OPIOID SUBSTITUTION TREATMENT:
NORTHERN IRELAND SUPPLEMENTARY GUIDANCE FOR COMMUNITY PHARMACISTS 2019
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Foreword

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Background to the NI supplementary guidelines

UK Guidelines on the clinical management of drug misuse and dependence were published in 1991 and subsequently updated in 1999, 2007 and, most recently, 2017. These guidelines have been developed by an expert group that has reviewed the evidence base and been subjected to wide consultation. With each revision the guidelines have grown in size and the most recent version now runs to 330 pages. While the UK guidelines address the full range of illicit, prescription and over the counter drugs which may be misused, they do focus on the treatment options for opioid dependence.

In the 1990’s the number of heroin users in Northern Ireland was very low and those who did engage with addiction treatment services would be offered detoxification in line with the NI CREST Guideline on opioid detoxification (1999).

As the number of heroin users seeking treatment across Northern Ireland increased in the early 2000’s NI guidelines were published to support opioid substitute treatment as NI Guidelines on Substitution Treatments for Opiate Dependence DHSSPS (2004).

The 2004 guidelines were replaced by the Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines (2013). Parts of this document, such as the section on how to choose between methadone and buprenorphine as an opioid substitute treatment, are reflected in the most recent Drug misuse and dependence: UK guidelines on clinical management (2017). However there were some areas of divergence between the NI (2013) and UK (2017) clinical guidelines, such as the frequency of reviewing response to treatment and the provision of take-home doses.

Therefore the NI Department of Health has now adopted the “Drug misuse and dependence: UK guidelines on clinical management (2017)” and withdrawn the
“Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines (2013)”.

The sections of the “Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines (2013)” which were primarily intended to assist dispensing pharmacists remain helpful models of good practice. They will therefore be largely retained with some amendments and additions but are now published in this document as “Opioid Substitute Treatment; Northern Ireland Supplementary Guidance for Community Pharmacists (2019)”. Additional guidance from “Drug misuse and dependence: UK guidelines on clinical management (2017)” and other key documents is included or referenced throughout this document.

Delivering safe and effective opioid substitute treatment requires an agreement and therapeutic alliance involving the patient, prescriber, key worker and community pharmacist to ensure that information on progress in treatment can be shared in a timely way and particularly when the patient is facing challenges on his/her road to recovery.
Introduction

Opioid substitute treatment (OST) is the term used to describe the prescribing of an opioid medication to assist patients who are seeking treatment for dependent use of heroin or other opioids. Opioid substitute treatments are effective in substantially reducing illicit opioid use, HIV risk behaviours, death from overdose, poor health, criminal activity, and also reduce the adverse financial pressures and other stresses on drug users and their families.

Only methadone and buprenorphine are licensed and approved by NICE in the UK for use as an OST. During the initiation of an OST most patients will be expected to have their daily dose of an OST dispensed and consumed under the direct supervision of a pharmacist 5-7 days per week. It is important to closely monitor the patient’s progress during the first month of induction onto an OST when there is a small increase in the risk of death. High levels of supervised consumption of OST reduce the risk of diversion of prescription drugs to people outside of treatment which can have fatal consequences. The responsibility for the level of supervision lies with the prescriber in consultation with the multidisciplinary team and patient. The level of supervision may be relaxed to allow take home doses which may reflect the patient’s progress in treatment or a change in personal circumstances. Some patients may drop out of treatment if they are not permitted take home doses.

The Drug Misuse and Dependence: UK guidelines on clinical management (2017) offer the following advice:-

“Methadone and buprenorphine are both effective medicines for maintenance treatment of heroin dependence, particularly when taken within the optimal dose range”

“Supervised consumption should be available to all patients to support induction on to opioids, and provided for a length of time appropriate to their individual needs and risks”.

“For treatment of addiction to opioids other than heroin, methadone or buprenorphine substitution is commonly used but alternative opioids may sometimes be chosen after careful consideration”
Some GPs have agreements with their local specialist drug services that they will prescribe opioid substitute treatment for users, in conjunction with specialist drug services within an enhanced shared care agreement.

**Opioid Substitute Treatment**

Opioid substitute treatments have primarily been prescribed for individuals who have become dependent on heroin but they are increasingly also being prescribed to treat addiction to opioid medications including over the counter codeine products, tramadol, oxycodone, morphine and fentanyl.

The medicines which are licensed for use as opioid substitute treatments in the UK are as follows:-

**Methadone**

Methadone, a full opioid receptor agonist, is prescribed in liquid form (1mg/ml oral solution) rather than tablet form. Sugar free preparations of methadone are available but most of the dental harms associated with methadone may be due to the acidity rather than the sugar content of this medication. Methadone is usually prescribed once daily, with an initial daily dose of 20–30 mg that is gradually increased, usually at weekly intervals. For most patients the optimal target dose of methadone is between 60 -120mg a day and occasionally more, but some individuals will stabilise and cease illicit drug use on lower doses.

