

NSW Policy for the Use of Buprenorphine

in the Treatment of Opioid Dependence

NSW HEALTH DEPARTMENT

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SHPN: (DPB) 010126

ISBN: 0 7347 3327 5

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August 2001

Foreword

The NSW Drug Summit 1999 Government Plan of Action identified the need to increase the range of treatment options available to people with opioid dependence.

The *New South Wales Policy for the Use of Buprenorphine in the Treatment of Opioid Dependence* has been developed by the Drug Programs Bureau following a process of consultation with local clinicians, national and international experts. It was also developed with consideration of published evidence on the use of buprenorphine in the treatment of opioid dependence.

The policy describes how buprenorphine will be introduced in NSW and provides detail for health administrators and clinicians on how it is to be applied. It should be used with reference to the:

- *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*
- *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*

Buprenorphine has shown to be effective in the long-term as a maintenance treatment and in the short-term as part of an opioid withdrawal program.

Buprenorphine as a treatment for opioid dependence is a welcome addition to the pharmacotherapy treatment options available in NSW.



Michael Reid
Director-General

Contents

Executive summary.....	1
1. Introduction	5
Aims of the Policy	5
Development of the Policy	5
Registration and availability	5
Aims of buprenorphine treatment	5
Properties of buprenorphine	6
Alternative treatment options.....	6
Comparison with methadone	7
Service provision – methadone and buprenorphine	7
2. Legislative and administrative requirements.....	8
3. Introduction of buprenorphine treatment.....	9
Principles that guide the NSW service delivery model	9
Gradual introduction	10
Stage 1 - the first 12 months	10
Stage 2 - after the 12-month introductory period.....	11
4. Commencing treatment	12
Assessment for buprenorphine treatment.....	12
Suitability for buprenorphine.....	12
Contraindications to buprenorphine	13
Precautions	14
Priority entry into buprenorphine treatment.....	14
Choice between treatment with methadone or buprenorphine	14
Information for patients.....	15
Treatment Agreement	15
Commencement dose.....	15
Transferring from methadone maintenance	15
5. Ongoing treatment	16
Treatment plans – detoxification	16
Detoxification dosage regime.....	16
Treatment plans maintenance.....	17
Alternate-day dosing in maintenance programs	18
Length of maintenance treatment.....	18

Contents

6. Case management	19
7. Children and young persons (Care And Protection) Act 1998	20
8. Takeaway doses	21
Rural and remote areas	21
Preparation and supply of takeaway doses.....	22
Patients with takeaway doses who are admitted to hospital.....	22
9. Urine drug testing	23
10. Dosing location	24
At the commencement of treatment	24
Exemption to commencing dosing at a specialist clinic	24
Retail pharmacy dosing	24
Notification of changes to dosing location	25
Dosing of patients in police cells, multiple administration points, and administration of methadone to patients at home	25
11. Use of other drugs, including alcohol	26
Patient safety.....	26
Overdose at the administration point	26
Patient administered a dose higher than prescribed	26
12. Hospital in-patients	28
Legal restrictions on prescribing drugs of addiction to inpatients.....	28
Treatment of an inpatient currently on a buprenorphine maintenance program	28
Commencement of a maintenance program in hospital.....	29
Management of opioid withdrawal in hospital using buprenorphine	29
13. Analgesia	30
14. Pregnancy and breast feeding	31
Risks	31
Pharmacotherapy in pregnancy and breast feeding	31
Issues to be addressed during the initial assessment	31
Women on buprenorphine who become pregnant.....	32
Neonatal abstinence syndrome.....	32

Contents

15. Completing buprenorphine treatment	33
Readmission to treatment	34
Transfer to naltrexone	34
Involuntary termination of treatment	34
Complaints mechanism.....	34
Exiting and transferring patients	35
16. Prisoners	36
Detoxification.....	36
Maintenance.....	36
Prisoners released on buprenorphine	36
17. Quality assurance mechanisms	37
The Pharmacotherapy Credentialling Sub-Committee.....	37
Credentialling of prescribers	37
Limits on the number of patients able to be treated	37
Locums	38
Accreditation of clinics	38
Authorisation to treat individual patients	38
Data collection and reporting	39
Prescriptions.....	39
Storage and administration of buprenorphine	39
18. Chief sources	40
Appendix	41-53
Appendix A – further reading.....	41
Appendix B – further information and advise.....	42
Appendix C – Example of an assessment module for buprenorphine treatment	43
Appendix D – Acknowledgments	54

Executive summary

Introduction of buprenorphine

Buprenorphine treatment aims to reduce the health, social and economic harm to the individual and the community that is associated with illegal opioid use. It is used in both detoxification and maintenance treatment. This policy refers to both applications of the treatment.

The introduction of buprenorphine treatment in NSW will occur in two stages. The initial stage will extend for the first 12 months following the release of this document. During this stage the focus will be on gaining experience with the drug, embedding quality controls and improvement processes and keeping to a minimum any unintended consequences of treatment. Gradual lessening of controls and increase in availability will occur as service providers become experienced with the treatment and the demand for increased availability is determined.

Approval to prescribe buprenorphine

Medical practitioners currently approved to prescribe methadone by the NSW Health Department and who have successfully completed additional formal credentialling in buprenorphine will be approved to prescribe buprenorphine. Medical practitioners who are not currently approved methadone prescribers will be required to successfully complete the NSW Pharmacotherapy Accreditation Course, which includes training in the use of methadone, buprenorphine and naltrexone.

Current methadone prescribers who are granted approval to prescribe buprenorphine by the NSW Health Department will receive a 15% increase in the number of patients they are allowed to prescribe pharmacotherapy. This is to cater for patients to be treated with buprenorphine.

After the 12 months access to buprenorphine treatment will be expanded. General medical practitioners will then be able to gain approval to prescribe buprenorphine for up to two patients without completing the Pharmacotherapy Accreditation Course requirements.

Treatment suitability

Buprenorphine treatment is suitable only for people assessed as opioid dependent. Suitability for treatment with buprenorphine needs to be assessed having regard to its contraindications as well as issues such as informed consent.

