STAFFORDSHIRE SUBSTANCE MISUSE COMMISSIONING TEAM

PHARMACEUTICAL CARE FOR SUBSTANCE MISUSERS

-

GUIDELINES FOR SUPERVISED CONSUMPTION OF METHADONE/BUPRENORPHINE

Table of Contents

Acknowledgement

This pack has been developed by the County Drug and Alcohol Action Team, PCTs, LPCs, Community Teams and Lloyds Pharmacy.

Special thanks and acknowledgement for the continued support of Lloyds Pharmacy who have allowed the use and modification of their Pharmaceutical Care for Drug Users pack.

Thanks also to colleagues and partners who have contributed to the production of this document, especially the Supervised Consumption Working Group.

It is hoped the pack will help clarify and standardise procedures across the county.

Introduction

Drug-substitute prescribing has been available in the UK since the late 60's. The only two licensed substitutes in the treatment of opiate dependence are methadone (physeptone) and buprenorphine (subutex, temgesic).

Methadone is the most comprehensively researched and prescribed oral substitute. Buprenorphine on the other hand, was introduced in the UK in 1998 as an alternative to methadone maintenance and the management of opiate withdrawal. The use of buprenorphine in the treatment of drug dependence has been growing since April 2000 when it was allowed to be prescribed and dispensed in instalments using.

Objectives

When you have read this pack, you will be able to:

- Understand the reasons behind drug-substitute prescribing
- Understand the pharmacology, pharmacokinetics, dosing and adverse effects of the two licensed drug substitutes in the UK - methadone and buprenorphine
- Begin to understand the interactions of methadone and buprenorphine with other drugs
- Appreciate the value of supervising the consumption of drug substitutes

Why Substitutes?

Prescribing of diamorphine (heroin) for drug users is only permitted under a special licence from the Home Office. Substitutes are therefore used to alleviate withdrawal symptoms, and to stabilise and reduce the use of illicit drugs. They are commonly prescribed in almost all treatment regimes - stabilisation, maintenance, reduction and detoxification (see chapter 5 of Department of Health, [DoH] 2007)

An ideal drug substitute should possess the following characteristics:

- Can be given orally
- Can reduce severity of craving and withdrawal
- Has a slow onset of action with minimal euphoric effects (so that it is less likely to be diverted to the black market)
- Can be easily titrated to achieve the correct dose
- Long lasting to allow daily or less frequent dosing
- Is acceptable to Clients
- Can block or considerably reduce the effects of illicit drugs

Methadone

Methadone is a synthetic orally active opioid first developed in Germany in 1941. It is available as a 1mg/ml oral solution, 5mg tablet and 10mg/ml injection, and is classed as a Schedule 2 controlled drug under the Misuse of Drugs Act 1971. Only the oral solution is licensed for use in the treatment of opiate dependence, although tablets and injections are sometimes used in exceptional circumstances, e.g. when clients have responded poorly to oral methadone. Methadone tablets have been reported to be misused by injecting the

solution made from the crushed tablets. This practice is very dangerous and damaging and can lead to severe consequences such as amputation. Methadone injections on the other hand, have a very high currency on the illicit market and therefore are used less frequently. From 2002, physicians who wish to prescribe methadone injections must be specially licensed by the Home Office.

A green colouring is usually added to the oral solution to distinguish it from other preparations and to deter users from injecting the solution. The oral solution is also available as a colour-free preparation but this should only be used when there is an absolute clinical need, e.g. allergy to the dye, as the colour-free preparation has a higher potential for being misused by injecting.

Pharmacology and Pharmacokinetics

There are four major types of opioid receptors in the central nervous system: mu (μ), kappa (κ), delta (δ) and sigma (σ). The euphoria, physical dependence and respiratory depression effects produced by opioids are thought to be mediated by the μ receptors. Methadone is a μ receptor agonist.

- An agonist is a chemical that binds with specific receptors and triggers off a cascade of neurological activity which result in the full extent of effects that are experienced by the individual

Methadone is absorbed from the gastrointestinal tract within 30 minutes of being taken orally. The plasma level peaks at about four hours. Methadone has a long half-life (24-48 hours) and is usually given once daily.

Methadone is broken down principally in the liver and the metabolites are excreted via the kidneys. Traces of methadone (2-10%) are also excreted in urine unchanged. When checking the compliance to the treatment through urine testing, both methadone and its metabolites should be tested for as the presence of methadone alone, without the metabolites, indicates the urine has been tampered with, i.e. the sample has been laced with methadone to give a false positive result.

Dosing

There is no stated maximum daily dose in the British National Formulary (BNF). The Client's history of opiate use should be assessed carefully in order to achieve the correct dose. The quantity, frequency, route of administration, and use of other drugs such as benzodiazepines and alcohol should be considered.

A single 20 - 40mg dose of methadone can produce life-threatening effects in non-tolerant adults, and a 5mg dose can kill a child. This is mainly due to respiratory depression. There have been several cases of fatal accidental poisonings reported in the children of opioid-dependent parents.

a. Commencement Dose

The initial daily dose may be between 10mg and 40mg (BNF, 2008). However, an initiation dose is generally between 10mg and 30mg per day. Caution is urged due to the risk of overdose especially with 'treatment naïve' clients where a dose range of 10mg-20mg daily should be utilised (DoH, 2007) . For heavily dependent clients where there is evidence of persistent moderate to severe withdrawal symptoms then a supplementary dose on the same day may be considered after careful assessment by the prescriber (DoH,2007). Usually a client will have a daily supervised consumption prescription via their chosen pharmacist for at least the initial 3 months.

b. Stabilisation Period

Increases should not exceed 10mg per day and be no more than 30mg in any week until no signs of withdrawal or intoxication. Usual dose range is between 60mg and 120mg per day (BNF, 2008; DoH 2007). Stabilisation is normally complete by the end of week 6, although some Clients may take longer. It is proposed that, at low doses of 15-25 mg, methadone simply prevents opioid withdrawal symptoms but the craving for opioids remains. At higher doses, a progressive reduction in craving occurs with increasing dose. Finally, at a dose of 80-120 mg/day 'narcotic blockade' is achieved. It blocks the euphoriant effects of other opioids without producing euphoria itself. However, the difficulty is tailoring the dose correctly and safely to avoid overdose.

c. Maintenance Dose

After dose stabilisation, there is increasing evidence of the benefit in maintaining the Clients on a daily dose of between 60-120mg however doses are usually between 40–60mg. For Clients with a high tolerance, higher doses may be required. Plasma methadone monitoring can be useful in determining the adequacy of dosage, especially when good treatment compliance is ensured through supervised consumption.

If a client has missed more than 3 consecutive daily 'pick-ups' a pharmacist is normally unable to dispense the next day's dose without clarifying with the prescriber that it is safe to do so. This is because the Client's tolerance may have altered and there is a risk of intoxication. If 5 or more daily doses of methadone have been missed, the Client will definitely require a full assessment before treatment is recommenced.

Methadone maintenance is only effective when given as part of a structured maintenance programme, which incorporates psychosocial interventions to enable the Clients to remain stable, reduce illicit drug use, improve health and reduce criminal activity.

The Client and accompanying carers should be provided with information on the recognition of methadone toxicity.

d. Drug Reduction Regimes

When the Client is stabilised on methadone, it may be appropriate to set up a formal drug reduction regime. This should only be carried out with the Client's agreement. It may take months or even years for a Client to feel ready for a reduction regime.

The daily dose can be reduced by 5 - 10mg every week or every fortnight. The Client should abstain completely from heroin. Regular clinical reviews should be carried out. If the Client is not fully compliant, it is best to continue with a stabilised maintenance dose.

