

**NORTHERN IRELAND GUIDELINES ON
SUBSTITUTION TREATMENT
FOR OPIATE DEPENDENCE**

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NORTHERN IRELAND GUIDELINES ON SUBSTITUTION TREATMENT FOR OPIATE DEPENDENCE

1 INTRODUCTION

These guidelines for substitution treatment set out the recommended approach to assessment in general practice and specialist treatment agencies, together with initiation of treatment, stabilisation and continuation of treatment. These guidelines are intended to be used as a framework on which to exercise clinical judgment according to individual circumstances. They are also intended to supplement the guidance contained in Drug Misuse and Dependence – Guidelines on Clinical Management, otherwise known as the ‘Orange Book’.

The aim of the opiate substitution is the reduction of drug related harm, including harm to health. The major objectives are as follows:

- a. Improvement in the physical and mental health of drug misusers dependent on opiates.
- b. Reduction or elimination of injecting drug misuse.
- c. A reduction in the prevalence of illicit opiate dependence.
- d. A reduction in criminal activity related to opiate dependence

2 BACKGROUND

2.1 The Drug Strategy for Northern Ireland published in August 1999 sets out the Government’s vision for tackling the problems of drug misuse. The overall aim is to reduce the level of drug related harm which is supported by four key over-arching objectives:

- a. To protect young people from the harm resulting from illicit drug use.
- b. To protect the communities from drug related antisocial criminal behaviour.
- c. To enable people with drug problems to overcome them and have healthy and crime free lives.

- d. To reduce the availability of drugs in communities.
- 2.2 In 1999 the four UK Departments of Health jointly published guidance in relation to treatment of drug misuse, entitled *Drug Misuse and Dependence - Guidelines on Clinical Management*, more commonly known as the ‘Orange Book’. This guidance sets out key aspects of optimal treatment and care for drug misusers, including the use of substitute treatments and maintenance therapy for heroin dependence delivered by a range of services from primary health care through to specialist drug services.
- 2.3 The scale and pattern of drug misuse in Northern Ireland differs from that in other parts of the UK. For many years the number of heroin dependent persons was small and the Northern Ireland Committee on Drug Misuse (NICDM) considered that it was not appropriate to introduce a widespread substitute prescribing programme in Northern Ireland. The Drug Strategy for Northern Ireland requested that NICDM should keep the situation under review.
- 2.4 Subsequently NICDM asked the DHSSPS to commission research to establish more accurately the number of problem heroin users in Northern Ireland. The report: *Prevalence of Problem Heroin Use in Northern Ireland* was published in March 2002 and estimated that there were between 695 and 1250 problem heroin users in Northern Ireland. The DHSSPS also commissioned a report: *Review of Research on Substitute Prescribing for Opiate Dependence and Implications for Northern Ireland*. This report, together with the DHSSPS’s response to the recommendations it contained, was published in January 2003, and recommended the development of substitute prescribing services.
- 2.5 The DHSSPS then established a Substitute Prescribing Implementation Group with representation from service users, providers and commissioners, to progress the implementation of substitution prescribing services on a Northern Ireland wide basis.

This Group set up four committees to take the implementation forward:

- i. The Regional Model Committee
- ii. The Training Committee
- iii. The Communications Strategy Committee
- iv. The Evaluation and Monitoring Committee

3 SUBSTITUTE PRESCRIBING – THE NORTHERN IRELAND MODEL

- 3.1 The main principle of the Northern Ireland Model is that it should operate on the basis of **shared care**.
- 3.2 Shared care encompasses the statutory addiction services, primary care, local pharmacies, voluntary addiction services, any other agencies who may be involved in providing care and support, and importantly the user of the service themselves.
- 3.3 Shared care should operate on the basis that there is a shared and agreed approach to the provision of substitute treatment. All participants subscribe to the agreed care pathway and undertake to share information where appropriate, and with the agreement of the user of the service.
- 3.4 It is recognised that training for local General Practitioners in substitution therapies until now has been limited. Therefore currently it is intended that initiation of treatment and stabilisation will be undertaken by the specialist statutory addiction treatment services. As individuals who are receiving substitution treatment are stabilised a significant part of their care and prescribing should be transferred to the General Practitioners. Transfer of this care into the primary care setting should include the continued involvement of addiction workers from the statutory specialist addiction services, or from the voluntary addiction services, as **key workers**. As experience of substitute prescribing is accumulated in primary care, some General Practitioners, with appropriate training and supervision, may wish to develop specialist expertise and participate directly in the initial stages of care.
- 3.5 Both the specialist addiction treatment services and general practitioners will be enabled to issue prescriptions that can be dispensed at local pharmacies who are participating in the service.
- 3.6 Participating pharmacies will have arrangements for daily dispensing of substitute treatments and supervision of consumption on their premises.

4 ELIGIBILITY FOR SUBSTITUTE PRESCRIBING

- 4.1 Eligibility for substitute prescribing is based on the presence of opiate dependence. In particular this refers to dependence on Heroin, or Diamorphine, Morphine, Pethidine, Methadone, Nalbuphine and other powerful opiates or opioids.
- 4.2 Although injecting drug use will commonly be the pattern of consumption in those who are being considered for substitute prescribing, nevertheless individuals with other routes of consumption are also eligible. This is due to the considerable harm that can accrue, or risk that may be present, as a result of non-injecting forms of consumption, and to prevent progression to injecting drug use where this seems likely to occur.
- 4.3 Periods of dependence of less than one year, or intermittent periods of dependence, may be more appropriately dealt with by other interventions. The decision to institute substitute prescribing is an individual clinical one based on weighing up the risks and harm occurring from the opiate dependence versus the benefit and risks of substitute prescribing.
- 4.4 Absence of a previous history of treatment should not preclude access to the substitute prescribing service.
- 4.5 These guidelines apply to individuals aged 18 years or above.

5 ACCESSING SERVICES

- 5.1 Those registered with a GP -

It is anticipated that most users who seek substitute treatment for opiate dependence will be registered with a local GP. Where this is the case referral of the user to the specialist addiction treatment service should be undertaken by the user's GP in order to promote the optimal outcome from a shared care approach. Voluntary addictions services, or counselling services, may have an important advocacy role on behalf of the users and facilitate referral via the GP to specialist addiction treatment services.

- 5.2 Those not registered with a GP -

Specialist addiction services will accept a user not registered with a GP who presents to them for assessment and initiation, where appropriate, of

substitute therapy. Initial specialist treatment should provide good multi-disciplinary care in relation to the addiction problem, but cannot be expected to be a replacement for primary care services. Once a user has entered treatment with the specialist services then all efforts should be made to have the user registered with a GP.

6 INITIAL GP CONSULTATION

- 6.1 Prior to referral to the specialist addiction treatment services a general practice consultation will take place. As well as considering referral for substitute prescribing services this consultation should be seen as an opportunity to provide interventions related to the general health of the user, for instance, treatment of any concomitant infections, advice on the use of needle and syringe exchange schemes, advice on safe sexual practice and treatment of any co-morbid mental health disorder. A check should be made for pregnancy. Other interventions, as specified in the 'Orange Book', should also be considered.
- 6.2 The initial consultation should include enquiries about opiate dependence and injecting drug use. Signs of dependence include:
- Continuous opiate use or the presence of physiological opiate withdrawal phenomena on reduction or cessation of opiate use.
 - Continued use of opiates despite the harm that is being caused.
 - Continuing strong desire to obtain and use the opiate.
 - Tolerance to the opiate being misused.
 - Difficulty controlling the opiate taking behaviour.
 - Progressive neglect of other interests as a result of opiate using behaviour.
- 6.3 It is important from both clinical and public health perspectives that GPs are open to hearing about a range of addiction and substance misuse problems. At the same time they should not feel necessarily obliged to prescribe any psychoactive drug.