Doses of methadone higher that 120mg a day are most likely to be required in patients who are intrinsically rapid metabolisers of this drug or who are also being prescribed enzyme inducing medications such as carbamazepine. High doses of methadone increase the risk of QTc prolongation, a risk factor for cardiac arrhythmias which can be fatal, as well as a range of metabolic effects including weight gain and sexual dysfunction.
Buprenorphine

Buprenorphine is a partial opioid agonist, which is taken sublingually and is largely inactive if swallowed. It was originally introduced into the UK under the trade name Subutex® but generic formulations are now available and are preferred.

For a minority of patients Subutex® may be appropriate and in such cases the word Subutex® must be written on the prescription.

Buprenorphine can be snorted or dissolved and injected. In some cases, where diversion is suspected, the prescriber may include an instruction on the prescription that buprenorphine tablets should be crushed before being taken under direct supervision. This practice, while off-label, may sometimes be undertaken with appropriate clinical governance approval and protocols (See section on supervision).

Alternative management strategies include switching the patient from buprenorphine onto a buprenorphine/naloxone combination (Suboxone®) or methadone.

Buprenorphine formulations

Buprenorphine is available as 400 microgram, 2 milligram and 8 milligram sublingual tablets.

Buprenorphine is also available as a freeze-dried oral lyophilisate wafer (Espranor®) in 2 milligram and 8 milligram strengths. This is not interchangeable with other formulations at the same dose as the bioavailability is 25-30% higher. The maximum single dose is lower than other preparations i.e. 18mg compared to 24mg (Suboxone®) or 32mg (Subutex®). At the time of writing, this formulation of buprenorphine is not currently approved for prescribing on SP1/SP2 forms in Northern Ireland and therefore should not currently be prescribed.

Buprenorphine/naloxone (Suboxone®)

Buprenorphine/naloxone (Suboxone®) is a 4:1 combination of buprenorphine and naloxone formulated in a sublingual tablet. There are three strengths currently available:

- 2mg buprenorphine / 500 micrograms naloxone
- 8mg buprenorphine / 2 milligrams naloxone
- 16mg buprenorphine / 4 milligrams naloxone

The addition of naloxone to buprenorphine acts as a deterrent to individuals who would wish to inject buprenorphine. Naloxone is an opioid antagonist which has very little effect when taken sublingually or orally and it is therefore administered by subcutaneous, intramuscular or intravenous injection to reverse the effects of an acute opioid overdose. Individuals who inject buprenorphine when combined with naloxone put themselves at risk of precipitating unpleasant symptoms of acute opioid withdrawal.
SECTION 1: Induction risks

There is an increased risk of death during the induction period for both methadone and buprenorphine. Although partial and full agonists offer a relatively safer option than continued drug misuse for some patients, it should be remembered both methadone and buprenorphine are dangerous drugs. Methadone presents a particularly high risk which can never be eliminated completely but can be reduced with proper supervision and by incorporating other safety factors. Treatment should only be initiated by those with specialist training, expertise and experience.

Induction risks for both drugs:

- Low opioid tolerance
- Too high an initial dose
- Concurrent use of CNS depressant drugs, including other sedatives and/or alcohol
- Excessively rapid dose increases
- Impaired hepatic, respiratory, cardiac or renal function

Induction risks with methadone:

- Guidance on the concurrent use of drugs which can increase methadone levels such as erythromycin or cimetidine is available from the following resources
  - The current BNF and individual drug data sheets which are available at the electronic Medicines Compendium (eMC).
    https://www.medicines.org.uk/emc/
  - “Drug Misuse and Dependence: UK Guidelines on Clinical Management 2017”
**Induction risks with buprenorphine:**

There is a risk of precipitating withdrawal which is increased if insufficient time is left before administering buprenorphine to patients who have recently used heroin or who have recently consumed long-acting opioids such as methadone.

At least eight hours should have elapsed since last heroin use when initiating buprenorphine, and it is best to wait until the patient is experiencing withdrawal symptoms. If switching from methadone, the methadone should be reduced to 30ml or less and an interval of at least 24 hours left between the last dose of methadone and the first dose of buprenorphine. If the patient wishes to switch from a higher dose, they should be adequately prepared and consent obtained.
SECTION 2: Initiation of treatment

Once assessment indicates that prescribing is a suitable option, prescribed treatment should generally be commenced promptly and no longer than 3 - 4 weeks from the date of initial referral, although complex assessments may take longer. Trust services will usually give priority to the following groups:

- Pregnant women
- HIV / Hepatitis B / Hepatitis C positive patients
- Patients being transferred from another treatment provider e.g. another Trust/region or prison
- High risk patients e.g. severe physical or mental health issues, high risk injecting practice
- Parents with children at potential risk

Care Plan

A written care plan should be developed across primary and secondary care and arrangements put in place to ensure ongoing joint working arrangements and communication between all relevant parties. A patient agreement should be drawn up with the patient and signed by all parties (see Appendix 1 for a sample version).