Adverse Effects

Long-term toxicity is very rare. The adverse effects are similar to other opioids, which include:

- Nausea & vomiting (especially in initial stages)
- Constipation
- Drowsiness
- Urinary retention
- Dry mouth
- Sweating
- Headache
- Facial flushing
- Pruritus (itchiness)
- Rashes
- Urticaria (an itchy skin eruption with transient lesions of varying shapes and sizes)
- Vertigo (dizziness)
- Decreased libido
- Mood changes
- Palpitations
- Postural hypotension

One major adverse effect of methadone is excessive sweating, especially night sweats. It is also associated with itching and constipation. Another rare side effect is thrombocytopenia (reduced platelet count which may result in bleeding disorders), which is most commonly seen in Clients with HIV or cirrhosis (liver damage) associated with spleen enlargement. Weight gain can also be a problem for some Clients.

Tolerance usually develops to most of these adverse effects except constipation. In the initial stages of opioid use, sexual desire may be enhanced. However, chronic administration tends to depress sexual desire and performance.

N.B. Risk of prolonged QTc intervals in patients taking high doses of Methadone. See advice in DoH (2007) pg 98.

Overdose

The level of tolerance varies from Client to Client and therefore the risk of overdose must be assessed individually. The signs and symptoms of methadone overdose are:

- Respiratory depression
- Pulmonary oedema - abnormal accumulation of fluid in the lungs
- Arrhythmia secondary to hypoxia (inadequate cellular oxygen)
- Coma
- Hypotension
- Bradycardia
- Hypothermia
- Dysphoria – a state of feeling unwell or unhappy (characterised by depression and anguish)
- Hallucinations
- Heavy sedation
- Miosis (pinpoint pupils)

Concurrent use with benzodiazepines e.g. temazepam, or diazepam and/or alcohol significantly increases the risk of respiratory depression.

All of these symptoms except arrhythmia and pulmonary oedema can be reversed with an opioid antagonist (a drug that blocks opioid receptors) such as naloxone. There is, however, a risk of precipitating acute opioid withdrawal.

Due to the long half-life of methadone, up to 72 hours of naloxone administration may be required after an overdose with methadone.

Drug Interactions

Interactions can be pharmacokinetic and/or pharmacodynamic. Pharmacokinetic interactions affect the absorption, distribution, metabolism or excretion of methadone.
Pharmacodynamic interactions are the reactions between methadone and other drugs and may increase or reduce opiate effects of the drug.

The following table is adapted from BNF (2008) , DoH (2007) [table 10 page 110] and from www.emc.medicines.org.uk N.B. Always consult latest version of the BNF for any amendments to this list

Drug	Status of Interaction	Effect	Mechanism
Alcohol	Clinically important	Increased sedation, increased respiratory depression Combination may also have increased hepatotoxic potential	Additive central nervous system depression
Barbiturates	Clinically important	Reduce methadone levels Increased sedation Additive CNS depression	Barbiturates stimulate hepatic enzymes involved in methadone metabolism
Benzodiazepines	Clinically important	Enhanced sedative effect	Additive CNS depression
Buprenorphine	Clinically important	Antagonist effect or enhanced sedative and respiratory depression	Buprenorphine is a partial agonist of opiate receptors
Carbamazepine	Clinically important	Reduced methadone levels	Carbamazepine stimulates hepatic enzymes involved in methadone metabolism
Chloral hydrate	Clinically important	Enhanced sedative effect	Additive CNS depression
Chlormethiazole	Clinically important	Enhanced sedative effect	Additive CNS depression
Cimetidine	Two cases have been shown in patients taking methadone as analgesia	Possible increase in methadone plasma levels	Cimetidine inhibits hepatic enzymes involved in methadone metabolism
Cisapride Domperidone Metoclopramide	Theoretical	Theoretically might increase the speed of onset of methadone absorption, but not the extent	Possibly by reversing the delayed gastric emptying associated with opioids
Cyclizine and other sedating anti-histamines	Clinically important	Anecdotal reports of injection of cyclizine with opiates causing hallucinations Reports of injection of high doses of diphenhydramine with opiates to achieve 'buzz'	Additive psychoactive effectsAnti-muscarinic effects at high doses
Desipramine	Clinically important	Raised desipramine levels by up to a factor of two	Unknown interaction not seen with other tricyclic antidepressants
Other tricyclic antidepressants	Theoretical	Enhanced sedative effect, which is dose dependent	Additive CNS depression
Disulfiram	Avoid in combination with methadone formulations containing alcohol (check with manufacturers)	Very unpleasant reaction to alcohol which can be alarming	Disulfiram inhibits alcohol metabolism allowing metabolites to build up
Erythromycin	In theory should interact, but combination has not been studied	Increase in methadone levels	Decreased methadone metabolism
Fluconazole	In theory the same as ketoconazole	Raised methadone levels	Decreased methadone metabolism
Fluoxetine	Clinically important	Raised methadone levels but not as significant as for fluvoxamine	Decreased methadone metabolism
Fluvoxamine	Clinically important	Raised plasma methadone levels	Decreased methadone metabolism
Other SSRI	Theoretical	Raised plasma methadone levels	Decreased methadone metabolism
Grapefruit Juice	Should interact in theory and there have been several anecdotal reports	Raised methadone levels	Decreased methadone metabolism
Indinavir	Clinically important	Raised methadone levels	Decreased methadone metabolism

Drug	Status of Interaction	Effect	Mechanism

Ketoconazole	Clinically important	Raised methadone levels	Decreased methadone metabolism
MAOI (including selegiline and moclobemide)	Severe with pethidine Unlikely with methadone and has never been described	CNS excitation delirium, hyperpyrexia, convulsions, hypotension or respiratory depression	Unclear Avoid the combination if possible
Naltrexone	Clinically important	Blocks effect of methadone (long acting)	Opiate antagonist – competes for opiate receptors
Naloxone	Clinically important	Blocks effect of methadone (short acting), but may be needed if overdose suspected	Opiate antagonist – competes for opiate receptors
Nevirapine	Clinically important	Decreased methadone levels	Increased methadone metabolism
Nifedipine	Has been demonstrated in vitro only	Increased nifedipine levels No effect on methadone levels	Methadone increases the metabolism of nifedipine
Omeprazole	To date, demonstrated only in animals	Increased methadone levels	Possibly an effect upon methadone absorption from the gut
Phenobarbitone	See barbiturates above		
Phenytoin	Clinically important	Reduced methadone levels	Phenytoin stimulates hepatic enzymes involved in methadone metabolism
Rifampicin	Very important: most patients are likely to be affected	Reduced methadone levels	Rifampicin stimulates hepatic enzymes involved in methadone metabolism
Rifabutin	Occasionally clinically important	Decreased methadone levels	Increased methadone metabolism
Ritonavir	Clinically important	Ritonavir may increase plasma methadone levels	Inhibits methadone metabolism
Other protease inhibitors	Theoretical	May alter methadone plasma levels	Inhibits methadone metabolism
Urine acidifiers e.g. ascorbic acid – vitamin C	Clinically important	Reduced plasma methadone levels	Raised urinary excretion of methadone
Urine alkalinisers e.g. sodium bicarbonate	Clinically important	Increased plasma methadone levels	Reduced urinary excretion of methadone
Zidovudine	Clinically important	Raised plasma levels of Zidovudine No effects on methadone levels	Unknown
Zopiclone	Clinically important	Enhanced sedative effect	Additive CNS depression
Other opiates	Clinically important	Enhanced sedative effect Enhanced respiratory depression	Additive CNS depression
Other CNS depressant drugs (e.g. neuroleptics, hyoscine)	Clinically important	Enhanced sedative effect, which is dose dependent	Additive CNS depression

Buprenorphine (Subutex)

Buprenorphine is a semi-synthetic derivative of opium. It is derived from the morphine alkaloid thebaine. The drug has been available in the UK for decades, for the management of pain. It was licensed in the UK in 1999 for the management of opioid dependence, as an alternative to methadone. However, in other countries such as France, Italy and India, buprenorphine has been widely prescribed as an oral opioid substitute for many years.