- 6.4 The user should be provided with information on what to expect in relation to substitute prescribing practice at the specialist service and any waiting time in relation to the first appointment.
- 6.5 GP's should remember their legal obligation, under the Misuse of Drugs Regulations, for notification of addicts they have attended, whether they prescribe substitute medication or not, to the Chief Medical Officer of the DHSSPS in writing within 7 days.

7 INITIAL ASSESSMENT AT THE SPECIALIST TREATMENT SERVICE

- 7.1 On receipt of a referral the specialist addiction treatment services should send an appointment to the user. It is good practice in this appointment letter to include reference to the fact that the user should not necessarily expect a prescription on their first attendance at the clinic as time may be required for laboratory results and other enquiries to take place.
- 7.2 The clinical interview at the initial assessment should cover the following points:
- Current and previous use and misuse of substances, in particular opiates.
 - Alcohol intake, in particular the combination of alcohol, opiates and benzodiazepines.
 - Injecting behaviour, whether currently injecting, whether currently sharing needles or equipment, whether needles or other equipment were ever shared and what sites have been used for injection.
 - Family patterns of addiction, especially alcohol, codeine or benzodiazepine dependence.
 - Legal issues, any outstanding court cases, community orders or probation status, previous imprisonment and how the habit is funded.
 - Social status, married, cohabiting, contacts with family members, housing situation, child welfare and any child care proceedings with the local Social Services.
 - Previous treatment for substance misuse or associated problems.

- Assessment of mental and emotional well-being, especially psychosis, depression, risk of suicide or harm to others.
 - Pregnancy.
 - Medical history including general medical history and information on possible risk of infection with HIV, Hepatitis B and C and any history of testing for these viruses or previous immunisation for Hepatitis B. History of withdrawal fits due to either benzodiazepines, alcohol or other drugs.
 - Physical examination. The user should have a general examination including the respiratory, cardiovascular and gastrointestinal systems. An examination should be made for evidence of injecting at the appropriate sites. Signs of liver disease should be sought. It is good practice also to weigh the patient.
 - Collect a urine specimen for screening for drugs of abuse.
 - Consider requesting a collateral history from a reliable informant.
 - Consider undertaking a rapid drug screen in the clinic for an immediate result (although these results cannot be relied on to the same extent as laboratory investigations).
- 7.3 Consideration can be given to undertaking blood tests for Hepatitis B and C and HIV screening after suitable pre-test counselling, or alternatively the patient can be provided with information on these issues and arrangements made for these tests to be undertaken at a separate time.
- 7.4 At this first appointment a decision in principle can be made on whether prescribing is to be undertaken. This decision will be subject to the results of laboratory investigations and any other enquiries that are required to be made, for instance, further enquires may be required from the user's relatives, or staff at other treatment agencies in order for an accurate assessment to be completed. The user's consent will be required in order for these enquiries to take place and these enquires should be carried out as soon as practical.
- 7.5 If there is doubt about opiate dependence the user can be asked to return for a new appointment having abstained from opiates and thus

demonstrating signs of withdrawal. This technique should not be used where there is any suspicion of pregnancy.

- 7.6 If it is clear at the first appointment that substitute prescribing is not the most appropriate treatment then this should be made clear to the user at this point, and alternative care arrangements made.
- 7.7 If it is clear that it is likely that substitute treatment will be prescribed then a second appointment should be made at a time when the results of urine screening tests are available and other enquiries have been completed.
- 7.8 An explanation should be given as to the medication that will be prescribed, the mechanism of issuing prescriptions, which pharmacists are available to dispense the prescriptions and the nature of the supervision that will be required at the pharmacy. In addition agreement should be reached on a suitable form of identification that can be used at the pharmacy.
- 7.9 Other medical or social interventions that are appropriate at the first appointment can also be completed.
- 7.10 Doctors should remember their legal obligation, under The Misuse of Drugs Regulations, for notification of addicts they have attended, whether they prescribe substitute medication or not, to the Chief Medical Officer of the DHSSPS in writing within 7 days. Consent should be sought from the user for agreement to participate in the Drug Misuse Database.
- 7.11 Appropriate monitoring and evaluation of substitute prescribing is an essential element of good practice. An anonymised database will be established which will record the characteristics, treatment history and outcomes of all users referred for assessment for substitute prescribing. Full details are given in Appendix A (Monitoring and Evaluation Arrangements for Substitute Prescribing in Northern Ireland).
- 7.12 As part of the monitoring system, services responsible for assessment and initiation should actively encourage users to consent to their information to be included in the Northern Ireland Drug Misuse Database (DMD) and in such instances services should return DMD forms promptly. Completed DMD forms will be used to establish a separate database in relation to those accessing substitute prescribing (the Substitute Prescribing Monitoring System). Special arrangements will apply to

those clients who withhold consent to their data being included on the DMD. Full details are given in Appendix A.

8 THE SECOND APPOINTMENT

- 8.1 At this appointment the clinicians should review the patient with the urine drug screen results and any other information that has come to light from other enquiries.
- 8.2 A decision is then made on appropriate management, including the prescription of substitute medication (see section 12). If substitute treatment is to be provided then agree and complete a standard contract. (See Appendix B)
- 8.3 Contact is made with the local participating pharmacy by telephone, making arrangements for acceptance of the user for treatment and the means of identifying the user.
- 8.4 Define and agree the aims of treatment with the user and processes for monitoring progress. Then establish the arrangements for the key worker.
- 8.5 Agree with the user the medication and dosage that is to be prescribed, sign the contract, and agree the next appointment date.

9 SUBSEQUENT APPOINTMENTS

- 9.1 Here the patient can be reviewed and progress monitored and, where prescribing has commenced, if adjustment of dose is required this can be done by the current prescriber (see guidance on induction and stabilisation)

10 GENERAL ASPECTS OF CARE AND TREATMENT

- 10.1 Research shows that prescribing medication alone may not produce the best outcomes. Practical support and counselling should also be available as an integral part of a service. This can be provided by any one of a number of professionals, either from the specialist addiction treatment service or the voluntary sector agencies.
- 10.2 It is essential to ask for the user's consent for the clinic staff, staff undertaking counselling and support, and pharmacy staff to liaise, where necessary, in a confidential manner in order to co-ordinate and enhance the users care. Such liaison should occur with the consent of the user and

may include the other agencies involved. Normal consent and confidentiality procedures should apply.