All treatment providers should be aware of the community pharmacies in their area that provide a supervised consumption service. The prescriber or a member of the shared care team must contact the pharmacist to get their agreement to provide the service and inform them that a new patient will be presenting at the pharmacy. The following information must be supplied:

- Patient details: name, address, date of birth
- Prescription details i.e. drug name, daily dose, start date, supervision arrangements
- Patient description
- Any previous difficulties encountered with other pharmacies

An agreement should be reached on the date and time that the new patient will present at the pharmacy.
Prescriptions


These documents emphasize that communication between pharmacists, prescribers and keyworkers is essential and particularly important if the patient is missing doses or appears to be unwell.

They also include the Home Office approved wording for writing instructions for supervision and dispensing take-home doses for opioid substitute prescriptions.

Prescriptions for methadone and buprenorphine must be written in instalments of up to 14 days. In Northern Ireland GPs can prescribe these medications on a HS21 form while prescribers working in a secondary care drug addiction clinic must use a Substitute Prescribing Form (SP1 or SP2, see section 14).

Many prescribers working in secondary care can produce computer generated prescriptions similar to GPs.

“Although not a legal requirement there is a strong recommendation that prescriptions for Schedule 2, 3 and 4 controlled drugs are limited to a quantity necessary for up to 30 days clinical need” Safer Management of Controlled Drugs – A guide to good practice in primary care (Northern Ireland) DHSSPS (2013) p47 https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/safer-management-of-controlled-drugs-a-guide-to-good-practice-in-primary-care-version.pdf
SECTION 3: Supervision vs. Take Home Supply

The supervised self-administration of medication by pharmacists optimises compliance and minimises leakage of the prescribed medication into the illicit market. However safety must be balanced against the need to provide a patient-centred approach when considering requests for increased take-home doses.

The Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines 2013 (now superseded) included the following guidance:-

“Ideally new patients should be started on a supervision regime of at least 6 days per week for a minimum of three months. When patients are transferred from another service consideration may be given to varying this period of supervision, being mindful of the effect the change of situation may have on a patient”.

After 3 months of supervised consumption an assessment of the patient’s stability should be undertaken. This requires a holistic review of drug use, the patient’s attitude and motivation to treatment and their social and personal circumstances.

In addition, the following factors should be considered:

- a. Patient attendance at pharmacy and clinical review appointments
- b. Patient’s attitude to treatment including commitment to controlling or abstaining from drug use including alcohol
- c. Drug screening results
- d. Change in patient’s general health, wellbeing and social circumstances e.g. working arrangements
- e. Continued use of illicit drugs or misuse of prescribed drugs whilst on substitute medication and reasons for this
- f. Assessment of risk of overdosing including past history
- g. Patient’s and clinician’s perception of stability on current dose of treatment i.e. patient’s dose is not still being titrated upwards
- h. Concerns about diversion
If appropriate, patients can move to reduced supervision arrangements to allow a greater number of take home doses and in this case the following points apply:

i. The number of supervised doses should normally be reduced in a step wise manner.

j. There should be discussion with the patient about the importance of safe storage particularly if there are any concerns such as children at home.

k. The **maximum** number of take home doses is normally 6 days at any one time, with one supervised consumption per week.

l. The maximum volume of methadone for take home should not normally exceed 600mls. If this volume is exceeded then the healthcare team should be involved in the decision on an individual case basis.

m. Take home doses should remain under regular review. Patients should be advised that the frequency of supervision can increase as well as decrease. An increase in frequency of collection or supervision may be required for some patients but should be seen as an effort to increase level of support rather than a punishment.

The updated UK guidelines on clinical management (2017) support a more flexible and individualised approach to providing take home doses earlier in their treatment, particularly for those individuals who are in regular employment or have difficulty accessing their dispensing pharmacy, while at the same time being ready to increase supervision and support should there be evidence of drug diversion or unstable drug use.

SECTION 4: Management of patients across specialist services and primary care

Transferring stable patients to primary care

Whilst generally patients commence treatment in secondary care, many patients, once stable, can be managed successfully under a shared care arrangement between Community Addiction Teams (CAT) and General Practice.

All GPs providing this service should be suitably trained and operating under a Local Enhanced Service (LES). The GP involved in provision of service may be either the patient’s own GP or another provider in the area. When the responsibility for prescribing an OST is transferred from secondary to primary care the receiving GP and the Community Addiction Service (CAS) both have a responsibility to share relevant clinical or other information to ensure safe and effective care.

The following steps should be taken when transferring a patient from secondary to primary care:

a. Patient is assessed by keyworker and secondary care prescriber for suitability of transfer of care
b. CAS discusses transfer with patient
c. CAS identifies Shared Care GP within patient’s locality and discusses transfer with this GP
d. CAS communicates intention to transfer patient with patient’s own GP (if not the Prescribing / Shared Care GP)
e. CAS provides GP with a summary of the comprehensive assessment and a recent care plan
f. Keyworker informs community pharmacist of transfer
g. Start date is communicated to all involved
h. A new service user and provider agreement is drawn up

Managing a patient’s care normally requires a multidisciplinary approach; this should be provided in collaboration with others such as other primary care practitioners, keyworkers, practice nurses, community pharmacists, practitioners with a special interest and addiction specialists. GPs may for historic reasons have managed
patients outside a shared care model; when this is the case all review and reporting requirements outlined elsewhere within the guidelines still apply.