Growing evidence suggests that buprenorphine is as effective as methadone in opioid maintenance when used in equivalent doses. There is as yet not sufficient evidence to recommend buprenorphine as a detoxification agent, although it has been reported to be more effective than symptomatic medications such as clonidine and benzodiazepines in detoxification from heroin.

In the context of drug dependence management, buprenorphine is available as 0.4mg, 2mg and 8mg sublingual tablets (as *Subutex*, manufactured by Schering-Plough). It is a Schedule 3 controlled drug as defined by the Misuse of Drugs Act 1971.

Pharmacology and Pharmacokinetics

Buprenorphine is a partial agonist at μ and κ receptors, and an antagonist at δ receptors. The role of μ receptors in opioid dependence have been explained earlier. κ receptors are responsible for miosis and sedation effects, whereas δ receptors are thought to be responsible for dysphoria, hallucination, respiratory stimulation and vasomotor stimulation (constriction of blood vessels).

- A partial agonist binds with the receptors but only results in a partial response (c.f. full response produced by an agonist).
- An antagonist on the other hand, binds with the receptors without producing the intrinsic effects at all.

Being a partial agonist at μ receptors, buprenorphine exerts sufficient opiate effects to prevent or alleviate opioid withdrawal with milder, less euphoric and sedating effects than other opioids such as methadone, morphine or heroin.

Buprenorphine has a very high affinity for these opioid receptors, i.e. it can displace other opioids from the receptors. This property, in conjunction with its partial agonist and antagonist characteristics, render buprenorphine the capacity to precipitate rapid opioid withdrawal if taken in the presence of other opioids. This has a significant implication when transferring a patient from methadone or heroin to buprenorphine.

The partial agonist properties of buprenorphine make it easier for some Clients to become stabilised. Other advantages include low euphoric effects even at high doses, less risk in overdose and lower risk of respiratory depression. Anecdotally, buprenorphine is easier to detoxify than methadone. There is also a theoretical advantage that Clients are less likely to use other opioids on top due to its blocking effects.

Due to extensive first pass metabolism, i.e. pre-systemic metabolism by gastric acid and the liver, buprenorphine is not effective when swallowed. The current dosage form (as *Subutex*) is designed to be taken sublingually (under the tongue) where it will be absorbed rapidly from the buccal mucosa. Peak plasma concentration occurs between 90 - 150 minutes but most Clients subjectively experience the effects at around two to four hours. Its clinical effects peak at 1 - 4 hours post dose.

Buprenorphine has a long half-life. When given at low doses (2 - 4mg), it is effective for up to 12 hours. At high doses (e.g. 16 - 32mg), it can exert effects for up to 48 - 72 hours. It is usually prescribed as a once daily dose but its long half-life allows alternate days or three times a week dosing for some Clients who are on a maintenance programme.

Once absorbed, buprenorphine is metabolised principally in the liver and excreted in the faeces and urine. It cannot, however, be detected on routine urinalysis for opioids. Some laboratories can test the presence of buprenophine via microplate urine tests by special arrangement.

As with any other opioids, buprenorphine should only be used with extreme caution in Clients with liver impairments because the risk of respiratory depression is high. The product licence does not cover Clients under 16 year old and breast-feeding women. Although it is not contra-indicated in pregnancy, practitioners who choose to prescribe buprenorphine for pregnant women should report to the manufacturer (Schering-Plough). Clients on buprenorphine who subsequently become pregnant should be referred to a specialist. They should be informed that the treatment could be continued and also be made aware of the fact that there is a lack of safety evidence.

Dosing

It is recommended that buprenorphine should only be initiated by a specialist practitioner. The prescription can then be continued by a general practitioner once the Client has been stabilised.

a. Induction

Prior to the commencement of buprenorphine, Clients on methadone should reduce the dose to 30mg daily or less, and/or reduce their dose of heroin. The first dose of buprenorphine should only be given at least 24 to 48 hours after the last dose of methadone, and at least 8 hours after the last dose of heroin, preferably when the Client is experiencing mild withdrawal symptoms.

The starting dose is usually 4 - 8mg depending on the level of dependence, as a single dose. If there are signs of withdrawal and/or craving, increase the daily dose by up to 4mg per day until the Client is stabilised. The daily dose should not exceed 32mg. If the Client experiences

intoxication or severe side effects, the daily dose should be reduced by 2 - 4mg. The usual effective daily dose is 12 - 24mg.

Please ensure that the client has and understands the need for a warning card.

b. Maintenance

In maintenance, 8mg of buprenorphine is roughly equivalent to 60mg of methadone. However, it is not a linear relationship and direct equivalence is difficult to estimate.

Buprenorphine maintenance dose range is 8 - 32mg daily. The most usual dose range is between 12 - 24mg per day. The maximum dose of buprenorphine is 32mg but in practice, such high doses are usually used in alternate days/ three times a week regimes.

Due to the lack of evidence and experience, doses higher than 32mg per day should not be used.

c. Reduction & Detoxification Regime

Once a Client has been stabilised on buprenorphine, a reduction or detoxification regime may be considered providing there is no ongoing use of heroin, alcohol or benzodiazepines, nor recent history of overdose. It is crucial to set treatment goals with the Client at the outset; the Client's expectations, concerns and aftercare needs should be addressed. The Client should not be made to withdraw more quickly than they can cope with as there is a high risk they may resort to illicit drugs again.

The following gradual dose-reduction schedule may be used:

Daily Dose	Reduction Rate
> 16mg	4 mg every week or fortnight
8 – 16mg	2 - 4mg every week or fortnight
2 – 8mg	2mg every week or fortnight
< 2mg	0.4 - 0.8mg every week or fortnight

Some Clients may decide to reduce more slowly or quickly than this.

Adverse Effects

Most adverse effects of buprenorphine are similar to other opioids, which are described in the Methadone section earlier. Some Clients have reported experiencing a metallic taste and 'clear-headedness' (as opposed to the 'clouding' associated with heroin and methadone). Ironically, Clients may find this 'clarity' quite uncomfortable.

Other reported adverse effects of buprenorphine are associated with opioid withdrawal due to its antagonist effects, including rhinorrhea (runny nose), yawning, pain, abdominal spasm, insomnia etc. It can sometimes cause orthostatic hypotension (low blood pressure on standing) which may result in dizziness and falls if the Client gets up too quickly from sitting or lying down.

Overdose

The risk of respiratory depression, sedation and coma is lower than other opioids but it can be significant when used in combination with benzodiazepines, alcohol and other central nervous system depressants such as barbiturates, tricyclic antidepressants etc.

Buprenorphine is not easily displaced by the antagonist naloxone, high doses (10-30 times the normal naloxone dose for opioid reversal) will be required to reverse the effects. The long duration of actions of buprenorphine should be taken into consideration. The basic principles of maintaining respiration and circulation should be used.

Drug Interactions

The main interactions of buprenorphine are due to its opioid activities, and are similar to that of methadone.

Due to buprenorphines high affinity and its partial agonist and antagonist activities at opioid receptors as explained earlier, buprenorphine may precipitate opioid withdrawal syndrome when given to Clients who are taking other opioids. It also reduces the analgesic effects of other opioids.

Update on crushing buprenorphine

This is not a current enhanced service but might be commissioned at a later date.

The NPA (National Pharmaceutical Association) has agreed to provide indemnity cover to members providing a crushed Subutex service providing a protocol is followed. Subutex (buprenorphine) is used as an adjunct in the treatment of opiate dependence. Subutex is a sublingual formulation, which takes minutes to dissolve. This leads to the risk of the tablet being removed for injection or sale. To speed the dissolving process, prescribers and pharmacists have crushed the tablets. The instances of crushing are on the increase.