Research evidence does not clearly indicate superiority of buprenorphine over methadone for specific groups of patients. Patients suitable for treatment with a pharmacotherapy treatment should be provided with sufficient information to make an informed choice between buprenorphine and methadone. The choice between buprenorphine and methadone treatment should not be based on age, length or severity of dependence.

Executive summary

Dose

The initial dose of buprenorphine should not exceed 8mg and is usually between 2mg and 8mg. If transferring from methadone, the initial dose should not exceed 6mg.

Due to buprenorphine's partial agonist properties, an opioid withdrawal syndrome can result when transferring from high doses of methadone to buprenorphine. The appropriate dose of methadone when a patient is transferring to buprenorphine is less than 40mg and preferably less than 30mg.

The maximum daily dose of buprenorphine should not exceed 32mg.

Evidence suggests that a significant proportion of patients on buprenorphine can be adequately maintained by receiving a dose every alternate day and some even every third day. Daily dosing is recommended for the initial period of stabilisation and during detoxification.

Comprehensive treatment

Treatment plans are central to the provision of effective buprenorphine treatment. They should be developed for patients undertaking withdrawal treatment. Patients engaged in a maintenance program should have a comprehensive treatment plan developed.

Buprenorphine treatment should include a range of services that can assist individuals to reduce their concomitant problems. A case management approach should be offered to all patients that includes strategies to assist patients to:

- reduce heroin and other drug (including alcohol and tobacco) use
- reduce risks associated with the hepatitis A, B and C and HIV viruses
- access medical, psychiatric and psychological assessment and care
- access other services based on the patient's specific needs
- access additional ancillary services such as: crisis intervention, social, vocational and economic assistance and counselling.

Child protection

Child protection and care issues arise in the treatment of opioid dependent people. The treating team should be familiar with the *Children and Young Persons (Care and Protection) Act 1998* and respond in accordance with their obligations. At least one clinician in the treating team is encouraged to view the children of a patient on buprenorphine each three months.

Takeaway doses

There is the potential for diversion and misuse of buprenorphine. In general there will be no takeaway doses, except where a patient can only tolerate daily dosing and where a formal second opinion has recommended them or in an emergency.

Urine analysis

Urine drug screening of patients in buprenorphine maintenance programs will be determined by the same principles as are applied in methadone maintenance programs. Buprenorphine will not always be detectable by urine testing.

Dosing site

Patients not in treatment who then commence buprenorphine will initially be dosed in a highly supervised setting. A minimum initial period of one month at a highly supervised setting will be required before patients who are stable and assessed as suitable can be transferred to a retail pharmacy. Patients who are stable on methadone and are transferred to buprenorphine can be treated at retail pharmacies without a period of assessment at a specialist clinic.

Medical emergency procedures should be in place for patients who demonstrate signs of drug overdose at the administration point. The effects of buprenorphine, due to its strong affinity to m opioid receptors, are not reversed by usual dosages of the opioid antagonist, naloxone.

In-patient treatment

Buprenorphine is used to treat opioid dependent hospital in-patients through continuation of a maintenance program, commencement of a maintenance program, or management of opioid withdrawal. Hospital in-patients known or suspected to be a drug dependent person may be prescribed buprenorphine for up to 14 days following their admission without the authority of the NSW Health Department.

Analgesia

Patients on buprenorphine have a reduced response to analgesia. People who have pain will require treatment with alternatives to opioids where indicated, or higher doses of opioid analgesia.

Use in pregnancy

Buprenorphine is, at this time, contra-indicated for pregnant or breast feeding women. Methadone is the treatment of choice for women assessed as appropriate for pharmacotherapy during pregnancy.

Completing treatment

The successful withdrawal from buprenorphine with persisting good functioning, including good health and social functioning, is an important objective of the treatment. Planning for successful withdrawal from buprenorphine should commence from the initiation of treatment. The case management approach should include work towards goals, that when achieved, prepare a patient to live well without buprenorphine.

Easy access back into treatment if needed is an important element of buprenorphine treatment. If relapse occurs within two weeks of leaving treatment and the patient seeks readmission, treatment should be offered expeditiously and without recrimination.

Executive summary

Naltrexone has the potential to assist people to remain abstinent from opioids after withdrawal from buprenorphine. Transfer from buprenorphine to naltrexone is less difficult for patients than from methadone, however withdrawal symptoms can be precipitated.

Prisoners

Buprenorphine should be trialed as a withdrawal and maintenance medication for prisoners. There is no evidence to suggest buprenorphine maintenance should be preferred to methadone maintenance treatment in the prison setting.

Quality assurance

There are a number of quality assurance mechanisms that apply to buprenorphine treatment. The Pharmacotherapy Credentialing Subcommittee makes recommendations to the Director General on the approval of medical practitioners as prescribers of drugs of addiction under the State's Drug Dependence Treatment programs. Accreditation of services against agreed standards applies to buprenorphine. Services that hold a licence to supply buprenorphine or methadone will, as a condition of their licence, be required to achieve accreditation with an approved organisation. The Methadone Accreditation Standards will be adapted to apply to buprenorphine and methadone.

Introduction

Aims of the Policy

This Policy aims to:

- describe how buprenorphine will be introduced in NSW
- provide policy detail relevant to NSW.

This policy is the New South Wales supplement to the Commonwealth Department of Health and Aged Care's:

- *National Buprenorphine Policy*
- *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence.*

This Policy should be applied in conjunction with these and the *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*.

It should be noted that in specific or unforeseen circumstances clinicians may need to vary their clinical practice from that suggested in this Policy. In such instances they should clearly document the reasons for such variations in the patient record. It is expected that variations would be within the bounds of what is considered to be in accordance with the recognised therapeutic standard of what is appropriate in the circumstances [as required under the *Poisons and Therapeutic Goods Act 1966 (NSW)* and *Poisons and Therapeutic Goods Regulation 1994 (NSW)*].

In light of limited published evidence on the use of buprenorphine in Australia, this Policy will be reviewed 18 months after the introduction of buprenorphine in NSW.

Development of the Policy

This Policy has been developed by the Drug Programs Bureau, NSW Health Department, following consultation with local clinicians, national and international experts. Reference has been made to the *National Buprenorphine Policy*, the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence* and the *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*.