New patients should not present in a pharmacy with a GP-issued HS21 for opioid substitution therapy if they are not under a shared care agreement or any future modified scheme which has been approved by the Department of Health. If this should happen, the pharmacist should check with the prescriber if this was their intention. The pharmacist can also discuss with the local pharmacy adviser if needed.

Transfer from primary care to specialist service

If a GP concludes that the shared care model is no longer appropriate and that the patient requires to be transferred to the specialist service, prompt transfer should be arranged so that the new specialist service clinic prescription will follow on seamlessly from the existing primary care prescription. Discussion should take place directly between the GP and specialist addiction service clinician. The GP should contact the community pharmacy to advise of the transfer and the need to cancel the remainder of the prescription if appropriate.
SECTION 5: Missed doses

The action to be taken by the community pharmacist will depend on the number of consecutive missed doses as follows:

a. **Missed 1 dose**: The situation should be reviewed by the pharmacist and discussed with patient. The patient should be maintained on their current prescription unless there are concerns about acute intoxication or recent high risk drug use, in which case the pharmacist should discuss the case with the prescriber or keyworker before dispensing medication. The pharmacist should also alert the prescriber or keyworker if the patient is missing doses on a regular basis.

b. **Missed 2 consecutive doses**: The pharmacist must contact the keyworker before the end of the day coinciding with the second consecutive missed dose. The keyworker will then attempt to contact the patient to establish the reason for missing doses, encourage the patient to remain in treatment and update the pharmacist on any changes in the management plan. The patient should be maintained on their current prescription unless there are concerns about acute intoxication or recent high risk drug use. It is important to try and avoid patients missing 3 doses, at which stage they are likely to need a dose reduction, or are at risk of dropping out of treatment.

c. **Missed 3 or more doses**: The prescription should be held until the patient has been reviewed by the keyworker and/or prescriber. They will consider whether to recommence their current OST at a lower dose or discontinue OST until it can be reinitiated by the addiction service. If the patient’s dispensing regime is less than daily dosing the prescriber should consider increasing the level of supervision.

The pharmacist should keep a record of communications with healthcare staff.

For more information on missed doses see *Drug misuse and dependence: UK guidelines on clinical management (2017)* pp 106-107.

SECTION 6: Lost prescriptions or medication

Practitioners should be familiar with the local prescription security policy. As prescriptions for OST are to be dispensed and supplied by a named pharmacy on every prescription it is unlikely that lost prescriptions will be accepted at an alternative pharmacy.

The action required to be taken in relation to lost prescriptions will depend on the circumstance of each case involving a lost or stolen prescription, but practitioners should consider the following:

a. The patient should be advised that they must report the loss to the police and obtain an incident number if they were responsible for the prescription / medication at the time of loss.

b. Service providers should report lost/stolen prescriptions to the Counter Fraud Unit by calling the HSC Fraud Hotline on 0800 096 33 96 or report online at:
   http://www.hscbusiness.hscni.net/services/Counter%20Fraud%20and%20Probity%20Services.htm

c. When a prescription is reported as being lost prior to being dispensed the prescriber may consider issuing a replacement if it is established that there is little risk of “double prescribing”. Contact should be made with the designated community pharmacy and any duplicate script should have “DUPLICATE SCRIPT” transcribed across the top to reduce the possibility of a second dispensing.

d. The consequence of not continuing treatment needs to be weighed against the risk of relapse and overdose.

e. Where medications have genuinely been lost, the risk to others including children should be considered and discussed with patient or others as appropriate.
SECTION 7: Travelling within the UK and abroad

See Drug Misuse and Dependence: UK Guidelines on Clinical Management 2017 Appendix 6: "Travelling abroad with controlled drugs"

Patients travelling abroad can be considered for take home doses of normally up to 14 days. In some circumstances arrangements can be made to have OST dispensed from a local pharmacy or drug service at their destination while the patient is away if their stay exceeds 14 days or if the patient is not stable. In exceptional circumstances only, up to 30 days of medication can be supplied. The decision about the most appropriate arrangement needs to be made on an individual basis.

Further points for consideration:

a. Patients should provide documentary evidence of travel and should provide reasonable notice.

b. For travel within the UK a reciprocal agreement exists whereby both HS21 prescriptions and SP1/SP2 prescriptions can be dispensed by community pharmacies in England, Scotland or Wales. Contact with a local pharmacy should be made in advance of travel by the prescriber to facilitate the patient receiving supplies of their medication.

c. If travelling abroad patients should be encouraged to contact “Release” (Telephone number: 020 7324 2989; E-Mail: ask@release.org.uk; Website: www.release.org.uk). They provide guidance on import/export of controlled drugs.

d. It is the patient’s responsibility to check legal issues regarding import/export of any medications carried with the embassy of the destination country.