But crushing Subutex is 'off licence' and so the manufacturer is unwilling to recommend or endorse the crushing of tablets. Their view is that no studies have been carried out on the impact of crushing the tablets. Crushing increases the surface area of the drug and will thus increase the dissolution and absorption of the drug. On the other hand, crushing increases saliva production, which will enhance the possibility of swallowing unabsorbed drug therefore reducing slightly its blockade effects. An increasing number of National Pharmacy Association (NPA) members are now involved in the provision of a crushed Subutex service and are contacting the NPA to enquire whether the NPA will provide professional indemnity cover. The NPA will provide PI cover for members providing the service (and anyone employed or engaged by the member). However this cover is conditional upon compliance with a 'model protocol' developed by the NPA.

(Press release issued by the Royal Pharmaceutical Society of Great Britain dated 29th March 2005quoting National Pharmaceutical Association. It refers people to the NPAnet intranet service for details on the NPA protocol).

Buprenorphine-naloxone (Suboxone)

Suboxone is buprenorphine with the μ-opioid receptor antagonist naloxone added which is intended only to prevent abuse (i.e. injection) of the buprenorphine, not, as is commonly misunderstood, to block the effects of other opiates.

In the context of drug dependence management, suboxone is available as 2mg / 500mcg (buprenorphine 2mg and naloxone 500mcg) and 8mg / 2mg (buprenorphine 8mg and naloxone 2mg) sublingual tablets (as ***suboxone***, manufactured by Schering-Plough). It is a Schedule 3 controlled drug as defined by the Misuse of Drugs Act 1971. At time of writing (March 2009) suboxone is also a 'black triangle' drug.

Pharmacology and Pharmacokinetics

Buprenorphine is an opioid partial agonist/antagonist which binds to the μ (mu) and κ (kappa) receptors of the brain. Its activity in opioid maintenance treatment is attributed to its slowly reversible properties with the μ receptors, which over a prolonged period, might minimise the need of addicted patients for drugs.

Opioid agonist ceiling effects were observed during clinical pharmacology studies in opioid-dependent persons.

Naloxone is an antagonist at μ (mu)-opioid receptors. When administered orally or sublingually in usual doses to patients experiencing opioid withdrawal, naloxone exhibits little or no pharmacological effect because of its almost complete first pass metabolism. However, when administered intravenously to opioid dependent persons, the presence of naloxone in Suboxone produces marked opioid antagonist effects and opioid withdrawal, thereby deterring intravenous abuse.

Naloxone: Following intravenous administration, naloxone is rapidly distributed (distribution half-life ~ 4 minutes). Following oral administration, naloxone is barely detectable in plasma; following sublingual administration of Suboxone, plasma naloxone concentrations are low and decline rapidly. The medicinal product is metabolized in the liver, primarily by glucuronide conjugation, and excreted in the urine. Naloxone has a mean half-life from plasma of 1.2 hours.

Special populations:

Elderly: No pharmacokinetic data in elderly patients are available.

Renal impairment: Renal elimination plays a relatively small role (~30 %) in the overall clearance of Suboxone. No dose modification based on renal function is required but caution is recommended when dosing subjects with severe renal impairment.

Hepatic impairment: Hepatic elimination plays a relatively large role (~70 %) in the overall clearance of Suboxone and the action of buprenorphine may be prolonged in subjects with impaired hepatic clearance. Lower initial Suboxone doses and cautious titration of dosage may

be required in patients with mild to moderate hepatic dysfunction. Suboxone is contraindicated in patients with severe hepatic dysfunction.

Dosing

It is recommended that buprenorphine should be initiated by a specialist practitioner. The prescription can then be continued by a general practitioner once the client has been stabilised

Induction: same principles apply as with buprenorphine.

The starting dose with adults and children over 15 yrs old is usually 2 – 8mg once daily, increased in increments of 2 – 8mg daily according to response up to a maximum of 24mg daily

Supervised Consumption

Supervised consumption or supervised self-administration of drug substitutes started in Greater Glasgow in the early 90's. This practice offers three main advantages:

- Improved treatment compliance by ensuring that the prescription is taken in the dose and at the time intended
- Reduced diversion of prescribed drugs onto the illicit market
- Reduced death from accidental ingestion of prescribed drugs by opiate naïve individuals

The Department of Health *Clinical Guidelines* (ref. 5) recommends that all new Clients being prescribed methadone should be supervised by a professional for at least the first 3 months subject to compliance. Given the potential for its misuse, this should be equally applicable to buprenorphine. As the professional responsible for dispensing most of the substitutes, community pharmacists are ideally placed to carry out the supervision.

This arrangement could be relaxed after the initial supervision period if the prescriber is satisfied that compliance will be maintained. This relaxation of supervision can be seen as an important component of rehabilitation and re-establishment of responsible behaviour.

When a Client restarts treatment of a drug substitute after a break, or receives a significant increase in the dose, daily dispensing with supervised consumption should be re-instated for a period of time agreed locally.

During times of crisis or periods of relapse, Clients should be supervised again. This must not be seen as a failure of treatment but a way to assist the Clients through difficult times.

Some Clients may refuse to be supervised for a number of reasons:

- Concerns about confidentiality and being identified as drug users
- Fears of the unknown
- Doubts about the trust that they thought they had gained from the treatment team

The supervision procedure should therefore be discreet and efficient. The pharmacist and assistants should be mindful of the Clients' dignity. The procedure and the aims should be explained to the Clients prior to the commencement.

Health and Safety

As with the harm minimisation services, offering dispensing and supervised consumption services to the Clients does not usually compromise the health and safety of the employees and other customers. The majority of Clients on supervision do not create any problems for the pharmacy. By treating the Clients with courtesy and establishing mutual respect, the risk of violence or intimidation is very small.

Keep your methadone safe

Simple steps to storing Methadone safely – information provided by Lloyds Pharmacy.

DOs

- ☑ Keep it out of reach of children
- ☑ Keep it out of sight of others
- ☑ Keep it in a locked cupboard or child-proof box
- ☑ Keep your Methadone in its original bottle with its child resistant cap

DON'Ts

Don't leave your Methadone:

- ☒ On the floor
- ☒ On tables
- ☒ In the fridge
- ☒ Within reach in the bathroom
- ☒ Beside your bed
- ☒ In coat pockets
- ☒ In your shopping bags or handbag

Remember as little as 5mls can be fatal to a child and 50mls can kill an adult who has no tolerance

If anyone takes methadone and
it is not prescribed for them
this is a medical emergency – call 999

Operating Procedure

1 Local Contacts and Inter-Professional Relationship

1.1 The pharmacist on duty and trained employees involved in the provision of the service (the Operators) must establish good working relationships with the scheme co-ordinator of the Drug Action and Alcohol Team (DAAT), the prescribers or any other drug misuse service commissioning authority, drug addiction clinics and other workers involved in the care of drug users in the local area.

1.2 The Operators must be aware of the availability and contact details of similar facilities and all drug service agencies in the local area.

1.3 Appendix 1 should be filled in with the required information and one copy displayed in the dispensary.

2 Operator Training

2.1 All Operators must have read and understood these guidelines and also undertake any other training required by the commissioning authority.

2.2 The professional responsibilities of the prescribers and the pharmacists must be clarified at the outset.

2.3 All employees must be briefed to treat all users of the Service (the Clients) with respect and courtesy.

2.4 Once the Service is in operation, any new employees should be briefed of its existence on their first day of service. Appropriate training (as stated above) should be started within the first month.

3 Vaccination

3.1 It is strongly recommended that all operators/employees should be offered Hepatitis B vaccination and should sign the declaration form, in line with the Company Policy.

3.2 Hepatitis B vaccination is normally available from individual general practitioners (GPs). The commissioning authority or pharmacy should meet the costs depending on local agreements. Contact the HR Department for the funding procedure if the local commissioning authority does not pay for the vaccination.

3.3 If an employee decides not to have the vaccination, the pharmacist should ensure that the employees concerned are fully aware of the risk. A declaration (Appendix 4) stating

the reason(s) for not having the vaccination should be signed and dated and given to the employer.