11 DRUG SCREENING OF URINE

- 11.1 Urine screening for drugs should be carried out as part of the initial assessment to confirm the presence of drugs of misuse. It is also used on an ongoing basis to check for compliance with therapy and continuation of illicit drug misuse. Frequency of testing is very much dependent on individual user circumstances. Less stable users may require more frequent testing.
- 11.2 Urine test results need to be interpreted in the light of other clinical findings. They can assist in the overall management of the patient but should not be used as a mechanism to withdraw treatment. In occasional cases urine results, in addition to other aspects of behaviour, may form the basis for withdrawing treatment.
- 11.3 Urine specimens should be collected in a plain sterile universal container with no preservative. Containers should be tightly sealed and labelled with the patient's identification and a fully completed request form should accompany each sample.
- 11.4 If evidence arises of tampering with urine samples for drug screening then consideration can be given to supervising the collection of the urine sample or measuring the temperature of the sample.
- 11.5 Urine samples should be sent for analysis to the Toxicology Laboratory at the Belfast City Hospital, who undertake screening for a standard range of illicit drugs. If a patient is taking buprenorphine, this should be specified on the screening request. Similarly if on other opioids, such as Nalbuphine (Nubain) or codeine products, these should also be specified on the request. In addition if there are any other specific substances that require to be tested for the staff at the laboratory are more than happy to discuss the feasibility of this. Further information on sample collection, advice on transportation and assistance with the interpretation of results is available from the professional staff at the laboratory. (Tel No: 028 90 329241 – Toxicology Laboratory)

12 PRESCRIBING

- 12.1 Methadone and Buprenorphine are the only licensed treatments for opiate substitution. Dihydrocodeine has not yet been demonstrated to be effective and has drawbacks in that large numbers of tablets may be required. Dihydrocodeine has a particularly high street value and has been known to be involved in fatalities. If Dihydrocodeine use is contemplated reference should be made to the 'Orange Book', page 49.
- 12.2 If the patient is to embark on a maintenance programme explain that the contract is open ended but that treatment options, including increases or decreases in dose and detoxification, will be discussed as appropriate.
- 12.3 Discuss with the user the danger of respiratory depression with all opiates, particularly if abused or used in conjunction with quantities of other sedative drugs such as benzodiazepines, barbiturates and alcohol. Users should be informed also of the risk of domestic or road accidents as a result of sedation.
- 12.4 Explain to any accompanying person that if there is evidence of any drowsiness or respiratory depression then medical help must be obtained immediately.
- 12.5 If Methadone is being used explain that it has a long half-life and that the blood level will continue to rise for up to a week after starting on treatment and after a dose increase.
- 12.6 A number of opiate addicts also use benzodiazepines. Prescribing benzodiazepines in addition to substitute medication may sometimes be necessary, but it is likely to complicate the management and will introduce a risk of intoxication as well as co-dependence . Benzodiazepines may create a greater risk of inducing respiratory depression and there is also a risk of diversion of supplies. If Benzodiazepines are being prescribed reference should be made to guidance in the Orange Book (page 40-41)

13 METHADONE INDUCTION AND STABILISATION

- 13.1 Methadone should be prescribed and dispensed in the form of methadone mixture 1mg per 1ml. In deciding on the initial dose of methadone consideration should be given to the user's tolerance to opiates, which is based on the history from the user, the quantity of heroin or other opiates used and the route of administration. The use of other drugs, such as

benzodiazepines or barbiturates, and quantity of alcohol consumed should also be taken into consideration.

- 13.2 It should be recognized that purity of illegal heroin varies, and may change over time. Caution should be exercised during the induction period to minimize the risk of therapeutic overdose.
- 13.3 The starting dose of methadone is 10-20 mgs/day. If it is feasible to clinically supervise the user over a period of four hours a further dose can be given, depending on the severity of withdrawal symptoms, on the first day of treatment. Where these withdrawal symptoms are mild no additional methadone is given. If the withdrawal symptoms are moderate (muscle aches and pains, pupil dilatation, nausea, yawning) 5-10mgs can be given in addition to the starting dose. Where withdrawal symptoms are severe (vomiting, piloerection, tachycardia, elevated blood pressure) then an additional 20-30mgs can be given in addition to the starting dose.
- 13.4 In most cases a total dose of 40mgs should never be exceeded on the first day. In the exceptional event of a specialist addiction service requiring doses in excess of 40mgs per day reference should be made to the 'Orange Book'.
- 13.5 Stabilisation will be achieved over a period of several days to several weeks. In the initial period of stabilisation the daily dose of Methadone should be increased by no more than 5-10mgs per day, and in total should not usually be increased by a quantity of more than 30mgs above the starting dose over the period of the first week.
- 13.6 Further increases beyond this maximum dose for the first week should be in quantities of no more than 10mgs per week.
- 13.7 During the induction period the user will need to be seen daily by the prescribing doctor or key worker. Where deemed necessary by the clinicians, for physical or psychological reasons, users may be admitted for induction and/or stabilisation where such facilities are available. Urine drug screens should be undertaken at least weekly. Once stabilisation is achieved prescriptions should be issued fortnightly.
- 13.8 Following the initial induction onto methadone, and in order to achieve the best results from maintenance therapy, the oral maintenance dose should be increased as appropriate. Most users who have become tolerant to opiates will be stabilised on a dose of between 60mg to 100mg per day. Stabilisation will usually be completed by the end of the sixth week of

methadone treatment. The aim should be to find the most effective dose of methadone to achieve the identified therapeutic objectives.

14 INDUCTION AND STABILISATION WITH BUPRENORPHINE

- 14.1 Buprenorphine is prescribed and dispensed in the form of buprenorphine tablets for sublingual use. For the purpose of treatment of opiate dependence tablet strengths are as follows: 400microgms, 2mgs and 8mgs
- 14.2 The first dose of buprenorphine should not be taken until at least eight hours after the last dose of heroin or other opiate, and at least 24-36 hours after the last dose of methadone (or other long acting opiate). The first days dosage should be buprenorphine 4mgs.
- 14.3 **Precipitated withdrawal can occur with induction onto buprenorphine if opiate withdrawal has not already commenced.**
- 14.4 On the second day of treatment, if there is evidence of ongoing withdrawal effects, the dose can be increased to 8mgs. Further increases of 2-4mgs can be made on subsequent days if there is evidence of ongoing withdrawal. This evidence may become apparent over a period of at least the first two weeks. In most cases stabilisation is likely to have occurred over a period of the first two weeks. As with methadone after the initial induction the oral maintenance dose of buprenorphine should be increased as appropriate with the aim of finding the most effective dose to achieve the identified therapeutic objectives.
- 14.5 If an episode of precipitated withdrawal does occur the most appropriate treatment is reassurance and symptomatic treatment, e.g. buscopan, loperamide, NSAID's, lofexidine etc. Further doses at this point of buprenorphine are likely to exacerbate the syndrome.
- 14.6 Supervision of buprenorphine consumption is slightly more time consuming than supervision of methadone consumption. It requires the patient to remain on the premises for a period of at least five minutes and demonstrate that the tablet has largely dissolved before leaving. Care needs to be taken that the user does not remove one or more of the tablets that have been placed in the mouth.
- 14.7 Once the patient has stabilised consideration should be given to alternate day dosing which can be effective in some individuals.

15 USERS SWITCHING TREATMENT FROM METHADONE TO BUPRENORPHINE

- 15.1 Where a user is receiving methadone it is recommended that the dose of methadone be gradually reduced to 30mgs per day. The user will then need to abstain from methadone for at least 24-36 hours until withdrawal features are in evidence before commencing buprenorphine due to the risk of a marked precipitated withdrawal effect. Once abstinence induced withdrawal is in evidence then buprenorphine can be commenced in a dose of 4mgs on the first day and further increases can be made in accordance with general induction onto buprenorphine, as described above.