e. Methadone tablets may be considered more appropriate for supply when travelling rather than large quantities of syrup. Due consideration should be given to the risk of injection of crushed tablets and an increased risk of diversion.
f. The patient should be given a letter by the prescriber confirming treatment, dose and length of stay and advised to carry this with them whilst travelling.

g. The patient’s home community pharmacist should be advised of the travel arrangements.
SECTION 8: Sharing care with pharmacy

This guidance includes a summary of some of the legal and professional requirements particularly relevant to the storage, supply and destruction of substitute treatments in community pharmacy. For more comprehensive direction consult the following documents:

- Northern Ireland Legislation

- Home Office

- Medicines and Healthcare products Regulatory Agency (MHRA)
  [www.mhra.gov.uk](http://www.mhra.gov.uk)

- Department of Health “The Safer Management of Controlled Drugs – A guide to good practice in primary care (Northern Ireland) Revised 2013 (v3)

- “Drug Misuse and Dependence: UK Guidelines on Clinical Management” 2017

- Pharmaceutical Society of Northern Ireland document Medicines for Human Use (Part 2): Controlled Drugs & Accountable Officer Regulations

- The Care Quality Commission. The safer management of controlled drugs
The pharmacist must ensure that the supervised consumption of treatments for substitution therapy is carried out in an appropriate manner, have a good understanding of the addictions service and provide a quality service to patients.

A directory of NI drug and alcohol services can be found at the following website:

http://www.drugsandalcoholni.info/services-near-you/

Pharmacist responsibilities

a. The pharmacist must have the necessary training to provide this service as outlined in the service specification.

b. They must ensure there are appropriate Standard Operating Procedures (SOPs) in place within the pharmacy. Protocols should be followed for the receipt and dispensing of the prescription, and supervising the consumption of OST.

c. The pharmacy layout and staffing should be appropriate and adequate to allow provision of this service.

d. Each patient should be introduced to appropriate members of the pharmacy team to aid recognition when locums are working.

e. OST medicines should be stored, and disposed of according to the regulations.

f. All relevant documentation and records should be completed.

g. The pharmacist should liaise with the prescriber and other members of the shared care team if there are any queries or concerns.

h. The pharmacy team should ensure the dignity of the patient at all times and respect the patient’s rights to privacy and confidentiality.

i. Supervision of medicines should be conducted in a discreet manner that does not cause embarrassment to the patient.

Ideally a private consultation room should be available in the pharmacy to ensure patient confidentiality during consultation or dispensing/supervised consumption of medication. If supervision does need to take place elsewhere it should be with the agreement of the service user.
j. The pharmacist should advise the patient on medicines information including the safety and storage of take home doses. This should be reinforced as necessary throughout the treatment. General health information should also be provided.

k. The pharmacist should consider if there may be any important interactions between methadone or buprenorphine and any other prescribed medications and inform the prescriber of any potential clinically significant interactions.

l. Patient identity checks are important to ensure continuity of care (see SECTION 9, box “Patient Identity”)

m. The pharmacist should document on the patient medication record any relevant discussions with other clinicians e.g. actions taken when doses are missed.
SECTION 9: New patients

A prescriber or a member of the shared care team should contact the pharmacist to inform them that a new patient will be presenting at the pharmacy and the following information should be supplied/ requested:

- Patient details: name, address, date of birth
- Prescription details: drug name, formulation, daily dose, start date, supervision arrangements
- Patient description
- Patient ID

An agreement should be reached on the date and time of presentation.

Patient Identity

Unlike most other dispensing situations there is virtually no time interval between supply and consumption; it is therefore important that robust systems are in place for identity confirmation to prevent potentially fatal errors. Particular care should be taken if there are language difficulties, if patients have similar names or when locum pharmacists are providing cover.

It should be explained to the patient that identity checks are for their own safety. While many pharmacists will know their regular patients very well it is still good practice to confirm identity at every dispensing. This will ensure familiarity with the process when locums are providing cover.

Photographic identification (ID) is good practice. This can be by an agreement with the patient to produce photographic ID, such as a driving licence, on each occasion substitute medication is to be dispensed. Alternatively a labelled photograph held in the pharmacy may be useful however the patient must give permission for this. A patient medication record card may provide an alternative but be aware of the possibility of misuse by another individual.

Also it is good practice is to ask for an additional patient identifier such as date of birth. The patient should be asked to supply the information using an open question (as opposed to the pharmacist supplying the information for a yes/no reply). Residential address may not be an appropriate check as patients will often tend to live in close proximity to each other.
First Meeting

The patient should present at the pharmacy at the agreed time and date and produce photographic ID which matches the patient description previously given. The pharmacist should introduce themselves and the pharmacy team to the patient.