4 Facilities Required

4.1 The service should be offered in the consultation area or a quiet area of the pharmacy when there is no consultation area, so the Client can seek advice from the Operator without being easily overheard by other customers.

4.2 A clinical waste container should be safely located so that the Client can dispose of their used medicine bottle or cup themselves under the supervision of an Operator.

4.3 Plastic disposable cups are required for pouring methadone solution from the dispensing bottle, and buprenorphine tablets should be placed from the strips into plastic cups before self-administration.

4.4 A jug of water should be available for the Clients.

4.5 Sufficient amount of the required drug substitute(s) and any other items for the provision of the Service should be in stock at all times.

4.6 Necessary records must be kept in the format specified by the commissioning authority and must also comply with the provisions of the Misuse of Drugs Act 1971. These records must be kept secure.

5 New Clients

5.1 All new Clients should be referred directly by the prescriber or drug treatment agency, either personally or via the telephone.

5.2 If the pharmacy does not have the capacity to take on a new Client, the prescriber should refer the Client to another pharmacy before the Client presents him/herself at the pharmacy.

5.3 If a pharmacy can not be allocated to the client, this must be reported to the DAAT who will look at increasing the numbers of pharmacies on the scheme. The Client's details and a brief description of appearance should be obtained from the prescriber or drug treatment agency.

5.4 If a new Client presents for the service him/herself, the prescriber, or drug services, should be contacted to confirm the validity of the prescription and the identity of the patient. Unless the pharmacist is familiar with the prescriber, the prescriber's telephone number should be obtained from the telephone directory. If the pharmacy does not have the

capacity to take on a new Client, the pharmacist should refer the Client back to the prescriber or drug treatment agency.

6 Client Contract

6.1. It is best practice for every Client to read and sign a service contract (4-way contract) prior to the commencement of their regular prescription instalments. This is, as a minimum, an agreement between pharmacist and Client but should include prescriber and key worker also.

6.2. Unless the commissioning authority provides a locally agreed Client contract, the standard contract as specified in Appendix 5 should be used.

6.3. The provisions of the contract should be read out discreetly to the Client if the Client is unable to read it him/herself.

6.4. Unless otherwise agreed with the commissioning authority, this should be a four-way contract, i.e. between the Client, pharmacy, the prescriber and the commissioning authority.

6.5. The Client and the pharmacy should each keep a copy of the contract. Depending on local agreement, the prescriber and the commissioning authority should also keep a copy of the contract.

7 Prescription and Daily Doses

7.1. The pharmacist should ensure that the prescription complies with the provisions of the Medicines Act 1968 and the Misuse of Drugs Act 1971. Refer to the latest *Medicines, Ethics and Practice* for more information.

7.2. The reverse section (Exemption Declaration and Prescription Charges) of the prescription should be filled in by the Client properly, and all prescription charges collected if applicable.

7.3. If applicable, the prescription should be clearly marked with 'supervised consumption', the instalments and intervals.

7.4. Instructions given on the prescription must be adhered to strictly. Sugar- and /or colour-free products have a greater potential for abuse than syrup based and coloured products. These must not be dispensed unless specifically prescribed.

7.5. Some prescribers are exempt from the handwriting requirement. All details required by Misuse of Drugs Act 1971 should still be specified and the prescribers must still sign and date the prescriptions by hand. If the pharmacist is unsure of a prescriber's exemption status,

confirmation should be obtained from the Home Office directly on 020 7273 2446 or 020 7273 3866.

7.6. The daily dose should be prepared in advance to prevent undue delay when the Client presents in the pharmacy.

7.7. All measurements or counting should be double-checked.

7.8. The daily dose should be packed and labelled in the usual manner in the dispensing bottle or carton, and locked in the Controlled Drugs cabinet. Dispensing from bulk supply straight into cups and presenting to the Client is in contrary to the Medicines Act 1968.

7.9. A plastic bottle can be used for a daily methadone dose consumed on pharmacy premises.

7.10. Take-home methadone should be dispensed in a child-resistant, glass dispensing bottle.

7.11. Unless it is previously agreed with the prescriber and the drug treatment agency, daily doses must not be issued to a representative. Misuse of Drugs Act allows patients to authorise an agent to collect the dose on their behalf. The authorisation must be in writing to the pharmacist. Compare the signature of the Client, to the one on the reverse of the form and retain the authorisation note in the Controlled Drugs register.

8 Supervision Procedure - Methadone

8.1. The supervision should only be carried out by the Pharmacist or suitably trained/nominated deputy, in a quiet, semi-private or private area (the consultation area). It should **not** take place in the dispensary or staff room.

8.2. Clients must be treated with due respect and courtesy. The Service should be delivered in a friendly, informal, non-judgemental manner.

8.3. If the Operator considers the Client's behaviour unacceptable, or if the Client appears intoxicated with drugs and/or alcohol, or if the Operator has any other concerns, the dose should be withheld and the prescriber should be contacted immediately.

8.4. The Client's identity must be confirmed using name, address and date of birth prior to the dose being issued.

8.5. Clients should remove any chewing gum from the mouth before taking the dose. If the Client wishes to dispose of their gum it needs to go in the clinical waste bin. It should NOT be placed on any surfaces and should be treated as clinical waste.

8.6. The Client should check the name, quantity and dose on the label, then pour the daily dose into a disposable plastic cup before self-administration. If the Client prefers, they may take the daily dose straight from the labelled bottle.

8.7. The Operator must be satisfied that the dose has actually been swallowed, by offering the Client a drink of water (using same cup as before) after taking the dose. If the Client does not want a drink, the Operator should ask questions that need a spoken answer.

8.8. The dispensing cup should be disposed of by the Client immediately after self-administration. The bottle, if not drunk from, can be reused for up to one week.

8.9. The Operator must ensure that the instalment section of the prescription, the Controlled Drugs Register or approved NPA Register, and any other necessary paperwork or electronic recording specified by the commissioning authority are completed immediately after the supervision.

8.10. The clinical waste container should be sealed and changed when it is three-quarters full.

9 Supervision Procedure – Buprenorphine (Subutex and Suboxone)

9.1. The supervision should only be carried out by the pharmacist or a suitably trained/nominated deputy, in a quiet, semi-private or private area (the consultation area). It should not take place in the dispensary.

9.2. Clients must be treated with due respect and courtesy. The service should be delivered in a friendly, informal, non-judgemental manner.

9.3. If the Operator considers the Client's behaviour unacceptable, or if the Client appears intoxicated, or if the Operator has any other concerns, the dose should be withheld and the prescriber should be contacted immediately.

9.4. The Client's identity must be confirmed using name, address and date of birth prior to the dose being issued.

9.5. Clients should remove any chewing gum from the mouth before taking the dose. If the Client wishes to dispose of their gum it needs to go in the clinical waste bin. It should NOT be placed on any surfaces and should be treated as clinical waste.

9.6. Client should check the name, quantity and dose on the label.

9.7. Client should have a drink of water to moisten the mouth.

9.8. The Operator should pop all the tablets out, place in a disposable plastic cup and hand over the cup to the Client. If undertaking crushing of Subutex please see page 13 'Update on Crushing Buprenorphine'.

9.9. Client should place the tablets under the tongue and leave to dissolve. They should not be swallowed. For Clients who are on high doses, it may be necessary to take a few tablets at a time.

9.10. The Client should be observed for 5 minutes or until all the tablets are dissolved. Once dissolved, the active ingredient will pass through the buccal mucosa and what remains is actually chalky residue that can be swallowed.

9.11. The Operator should watch the Client continuously for 5 minutes. The Operator should ensure that the tablets are placed into the mouth, under the tougue, and confirm that the tablets have been absorbed.

9.12. The Operator must be satisfied that the tablets are not concealed in the mouth, by offering the Client a drink of water afterwards, using the same cup as before. If the Client does not want a drink, the Operator should ask questions that need a spoken answer.