Registration and availability

Buprenorphine was registered by the Therapeutic Goods Authority for use in Australia for the withdrawal and maintenance treatment of opioid dependence on the 27th October 2000.

Aims of buprenorphine treatment

Buprenorphine is indicated for the treatment of opiate dependence, including maintenance and detoxification, within a framework of medical, social and psychological treatment. Buprenorphine treatment aims to reduce the health, social and economic harm to the individual and the community that is associated with illegal opioid use.

Introduction

Specific objectives of buprenorphine treatment are to:

- reduce illegal and other harmful drug use
- improve the patient's health and well-being
- reduce transmission of blood-borne infectious diseases
- reduce deaths associated with opioid use
- reduce crime committed by patients
- facilitate an improvement in the patient's social functioning
- improve the economic status of patients and their families
- ultimately to achieve abstinence from drug use, including cessation of buprenorphine.

All of these objectives will not necessarily be achieved with each patient, nor at the one time or to the same degree in each program setting. Nevertheless, buprenorphine treatment should be provided to individuals where the expected benefits achieved will outweigh any negative health or social consequences of providing the treatment.

Properties of buprenorphine

Buprenorphine is a partial opioid agonist. It is used as a component of maintenance and detoxification treatment for opioid dependent individuals. Although most clinical research relating to buprenorphine has examined its role as a maintenance pharmacotherapy, it has also been identified as potentially useful in the management of heroin withdrawal.

Buprenorphine maintenance reduces illicit opioid use, HIV risk behaviour and crime and improves general health. Buprenorphine ameliorates problems associated with opioid dependency because its pharmacological characteristics reduce the discomfort of opioid withdrawal and craving for opioids. The regular administration of a consistent buprenorphine dose provides stability and structure and within buprenorphine programs the therapeutic relationship established with each patient can facilitate social reintegration and access to other services.

In detoxification, buprenorphine is effective in reducing withdrawal symptoms and is associated with higher rates of completion of withdrawal than achieved with symptomatic treatment. Typically, five days of reducing doses of buprenorphine is used to treat the heroin withdrawal syndrome.

Alternative treatment options

Buprenorphine as a maintenance or withdrawal treatment, is one of a range of responses to problems associated with opioid use. Other treatment options for opioid dependent people include:

- methadone maintenance treatment
- opioid antagonist treatment with naltrexone as part of a comprehensive relapse prevention program
- detoxification in an outpatient, home or residential setting using medication other than buprenorphine to ameliorate withdrawal symptoms
- outpatient counselling and day programs (no pharmacotherapy involved)
- residential rehabilitation services
- self-help groups.

Comparison with methadone

Maintenance treatment

To date methadone maintenance has been the main pharmacological treatment of opioid dependence. Current available evidence suggests that, in some contexts, buprenorphine maintenance is as effective as methadone in reducing drug use, crime, health problems and risk of contracting HIV. It should be noted, however, that at this time, evidence related to buprenorphine's use in the Australian setting is limited.

The pharmacological characteristics of buprenorphine (a partial agonist) differ from methadone (a full agonist). The different characteristics of buprenorphine create potential benefits in the treatment of opioid dependence compared to methadone:

- it is safer in overdose, causing less suppression of respiration
- the drug may be administered every second day for many patients due to its long duration of action
- transition to other pharmacotherapies such as naltrexone or methadone is possible giving flexibility of treatment
- patients may find it easier to withdrawal from.

Possible disadvantages of buprenorphine as a result of the drug's characteristics include:

- it is more time consuming to administer – it can take between 2 and 7 minutes to be absorbed sublingually
- the drug may be more vulnerable to diversion because it is in tablet form and can be secreted in the mouth and later removed
- if inappropriately injected there is high risk of emboli
- there is uncertainty whether patients who have previously needed to be maintained on high dose methadone will be as effectively retained in treatment by the partial agonist properties of buprenorphine.

Detoxification

Methadone reduction regimes have been used to treat heroin withdrawal. Reducing dosages of methadone over 10 to 21 days have, for example, been shown to be effective in reducing heroin withdrawal symptoms for patients. Buprenorphine has also been used in withdrawal regimes over varied lengths of dosage reduction. There is no direct comparison data to identify relative effectiveness. Buprenorphine's safety profile and lower rebound withdrawal symptoms after cessation suggest it may be a preferable option. It should be noted however that detoxification alone is not an effective treatment. Relapse rates are very high after completion of any withdrawal. Linking people to other treatments after detoxification is thought to improve outcomes.

Service provision – methadone and buprenorphine

Services or clinicians that provide methadone treatment should also develop the capacity to make buprenorphine available. The availability of both treatment options creates better opportunities for matching treatment to patients' needs and wants. Services or clinicians are not encouraged to provide only buprenorphine or only methadone treatment.

The legislative and administrative requirements

Buprenorphine is a Schedule 8 drug. The prescribing and administration of this drug must be undertaken in accordance with the statutory requirements of the *Poisons and Therapeutic Goods Act 1966 (NSW)* and the *Poisons and Therapeutic Goods Regulation 1994 (NSW)*.

In general, authority to prescribe buprenorphine for the purpose of treating a drug dependent person in NSW will only be issued to medical practitioners approved by the Director-General, NSW Health Department.

Application must be made to the Pharmaceutical Services Branch of the NSW Health Department on an individual patient basis. Each authorisation will be valid for up to 1 year.

The Pharmacotherapy Credentialling Sub-Committee of the NSW Medical Committee is the body responsible for providing advice and making recommendations to the Director-General concerning the approval of medical practitioners to prescribe buprenorphine.

Introduction of buprenorphine treatment

Principles that guide the NSW service delivery model

The service model for buprenorphine treatment in NSW will establish the optimal mix of:

1. service availability
2. quality of service
3. actions to minimise unintended consequences of treatment.

Service availability refers to an adequate number and location of providers able to treat the different groups of patients across all geographical regions.