The pharmacist and patient must discuss and agree a contract (preferably written). It may be incorporated into the multidisciplinary ‘Service patient and provider agreement’ (see Appendix 1 for an example). The agreement should include the following:

a. The method of checking the patient’s identity prior to dispensing (see boxed text “Patient Identity”)
b. That the patient will attend alone
c. The most appropriate time for collection of doses
d. Arrangements for weekend and Bank Holiday doses
e. That the patient must demonstrate that they have taken the dose appropriately i.e. methadone has been swallowed, buprenorphine has dissolved under the tongue
f. That unsuitable or offensive behaviour towards pharmacists or their staff will result in the termination of the contract
g. That the pharmacist will exercise their professional judgement and doses will not be supplied or supervised if the patient appears intoxicated by drugs or alcohol
h. That the prescriber/keyworker will be told when there have been two consecutive missed doses or if there has been any other pattern of repeated missed doses e.g. failure to attend every Monday. In such circumstances the prescriber will review the prescription before reinstatement of supply is considered (see Section 5 Missed Doses).
i. That missed doses will not be supplied at a later date
j. The prescriber/ keyworker will be told if there are any concerns about the patient’s physical or mental health or social circumstances (see comments Section 16 Communication)
k. The pharmacist is unable to supply the dose to a representative (but see below)

The pharmacist may supply the dose to a representative when this is expressly stated on the prescription

l. If the patient cannot attend the pharmacy due to medical reasons, he/she must contact the prescriber or keyworker who must contact the pharmacist. It is not appropriate for the patient to contact the out-of-hours GP service in relation to this.

If the contract is a written one, then a copy should be given to the patient.
SECTION 10: Prescription validity

The prescription can be a secondary care issued SP1/SP2 or a GP issued HS21.

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

a. It is written so as to be indelible (i.e. handwritten or printed from clinical system), be dated and be signed by the person giving it with his usual signature
b. It specifies the address of the person issuing it
c. It specifies the name and address of the person for whose treatment it is issued
d. It specifies the name of drug e.g. methadone or buprenorphine
e. It specifies the dose to be taken e.g. 50mg daily, 4mg daily
f. It specifies the form e.g. oral solution and strength of the liquid.
Methadone should always be prescribed as an oral solution 1mg/ml strength
g. It specifies either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied e.g. 50 (fifty) mls or 10 (ten) tablets
h. In the case of a prescription for a total quantity intended to be dispensed by instalments, contains a direction specifying the amount of the instalments that may be dispensed and the intervals to be observed when dispensing

In addition for substitute prescribing the prescription must indicate:

i. The start date i.e. the date the first dose is to be dispensed (this is in addition to the date of issue)
j. Whether supervision is required
k. Arrangements for weekends or Bank Holidays should be explicitly stated on the prescription and not require interpretation e.g. ‘Dispense on Saturday for Sunday’
l. The pharmacy name
A prescription for methadone or buprenorphine must not be supplied:

m. unless the pharmacist is either acquainted with the prescriber’s signature and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine

n. before the appropriate date specified on the prescription

o. later than 28 days after the appropriate date on the prescription

p. In the case of an instalment prescription, unless the first instalment is dispensed within 28 days of the issue date with the remaining instalments dispensed in accordance with the instructions.

It should be noted that under NHS (General Medical Service Contracts) Regulations 2004; Part 3 Regulation 39 (4), with regard to prescribing methadone or buprenorphine for the treatment of addiction by instalment dispensing, GPs are directed to “order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.”

In general methadone should be prescribed as a sugar free (SF) preparation

See p 39: Appendix 2: Home Office approved wording on collection of doses (Appendix 2)

Also refer to the “Drug misuse and dependence: UK guidelines on clinical management (2017)”; section A4 “Writing prescriptions”, pp 277-292 for a more extensive list of examples of prescribing, dispensing and supervision situations.
SECTION 11: Dispensing medications

The daily dose should be dispensed and labelled appropriately before the patient arrives. Prepared daily doses must be locked in the CD cupboard (see storage requirements).

The following should be adhered to when dispensing:

a. Two members of staff should, where possible, check the volume, strength and formulation (sugar-free) of methadone or the strength and quantity of buprenorphine dispensed.

b. Self-checking is not recommended other than in exceptional circumstances when it is in the patient’s best interests to do so and procedures are followed to ensure patient safety. For example, leaving a suitable time gap between dispensing and checking steps to provide a mental break.

c. Use the smallest reasonably sized plastic or glass bottle for dispensing methadone. Doses must not be dispensed directly into a disposable plastic cup.

d. The label must include:
   - Patient’s name
   - Methadone/buprenorphine strength, form, quantity and dose
   - Whether supervised or take home
   - Date of dispensing
   - Name and address of the pharmacy
   - ‘Last dose’ when appropriate

e. Take home doses of methadone must be dispensed in separate bottles for each day with child resistant caps

f. There is no requirement for take home doses of identical strength buprenorphine tablets to be dispensed in separate containers for each day as the tablets are easily counted by the patient

g. If a mixture of strengths is involved, these must be dispensed and labelled separately in accordance with standard ‘best practice’ procedures
SECTION 12: Supervision

For methadone, buprenorphine and buprenorphine/naloxone

a. The patient should not witness removal of the dispensed container(s) from the CD cupboard

b. The patient’s identity should be checked before the dose is administered

c. The supervision procedure should be discreet and efficient, to be mindful of the patient’s dignity and the pharmacist’s time

d. Supervision should not take place in the dispensary but rather should occur in a quiet area, ideally the consultation room

e. The patient should be informed in advance of the last dose on the current prescription to allow timely supply of next prescription

f. In cases where disposable plastic cups are used, provision must be made for safe disposal to ensure no cross infection is possible.

g. Patients should not be allowed to bring opened containers of drinks into the pharmacy.