16 USERS SWITCHING FROM BUPRENORPHINE TO METHADONE

- 16.1 Some users may need to transfer from buprenorphine to methadone. Possible reasons for this include: intolerable side effects, an inadequate treatment response, patient choice, and complications around the interaction of other drugs such as opiate agonists e.g. users requiring frequent opioid analgesia for recurrent pain.
- 16.2 If a user is stable on buprenorphine, methadone can be commenced 24 hours after the last dose, at an initial daily dose of up to 40mg. Appropriate dosage levels vary according to the dose of buprenorphine and individual factors. The following table gives guidance but dose levels of methadone should be titrated according to the response (being mindful of the residual blocking effect of buprenorphine which may last for a number of days):

Dose Levels
(guide only)

| Buprenorphine Dose | Methadone Dose |
|--------------------|----------------|
| >8mg | 40mg |
| 4mg | 20mg |
| 2mg | 10mg |

17 SHARING CARE WITH GENERAL PRACTICE

- 17.1 A key component of shared care is that most users stabilised on substitute treatment should receive care and prescriptions from their General Practitioner. Good communication and a flexible approach will underpin success in shared care.
- 17.2 Once a user is stable the statutory addiction service should contact the participating GP seeking their agreement to participate in shared care arrangements. Arrangements should be in place to provide adequate information on the user's progress, the current medication and dosage, the pharmacy that is being attended and who the key worker is. This information should be provided in a standardised written format for the General Practitioners records.
- 17.3 Following stabilisation and on transfer of the oversight of ongoing treatment in relation to Substitute Prescribing to the user's GP, key workers should advise the Substitute Prescribing Monitoring System of information relating to the users treatment (drug used, dosage, consumption arrangements etc). Full details are given in Appendix A.
- 17.4 Prescriptions should be issued fortnightly. If the key worker involved with the user is in regular face-to-face contact with the user then consultations with the doctor may occur less frequently. However, if no key worker is involved then monthly consultations are recommended, issuing fortnightly prescriptions.
- 17.5 Only users who are very unstable, or particularly high risk, or have special needs should be treated in the long-term by the specialist services. The specialist services should be available to review any user who has been transferred into general practice, and who is causing concern to the General Practitioner.
- 17.6 General Practitioners may need to make adjustments to prescribed medications from time to time. These adjustments should be made in accordance with the prescribing guidance as set out in these guidelines.
- 17.7 General Practitioners should participate in the regular 3 monthly clinical review undertaken by the key worker.

18 FURTHER ASPECTS OF CARE ONCE STABILISATION HAS BEEN ACHIEVED

- 18.1 During induction and after stabilisation examinations for needle marks should be undertaken from time to time with the user's agreement. The user's weight can also be a useful guide to progress.
- 18.2 Further issues that may need attention during the course of maintenance treatment may include education in regard to safe sexual practices and contraception. If screening for Hepatitis B and C and HIV has not been undertaken the issue can be discussed and appropriate screening arranged. A course of Hepatitis B vaccination should be offered if the user has not already received it.
- 18.3 At the stage of initiation of substitute prescribing, or at any stage during the course of stabilisation or maintenance treatment, consideration should always be given to the possibility that the patient has become pregnant, and if any doubt exists a pregnancy test should be offered.
- 18.4 Once stabilisation is achieved a comprehensive review of progress should be undertaken three monthly by the key worker. This should involve other participants in the shared care arrangements and include:
- Review of treatment goals and progress towards their achievement.
 - Evidence of continued use of illicit or unprescribed drugs.
 - Use of alcohol.
 - Injecting drug use.
 - Attendance at treatment times and clinic appointments.
 - Behaviour towards treatment staff and pharmacy staff.
- 18.5 Following treatment review, the key worker should notify the Substitute Prescribing Monitoring System of the outcome of the review in the agreed format. Notification should also be made of any users who have ceased using Substitute Prescribing Services. Full details are given in Appendix A.

19 SHARING CARE WITH PHARMACY

- 19.1 Most users will have their medication dispensed and supervised by a community pharmacist. The pharmacist will ensure the safe and appropriate use of Methadone and Buprenorphine supplied by installments and will build a rapport with the user that is beneficial from a health promotion viewpoint. Good communication within a reasonable timeframe and a flexible approach will underpin success in the shared care approach. (Appendix C – Guidance for Pharmacists)
- 19.2 The prescriber must telephone the pharmacist to inform them that a new user is going to present a prescription and provide the following information;
- Name, address, date of birth
 - Prescription details i.e. drug name, daily dose, start date
 - User description
- 19.3 The pharmacist must inform the prescriber or key worker, where appropriate, of the following:
- A new user who does not present as agreed.
 - Any missed doses or whole doses not consumed under supervision.
 - A user attempting to avoid supervised consumption.
 - Unacceptable behaviour e.g. shoplifting, verbal or physical abuse of pharmacy staff, deviation from the contract.
 - Intoxication.
 - Deterioration in health and other health concerns.
 - Problems concerning the prescription.
 - A new user presenting without prior contact from the prescriber.
- 19.4 Addictions Unit or GP practice staff may contact the pharmacist to advise if the user is unable to collect a dose for medical reasons.

19.5 The prescriber must ensure the prescription is written appropriately to comply with the requirements of the Misuse of Drugs Regulations (Northern Ireland) 2002 in that it is:

- Signed and dated by the prescriber.
- In the prescriber's own handwriting unless the prescriber is exempt from handwriting regulations.
- Written in ink or otherwise so as to be indelible and include the:
 - **Patient's name and address**
 - **Name of the drug** e.g. Methadone or Buprenorphine
 - **Form** e.g. Mixture, Mixture SF, Tablets
 - **Strength** e.g. 1mg/ml, 400mcg, 2mg, 8mg
 - **Total quantity** in both words and figures
 - **Dose** e.g. 50mg daily, 4mg daily

19.6 In addition the prescription must indicate:

- The start date i.e. the date the first dose is to be dispensed.
- Whether supervision is required.
- Arrangements for weekends or Bank Holidays e.g. 'Dispense on Saturday for Sunday'.
- The pharmacy name.

19.7 The pharmacist will check the legality of the prescription and that the quantities and user's details are correct.

19.8 At the first meeting the pharmacist will check the user's identity, register the user on the Patient Medication Record and discuss arrangements for dispensing and supervision with the user. This will include an agreement on a suitable time for collection of doses and an explanation of the circumstances where a dose will not be dispensed. In addition the user will be advised that the prescriber will be contacted if doses are missed or if there are concerns about the user's general health. This agreement should be in the form of a written contract signed by the user and the pharmacist. Advice will be given on the safety of take home doses.

- 19.9 The pharmacist will ensure the dignity of the user at all times and will supervise consumption in a discreet way that does not cause embarrassment.
- 19.10 The pharmacist will ensure the Methadone and Buprenorphine are stored, dispensed, supervised and disposed of appropriately and that appropriate records are maintained.

20 SHARING CARE WITH THE VOLUNTARY SECTOR

- 20.1 Voluntary sector addiction agencies should be encouraged to become participants in the shared care arrangements. Users should be encouraged to receive regular counselling and non-medical support in addition to any medical management. The specialist addiction workers in the community addiction teams can also provide counselling. In addition the key worker role can also be provided by appropriately trained and supervised members of the voluntary sector addiction agencies.
- 20.2 Arrangements should be in place so that there is good liaison between the statutory addiction treatment services, local GP's, pharmacists participating in the substitute prescribing scheme, and local voluntary addiction counselling agencies.