9.13. The disposable plastic cup should be discarded into a clinical waste bin immediately after the supervision.

9.14. Buprenorphine is a Schedule 3 Controlled Drug, and therefore does not require entry into the Controlled Drugs Register. However, the instalment section of the prescription and other locally specified paperwork or electronic record must still be completed immediately after the supervision.

10 Uncollected Doses

10.1. Uncollected doses must not be supplied at a later date as such supply will be classed as dispensing Controlled Drugs without a valid prescription.

10.2. The prescriber or drug treatment team should be informed of any missed doses. If three or more doses are missed, the prescriber will have to reassess the patient and review the prescription before reinstatement.

10.3. Before the end of business each day, the PMR (patient medical record) must be updated to indicate any uncollected doses. The instalment section of the prescription must be noted with the date and the words 'Not Collected'. Any other locally specified documentation must be noted too.

10.4. The uncollected drug must be marked as uncollected and the batch and expiry date written on the bottle. It must be stored in the Controlled Drugs cabinet. The drug can be reused provided that it has not expired.

10.5 If a client requests to take a dose less than the prescribed dose:

The pharmacist will supply the prescribed dose (on most occasions the prescribed dose is prepared before the client arrives at the pharmacy).
The client is free to choose to consume less than the amount supplied. The pharmacist will then dispose of the untaken portion of the dose recording his action in the register.
The pharmacist will advise the client to seek a review of his/her dose with the prescriber as soon as possible and will inform the prescriber immediately

11 Remuneration

11.1 All the completed prescriptions should be endorsed, stamped and double-checked.

11.2 Completed prescriptions should be sent to the Prescription Pricing Authority for payments at the end of each month.

11.3 Claim forms (Appendix 2) to be received at the DAAT address by post or fax (01785 223177) on or before the 15th day of the month, following the claim. Staffordshire County Council will reimburse the claim as agreed with the pharmacy i.e. either monthly or quarterly. All remuneration will be paid directly to the address given by the pharmacy on the pharmacy details sheet (Appendix 3).

12 Dealing with Discarded Sharps and Needle Stick Injury

All employees should follow the procedure stated in Appendix 7. The following points should also be noted if you find a discarded needle:

- Do not handle the needle/syringe with your hands
- Sweep up using brush and pan
- Place in a screw topped jar or strong cardboard box with a lid and keep them out of children's reach
- Take the needles/syringes to your nearest Environmental Health Department (who may also arrange for collection)

Or ring your local Environmental Health Department.

13 Client Confidentiality

13.1 Client confidentiality is of paramount importance, as with any other pharmaceutical services offered. Refer to the *Medicines, Ethics and Practice* (Section 2 Part 2) for further information.

13.2 All employees must respect and protect the confidentiality of the Client. This duty extends to any information relating to a Client acquired in the course of providing the service.

13.3 Confidential information includes any personal details and drugs used, both prescribed and non-prescribed.

13.4 Clients who are on regular drug substitute treatment may also use the needle exchange service. Many prescribers regularly test the urine of Clients for other concomitant illicit drug use and it should be through this mechanism that any breach of treatment contract is detected. Unless it is pre-agreed otherwise, the Operator must not report such incidents to the prescribers as this is breaking the confidentiality of the Clients concerned.

References

1. Berkshire Substance Misuse Protocol Group (2001). *Management and Treatment of Substance Misuse in Berkshire*. Berkshire Substance Misuse Protocol Group, Reading.
2. British National Formulary [BNF] (Sept 2008). *British National Formulary*. BMA & RPSGB, London.
3. CPPE (1998). *Drug Use and Misuse*. CPPE, Manchester.
4. CPPE (2002). *Opiate Treatment: Supporting Pharmacists for Improved Patient Care*. CPPE, Manchester.
5. DoH (2007). *Drug Misuse and Dependence – Guidelines on Clinical Management* Joint publication by the DoH, The Scottish Excutive Department of Health, Welsh Office, Department of Health and Social Services Northern Ireland. HMSO, London.
6. RCGP (2003). *Guidance for the Use of Buprenorphine for the Treatment of Opiod Dependence in Primary Care*. RCGP, London.
7. RPSGB (July 2004). *Medicines, Ethics and Practice: A Guide for Pharmacists*. RSPGB, London.
8. Sheridan J and Strang J (2003). *Drug Misuse and Community Pharmacy*.The Taylor & Francis Group, London.
9. Wills S (2002). *Drugs of Abuse*. The Pharmaceutical Press, London.
10. Lloyds Pharmacy. *Pharmaceutical Care for Drug Users.*

Further Reading

1. Luger L, Bathia N, Alcorn R, Power R (2000). *Involvement of community pharmacists in the care of drug misusers: pharmacy-based supervision of methadone consumption*. Int. J. Drug Policy, 11(3), 227-234

2. Matheson C, Bond CM, Pitcairn J (2002). *Community pharmacy services for drug misusers in Scotland: what difference does 5 years make?* Addiction, 97(11), 1405-11

3. Sheridan J and Walker M (28 Sept 2002). *Other Ways to Treat Opiate Dependence*. Chemists & Druggist, p17-20

4. Stone E, Fletcher K (2003). *User views on supervised methadone consumption*. Addict Biol, 8(1), 45-48

Useful Links

- **Substance Misuse Management in General Practice (SMMGP)** - a developing network to support GPs and other members of the primary health care team who work with substance misuse. The project team produces the Substance Misuse Management in General Practice newsletter (Network), and organises the annual conference 'Managing Drug Users in General Practice'

  www.smmgp.demon.co.uk

- **The Methadone Alliance** - the Alliance supports people who receive prescribed drugs for the treatment of their drug dependency, including buprenorphine

  www.m-alliance.org.uk

- **Streetdrugs.org** - A US-based site, with up-to-date information on a comprehensive range of illicit and prescription drugs with potential for misuse

  www.streetdrugs.org

- **FRANK –** A website that contains a range of practical suggestions for parents on how to talk to their children about drugs, information for friends and for young people, links to other great websites and how to obtain copies of free information.

  www.talktofrank.co.uk

- **National Treatment Agency -** The NTA is a special health authority, established by the Government in 2001 to improve the availability, capacity and effectiveness of drug treatment in England.

  www.nta.nhs.uk

- **Drugs.gov.uk -** provides drugs professionals with the latest news and guidance from government about the Drugs Strategy.

  www.drugs.gov.uk

  - **Drug Scope**

  www.drugscope.org.uk

- **Exchange Supplies –** offers comprehensive free online information on drugs, harm reduction, needle exchange, safer injecting, drug treatment, their products/paraphernalia supplied to needle exchanges (syringe-id, citric acid, vitC, stericups, sterifilt and water ampoules) and the National Conference on Injecting Drug Use and National Drug Treatment Conference.