For methadone

h. The pharmacist should provide the opportunity for the patient to check the name of the medicine, quantity and dose on the label before dose is taken

i. The dose should be poured into a suitable container and given to the patient

j. 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 patient or other means of ensuring that the methadone is not retained in the mouth

For buprenorphine and buprenorphine/naloxone

k. The pharmacist should provide the opportunity for the patient to check the name of the medicine, quantity and dose on the label before dose is taken

l. Ideally, the patient should have a drink of water before dispensing to moisten the mouth
m. The pharmacist should pop the tablets out of the blister pack, either into the patient’s hand or into a small disposable cup

n. 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

o. The tablet should not be swallowed, as it is ineffective if taken this way

p. The patient should be observed for five minutes or until the pharmacist is satisfied (either by conversing with the patient, water being swallowed or other means) that the medication has not been concealed in the mouth and is fully dissolved. Once dissolved, what remains is a chalky residue that can be swallowed.

q. When the total daily dose of buprenorphine requires three or more individual tablets to be taken the advice of the manufacturer is that no more than two tablets of any strength should be placed in the mouth and allowed to dissolve at one time. The patient should be encouraged to comply with this and be supervised appropriately; it is accepted in practice this may be difficult to achieve with some individuals.

**Crushing buprenorphine tablets**

This means of dispensing buprenorphine which was devised to make supervision simpler but it is generally not recommended and should not be routinely carried out unless explicitly requested by the prescriber. Crushing buprenorphine sublingual tablets is outside the manufacturers marketing authorisation and will render the product unlicensed. Both prescriber and pharmacist should be aware of the liability issues with using unlicensed methods and be prepared to accept responsibility for any adverse events which may result. Pharmacists who are considering crushing buprenorphine tablets before administration need to be satisfied that this is in the patient’s best interests as there is the potential for the product’s bioavailability profile to be distorted. Crushing will affect the rate of dissolution of the drug and may result in a variable dosage being absorbed as any drug swallowed will be lost to first-pass metabolism. The prescriber and the patient should agree to the tablets being crushed before administration and the patient should be informed of the risks and the
benefits of crushing. Any crushing of buprenorphine tablets should be for the benefit of the patient, rather than the convenience of the pharmacist.

Suboxone™ must not be crushed

In the first instance any issues with supervision should be discussed with the prescriber as a switch to methadone may be more appropriate. Any change from crushed tablets back to whole tablets should also be discussed with the prescriber.

See RPSGB guidelines on crushing buprenorphine, April 2005
SECTION 13: CD Register

On supplying methadone to a patient, the CD register must be completed within 24 hours. 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. It is good practice to complete the register at the time of supply to the patient. Buprenorphine 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.

SECTION 14: Prescription processing

The prescription form must be completed with the prescription code endorsements and date of dispensing/ supervision as appropriate. The original prescription should be kept until it expires or is completed. It is then submitted to BSO for payment in the usual way. Uncollected doses can be reused. In order to claim a dispensing fee in this instance the prescription should be coded as normal but the quantity entered as ‘0’. Examples are illustrated below:
SECTION 15: Storage and disposal of methadone and buprenorphine

a. All stocks of controlled drugs must be stored in accordance with the Safe Custody Regulations. The Department of Health has advised that storage in the approved CD time delay safe would fulfil the requirements of the Regulations.

b. Disposable plastic cups must be discarded after single use.

c. Labels must be removed from all bottles including stock bottles prior to disposal.

d. Patient names should be removed from dispensing labels prior to disposal to maintain patient confidentiality.

e. For take-home doses the safe storage message should be reinforced to the patient;

- It should ideally be kept in a locked cupboard
- It should never be accessible to children
- It should not be kept in a refrigerator for both safety and stability reasons (the colouring may precipitate in some brands)
- It should never be transferred to another container

Store all dangerous medicines in a high place well away from children and vulnerable adults, preferably in a locked container
SECTION 16: Communication between pharmacists, prescribers and keyworkers

A list of contact names and telephone numbers for prescribers and local addiction teams should be kept and maintained in the pharmacy.

The pharmacist must inform the prescriber or keyworker, where appropriate, of the following:

- A new patient who does not present as agreed
- Two consecutive missed doses or if there is any other pattern of repeated missed doses e.g. failure to attend every Monday
- A patient 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 patient presenting without prior contact from the prescriber
- Any concerns regarding the patient’s social circumstances including child safety and protection issues
- Any concerns that the patient may present a risk to self or others by driving

Addictions Unit or GP practice staff may contact the pharmacist to advise if the patient is unable to collect a dose for medical reasons.