21 SPECIAL CASES

21.1 Concurrent Medical Illness

Users with severe liver disease, in particular where liver function is compromised, who are being treated with methadone should receive smaller doses due to altered metabolism in the liver leading to potentially higher blood levels.

User's suffering from tuberculosis who are receiving treatment with Rifampicin may require higher doses or more frequent administration due to accelerated metabolism of methadone.

Users who are on anticonvulsant medication may also require special consideration, in particular phenytoin, phenobarbitone or carbamazepine may accelerate methadone metabolism and users may be more suitably managed on valproate. Any changes to anticonvulsant medication in these circumstances should be undertaken very gradually.

A more extensive list of drug interactions is contained in the 'Orange Book', pages 115-119 and the British National Formulary (BNF)

21.2 Pain Relief

Prescribing for pain relief for users who are receiving regular methadone or buprenorphine should as much as possible be undertaken using non-opiate medications. Non-steroidal anti-inflammatory drugs and paracetamol can be helpful. If opiates are required these will be needed in relatively large doses.

Where difficulties arise in the management of genuine chronic pain it is probably best to discuss such cases with a pain relief specialist.

Addition of doses of another opiate or opioid where buprenorphine is being prescribed will be ineffective.

Do not increase the methadone dose for purposes of analgesia, as it will be ineffective. Do not prescribe "as required" doses of methadone or buprenorphine for pain relief.

21.3 Pregnancy

During pregnancy withdrawal from prescribed or illicit drugs carries particular risks, including foetal distress which can threaten the viability of the foetus.

If pregnancy is confirmed in a patient seeking opiate substitution treatment then management should always be under the care of the specialist statutory addiction treatment services. The statutory addiction treatment services should operate in conjunction with the local obstetric service and GP in dealing with these cases. It is recommended that a local joint protocol for the care of these cases should be established.

Methadone is the preferred substitution drug for use in either maintenance treatment or detoxification during pregnancy as the safety of buprenorphine in these circumstances has not been established.

21.4 Admission To An Acute General Hospital, Or An Acute Psychiatric Hospital, Or An Accident & Emergency Department

Opiate substitution treatment where appropriate should be continued during admission to an acute general hospital, psychiatric hospital bed or

A&E. The fact that a person is on opiate substitution treatment should not, in any way, preclude admission to either a general hospital or a psychiatric hospital.

The admitting doctor in these circumstances should at the earliest stage make contact with the prescribing doctor or the relevant key worker to confirm the fact that the patient is receiving substitute treatment and to confirm the dosage and frequency of that medication. The relevant treatment service, or doctor, providing the substitute treatment should be willing to convey prompt information to the hospital in order that the prescriptions can be continued. Where feasible the key worker involved with the patient should undertake liaison visits to the hospital, both to review progress of the patient and to reassure staff at the hospital and to contribute to plans for discharge.

21.5 Detention in Custody and Release from Custody

Where a user is detained in custody, either in a police station or in a prison, and the detainee states that they are on substitute medication, the relevant authorities should refer the case immediately to their medical services. The attending doctor should take all reasonable steps to confirm that the detainee is in fact receiving an opiate substitute prescription, and this can be undertaken by making contact with the prescribing doctor, the key worker or the dispensing pharmacy.

An assessment should be made for evidence of the presence of opiate dependence and for any features of opiate intoxication or withdrawal present at the time. If the doctor is unable to confirm that the detainee is in receipt of a substitution prescription he should make arrangements to review the user seeking evidence of opiate withdrawal. If opiate withdrawal symptoms arise then the attending doctor should treat appropriately in accordance with their locally produced guidelines for these circumstances.

In the circumstances where the attending doctor is able to confirm that the detainee is receiving a substitute prescription then that prescription should be continued following an assessment that confirms there is no evidence at the time of prescribing medication that the patient is intoxicated.

In the case of an individual who is released from custody and has not been receiving substitute treatment the prescribing doctor should consider whether a reduced dose is required in the interests of safety. This is in

view of the risk of decreased tolerance to the drug and consequent toxicity.

21.6 Travelling Abroad

This section should be read in conjunction with the section below covering take-home medication.

When a patient has been stabilised then consideration can be given to providing the patient with sufficient quantity of medication to take on holiday, either abroad or at a significant distance from the dispensing pharmacy.

An open general licence can be obtained for any individual who is entering or leaving the United Kingdom with prescribed controlled drugs which are to be self-administered or administered to a member of their household traveling with them. Certain conditions are attached to this licence (including maximum quantities allowed) and it is important to remember that this licence does not authorize importation of the drug into the country of destination so the patient should take responsibility for clarifying that it is legal to take the particular quantity of medication into the jurisdiction to which they are travelling. The individual must also carry written authorization from the prescriber and should be in personal possession of the drugs. Therefore treatment services or the prescribing doctor should provide a covering letter for the individual confirming that the medication is being prescribed as part of a treatment plan.

Individuals traveling within the United Kingdom (for example from Northern Ireland to Scotland) do not require licensing but should always carry written authorization from the prescriber and be in personal possession of the drugs.

Any advice should be sought from the Misuse of Drugs Inspector, DHSSPS [Tel 028 90 523348] as far in advance as possible of the proposed traveling date.

Advice should also be given to the individual on the risks of using additional illicit substances or medications in a new location or the hazards of consuming large quantities of alcohol in addition to the prescribed substitute medication.

21.7 Users on Substitute Treatment from outside Northern Ireland presenting for treatment

Users in these circumstances should be dealt with in the same manner as users presenting initially for substitute treatment. Generally for short stays it is the users responsibility to ensure that they have sufficient medication to cover them while in Northern Ireland, or alternatively if a longer stay is being planned that their treating doctor, or treating agency, should make contact with the local specialist treatment service to make arrangements for a smooth hand over of care and treatment. Users presenting to a General Practitioner, where prior arrangements have not been made, should not expect to be issued with an immediate prescription in these circumstances, due to possible hazards.

Where no previous contact has been made the doctor making initial contact should endeavour to contact the original prescribing doctor or agency to confirm the fact of substitute prescribing, the dosage and frequency of drugs and the date of the last prescription and quantity of medication received.

If the doctor is able to confirm prescribing details and that the user has previously been stable then consideration can be given to continuing these prescriptions in general practice. However, if there are any doubts in regard to further management of the case referral should be made to the local specialist addiction treatment services.

22 **TAKE HOME MEDICATION**

It is recognised that for some individuals take home medication will be a stepping stone in the progress of managing their condition. This involves the user taking increased responsibility for their own welfare and such medication will be considered for consumption at home in the following circumstances:

- 6 months after stabilisation.
- Evidence of good compliance and benefits from treatment.
- Exceptional circumstances as deemed appropriate by the relevant multi-disciplinary clinical team.

Decisions on take home medication will usually occur as part of the overall three monthly clinical review co-ordinated by the key worker. In

addition to the above circumstances it is recognised that take home doses of medication will be required to cover Sundays and other holidays when participating pharmacists are not normally open.