  www.exchangesupplies.org

- **Centre for Pharmacy Postgraduate Education**

  www.oppe.manchester.ac.uk

Appendix 1 Contact Details

Organisation	Address	Tel No
Substance Misuse Commissioning Tem	Block C, Floor 3, Tipping Street, Stafford ST16 2DH	01785 277578
Staffordshire Drug Interventions Programme	18 Martin Street, Stafford ST16 2LJ	01785 270080
Community Substance Misuse Team - Burton	150 Station Street, Burton upon Trent, Staffs, DE14 1BG	01283 545071
Community Substance Misuse Team - Cannock	Park House, Park Road, Cannock, Staffs, WS11 1JN	01546 468667
Community Substance Misuse Team - Stafford	18 Martin Street, Stafford, Staffs, ST16 2LJ	01785 251820
Community Substance Misuse Team - Tamworth	1a King Street, Tamworth, Staffs, B79 7DB	01827 310040
T3 Young People's Service	Suite 1, 7 – 8 Mill Street, Stafford ST16 2AJ	01785 241393
Edward Myers Centre	Harplands Hospital, Hilton Road, Harpfields, Stoke-on-Trent, ST4 6TH	01782 441713
Cannock Chase Hospital	Accident &Emergency, Brunswick Road, Cannock, Staffs, WS11 5XY	01543 372757
Stafford District General Hospital	Accident & Emergency, Weston Road. Stafford, Staffs, ST16 3SA	01785 257731
Queens Hospital	Accident & Emergency. Belvedere Rd, Burton upon Trent, Staffs, DE13 0RB	01283 566333
Coton House	St Georges Hospital, Addiction Unit, Corporation Street, Stafford, ST16 3AG	01785 221315
Community Addiction Team – Newcastle	Silverdale Medical Centre, Vale Pleasant Road, Silverdale, Newcastle, Staffs, ST5 6PS	01782 624890
Community Addiction Team – Staffs Moorlands	Bucknall Hospital, Eaves Lane, Bucknall, Stoke on Trent ST2 8LD	01782 275035
Dr Scott GPSI	Silverdale Medical Centre, Vale Pleasant Road, Silverdale, Newcastle, Staffs, ST5 6PS	01782 624612
Dr Palmer GPSI	Browning Street Surgery, 10 Browning Street, Stafford, Staffs, ST16 3AT	01785 258249
Dr Upton GPSI	Bucknall Hospital, Eaves Lane, Bucknall, Stoke on Trent ST2 8LD	01782 275035
Dr Muller GPSI	Westgate Practice, Greenhill Health Centre, Church St, Lichfield, WS13 6JL	01543 414311
Drug Rehabilitation Requirement – Burton	Horninglow Street, Burton upon Trent, Staffs, DE14 1PH	01283 565951
Drug Rehabilitation Requirement – Stoke on Trent	Probation Office, Eaves Lane, Bucknall, Stoke on Trent, ST2 8JY	01782 261961
Drug Rehabilitation Requirement – Tamworth	Moor Street, Tamworth, Staffs, B79 7QZ	01827 302604
Drug Rehabilitation Requirement - Stafford	North Walls, Stafford, Staffs, ST16 3BL	01785 252503
Prolific Offender Project – Tamworth	Tamworth Police Station, Spinning School Lane, Tamworth, Staffs, B79 7BB	01785 234600
Prolific Offender Project – Stafford	Police Station, Eastgate Street, Stafford, Staffs. ST2 2DQ	01785 234024
Prolific Offender Project - Hanley	Hanley Police Station, Bethesda, Stoke on Trent, Staffs, ST1 3DR	01785 233167
Prolific Offender Project - Newcastle	Probation Service, Ryecroft, Newcastle, Staffs, ST5 2DT	01782 717074
South Staffs PCT	Mark Seaton, Pharmacy Advisor, Block D Beecroft Court, Off Beecroft Road, Cannock, Staffs, WS11 1JP	01543 465100
North Staffs PCT	Manir Hussain, Pharmacy Advisor, Bradwell Hospital, Talke Road, Chesterton, Newcastle, Staffs, ST5 7NJ	01782 425440

Appendix 2 Claim Form

From: ……
……..
……..

Contact Name: ……..…
Contact Number: ……..
Return for Month: ……..

Supervised Methadone/Buprenorphine Consumption: Pharmacist Buprenorphine Dispensing Record

Patient ID														
DoB	Client's Initials	Gender M/F	New Client (✓)	Name of Prescriber	Date of Script	Script Number	No of Days Supply	Buprenorphine or Methadone B / M	Daily Dose	Doses Supervised	Doses Taken Home	Doses Not Collected	Problems/Comments	Prescriber Contacted (Date)

Number of New Clients this month		**Methadone**	£1.50 per supervision	Totals			
		Buprenorphine	£3.00 per supervision	Totals			
					Total Amount Claimed		

Please send monthly return to: Staffordshire County Drug Action Team, Leaven House, University Court, Staffordshire Technology Park, Beaconside, Stafford ST18 0GE
Tel: 01785 358605 Fax: 01785 358606

Appendix 3 Pharmacy Information Street

Staffordshire County Drug and Alcohol Action Team

SUPERVISED CONSUMPTION SCHEME

Pharmacy Name: _____

Pharmacy Address: Opening Times:

	Monday: **Tuesday:** **Wednesday:** **Thursday:** **Friday:** **Saturday:** **Sunday**:

Telephone: _____ Fax: _____

E-mail: _____

Main Contact: _____

Designation: _____

Pharmacy Name: _____

How many clients are you currently supervising?				
Maximum number of clients you are willing to supervise				
Do you currently have consultation area?	Area		Booth	
Would you consider a needle exchange?	Yes		No	

PAYMENT ARRANGEMENTS

If you want payment to be sent to an address other than the pharmacy, please give details:

_____

_____

_____

_____

_____

Appendix 4 Hepatitis B Vaccination Declaration Form

Employee Name_____

Pharmacy Name_____

Please sign the declaration below (a copy to be kept by employee and employer).

1. I confirm that I have agreed to undertake a course of Hepatitis B immunisation.

"Once I have agreed to complete the immunisation process, it is my responsibility to ensure that I complete the full course of injections in line with medical advice"

Signature_____ Print Name_____ Date _____

Or

2. I understand that if I choose not to receive the Hepatitis B immunisation as recommended, and participate in services for drug misusers I will be doing so entirely at my own risk.

Signature_____ Print Name_____ Date _____

Or

3. I confirm that I have already been immunised against the Hepatitis B virus.

Signature_____ Print Name_____ Date _____

Appendix 5 Four Way Contract

(Modified from *Management and Treatment of Substance Misuse in Berkshire*, ref. 1)

I, the Client named below, understand and agree to the following conditions of treatment:

1. I will collect my prescription in person from the pharmacy named below on specified days, between _____and _____(specify time). If I fail to collect a dose on the specified day and time, I will not be able to collect that dose at a later time.
2. If I fail to collect my dose for three days or more, my subsequent doses will be withheld and my treatment will be reassessed.
3. I will not have my prescriptions dispensed by any other pharmacy without renegotiating my Four-Way contract with the drug treatment agency, doctor and another pharmacy.
4. If it is instructed in my prescription, I will consume my daily doses (except bank holidays and Sundays) at the pharmacy named below, under the supervision of the pharmacist or a pharmacy assistant.
5. My doctor/drug treatment agency will be notified in the event of non-attendance.
6. I will keep my appointments with my doctor/drug treatment agency named below.
7. The doctor, drug treatment agency and pharmacist named below have the right to discuss my case and may see me individually and together if appropriate.
8. If my doctor or the pharmacist considers that I am not in a fit state, my dose will be withheld.
9. I will not be a nuisance, abusive or violent to the general practice, agency or pharmacy employees.
10. I will not take any drugs other than those prescribed to me and I will provide a urine sample for analysis when requested.
11. I am responsible for any drugs, which I am prescribed and if I should lose them or take them other than as directed, they will not be replaced.
12. I will abide by any other conditions, which my doctor and pharmacist may wish to make.
13. I understand that I can only obtain prescriptions from the doctor named in this contract unless alternative arrangements are made.

	Name	Signature	Contact No.	Date	Copy
Client					Blue
Key Worker					Yellow
Prescribers					Pink
Surgery Address					
Pharmacist					Green
Pharmacy Address					

Appendix 6 Needle Stick Injury Emergency Escalation Procedure

Needle Stick Injury Emergency Escalation Procedure

Although safety policies and procedures on the use of sharps are continually being monitored and improved, the risk of a needle stick injury can never be completely eliminated. In the rare event that such an incident occurs, the following emergency escalation procedure should be followed:

Needle stick injury to a person

The injured person should encourage the wound to bleed with soap and water. The injured person should contact the local Accident and Emergency Department for medical treatment and advice.

The incident should be recorded in an accident report book.

