Guidelines for Supervised Consumption of Opioid Substitute Treatments in Pharmacies

Addictions Services, NHS Lanarkshire
Lanarkshire Alcohol and Drug Partnership
Lanarkshire Area Pharmaceutical Committee
Second Edition - August 2013

Version 2.1
Author: Duncan Hill
January 2014
FOREWORD

The purpose of this booklet is to assist all pharmacists and their staff involved in the dispensing and supervised consumption of opioid substitutes in the pharmacy. It is intended that pharmacists use the information in this booklet to aid the production of their own in–house dispensing and supervision protocol.

If you have any comments regarding the content or format of these guidelines please contact:

Duncan Hill, Specialist Pharmacist in Substance Misuse, NHS Lanarkshire
Telephone 01698 266717
Mobile 07920 711131
E-mail Duncan.hill@lanarkshire.scot.nhs.uk

ACKNOWLEDGEMENTS

Previous edition author and contributors:

Alastair Thorburn, George Lindsay, Anne Mine, Janet Park

Current edition

David Brown, Dorothy Findlay

Version 2.1
Author: Duncan Hill
January 2014
Contents

Foreword

1. Introduction
2. The need to supervise the consumption of methadone in pharmacies
3. Provision of a supervised methadone service
4. What is methadone substitution
5. Prescription requirements
6. Practical aspects of operating a supervised consumption programme
7. Education and training
8. Liaison
9. Medico-Legal aspects
10. Administrative arrangements
11. Useful contact information

Further reading

Appendix A Approved wording used on prescriptions
Appendix B Sample pharmacy – patient agreement
1. INTRODUCTION

Drug misuse continues to present a serious public health problem in Lanarkshire, characterised by drug injecting and poly-drug misuse. NHS Lanarkshire Board is committed to the Scottish Government’s drug and alcohol strategy, “The Road to Recovery”, which promotes patient’s and society’s recovery from drug and alcohol misuse, reduces the harm inflicted on the individual and the community and also minimises the consequences for the family and the community at large. This type of strategy also gives the individual an opportunity to adopt a more stable lifestyle whilst progressing on their individual journey towards recovery.

Pharmacists have a crucial role to play in the delivery of elements of the strategy:

- The dispensing of substitute drugs such as methadone and buprenorphine to individuals prescribed these medications
- The provision of sterile injecting equipment to those who cannot or are not yet ready to give up intravenous drug misuse.

Neither approach is mutually exclusive. It has been noted that, even in the most effective methadone programmes, some individuals will continue to inject, therefore, some people on a substitute programme may still require sterile injecting equipment. Findings from the National Treatment Outcome Research Study (NTORS) in England and the Impact of Methadone In Glasgow (IMIG) Study demonstrate that although people receiving methadone may not entirely give up injecting heroin, they inject less frequently than those people who are not on a methadone treatment programme.

2. THE NEED TO SUPERVISE THE CONSUMPTION OF OPIOID SUBSTITUTE TREATMENTS (OST) IN PHARMACIES

Supervising the consumption of OST by patients, on a daily basis, has emerged as a key component of OST programmes. Patients given a dose to take away cannot always be relied upon to consume it. There is a possibility that some of the doses could be shared or sold on the black market.

Methadone is most frequently prescribed in the form of methadone mixture 1mg/ml. The biological half-life of methadone is between 1-2 days, making it suitable for once daily dosing.

Suboxone is the alternative to methadone treatment. It is prescribed in the form of Suboxone sub lingual tablets (buprenorphine : naloxone 4:1 ratio). The biological half life is longer than methadone, allowing dosing to be daily or less frequent.

Whilst supervision is desirable when patients enter the programme, it is important to note that supervision itself may create a secondary dependence. Most guidelines recommend the prescribing of daily supervised consumption for a minimum of first 3 months of treatment.
It is important that once the patient is stabilised that there is an opportunity for the individual to accept a degree of responsibility. This can be done by allowing “take home” privileges e.g. increasing the dispensing intervals from daily to every second day and then to twice weekly. The pharmacist should recognise that daily supervision may need to be reinstated in times of crisis or relapse. This should not be considered as a failure of the programme or the individual. Drug misuse is a chronic relapsing condition and patients may relapse frequently. An individual may require several attempts before becoming stable and eventually drug free.

3. PROVISION OF A SUPERVISED OST SERVICE

The Lanarkshire Alcohol and Drug Partnership (ADP) and the Area Pharmaceutical Committee (APC) support the supervised consumption of methadone within community pharmacy premises. Ideally the service should be provided from a large number of pharmacies. Currently 95% of pharmacies in Lanarkshire provide this service. It is recognised that not all pharmacists may wish to participate and provision of such a service remains voluntary.