23 REVIEW OF THESE GUIDELINES

These guidelines should be subject to a review at a period of no more than three years after their introduction and this review should be commissioned by the DHSSPS/DAST.

In particular this review should consider whether sufficient progress has been made in general practitioners gaining experience of substitute prescribing, and in the extent and quality of educational experiences that they have had access to, in order to facilitate initiation and stabilisation of substitute prescribing in general practice.

Monitoring and Evaluation Arrangements

1 Principles

1.1 The following principles have informed the development of monitoring and evaluation arrangements for Substitute Prescribing.

- Monitoring should provide an appropriate overview of substitute prescribing to the DHSSPS, Service Commissioners, Service Providers, service users, and the public.
- Key information necessary for the evaluation of Substitute Prescribing should be collected as part of the monitoring process as appropriate.
- Monitoring information should reflect and complement good practice and the management arrangements for Substitute Prescribing.
- Monitoring and evaluation arrangements should respect the confidentiality of service users. Monitoring and evaluation data should be used for no other purpose and handling and release of data should meet National Statistics standards. In order to maximize the utility of monitoring information, data will be required for all users accessing Substitute Prescribing services.
- Monitoring and evaluation arrangements should minimize demands on Treatment Services consistent with obtaining appropriate data.

2. Northern Ireland Model of Treatment Delivery and Implications for the Collection of Monitoring Data

2.1 Monitoring arrangements should take full cognisance of the way in which Substitute Prescribing treatment will be delivered in Northern Ireland. As currently set out in the main document, treatment will be delivered within a shared care model with the following stages:

- i. **Referral** from primary care to specialist addiction services for assessment and induction.

- ii. **Assessment** by specialist services of clients for Substitute Prescribing.
 - iii. If a client is suitable for Substitute Prescribing, **induction and stabilisation** on agreed drug and dose will take place. Following stabilisation, shared care arrangements will mean that, in most circumstances, day-to-day prescribing will pass to primary care.
 - iv. Regular **review** of treatment. Review will involve input from all participating in shared care and be led by the Key Worker, who will initially be situated in specialist services.
 - v. **Discontinuation** of treatment.
- 2.2 Substitute Prescribing data will therefore be collected at four key points in a client’s journey through treatment – viz following **initial interviews** at addiction services; following **stabilisation**; at **review** [this point will re-occur at intervals through treatment]; and when a client **discontinues** treatment.
- 2.3 The model outlined above reflects the “ideal” case and a number of clients will not follow precisely the route shown above – for example, some will not have a GP and will approach secondary services directly or through another pathway; others will take a long period to stabilise; yet others may drop in and out of treatment.
- 2.4 Key Workers, who will be located in specialist addiction services, will play a central function in the treatment of those in receipt of Substitute Prescribing. The specialist addiction services will therefore be in the best position to take the main responsibility in providing information to monitor the delivery of Substitute Prescribing.
- 2.5 With individual addiction services only aware of those clients under treatment with them there will remain a requirement for consistent data to be collected at a Northern Ireland level. The data will therefore be collated by the Drug and Alcohol Information and Research Unit (DAIRU) within DHSSPS.

3 The Client Monitoring Process

- 3.1 To maintain consistency with the model of service delivery outlined above, and to allow for appropriate monitoring information to be

collected, it is proposed that information should be collated by specialist addiction services at four points:

A: Following initial interviews with client

Data captured should include:

- (i) Treatment agency
- (ii) Basic client details e.g. age, gender, living arrangements, employment status, location, number of dependent children
- (iii) Main drug for which maintenance therapy is sought (including mode of administration, dosage etc)
- (iv) Other drugs misused (including alcohol)
- (v) Length of time dependent on main drug
- (vi) Previous treatment
- (vii) Date of referral and first interview
- (viii) Whether a client had been accepted for Substitute Prescribing treatment (and, if not, alternative treatment pathway).

These data largely reflect what is currently recorded on the Northern Ireland Drug Misuse Database (DMD) and a modified DMD form will be used to notify users to both the DMD and the Substitute Prescribing database. This would avoid duplication for service. Treatment services should actively seek to gain a client's consent to their data being included on the DMD. If that consent is not forthcoming, then treatment centres should notify to the Substitute Prescribing database only (in which instance a client's details would not be included on the DMD).

B. Following stabilisation of client

Data collected should include:

- (i) Substitute drug used (i.e. methadone, buprenorphine, other)
- (ii) Dosage
- (iii) Supervision arrangements
- (iv) Other additional treatment agreed
- (v) GP practice delivering primary care
- (vi) Nominated pharmacy.

C. On client review

Review will occur on a regular basis. Information collected at review will include:

- (i) Any change of substitute drug and dosage
- (ii) Any change of care arrangements (GP, pharmacy, secondary care etc)
- (iii) Any change of supervision arrangements
- (iv) Adherence to treatment regime
- (v) Changes in client circumstances (e.g. employment, housing situation).

D On a client discontinuing with Substitute Prescribing

Data would include:

- (i) Discontinuation of treatment
- (ii) Reasons for discontinuation
- (iii) Post-treatment destination (if known).

4 Confidentiality

- 4.1 In the above model there is a need to link information about individual clients from a number of stages in the process. Maintaining confidentiality will be effectively dealt with through collecting anonymised data on the lines of the system used for notification to the DMD. For this approach to work there will be an onus on individual treatment centres to identify clients when communicating information to the central database. There must also be an opportunity for the central database to identify potential duplicates in order to raise this with treatment centres.
- 4.2 The consequence of this is that individual specialist treatment services and/or key workers must maintain a local register with a referencing system that identifies individual clients within a service, and they must use this reference system when communicating with the central database. This will mean that the central database will not be able to identify individual clients.
- 4.3 It is recognized that the above arrangements may not be appropriate in all circumstances. For example there will be no information in relation to clients who do not progress to specialist addiction services. This may

include, for example, clients who fail to turn up, and also a small number of clients who are unwilling to attend specialist services and thus are dealt with entirely by primary care. Other mechanisms will need to be explored to ensure that these groups are covered.

5 Other Monitoring Data

- 5.1 In addition to client monitoring, other data can be monitored in relation to Substitute Prescribing. These data include prescription data, data on drug-related deaths; and data relating to seizures by law enforcement agencies of illicitly-held substitute drugs.

Prescription Data

- 5.2 The Central Services Agency (CSA) has developed the arrangements for the format, completion and handling of prescriptions used in Substitute Prescribing.
- 5.3 GPs prescribing substitute drugs will use the standard NHS prescription form (HS21) to add information about the supervision of the drug. Substitute drugs covered are methadone and buprenorphine – other drugs that may from time to time be used, such as dihydrocodeine, will not be covered.
- 5.4 In order to process payments to pharmacies in respect of supervision, CSA will extract prescriptions used for Substitute Prescribing – this will render them easily available for separate input into a Substitute Prescribing database.
- 5.5 Specialist services use a specially designed form (SP1). The SP1 will record standard information about the patient and the drug (form, strength, quantity) as well as information about the prescriber and dispenser. Information about supervision is also recorded.
- 5.6 CSA's intention is to maintain a database derived from returned revised SP1 forms.
- 5.7 It is intended to explore how information from the SP1 and the modified HS21 can be linked to form a unified Substitute Prescribing prescription database, data from which would inform us about:
- Drugs used (including information on dosage) and change over time.

