine testing when requested by my key worker/available worker (this may happen more frequently than you are used to).
6. If drug test detect benzodiazepines (Valium) then your medication will return to daily supervision. This includes prescribed benzodiazepines.
7. If drug tests detect ongoing opiate use then supervision will increase.
8. If key worker has concerns regards alcohol use then supervision will increase.
9. Persistent non-attendance for appointments and/or pharmacy will result in supervision increase (even if drug screens are clear).
10. Concerns regards mental/physical health/ or childcare will result in increased supervision.
11. Concerns regards changes in living arrangements may result in increased supervision.
12. I understand that this agreement will be reviewed on an ongoing basis.

Client signature___________________________________________________

Key worker signature_______________________________________________

Date: ________________

Appendix B

Increased takeaway agreement for Opioid Substitution Therapy (OST) to be supervised by significant other for holiday or period of incapacity.

(PAGE 1 OF 2)

Client name: ______________________________________

Dates of holiday / period of incapacity: ________________________________

Name of nominated person OST will be dispensed to and will be responsible for safe storage/daily dispense/supervision to the client: ________________________________

Date of Agreement: _____________________________________________

In order to authorise the above increased takeaway of OST as discussed with your key worker, we require you (the client) and the above nominated person to enter into this signed agreement to guarantee your side of the bargain by adhering to the terms at all times.

Agreement terms (nominated person)

1. I agree to ensure that the OST being dispensed to me will not be made available to anyone other than the client named above.
2. I agree to take full responsibility for ensuring that the OST dispensed to me will be kept out of reach of children and in a secure lockable box at all times that only I will have access to.
3. I agree to supervise each daily dose given to the above client to ensure it is consumed fully as prescribed.
4. I understand that any lost, spilled or stolen doses will not be replaced under any circumstances.
5. I confirm that “tolerance” has been explained to me by the key worker and been
informed that if, for any reason, the above named client misses three (3) or more doses in succession, I will withhold any further dispensing of OST doses and contact the key worker immediately to inform them that this has occurred, in order to receive appropriate advice.

6. I agree to contact the key worker at the earliest opportunity if I have any concerns and/or need any advice.

Print Name: ____________________________________________________
Signature: _____________________________________________________
Date: __________________________________________________________

(PAGE 2 OF 2)

Agreement terms (client)

1. I understand that the takeaway OST doses outlined above has been agreed purely on the basis that they are dispensed directly to the above nominated person.
2. I understand that the OST will be in the sole ownership/possession of the above named person who has agreed to store it safely and securely and dispense the prescribed daily dose to me.
3. I will adhere to each daily dose being dispensed to me under the supervision of the above named person just as it would have been at the pharmacy.
4. I understand that if, for any reason I miss three (3) or more daily doses of OST the above named person will withhold any further doses and will notify my key worker immediately to seek appropriate advice.
5. I agree that my key worker has advised me of overdose risks and I have knowledge and understanding of the various circumstances that can put me at increased risk of overdose. As part of this agreement I promise to minimise these risks at all times.

Print Name: ________________________________________________________
Signature: __________________________________________________________
Date: ______________________________________________________________

Key worker Signature: ______________________________________________
Date: ______________________________________________________________
Mission Statement: Benzodiazepines are increasingly present in the post mortem samples from individuals who have deceased, due to drug related reasons. It is the policy of NHS Lanarkshire Addiction Services medical and non-medical prescribers not to initiate new prescriptions for benzodiazepines, unless specifically requested by psychiatry and / or agreed with prescriber.

Background
Benzodiazepines have been prescribed and misused for a long period of time. Recently there has been a noticeable increase in the number of drug related deaths which have included a benzodiazepine determined at toxicology. Benzodiazepines are well known respiratory depressants and in conjunction with opiates and / or alcohol are a dangerous cocktail of medicines that all cause respiratory depression and have an unpredictable and exponential increase in risk of respiratory depression when taken together.

Recent published studies have highlighted that high numbers of patients accessing methadone programmes have used, either currently or previously, benzodiazepines either legally or illicitly. Chen et al (2011(2)), found that up to 47% of patients did so.

To reduce risks, NHS Lanarkshire Addiction Services have introduced a policy aimed at reducing the prescribing of benzodiazepines and introducing extra safety if prescribing in conjunction with Opiate Substitution Therapy. In general, continuation of benzodiazepine prescribing should only occur when there is a clinical need.

Diazepam is the drug of choice for use in benzodiazepine detoxification. The 2mg tablets strength should be used; 10mg tablets should not be prescribed, as these have a high “street value”, and are subject to diversion. It should always be remembered that “street valium” is rarely the strength expected, and may be adulterated with other substances, e.g. phenazepam, etizolam, diclazepam, amitriptyline, warfarin. Police reports following seizures in 2013, showed tablet strength variation of the illicit diazepam 10mg to range from 0mg to 40mg per tablet.

For patients prescribed other benzodiazepines they should be transferred to diazepam using the table below as a guideline for equivalence. Diazepam is to be

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**NHS Lanarkshire**

**Addiction Services**

**Benzodiazepine Reduction Guideline**
used, due to the relatively long half life and availability in different strengths and formulations. A liquid formulation is also available allowing smaller doses to be given.

Dosage equivalent chart (for conversion if required)(1)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlordiazepoxide</td>
<td>15mg</td>
</tr>
<tr>
<td>Diazepam</td>
<td>5mg</td>
</tr>
<tr>
<td>Loprazolam</td>
<td>500mcg</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>500mcg</td>
</tr>
<tr>
<td>Nitrazepam</td>
<td>5mg</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>10mg</td>
</tr>
<tr>
<td>Temazepam</td>
<td>10mg</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>0.25mg</td>
</tr>
</tbody>
</table>

The maximum dose prescribed should be 30mg daily. 30mg diazepam is typically sufficient to prevent withdrawal fits in patients claiming to use very high quantities of diazepam. (3)

Diazepam should not be stopped abruptly and the dose should be tapered. The rate of reduction is generally determined by the individual's capacity to tolerate symptoms associated with the reduction. Reductions of between an eighth and a tenth of dose every 2 weeks are normal. 2mg tablets will facilitate the reduction regimen by allowing smaller graduated reductions. If patients experience withdrawal symptoms, the dose should be maintained until the patient improves. The reduction schedule should be kept flexible. There is no evidence for the use of adjunctive medication for the relief of symptoms. (4)

Any patients on opiate substitution therapy and benzodiazepines should collect both medications daily, irrespective of any regimen prior to commencing the reduction of both substances. The opiate substitution should be supervised on day of collection

Consideration must be taken of “on top use” and the difficulties in identifying this through laboratory drug testing.

N.B. For alcohol detoxes it is recommended to use Chlordiazepoxide as the treatment of choice

N.B. This document is a guideline and any deviations from the suggested practice should be fully documented in patient notes.
References
(1) Orange Guidelines 2007
(2) Chen k, et al Benzodiazepine Use and Misuse Among Patients in a Methadone Program; BMC Psychiatry. 2011;11(90)
(3) Draft RCGP; Guidance for the use of benzodiazepines and similar drugs in general practice. 2011
(4) Dr Kylie Reed et al The changing use of prescribed benzodiazepines and z-drugs and of over-the-counter codeine-containing products in England: a structured review of published English and international evidence and available data to inform consideration of the extent of dependence and harm