4. WHAT IS OST SUBSTITUTION?

Methadone is a long acting full agonist of opioid receptors, and buprenorphine is a long acting partial agonist of opioid receptors. One oral dose each day can eliminate the need for additional opiates by preventing physical withdrawal symptoms in those who are opiate dependent.

When an individual first starts OST it may take some initial titration of the daily OST dose to achieve stabilisation. In spite of this substitution treatment, there may still be a craving for opiates, such as heroin, and also a craving to inject. There may be a temptation for the patient to divert some or the entire daily dose and therefore it is preferable that the consumption of the daily dose of OST is supervised. The requirement for continued daily supervision can be reviewed once the patient is stabilised on the treatment programme.

The benefits of supervision are:

- To ensure that adequate blood and tissue levels of OST are maintained, therefore reducing the need for additional opiates.
- To prevent diversion onto the black market
- To provide an opportunity for the pharmacist to make a daily assessment of compliance with the programme and of the general health and well being of the patient
- To provide an opportunity for the pharmacist to build a rapport with the patient that is beneficial. This could include general health and/or welfare advice.
5. PRESCRIPTION REQUIREMENTS

All prescriptions for controlled drugs (CDs schedule 2 and 3) must conform to Regulations 15 and 16 of the Misuse of Drugs Act (1985). Pharmacists are not permitted to supply methadone against a prescription unless the prescription complies with the regulations. (see British National Formulary section: “Controlled drugs and drug dependence” for full details of the prescription requirements)

Some prescribers have exemption from the handwriting requirements and pharmacists must be satisfied that the prescriber has that authority.

The instruction for daily dispensing must be clearly written for each item that has to be dispensed in instalments. In particular, the instalment provisions of the Regulations must be strictly adhered to. Pharmacists must contact the prescriber to clarify what is intended if a prescription is unclear or ambiguous. Appendix A has the wording of choice used in NHS Lanarkshire.

The prescription must clearly specify that supervision is required. If some doses are to be taken away e.g. on Saturday or Sunday this must be clearly indicated on the prescription.

Prescribers should clearly state and are encouraged to write the start date for dispensing on the prescription. This is intended to avoid overlap. Patients must be aware that missed doses cannot be taken or supplied at a later date.

Any problems with a prescription must be discussed with the prescriber. The pharmacist will be held responsible in law if methadone is supplied contrary to the Misuse of Drugs Regulations (1985). The Specialist Pharmacist in Substance Misuse (01698 266717 / 07920 711131) can be contacted if there are difficulties convincing a prescriber of the requirements of the controlled drug prescription regulations.

6. PRACTICAL ASPECTS OF OPERATING A SUPERVISED CONSUMPTION PROGRAMME

Standard Operating Procedures (SOP)

A written SOP should be in place in each pharmacy and all staff, including locums, should be familiar with the contents. The protocol should detail procedures to be followed when a new patient enters the programme.

A SOP should include the following:

- Maintenance of records including patient medication records.
- Identification of patients (essential to confirm identity of the person, especially on a first visit – confirming that the prescription is authentic is not the same as confirming the identity of the person attending the pharmacy)
- Checking the legality of the prescription as per regulations
- Procedure for preparation of daily doses
• Use of and cleaning of equipment e.g. measures, pump dispensers or electronic measuring devices (e.g. Methameasure)

• Procedure for consuming methadone e.g. individual cups should be used for each supervised consumption. A drink of water should follow consumption of methadone. Patients should be encouraged to chew sugar free gum after methadone consumption. Patients on buprenorphine should be encouraged to drink water before placing the tablet under the tongue. Supervision should be made as discreet and efficient as possible.

• Disposal of waste – remember to remove labels from waste methadone containers

• Doses to be collected for days when the pharmacy is closed

• Use of safety leaflets and stickers for containers. Reinforcement of the ‘safe storage’ message when supplying ‘take home’ doses.

• Confidentiality

• Acceptable behaviour in and around the pharmacy

These are only examples of topics that could be covered by the SOP and are given as a guide only.

The pharmacist and any other pharmacy staff should be friendly, supportive and non-judgemental and should have an understanding and professional attitude. Consumption of OST should preferably occur in a discreet area of the pharmacy. Patients should be encouraged to attend at quieter times agreed with the pharmacist. The interests of other customers are important and should be considered.