- Numbers of patients on Substitute Prescribing (as evidenced by the receipt of maintenance drug) at any one time or during a particular period, including a geographical breakdown and age/gender analyses.
- Retention in Substitute Prescribing treatment (as evidenced by continued receipt of the maintenance drug).
- Detailed data on supervision.

Drug-Related Deaths

- 5.8 Substitute Prescribing is intended to reduce the number of deaths due to the misuse of heroin and other opiates. However against this has to be set a possible increase in deaths from methadone and buprenorphine (or combinations of these with other substances, including heroin). Deaths could occur in those for whom the drug was prescribed; or to other drug users if the drug is diverted; or to others due to accidental ingestion.
- 5.9 The number of recorded drug-related deaths in NI over recent years has been low (for example 2001 – eight deaths). Not all of these were due to heroin misuse. However NI appears to differ from other parts of the UK in relation to the procedures for recording deaths where drug misuse has been suspected, and this could have resulted in an historical under-recording of drug-related deaths here. Also, in the UK as a whole, buprenorphine-related deaths are not recorded in large numbers. This may be related to the facts that buprenorphine does not show up in standard screening but has to be specifically looked for, and the allegedly low overdose risk of buprenorphine.
- 5.10 This issue will require development, but highlights the fact that care will have to be taken when interpreting figures on drug-related deaths. If procedures are changed to fall more into line with those in England and Wales and in Scotland, then any increase in recorded drug-related deaths could be attributable at least in part to changes in procedures and recording.

Seizures of Substitute Drugs

- 5.11 Following the introduction of Substitute Prescribing there is the possibility that prescribed substitute medication will be diverted and find its way onto the black market. In the UK as a whole in 2001, some 1.9

million doses of methadone were seized, mostly in small doses and the inference is that many of these seizures relate to substitute medication that had been issued under prescription. Levels of methadone and buprenorphine seizures will need to be monitored carefully as they may be an indicator to the extent of diversion.

6 Evaluation

- 6.1 Evaluation will have to consider if the aims and objectives of the Substitute Prescribing service are being met; how good practice can be promulgated (and poor practice curtailed); and the service improved.
- 6.2 The aim of the opiate substitution is the reduction of drug related harm, including harm to health.
- 6.3 The supporting objectives are:
 - a. Improvement in the physical and mental health of drug misusers dependent on opiates.
 - b. Reduction or elimination of injecting drug misuse
 - c. A reduction in the prevalence of illicit opiate dependence.
 - d. A reduction in criminal activity related to opiate dependence.
- 6.4 A full evaluation framework for Substitute Prescribing requires further development, however it will build on information collected for monitoring and will take account of outcomes in the following areas:
 - **Treatment.** For example the ability to attract appropriate clients to treatment, retention rates, adherence to treatment plans, progression rates. To enable an appropriate assessment of the success or otherwise of Substitute Prescribing services to attract users into treatment the estimates of the number of problem heroin users in Northern Ireland will require updating. There may also be a need to extend the problem drug prevalence data to include other substances that will be suitable for maintenance therapy (e.g. nubain). Positive outcomes in maintenance therapy will include those remaining on treatment.
 - **Harm Reduction.** Examination can be made of the impact of Substitute Prescribing on unsafe practices e.g. injection rates, sharing, co-use of other drugs and issues around morbidity and drug-related deaths will be considered here. Some use of monitoring data will be required here, but it is likely that specific

quantitative or qualitative research techniques will be most useful in determining these outcomes.

- **Diversion.** Diversion of prescribed drugs is a considerable issue and evaluation will have to assess the extent to which this is occurring. Data from seizures of methadone and buprenorphine and analysis of drug-related deaths might be useful here.
- **Lifestyle Outcomes.** The impact of Substitute Prescribing on employability, relationships, criminal behaviour, living arrangements etc will have to be examined.
- **Client Perception.** Although linked to most if not all of the above, client perceptions of the service are important in themselves.
- **Post –Treatment Outcomes.** Positive outcomes will include those who progress to successful detoxification.

Substitute Prescribing Contracts

The aim of any contract, which should be signed by the user and relevant professionals, is to ensure all parties are clear about what has been agreed and to promote the effectiveness of the treatment programme and the safety of the user and others.

A contract is centred around the user and the user will be signing that they understand and agree to the various conditions associated with the provision to them of a substitute prescribing service. Contracts should be drawn up between the user and the community pharmacist and the user and the prescriber with the involvement of the key worker.

The contract should include agreement by the user regarding:

- Confirmation that they are currently addicted to opiate drugs.
- Attending appointments with their GP, addiction services, key worker and community pharmacy regularly and at the agreed time.
- Attending appointments unaccompanied where possible and not engaging in aggressive, threatening or nuisance behaviour.
- Attending their chosen specified pharmacy for prescribed medication where the pharmacist will supervise consumption where appropriate .
- Accepting that if they attend the pharmacy intoxicated with alcohol, or drugs, their medication will be withheld and they will be required to make an alternative appointment.
- Taking full responsibility for their prescription and medication and recognising that these cannot be replaced.
- Recognising that if they fail to collect a dose on the specified day they will not be able to collect that dose on a later day.
- Agreeing that the prescriber will be notified in the event of non-attendance for collection of substitute medication and that after three days their treatment will be reassessed.

- Not using emergency appointments or house calls to discuss their prescription.
- Not seeking prescription of substitute medication from any other source.
- Not supplying any take home medication that they are given to others.
- Agreeing that no alteration will be made to their prescription without the prescribing doctor's permission.
- Providing urine samples, without tampering, when requested.
- Agreeing that they understand that substitute medication can cause serious harm or death in overdose, and also that methadone or buprenorphine (and benzodiazepines) are addictive and may cause drowsiness.
- Agreeing that if affected by drowsiness they will not drive or operate machinery and that they recognise the dangers of taking methadone or buprenorphine with alcohol.
- Accepting that it is not in their best interest to use any illicit or unprescribed drugs.
- Agreeing that the professional staff involved may discuss their case where appropriate.

Guidance for Pharmacists

1. First Meeting with the User

1.1 Identity Check

In most cases photographic identification will be required. This can be a labeled photograph held in the pharmacy, or agreement by the user to produce other photographic identification, such as a valid driving licence, on each occasion substitute medication is to be dispensed.

1.2 Contract

At the first meeting, the pharmacist and user should agree a contract for dispensing and supervision arrangements that would ideally include the following:

- That the user will attend alone.
- The most appropriate time for collection of doses.
- The method of checking the user's identity prior to dispensing.
- Arrangements for weekend and Bank Holiday doses.
- That the user must demonstrate that they have taken the dose appropriately i.e. swallowed methadone, under the tongue for buprenorphine.
- That unsuitable or offensive behaviour towards pharmacists or their staff will result in the termination of the contract.
- That the pharmacist will exercise their professional judgement and doses will not be supplied or supervised if the user appears intoxicated by drugs or alcohol.
- That the prescriber will be told of any missed doses and that if three or more doses are missed, the prescriber will review the prescription before reinstatement of supply is considered.

- That missed doses will not be supplied at a later date.
- If the user cannot attend, he/she must contact the prescriber or key worker as the pharmacist will be unable to supply the dose to a representative. It is not appropriate for the user to contact the out-of-hours GP service.

The contract may be written and a copy provided for the user.