Quality of service refers to:

- **Safety** – harm from treatment must be avoided and risk minimised. These may be harms by omission or commission, as well as from the environment in which treatment is carried out
- **Effectiveness** – treatment should produce measurable benefit
- **Appropriateness** – using evidence to select the treatment/intervention for the individual patient and at the right time
- **Consumer participation in health care delivery** – both a fundamental right and of considerable benefit to planning, delivery, monitoring and evaluation at all levels
- **Access** – equitable access on the basis of need, irrespective of ethnicity, age, sex, socio-economic group and geography
- **Efficiency** – resources utilised to achieve value for money

(Source: A Framework for Managing the Quality of Health Services in NSW, NSW Health, 1999).

The *NSW Drug Treatment Services Plan* provides a framework for drug and alcohol services. It identifies further service delivery issues that span across the above six dimensions of quality. The Plan emphasises that services be responsive, adaptable and accessible and that case management, continuity of care, a skilled and flexible workforce and a culture of improvement is integral to the way services operate.

Unintended consequences of treatment

In addition to potential benefits of buprenorphine, treatment can have unintended consequences, including:

- diversion of the drug for illegal use
- injection of the drug, causing damage to veins and local tissues and the risk of embolic complications and infection
- overdose, which can occur as a result of using other central nervous system depressants with buprenorphine

Introduction of buprenorphine treatment

- iatrogenic dependence, in people not adequately assessed
- disruption to the local amenity through congregation of patients
- community backlash to the drug when expectations of success are not met, the quality of treatment is poor, or there are too many unintended consequences of treatment.

Gradual introduction

The introduction of buprenorphine treatment in NSW will occur in two stages. The initial stage will extend for 12 months.

The initial stage will focus on gaining experience with the drug, embedding quality controls and improvement processes and keeping to a minimum any unintended consequences of treatment. Gradual lessening of controls and increase in availability will occur as service providers become experienced with the treatment and the demand for increased availability is determined.

Stage 1 – The first 12 months

To prescribe buprenorphine

Medical practitioners currently approved to prescribe methadone by the NSW Health Department and who have successfully completed additional formal credentialling in buprenorphine will be approved to prescribe buprenorphine.

Medical practitioners who are not currently approved methadone prescribers will be required to successfully complete the NSW Pharmacotherapy Accreditation Course, which includes training in the use of methadone, buprenorphine and naltrexone. These medical practitioners will then become approved prescribers of buprenorphine and methadone.

Number of patients per prescriber

Current methadone prescribers who are granted approval to prescribe buprenorphine by the NSW Health Department will receive a 15% increase in the number of patients for whom they are allowed to prescribe pharmacotherapy, in order to cater for patients to be treated with buprenorphine. For example, a methadone prescriber who had a limit of 100 methadone patients and becomes approved as a buprenorphine prescriber will have a new limit of 115 pharmacotherapy (methadone or buprenorphine) patients.

Newly approved pharmacotherapy prescribers will be granted patient numbers according to the present process for methadone, established by the Pharmacotherapy Credentialling Subcommittee.

Stage 2 – After the 12-month introductory period

After the initial 12 months access to buprenorphine treatment will be expanded.

General medical practitioners will be able to gain approval to prescribe buprenorphine for up to two patients without completing the Pharmacotherapy Accreditation Course requirements. Medical practitioners not credentialled to prescribe buprenorphine who wish to apply for this authorisation must meet the following conditions:

- the assessment and suitability of the patient for buprenorphine is discussed with a designated local Area Health Service drug and alcohol medical specialist and this is documented
- the patient is initially dosed from a specialist public unit, who will confirm the patient's suitability for buprenorphine treatment
- a case-manager is engaged
- the local drug and alcohol medical specialist agrees to be available to the general medical practitioner for consultation, at a minimum by telephone
- the general medical practitioner agrees to provide treatment in accordance with the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence* and the *NSW Buprenorphine Policy*.

If the above conditions cannot be met, a medical practitioner will not be authorised to prescribe buprenorphine for a drug dependent patient.

For approval to prescribe buprenorphine to more than two patients, medical practitioners must successfully complete the Pharmacotherapy Accreditation Course.

Commencing treatment

Clinicians requiring expert advice can obtain a second opinion from a drug and alcohol medical specialist. A drug and alcohol medical specialist may be accessible through the local general hospital. Alternatively, the State-wide Specialist Drug and Alcohol Advisory Service can be contacted 24 hours a day for advice from a drug and alcohol medical specialist on 1800 023 687.

Assessment for buprenorphine treatment

The National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence provide detailed assessment procedures for clinicians to follow before commencing buprenorphine treatment for any patient.

A patient transferring from another clinic or program must always be re-assessed by the new doctor before treatment can begin.

See Appendix C for an example of an assessment form.

Suitability for buprenorphine treatment

Buprenorphine treatment (detoxification and maintenance) is suitable only for people who are opioid dependent. Buprenorphine is a drug of dependence. In determining suitability for buprenorphine treatment, care should be taken to ensure patients meet the criteria for opioid dependence as listed in the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*.

In addition patients should agree to the conditions of the treatment program and provide informed consent to the treatment. Informed choice is an important prerequisite for treatment.

Under 18 years of age

If the patient is 16 years of age or older but less than 18 years of age and requires treatment with buprenorphine, a second opinion must be obtained before authority to treat the patient can be granted. This opinion must be documented. In such instances, buprenorphine may be preferred over methadone due to its lower risk of harm in overdose and less severe withdrawal syndrome.

Under 16 years of age

An exemption must be granted under the *Children and Young Persons (Care and Protection) Act 1998* to lawfully treat a drug dependent patient under 16 years of age with buprenorphine. The request for an exemption should include a second opinion from a drug and alcohol medical specialist nominated by the Area Health Service. To seek an exemption, the prescribing doctor must apply in writing to the Director-General through the Chief Pharmacist located at the Pharmaceutical Services Branch. The request for exemption will be forwarded on behalf of the Director-General to the Department of Community Services.

Contraindications to buprenorphine treatment

Drug reactions

A person with an established history of side effects to buprenorphine should not undertake buprenorphine treatment.

Pregnancy

Buprenorphine is, at this time, contraindicated for pregnant women and breast feeding women. There is insufficient evidence to state it is safe in these circumstances.

Opioid dependent pregnant women who present for pharmacotherapy treatment should be treated with methadone until the safety of buprenorphine in pregnancy is determined.