PATIENT AGREEMENT

Patients may have a written agreement with NHSL Addiction Service prescriber, part of which covers behaviour in and around the pharmacy. However pharmacists may wish to develop their own agreement which could cover the following:

• Time the dose may be consumed or collected (if you wish any restrictions)

• Arrangements for days when the pharmacy is closed

• The need to have a legally written prescription

• Reminder that missed doses will be forfeited and cannot be obtained at a later date

• Action to be taken if there is unacceptable behaviour in and around the pharmacy

Agreements should be tailored to the individual pharmacy’s requirements. The agreement could be written or verbal.

Version 2.1

Author: Duncan Hill

January 2014
THE SUPERVISED CONSUMPTION PROCEDURE

It is important that all supervised medication is correctly supervised within the pharmacy. There are obvious differences between the possible drugs used and supervision requirements differ. The best procedures are outlined below.

**Methadone Oral solutions**
- Have made up prior to collection
- Check patient details, against prescription and medicine
- Hand to patient in a suitable labelled cup
- Provide water after to rinse container and mouth then swallow (soft drinks cans should be avoided as they offer a receptacle if the solution has not been swallowed fully)
- Talking to the patient after also help to confirm the dose has been swallowed completely

**Buprenorphine (Suboxone/Subutex) preparations**
- Have made up prior to collection
- Check patient details, against prescription and medicine
- Provide water to patient in advance of the tablets and encourage patient to drink to ensure the mouth is moist (speeds up dissolution of sub lingual tablet)
- Hand medication to patient in a suitable labelled container
- Watch patient place tablet(s) under the tongue
- Allow patient to stand quietly until tablets fully dissolved (talking to the patient may result in more medication being swallowed)
- Check under tongue for residue (may be some small amount of chalky residue left)
- Talking to the patient after also help to confirm the dose has been taken completely.

7. EDUCATION AND TRAINING

Pharmacists routinely involved in the provision of this service may find the distance learning package 'Pharmaceutical Care in Substance Misuse' a useful source of information. This is available from the NES (Pharmacy)
8. LIAISON

The prescriber should contact the pharmacist to discuss acceptance of each new patient on the programme. Otherwise, the pharmacist should contact the prescriber to confirm the arrangements. (see appendix B)

Community and hospital pharmacists should liaise when an individual receiving daily OST is admitted or discharged from hospital

A representative of the police should liaise with the community pharmacist if the person is in custody and unable to attend the pharmacy for his/her daily dose.

The ADP and the APC support the wider role of pharmacists who provide services for drug misusers.

9. MEDICO-LEGAL ASPECTS

The General Pharmaceutical Council and the Royal Pharmaceutical Society provide guidance on all legal aspects and standards for professional indemnity, both of which can be found in the latest edition of ‘Medicines, Ethics and Practice’ (Royal Pharmaceutical Society).

Physeptone® tablets are not licensed for the treatment of opiate dependence. Lanarkshire prescribers have been advised not to prescribe tablets or ampoules of methadone for this purpose. Although the number of private prescriptions is known to be small, pharmacists should be extra vigilant when dealing with such prescriptions. Private prescriptions must be written on PPCD(1) forms, these are only available to prescribers on application to the Health Board.

Do not dispense any prescription unless certain about its authenticity.

‘Emergency supply’ of methadone mixture or buprenorphine tablets is not allowed in advance of receipt of the prescription. Dispensing of phoned or faxed prescriptions for schedule 2 and 3 controlled drugs is also not allowed. The pharmacist must be in possession of the original legal prescription before supplying the controlled drug.

Most prescriptions for OST will be written on a form GP10/ GP10 P / GP10 N however some prescriptions may be written by hospital or clinic based specialists and they will use an HBP prescription form. The use of HBP prescriptions is subject to exactly the same regulations as GP10 prescriptions.

10. ADMINISTRATIVE ARRANGEMENTS

SUBMISSIONS FOR PAYMENT

The number of methadone dispensing fees and supervision fees is calculated by the Prescription Pricing Division. All instalment prescriptions for methadone and other schedule 2 CD’s must be accompanied by the purple form (PD 70) detailing the daily instalments. Please note that the purple forms are not required for non-CD instalment prescriptions. Before submitting methadone prescriptions for payment please ensure that the summary details of the instalments have been transferred onto the original prescription using the advised endorsement procedure. If in doubt

Version 2.1

Author: Duncan Hill

January 2014
please refer to any endorsing guidelines issued by the pricing division or by the Community Pharmacy Scotland. (Website reference: http://www.communitypharmacyscotland.org.uk/_resources/files/Contractor%20Services/Publications/EndorsingGuide_Final2011.pdf, Pages 40 - 43)

For buprenorphine, the dispensing fees will be calculated by the Prescription Price Division as with methadone above but submissions for payment of **supervision fees for buprenorphine products only** should be made monthly using the approved form. **Forms should be sent to Ms Lynne Stewart, NHS Lanarkshire Headquarters, Kirklands Hospital, Fallside Road, Bothwell, G71 8BB.**
Appendix A: Approved wording for Methadone / Suboxone / Subutex prescriptions examples

Methadone HCl 1mg/1ml Oral Solution

Send 420ml (Four hundred and twenty)

The instructions as below relating to frequency. The format for the date is to be ddmmm (e.g. 24Feb) due to space restrictions on the computer systems.