The Public Health Agency maintains links to current local drugs and alcohol services:
http://www.drugsandalcoholni.info/services-near-you/
SECTION 17: Patient Medication Records

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

a. Name, address, DOB of patient
b. Medical conditions
c. Prescriber details
d. Medication details to include whether the dose is supervised or not
e. Other relevant information such as keyworker contact details

SECTION 18: Standard Operating Procedure (SOP)

Each pharmacy delivering this service should have a written SOP which is available for all staff including locums. This should be reviewed and updated regularly.

SECTION 19: Health information

Patients should be given information and advice on the safety of take home doses. Health promotion leaflets (if available) and advice on medicines should also be provided.

See the Public Health Agency range of health information leaflets:
http://www.publichealth.hscni.net/publications

Drug users who are smoking nicotine products should be encouraged to quit smoking using the full range of treatment options.

See BSO website: Stop Smoking “Pharmacists Guide to Smoking Cessation Service”
http://www.hscbusiness.hscni.net/services/2154.htm

See Public Health Agency “Stopping Smoking”
Appendix 1: Service User and Provider Agreement

Service User_____________________________        Keyworker____________________________

**Service Users**
I agree
To treat with respect all people I have contact with in connection with my treatment
To keep my appointments promptly and, unless absolutely necessary, unaccompanied
To accept responsibility for my prescription and medicines as replacements are not normally issued
To store any medicines I am allowed to take home safely away from others, especially children
To my prescription being withheld if I am intoxicated or have missed more than two consecutive daily doses
To provide samples for drugs of abuse screening
To allow sharing of relevant information by all professionals involved in my treatment and to voluntarily disclose my treatment if I attend other providers such as Emergency Department, Out-of-hours or my own GP
To participate in periodic reviews
To inform the Driver and Vehicles Agency (DVA) if I intend to continue driving, as required by law
To discuss any holiday plans with the clinic well in advance of travel and provide documentary proof of same
To supervised consumption of medicines in the pharmacy at mutually agreed times of day
Not to engage in any antisocial or illegal behaviour in the clinic or pharmacy including theft, shoplifting and verbal/physical aggression
Not to make any attempt to obtain medicines by deception or to sell any medicines provided
Not to conceal or carry weapons

**Service Providers**
I agree
To share relevant information with all professionals involved in the treatment
To participate in periodic reviews as necessary
To treat the above-named service user with respect
To ensure that the staff I work with treat the above-named service user with respect (Doctor/Pharmacist)
To provide high quality health care, as for any other service user (Doctor)
To provide adequate substitute drug treatment for the above-named service user (Doctor)
To provide a clear and legible prescription that meets legal requirements for controlled drugs (Doctor)
To contact a community pharmacist and arrange dispensing (Doctor)
To give the service user regular therapeutic support sessions at the shared care clinic (Keyworker)
To provide a personal programme plan to meet the needs of the service user (Keyworker)
To facilitate access to other Health & Social care as appropriate for the service user (Keyworker)
To facilitate access to other external services as appropriate for the service user (Keyworker)
To provide the service user with information about medicines (Pharmacist)
To ensure that the supervised dispensing takes place in a private area of the pharmacy (Pharmacist)
To explain protocols for missed doses (Pharmacist)
To provide a pharmacy practice leaflet giving information about the service (Pharmacist)

Attention: If you fail to benefit from treatment a case review will be arranged to review your care

<table>
<thead>
<tr>
<th>Service user:</th>
<th>Date:</th>
<th>Pharmacist:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keyworker:</td>
<td>Date:</td>
<td>Doctor:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

Warning: Methadone or buprenorphine can be dangerous, especially when taken by anyone who has no tolerance to it or with other opioids, benzodiazepines and/or alcohol

NB This form is available on the BSO website (Word version)

http://www.hscbusiness.hscni.net/services/PharmBSES.htm
Appendix 2: Home Office approved wording on collection of doses

Where the prescription for a Controlled Drug contains a direction that specified instalments should be dispensed at specified intervals, supplies must not be made otherwise than in accordance with the directions unless the following text is on the prescription:

**Supervised Consumption**

“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 total amount prescribed less the amount prescribed for the day(s) missed may be supplied.”

**Unsupervised Consumption**

"Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e. the instalment less the amount prescribed for the day(s) missed) may be supplied". *

or;

"If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the missed days may be supplied.”

The Home Office approved wording to be used if the prescriber would like to ensure that the patient is not supplied with their dose if they have missed collecting their dose for three days is:

“Instalment prescriptions covering more than one day should be collected on the specified day. If this collection is missed, the remainder of the instalment (i.e. the total amount less the instalments for the days missed) may continue to be supplied in the specified instalments at the stated intervals, provided no more than three days are missed.”

Likewise, the following wording can be used to support the collection of Methadone when the pharmacy will be closed on the due date specified on the
prescription:

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

* NB this wording is already printed by default on SP1 and SP2 forms

See additional guidance on writing prescriptions in the “Drug misuse and dependence: UK guidelines on clinical management” (2017), pp 277-292
Appendix 3: References

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Appendix 4: Revision of the NI Primary and Secondary Care Opioid Substitute Treatment Guidelines to Supplementary Guidance for Community Pharmacists

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