All women who intend to undertake buprenorphine treatment should be advised of the issues in relation to safety of buprenorphine in pregnancy. Contraception advice should be given to women not wishing to become pregnant. Those wishing to become pregnant should be encouraged to consider methadone treatment as the first line maintenance pharmacotherapy.

Primary dependence on non opioid drugs

Buprenorphine treatment is not appropriate for people who are primarily dependent on non-opioid drugs such as alcohol, benzodiazepines, amphetamines, or combinations of these.

Incapable of providing informed consent

Buprenorphine treatment should not be considered if a person cannot provide informed consent to treatment due to a psychiatric condition such as:

- acute psychosis
- major depressive illness
- cognitive impairment
- amnesic disturbance
- severe adjustment disorders

Buprenorphine treatment should only be considered after the person's condition has been adequately treated.

Severe medical illness

Severe respiratory or hepatic impairment are contraindications to buprenorphine treatment.

Subjects less than 16 years of age

Current product information states that buprenorphine is contraindicated for subjects less than 16 years of age. Its safety and effectiveness in such subjects has not been established. All young persons who intend to undertake buprenorphine treatment should be advised of the issues in relation to its safety and effectiveness.

Commencing treatment

Precautions

The *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 2.1 recommends caution in treating people with buprenorphine who have:

- high risk polydrug use
- concomitant medical conditions
- concomitant psychiatric conditions
- chronic pain
- have been on methadone maintenance above 40mg within the last week.

Priority entry into buprenorphine treatment

People assessed suitable for buprenorphine treatment should where treatment is available, start the program without delay. If delays are unavoidable, priority should be given to:

- people whose health condition may pose a risk to others eg. people with HIV and their opioid-using partners
- people who are at imminent risk of serious harm due to their drug use.

Choice between treatment with methadone or buprenorphine

Research evidence does not clearly indicate superiority of buprenorphine over methadone. Patients suitable for treatment with a pharmacotherapy should be provided with sufficient information to make an informed choice between buprenorphine and methadone. The patient should be presented with a balanced description of the advantages and disadvantages of the two treatments. The choice between buprenorphine and methadone treatment should not be based on age, length or severity of dependence.

The National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence recommends the following factors be considered when choosing maintenance pharmacotherapies:

- response to prior treatment
- previous adverse effects
- logistics of participating in treatments
- ease of withdrawal from maintenance buprenorphine treatment
- expectations of the treatment
- capacity to transfer from methadone maintenance.

Once the above have been considered, buprenorphine should be particularly considered for:

- those who have had multiple unsuccessful methadone treatment episodes
- patients who are ambivalent about maintenance treatment.

There are some groups in NSW communities that have not readily accessed methadone maintenance treatment in the past. Examples include people from diverse cultural and linguistic backgrounds and some indigenous groups. Buprenorphine should be particularly considered for suitable patients from these groups.

Information for patients

Patients who are assessed as suitable for buprenorphine treatment should be supplied with verbal and written information about all aspects of the program offered and their rights and responsibilities.

Treatment Agreement

All patients must sign a NSW Health Treatment Agreement prior to commencing treatment.

Commencement dose

The initial dose of buprenorphine should not exceed 8mg and is usually between 2mg and 8mg. If transferring from methadone, the initial dose should not exceed 6mg.

Transferring from methadone maintenance

Due to buprenorphine's partial agonist properties, an opioid withdrawal syndrome can result when transferring from high doses of methadone to buprenorphine. The appropriate dose when transferring from methadone to buprenorphine, to minimise discomfort, is less than 40mg and preferably less than 30mg. Patients should have been on this methadone dose for at least one week prior to commencing buprenorphine. Refer to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence* Section 3.2 for detailed information on how to transfer patients from methadone to buprenorphine.

Ongoing treatment

Treatment plans – detoxification

A treatment plan for withdrawal should be developed through collaboration between the medical practitioner, patient, case worker(s), pharmacist/dispensing staff and carer(s). It should be documented. The plan should include:

- the setting in which withdrawal will occur
- information to be given to patient and carers, including strategies for coping with symptoms
- information to be given on how to get help in an emergency
- support that will be provided for the patient and by whom
- role of carers and mechanisms to support them
- medication regime, including frequency of dispensing
- monitoring procedures (including frequency and by whom)
- other medical, psychiatric, psychological or social investigations and interventions to be provided during withdrawal
- post-withdrawal treatment and care,
- communication with other relevant service providers
- monitoring of parenting, particularly of children under five and linking into relevant services to assist parenting skill development.

Detoxification dosage regime

Reference should be made to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 4, for comprehensive information on the management of opioid withdrawal using buprenorphine.

Buprenorphine will not ameliorate all opioid withdrawal symptoms, however it does significantly reduce discomfort. The use of benzodiazepines during withdrawal is, in general, not encouraged. If night sedation is necessary it should be prescribed for no more than two or three days.

The recommended withdrawal regime extends over approximately five days. While the withdrawal regime can be conducted over longer periods, it does not usually extend beyond 10 days.

The initial dose should be in the safe commencement dosage range (2mg – 8mg). The dose is increased according to clinical response to approximately 10mg by day three, then reduced over the remaining days of the withdrawal.

The proposed buprenorphine regime is:

Day	Dose	Acceptable range
Day 1	6 mg	(4mg – 8 mg)
Day 2	8 mg	(4mg – 12 mg)
Day 3	10 mg	(4mg – 16 mg)
Day 4	8 mg	(2mg – 12 mg)
Day 5	4 mg	(0mg – 8 mg)

Treatment plans – maintenance

Comprehensive treatment plans

Comprehensive treatment plans aim to increase the effectiveness of buprenorphine treatment for patients and the community. Plans should be developed in collaboration with the patient and other members of the treatment team (i.e. the prescriber, the case manager, the pharmacist/dispensing staff). The treatment plan should be initiated by the end of the first week of treatment.