**Daily**

Label 60mldailyDisp60Mon-Friand2x60SatCoddmmm <Supervise on day of collection>

Meaning: Dispense 60ml under supervision Monday to Saturday and take away dose for Sunday on Saturday. Commence on ddmmm

**Weekend take away**

Label 60mldailyDisp60Mon-Thurand3x60FriCodd/mmm <Supervise on day of collection>

Meaning: Dispense 60ml under supervision Monday to Friday and take away doses for Sunday and Saturday on Friday. Commence on ddmmm

**Mid week take away**

Label 60mldailyDisp60MonThursFriand2x60TueandSatCodd/mmm <Supervise on day of collection>

Meaning: Dispense 60ml under supervision Monday, Thursday and Friday and take away doses for Wednesday on Tuesday and Sunday on Saturday. Commence on ddmmm

**Alternate day**

Label 60mldailyDisp2x60MonandWedand3x60FriCodd/mmm <Supervise on day of collection>

Meaning: Dispense 60ml under supervision Monday, Wednesday and Friday and take away doses for Tuesday on Monday, Thursday on Wednesday and Sunday and Saturday on Friday. Commence on ddmmm

Version 2.1

Author: Duncan Hill

January 2014
**Weekly**

Label 60mldaily. Disp 7x60 on Tues. Com ddmm <Supervise on day of collection.>

Meaning: Dispense 60ml under supervision on Tuesday and take away the remainder then stamped with the Home Office approved wording.

If not supervised remove that statement “<Supervise on day of collection.>” but the remainder of wording stays the same

An example of how a prescription should look is:

**Methadone HCl 1mg/ml Oral Solution**

Send 630ml

Label 45mldaily Disp 45 MonTueFri2x45WedandSatCo25 Feb <Supervise on day of collection.>

Finishing with the home office approved stamp*, prescribers signature and date.

This means

Methadone HCl 1mg/ml Oral Solution

Send 630ml

Dispense 45ml under supervision Monday, Tuesday, Wednesday, Friday and Saturday, with take away doses for Thursday to be given on Wednesday and Sunday to be given on Saturday. The prescription is to start on the 25th February.

*Home Office Approved Stamp wording is:

Unsupervised:

Instalments due on the days when the pharmacy is closed should be dispensed on the day immediately prior to the closure.

Instalment covering more than one day should be collected on the specified day, if this is missed the remainder of the instalments (i.e. the instalment less the amount prescribed for the day(s) missed) may be supplied.
Supervised:

Instalments due on the days when the pharmacy is closed should be dispensed on the day immediately prior to the closure.

Supervised consumption of daily dose on specified days: the remainder of supply to take home.

If an instalment prescription covers more than one day and is not collected on the specified day, the amount prescribed less the amount prescribed for the day(s) may be supplied.
APPENDIX B: Sample Pharmacy/Patient Agreement:

I agree to the following conditions:

1. You should arrive at the pharmacy unaccompanied and in a sober state. Methadone / buprenorphine may be withheld at the discretion of the pharmacist and the prescriber will be informed.

2. You should treat staff and other customers with respect and you are entitled to be treated in the same way by pharmacy staff.

3. You are responsible for your prescription and medication and replacement medication may not be given.

4. Methadone / Buprenorphine will normally have to be consumed on the premises under supervision unless other arrangements have been authorised.

5. You should attend the pharmacy at agreed times.

6. Daily doses that are not collected will not be supplied at a later date.

7. Methadone/ buprenorphine can only be collected by the person named on the prescription unless a prior arrangement has been made.

8. If you require an alteration to supply arrangements e.g. away the next day or going on a short holiday then you must contact the prescriber to allow a new prescription to be provided.

9. Unacceptable behaviour such as:
   - Stealing from the pharmacy
   - Aggressive or abusive acts
   - Presenting forged prescriptions, may lead to a refusal to make any further supplies from this pharmacy. I agree to the above conditions,

---------------------------------------- signed (Patient)

----------------------------------------signed (Pharmacist)

----------------------------------------date

Version 2.1

Author: Duncan Hill

January 2014