Appendix 7 – Standard Operating Procedures – Dealing with Discarded Sharps, Dealing with Body Fluid Spillage, Needle Stick Injury, Spillage Contact to Skin, Eyes or Mouth and Dealing with Abusive Clients

1. Dealing with Discarded Sharps

1.1. If any discarded needles, syringes or any other contaminated sharps are found, the pharmacist on duty must be informed immediately.

1.2. The following procedure (1.3 - 1.13) is only applicable to removing sharps on the premises. Discarded contaminated sharps found external to the premises (e.g. in the rear garden) should be reported immediately to the number provided below for your area. Do not attempt to touch or remove the sharps yourself.

Cannock Chase (Environmental Health Services)	01543 462621
East Staffordshire (Environmental Health Department - Health and Safety Section)	01283 508000
Lichfield (Environmental Health Services)	01543 308000
Newcastle-under-Lyme Borough (Environmental Health Services)	01782 717717
South Staffordshire (Environmental Health Department)	01902 696000
Stafford (Waste Management Services)	01785 619000
Staffordshire Moorlands (Community Services Directorate)	01538 483483
Tamworth (Environmental Services Unit, Recycling / Waste Management Officer)	01827 709709

1.3. Persons clearing up the sharp must have read this procedure and signed the Hepatitis B declaration form (appendix 4).

1.4. Customers and all other employees must be warned not to touch or attempt to move such items and should stay well clear from the affected area.

1.5. Any cuts or abrasions on the skin must be covered with a waterproof and breathable dressing.

1.6. When dealing with an incident, ensure appropriate protective disposable gloves are worn.

1.7. The area where the sharp is located should be cordoned off and a sharps bin taken to the area. The sharp should only be removed with a long reacher to the sharps container. The area should then be wiped with an appropriate disinfectant or a solution of bleach.

1.8. Ensure that manufacturers' guidelines are followed when using disinfectant or household bleach. Also ensure that the area is well ventilated whilst doing this. It may also be necessary to test the products on a

small area of surface to ensure that the floor or work surface is not damaged in any way. The bleach should be diluted 1:10 with water and left in contact with surface for at least 2 minutes.

1.9. Once the area has been adequately cleaned, any swabs or wipes used should be treated as contaminated clinical waste, and disposed of into a waste container.

1.10. Personal protective equipment should only be removed at the end of the procedure and must also be disposed of as contaminated clinical waste into a waste container or cleaned with disinfectant or bleach according to manufacturers guidelines.

1.11. After removal of all personal protective equipment the hands should be thoroughly washed with bactericidal soap and water.

1.12. Finally the incident should be recorded within the Accident Report Book and the Internal Accident Report Form. The Health, Safety and Environment Department should be informed.

1.13. If for any reason this procedure cannot be followed, all staff must be kept well away from the affected area.

1.14. Sharps containers should be collected for disposal in accordance with the arrangements made by the local service commissioning authority. If there are any problems regarding storage and collection of these containers e.g. supply of containers or collection frequency, the commissioning authority or the collection contractor should be contacted.

2 Dealing with Body Fluid Spillage

2.1. If a spillage kit is provided by the local Health Authority, this kit and the relevant procedures should be used.

2.2. On discovery of any kind of body fluid spillage e.g. blood, vomit etc., the pharmacist on duty must be informed immediately.

2.3. Persons clearing up the spillage must have read this procedure and signed the Hepatitis B declaration form (appendix 4). Customers must stay clear from the affected area.

2.4. Any cuts or abrasions on the skin must be covered with a waterproof breathable dressing.

2.5. When dealing with these incidents, ensure you wear appropriate protective disposable gloves.

2.6. A clinical waste container should be carried by the handle to the location of the spillage.

2.7. Soak up as much of the spillage as possible, using absorbent material e.g. paper towels.

2.8. All used absorbent materials should be immediately 'double bagged' within two plastic bags and placed in a clinical waste container.

2.9. After collecting all the spillage, the area affected should be sprayed with disinfectant or wiped with a bleach solution (1 part household bleach to 10 parts water). Ensure that manufacturers' guidelines are followed while using these products, and that the area is well ventilated.

2.10. Once the area has been adequately cleaned, any material or equipment used should be treated as contaminated clinical waste and be placed in the waste container.

2.11. Personal protective equipment should only be removed at the end of the procedure and must also be disposed of as contaminated clinical waste into the container or cleaned with bleach or disinfectant following manufacturers guidelines.

2.12. After removal of all personal protective equipment the hands should be thoroughly washed with bactericidal soap and water.

2.13. The incident should be recorded within the Accident Report Book and the Internal Accident Report Form. The Health, Safety and Environment Department should be informed.

2.14. If for any reason this procedure cannot be followed, ensure all employees and customers are kept well away from the affected area. Contact the Health Protection Agency on 01785 221126 immediately for further assistance. Should you require assistance outside of office hours please contact the Stafford Hospital switchboard on 01785 257731 and ask for the on call Public Health Doctor.

3 Needle Stick Injury

3.1 In the unlikely event of a needle stick injury, the following procedure should be followed. This is summarised in Appendix 6.

3.2 The wound should be encouraged to bleed immediately.

3.3 The affected area should be washed thoroughly with bactericidal soap and water.

3.4 Contact the nearest Accident and Emergency (A&E) Department immediately for further advice and necessary treatment.

3.5 The incident should be recorded within an Accident Report Book.

4 Spillage Contact to Skin, Eyes or Mouth

4.1 In the unlikely event of blood or other body fluid spillage getting in the eyes or mouth, or in contact with the skin, this procedure should be followed.

4.2 The affected area should be irrigated with copious amount of water.

4.3 If the skin is affected, it should be washed with bactericidal soap and water.

4.4 Contact the nearest A & E Department immediately for further advice and any necessary treatment

4.5 The incident should be recorded within the Accident Report Book and the Internal Accident Report Form.

5 Dealing with Abusive Clients

5.1 Inviting drug users into the pharmacy does not necessarily increase the risk of disturbance or violence. Past experience shows that such risk can be minimised by treating all Clients with due respect and courtesy.

5.2 As an employee you have a responsibility never to place yourself, your colleagues or members of the public at risk.

5.3 Your workplace should be an environment where discussions about fear and other problems are not to be seen as marks of failure but as part of good practice.

5.4 Develop your own communication technique. It will help you to deal with verbal abuse without causing further aggression. Talk yourself out of problems.

5.5 Pacify rather than provoke the Clients who are focusing their aggression on you.

5.6 Stop and assess the situation. Think before you speak - consider the consequence of what you are about to say.

5.7 Consider whether the hostility is directed at you, the organisation or the individual themselves and try to react accordingly.

5.8 If you are in danger decide whether it is possible to leave the situation without further endangering yourself.

5.9 Consider whether another employee could handle the situation more effectively.

5.10 Never underestimate a threat of any kind and do not respond aggressively.

5.11 Stay calm, speak gently, slowly and clearly. Do not argue or be enticed into further argument. Avoid taking an aggressive stance (e.g. hands on hips or leaning forward).

5.12 Do not hide behind your authority, status or jargon. Tell them who you are, ask the person's name and attempt to discuss the problem with them as reasonable adults.

5.13 Keep your distance and try to avoid looking down on the aggressor.

5.14 Never touch an aggressor unless in self-defence. Remember the law – you are allowed to use **reasonable force** to defend yourself, or to make a citizens arrest.

5.15 Encourage the person to move - to go for a walk and think about the problem or offer to compromise and talk through it.

5.16 If the threat of violence is imminent, try to keep away from potentially dangerous locations or articles.

5.17 If you have a CCTV System attempt to stand where it is filming.

5.18 Make a mental note of potential escape routes. Keep yourself between the aggressor and a door or barrier, such as a desk.

5.19 Never turn your back – move gradually backwards if you need to escape.

5.20 If you manage to calm a situation down – do not let it flare up again. Choose your words and actions carefully, making a cautious but confident approach.

5.21 Go to the assistance of a colleague, but stay in the background.