The comprehensive treatment plan should set out the services to be provided and their timing. Services should include:

- dose review and adjustments
- setting and reviewing treatment goals
- medical and psychiatric review and treatments
- monitoring of progress
- harm reduction interventions (eg. advice on reducing risks of contracting or spreading hepatitis and HIV infection)
- supportive or skills focussed counselling
- assessment of suitability for retail pharmacy dosing and assistance in transfer of dosing to a pharmacy if suitable
- assistance with accommodation if required
- assistance with any vocational difficulties (eg. linking into training or employment services)
- monitoring of parenting, particularly of children under five and linking into relevant services to assist parenting skill development
- assessment of suitability for gradual withdrawal from treatment
- assistance in reducing concurrent drug use.

The comprehensive treatment plan should be reviewed three monthly with the patient. Completion of activities and progress against goals should be noted. Prior to review with the patient all members of the treatment team should contribute information and opinions to the review. An outcome of the review should be the development and documentation of a revised comprehensive treatment plan for the next 3 months.

Ongoing treatment

Dose increments

Doses can be increased by increments as needed, in accordance with the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 3.3.

The dose range that is usually most effective for patients is between 12mg and 24mg. There is however, significant individual variation in dose requirement.

Maximum maintenance dose

The maximum daily dose of buprenorphine should not exceed 32mg. To prescribe a dose in excess of 32mg, approval must be sought through the Pharmacotherapy Credentialling Sub-Committee.

Alternate-day dosing in maintenance programs

Daily dosing is recommended for the initial period of stabilisation and during detoxification.

Evidence suggests that a significant proportion of patients on buprenorphine can be adequately maintained by receiving a dose every alternate day and some even every third day. A trial of alternate day dosing is encouraged for all patients who have been stable on buprenorphine for at least two weeks. Stability is represented by a steady dose requirement and no evidence of intoxication or dangerous use of other drugs in that time. The benefits of less frequent dosing include reduced time spent in travel to the dispensing point, more time to undertake activities that promote improved social functioning and less congregation of patients around dosing points.

For further detail, refer to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 3.4.

Length of maintenance treatment

Patients should remain in treatment for the minimum time it takes to achieve their agreed treatment goals. The length of time required for treatment will vary amongst individuals. Regular reviews will assist in determining need for continued treatment.

While there is no one optimal duration of buprenorphine treatment, removing people from treatment too early may result in very poor outcomes, including high rates of relapse into illicit opioid use and a consequent increased risk of overdose.

Setting an arbitrary duration of treatment and withdrawing treatment at that endpoint is not recommended.

Case management

Patients with opioid dependence usually have concomitant psychological, social and health problems. An essential component of buprenorphine treatment is inclusion of a comprehensive range of services to assist individuals to reduce their concomitant problems.

A case management approach should be offered to all patients and include:

- interventions to reduce heroin and other drug (including alcohol and tobacco) use
- interventions to reduce risks associated with the hepatitis A, B and C and HIV viruses
- medical, psychiatric and psychological assessment and care
- crisis intervention
- social and economic assistance – vocational, financial, accommodation and family assistance contribute positively to treatment progress.

Brief, supportive and problem-oriented counselling can add to the effectiveness of treatment for patients with current life problems. Cognitive-behavioural therapy, motivational interviewing, relapse prevention counselling and social skills training are some approaches that can be employed.

Children and Young Persons (Care and Protection) Act 1998

It is common for child protection and care issues to arise in the treatment of opioid dependent populations. The *Children and Young Persons (Care and Protection) Act 1998* establishes a process for people who have reasonable grounds to suspect that a child or young person is at risk of harm from abuse or neglect, to report the matter to the Department of Community Services. The treating team should be familiar with this *Act* and respond in accordance with their obligations.

At least one clinician in the treating team is encouraged to view the children of the patient on buprenorphine each three months. This is to assess the need for care or protection intervention.

Takeaway doses

Takeaway doses for emergencies or special circumstances

Buprenorphine is a drug of dependence. It can be misused. Overdose of buprenorphine in combination with other central nervous depressant drugs can result in death. Takeaway doses can enable unstable patients to have more than one dose at a time, take buprenorphine while intoxicated with other drugs, or inject buprenorphine. Injection can cause venous damage, emboli and tissue necrosis and transmission of infectious diseases including HIV, hepatitis B and hepatitis C.

Of particular concern is the possibility that takeaway buprenorphine is diverted to someone for whom it was not prescribed. There is also a risk that children can ingest takeaway doses if not properly stored.

In general there will be no takeaway doses. This applies to the use of buprenorphine for detoxification and maintenance. There are two possible exceptions to this.

1. Patients who can only tolerate daily dosing

In this case the patient has been unable to tolerate alternate day dosing and requires regular takeaway doses. The patient should be referred to a drug and alcohol medical specialist nominated by the local Area Health Service for a formal second opinion. It will be usual for the assessment by the specialist to be conducted over a period of time in order to determine the stability and reliability of the patient. If it is the opinion of the specialist that it is necessary the patient receive regular takeaway doses, this should be documented in the patient's file. A maximum of two takeaway doses per week, not on consecutive days, may be prescribed.

2. In an emergency

One-off provision of takeaway doses can be provided where:

- there are health problems, such that the patient is incapacitated and unable to attend on site dosing
- there is an urgent need for travel and no alternate dosing arrangements can be made.

Takeaway doses should only be provided in such circumstances after careful assessment of the patient's stability and reliability. Takeaways should never be given if there is concern that they will be misused.

Rural and remote areas

In rural and remote areas buprenorphine programs may have to develop an alternative policy on takeaway doses for situations where 7-day-a-week on-site dosing for some patients will be impractical. Such a policy must address the objective of minimising the diversion and injection of buprenorphine and should define the degree of geographical inaccessibility that will exempt a rural patient from standard restrictions on takeaway doses. In general, dosing alternate day and every three days should be trialed prior to the provision of takeaway doses in rural areas.

Takeaway doses

Preparation and supply of takeaway doses

The legislation that governs the preparation and supply of methadone takeaway doses applies to buprenorphine. Buprenorphine takeaway doses should be provided in a labelled, clean new container fitted with a child resistant closure.

Patients receiving takeaway doses are to be informed that buprenorphine is for sublingual consumption only and advised of the dangers of its misuse, the hazards of using it in combination with other drugs and its toxic potential if taken by children or a person not tolerant to opioids.