1.3 Patient Medication Records

The following details should be entered into the Patient Medication Records:

- Name, address, DOB.
- Medical Conditions.
- GP and prescriber for substitute prescribing.
- whether the dose is supervised or not.
- Other relevant information.

A PMR card should be given to the user.

1.4 Introduction to Staff

The user should be introduced to appropriate members of staff to aid recognition when locums are working.

1.5 Additional Information

The user must be given advice and information on safe storage of take home doses. Other health promotion advice should be given as appropriate.

2 Storage and Disposal of Methadone and Buprenorphine

- 2.1 All stocks of controlled drugs must be stored in the CD time delay safe. However, it is recognised that this may be impractical for the storage of pre-prepared doses and authorisation to store these in the CD cabinet may

be obtained from the Misuse of Drugs Inspector DHSSPS (Tel no – 028 90 523348).

- 2.2 Disposable plastic cups must be discarded after single use
- 2.3 Labels must be removed from all bottles including stock bottles prior to disposal
- 2.4 Patient names to be removed from dispensing labels prior to disposal to maintain patient confidentiality
- 2.5 Uncollected doses can be reused. In order to claim a dispensing fee, the prescription should be coded as normal but the quantity entered as '0'.

3 Guidelines for Dispensing Methadone

3.1 Ensure the prescription complies with all the requirement of the Misuse of Drugs Regulations (Northern Ireland) 2002 in that it is:

- Signed and dated by the prescriber.
- In the prescriber's own handwriting unless the prescriber is exempt from handwriting regulations.
- Written in ink or otherwise so as to be indelible and include the:
 - **Patient's name and address**
 - **Name of the drug**
 - **Form**
 - **Strength**
 - **Total quantity** in both words and figures
 - **Dose** e.g. 50mg daily

3.2 **In addition the prescription must also state:**

- **The date the prescription will commence.**
- **Whether supervision is required.**
- **Arrangements for weekends or Bank Holidays if appropriate e.g. 'Dispense Saturday for Sunday'.**

- **The pharmacy name.**
- 3.3 The daily dose should be dispensed and labelled appropriately before the user arrives (when a prescription is current).
- 3.4 The label must include:
- User's name.
 - Methadone strength, form quantity and dose.
 - Whether supervised or take home.
 - Date of dispensing.
 - Name and address of the pharmacy.
 - 'Last dose' when appropriate.
- 3.5 The following should be adhered to when dispensing:
- Pharmacist and designated member of staff to check the volume of methadone dispensed. (An approved measure or pump can be used).
 - Use the minimum reasonably sized plastic or glass bottle.
 - Take home doses must be dispensed in separate bottles for each day with clic-loc caps.
 - Prepared daily doses must be locked in the CD cupboard (see above)
- 3.6 Containers can be reused for up to one week if all of the following criteria are met:
- Container suitably cleaned and dried daily.
 - Patient does not drink directly from the container.
 - Container is used only for one patient.

4 Guidelines for Supervision of Methadone

- 4.1 The user should not witness removal of the dispensed container(s) from the CD cupboard.
- 4.2 The user's identity should be checked before the dose is administered.
- 4.3 The supervision procedure should be discreet and efficient, to be mindful of the user's dignity and the pharmacist's time.
- 4.4 Ideally, supervision should not take place in the dispensary but should occur in a quiet area.
- 4.5 The user can check the name, quantity and dose on the label before swallowing. The dose should be poured into a new plastic disposable cup.
- 4.6 The pharmacist must be satisfied that the dose has been swallowed, either by water being swallowed after the methadone dose has been given, by conversing with the user or other means of ensuring that the methadone is not retained in the mouth.
- 4.7 The user should be informed in advance of the last dose on the current prescription.

5 Guidelines for Dispensing Buprenorphine (Subutex)

- 5.1 Ensure the prescription complies with all the requirements of the Misuse of Drugs Regulations (Northern Ireland) 2002 in that it is:
 - Signed and dated by the prescriber.
 - In the prescriber's own handwriting unless the prescriber is exempt from handwriting regulations.
 - Written in ink or otherwise so as to be indelible and include the:
 - **Patient's name and address**
 - **Name of the drug**
 - **Form**
 - **Strength**
 - **Total quantity** in both words and figures
 - **Dose** e.g. 8mg daily

5.2 **In addition the prescription must also state:**

- **The date the prescription will commence.**
- **Whether supervision is required.**
- **Arrangements for weekends or Bank Holidays e.g. ‘Dispense Saturday for Sunday’.**
- **The pharmacy name.**

5.3 The daily dose should be dispensed and labelled appropriately before the user arrives (when a prescription is current). Sometimes this may involve a mixture of strengths which must be separately labelled in accordance with standard ‘best practice’ procedures

5.4 The label must include:

- User’s name.
- Buprenorphine strength, form, quantity and dose.
- Whether supervised or take home.
- Date of dispensing.
- Name and address of the pharmacy.
- ‘Last dose’ when appropriate.

5.5 The following should be adhered to when dispensing:

- Pharmacist and designated member of staff to check the strength and quantity of Buprenorphine dispensed.
- Take home doses must be dispensed in separate boxes.
- Prepared daily doses must be locked in the CD cupboard (see above)

6 Guidelines for the Supervision of Buprenorphine

- 6.1 The user should not witness removal of the dispensed container(s) from the CD cupboard.
- 6.2 The user's identity should be checked before the dose is administered.
- 6.3 The supervision procedure should be discreet and efficient to be mindful of the user's dignity and the pharmacist's time.
- 6.4 Supervision should not, ideally, take place in the dispensary.
- 6.5 Ideally, the user should have a drink of water before dispensing to moisten the mouth. In such cases, provision must be made for safe disposal of drinking cups to ensure no cross infection is possible. Users should not be allowed to bring opened containers of drinks into the pharmacy.
- 6.6 The user can check the name, quantity and dose on the label(s) before taking.
- 6.7 The pharmacist should pop the tablets out of the blister pack, either into the user's hand or into a small disposable pot.
- 6.8 The tablet(s) should be placed under the tongue and left to dissolve. The active ingredient passes through the buccal mucosa and produces its effect.
- 6.9 The tablet should not be swallowed, as it is ineffective if taken this way.
- 6.10 The user should not leave until the staff are sure that the tablet is dissolved. Once dissolved, what remains is a chalky residue that can be swallowed.
- 6.11 The pharmacist must be satisfied (either by conversing with the patient, water being swallowed or other means) that the medication has not been concealed in the mouth.

7 Documentation

7.1 Coding Prescriptions

- The prescription form must be completed with the prescription code endorsements and date of dispensing/supervision as detailed.
- The original prescription should be kept until the prescription expires/is completed and then be submitted to the CSA for payment with the normal bundle at the end of the month.

7.2 CD Register

- On supplying a dose to a user, the CD register must be completed that day or the next day following. It should be remembered that completion of the register is an indication of a supply made and not of the dispensing process, so in the case of an uncollected dose, no register entry should appear.
- Buprenorphine (Subutex) is a Schedule 3 controlled drug and while it must be stored in a complying CD safe, it does NOT require entry into the CD Register.

7.3 Patient Medication Records

- PMR's must be kept up to date.
- A record of incidents and relevant information about the patient should be maintained on the PMR.

7.4 Evaluation and Monitoring

- Evaluation and Monitoring Forms should be completed at the designated periods.