Once in the possession of the patient, takeaway doses are the patient's responsibility. In general, takeaway doses that are reported as lost, stolen or damaged should not be replaced. Exceptions can be made where the medical practitioner conducts an assessment and determines significant risk to the patient or others through not dosing the patient. This will be for patients with specific medical indications, including pregnancy and HIV. Careful assessment and monitoring are required in these instances to ensure that the replacement dose is carefully titrated against the clinical condition of the patient. A replacement dose is not usually a full dose.

Patients with takeaway doses who are admitted to hospital

Patients with dispensed takeaway doses who are unexpectedly admitted to hospital should hand the takeaway doses to the ward staff and have their buprenorphine dispensed through the hospital pharmacy. This allows closer monitoring of the patient's clinical condition and greater certainty about the dose of buprenorphine that an in-patient is receiving. If a patient refuses to hand over his/her takeaway doses, they should not be administered their usual dose of buprenorphine. The patient's clinical condition should be monitored for evidence of intoxication or withdrawal and these should be treated appropriately. A drug and alcohol medical specialist should be consulted if there are concerns about the patient's clinical condition.

Urine drug testing

Urine drug testing is one method of monitoring the progress of patients during treatment, including extraneous drug use or buprenorphine diversion. Other methods include patient self reporting and clinical observation. Urine drug testing can be a useful way of monitoring treatment effectiveness however, its utility is limited because:

- urine samples may not be a reliable indication of drug use if urination is not observed
- supervised urine collection can be demeaning for the patient
- research suggests that urine testing does not reduce drug use
- there are significant financial and resource costs associated with urine drug testing
- false positive and false negative results occur.

Buprenorphine is difficult to detect by routine urine drug screening that relies on chromatography procedures. A consistent indication of whether a patient is consuming buprenorphine as prescribed may not be gained from this type of testing. ELISA or mass spectrometry are techniques that confidently detect the presence of buprenorphine.

Testing for buprenorphine should only be requested when there is a clinical indication.

The frequency of urine drug screening of patients in buprenorphine maintenance programs is determined by the same principles that apply to methadone maintenance programs (refer to the *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*, Section 4.4. p.29).

Dosing location

Specialist clinics (public or private) are in general, best placed to manage complex clinical issues and unstable patients. Community health centres and general hospitals including out-patient services can also provide multidisciplinary care on a daily basis and highly supervised care. Patients who behave in a way that disrupts the normal operations of retail pharmacies should be managed in a highly supervised setting. Stable patients should be preferentially managed within the retail pharmacy sector.

At the commencement of treatment

All patients will initially be dosed with buprenorphine in a highly supervised setting. The patient will continue to be dosed in that setting until assessed as suitable for a retail pharmacy.

A minimum initial period of one month at a highly supervised setting will be required to enable the clinician to monitor stabilisation on buprenorphine and suitability of a patient for the pharmacy setting. It should be recognised however, that most commonly two to three months will be needed for stabilisation.

Exemption to commencement of dosing at a specialist clinic

Medical practitioners who assess a patient as suitable to commence buprenorphine at a retail pharmacy must write to the Pharmaceutical Services Branch, NSW Health Department stating the reasons why the medical practitioner has decided on a retail pharmacy for initial dosing. This letter should accompany the application for authority to prescribe form. The responsibility and accountability for the decision to commence a patient at a retail pharmacy rests entirely with the medical practitioner.

Retail pharmacy dosing

A patient is suitable for a pharmacy when there is:

- absence of hazardous drug use
- low risk of diverting or misusing buprenorphine
- absence of behaviours that will disturb the normal operations of a pharmacy (eg. antisocial or violent behaviours), or that will be beyond the pharmacy staff's capabilities or desire to manage
- evidence of reliability and adherence to the conditions of the program over the preceding month
- ability to meet the financial commitments involved in being dosed at a retail pharmacy.

The criteria used to assess suitability to be dosed at a retail pharmacy are the same as those applied in methadone treatment. They are listed in the *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*, p30, Section 4.5.2.

The pharmacy should be accessible for the patient and there must be an available treatment place. The pharmacist should be consulted prior to being recommended to the patient. A meeting between patient and pharmacist should then be arranged to ensure both parties agree to the arrangement.

The clinicians involved in the patient's treatment (the prescribing doctor, the dosing staff, other case workers) should contribute to the decision on a patient's dosing location and this should be documented. Arrangements regarding the transfer of patients from clinics to retail pharmacy dosing should always include a clear understanding that the clinic will take the patient back if significant problems are experienced at the pharmacy.

Stable patients in methadone treatment transferred to buprenorphine

Patients who are stable on methadone and are transferred to buprenorphine in accordance with the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence* can be treated at retail pharmacies without a period of assessment at a specialist clinic, unless the treating practitioner believes that there is a particular need for specialist clinic care of the patient. These patients must meet the aforementioned criteria for retail pharmacy treatment.

Numbers of patients at retail pharmacies

NSW legislation restricts the number of patients dispensed methadone at retail pharmacies. A retail pharmacist must not, on any particular day, dispense methadone for consumption to more than 50 patients. This restriction has been applied to ensure that disruption to the local amenity is minimised.

The restriction on numbers applied to methadone will be amended to apply to patients on either methadone or buprenorphine. This will include patients on detoxification regimes.

Notification of changes to dosing location

The Pharmaceutical Services Branch must be notified of any permanent change in the dosing location of a patient and the date when the change occurred.

Dosing of patients in police cells, multiple administration points and administration of buprenorphine to patients at home

The procedures detailed for methadone in the *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*, Sections 5.9, 5.11 and 5.12 apply to buprenorphine.

Use of other drugs, including alcohol

The use of drugs other than prescribed buprenorphine (including alcohol and tobacco) may be monitored by self-report, by regular urine tests for drugs or by observation of changes in a patient's clinical condition or behaviour. Where there is a strong therapeutic relationship patients may report problematic use of other drugs. Patients using other drugs should be provided with interventions that are based on evidence of effectiveness and take into account patient wishes. The risk arising from drug use (eg overdose, serious illness, social devastation) will be the predominant consideration in the choice of interventions.

Patient safety

The use of central nervous depressants such as benzodiazepines, opioids and alcohol in combination with buprenorphine can result in life threatening overdose. In addition, toxicity from the combination of drugs can place patients at risk of injury and other health and social problems.

If patients presenting for their next buprenorphine dose show evidence of intoxication with these drugs, buprenorphine should be withheld until an experienced clinician can judge the safety of administering the dose.

Each clinic or dosing point should develop and document procedures for managing intoxicated patients presenting for dosing. These procedures should be developed through consultation between dosing staff and prescribing doctors. Patient safety should be the key consideration in the development of these procedures.

Overdose at the administration point

Medical emergency procedures should be in place for patients who demonstrate signs of drug overdose at the administration point. Such procedures will depend upon the severity and the urgency of the situation but should if necessary, include cardiopulmonary resuscitation, calling for an ambulance (or the resuscitation team if associated with a hospital), calling for urgent medical assistance, closely monitoring the patient and if indicated and possible, administering oxygen. The effects of buprenorphine, due to its strong affinity to μ opioid receptors, are not reversed by the usual doses of the opioid antagonist, naloxone. Refer to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Sections 5.2 and 5.3, for information about the management of overdose involving buprenorphine.

Patient administered a dose higher than prescribed

A patient who receives a buprenorphine dose in excess of that prescribed is not at the same risk of overdose as with methadone and other opioids. Nevertheless, the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 5.4, recommend the following procedures if an excess dose has been prescribed:

- notify the patient and the doctor
- warn the patient of the likely effects and risks associated with extra drug use and driving or operating machinery
- monitor the patient for at least six hours if
 - the patient is showing signs of toxicity such as sedation
 - has commenced treatment in the last 2 weeks
 - the dose administered is equal to or greater than 16mg
 - the patient's usual dose is 4mg or less
 - a dose of 64 mg or more was administered
- the medical officer should review the patient prior to the next dose.

Preventing an incorrect dose being administered

To minimise the possibility of dosing errors, the following procedures applied in methadone dosing should be adopted:

- attach a photograph to every patient's buprenorphine prescription/treatment card from which they can be easily and accurately identified
- if there is more than one patient with the same surname, make a cautionary note on the patient's buprenorphine treatment card alerting the staff
- put a cautionary note on the buprenorphine treatment card of new patients who are unfamiliar to staff. Staff should take extra care in these cases to elicit information from the patient about the effect of the dose in order to monitor the toxicity of the current dose.

Hospital in-patients

Buprenorphine is used to treat opioid dependent hospital in-patients in the following ways:

- continuation of a maintenance program
- commencement of a maintenance program
- management of opioid withdrawal.

Legal restrictions on prescribing drugs of addiction to in-patients

Under the provisions of section 28 of the *Poisons and Therapeutic Goods Act 1966 (NSW)*, a medical practitioner may not prescribe any drug of addiction for a person who in his/her opinion is a drug dependent person without the approval of the Director General, NSW Health Department. An exemption from this requirement is provided for in-patients of public hospitals. In this case, patients may be prescribed a drug of addiction for up to 14 days following the patient's admission as an in-patient even when the patient is known or suspected to be a drug dependent person.

Treatment of an in-patient currently on a buprenorphine maintenance program

In general, a patient on buprenorphine maintenance should continue buprenorphine treatment in hospital. Such a patient has one authorised buprenorphine prescribing doctor who has received specific authorisation to be the buprenorphine prescriber for that patient. When such patients are admitted to hospital, the hospital medical officer can take over prescribing the patient's buprenorphine for up to 14 days following the patient's admission as an in-patient.

When a patient on buprenorphine is admitted, the hospital medical officer should:

- verify the patient's identity
- contact both the authorised prescribing doctor and the patient's buprenorphine administration (dosing) point to confirm the current actual dose, the date and time of the last dose and whether the patient has been given any takeaway doses. This information helps to avoid administering an overdose of buprenorphine.

Provided there is no medical contraindication administer buprenorphine with the usual frequency for that patient (eg. daily, alternate days, every third day).

The patient's prescribing doctor should be advised of the approximate length of stay in hospital to prevent the patient being removed from the program through non-attendance.

When a patient is discharged from hospital, inform the authorised prescribing doctor and the administration point in advance to ensure that arrangements are made for the patient to continue the buprenorphine program without interruption.

Patients taking buprenorphine are unlikely to exhibit withdrawal symptoms until more than 24 to 72 hours have elapsed after the last dose of buprenorphine. If the patient demonstrates withdrawal signs and neither the authorised prescribing doctor nor the administration point can be contacted, the patient may be administered up to 8mg of buprenorphine.

Commencement of a maintenance program in hospital

A hospital medical practitioner is allowed under the legislation to treat an opioid dependent person with buprenorphine for up to 14 days following the patient's admission as an in-patient. If the medical practitioner is not an approved methadone prescriber the doctor should consult with a drug and alcohol medical specialist. Each Area Health Service should have a drug and alcohol medical specialist available for the hospital staff to contact. If such a person is not available locally, the 24 hour State-wide Specialist Drug and Alcohol Advisory Service can be contacted on 1800 023 687.

Commencement of a patient on buprenorphine maintenance in hospital should be undertaken in accordance with this policy and the guidelines set out in the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Sections 2 and 3. There should be a formal commitment by the ongoing (post discharge) buprenorphine treatment provider to continue buprenorphine treatment after discharge from hospital prior to commencement on a buprenorphine maintenance program. Particular attention in the assessment should be paid to ensuring the patient fully understands what is involved in the buprenorphine treatment program after discharge from hospital.

Management of opioid withdrawal in hospital using buprenorphine

Adequate treatment of opioid withdrawal in hospital is important to minimise patient discomfort and assist patients to successfully complete withdrawal. Some patients leave hospital against advice because they are not coping with the discomfort of withdrawal. Alternatively, they may self medicate with unsanctioned drugs that can confuse assessment and treatment in hospital. Buprenorphine is effective in reducing opioid withdrawal symptoms and increases the likelihood that a patient will remain in hospital for treatment of the primary condition for which they were admitted.

Another benefit of buprenorphine, due to its pharmacological properties as a partial agonist, is that it can provide easier transition to another treatment (eg. methadone, naltrexone, buprenorphine maintenance).

The use of buprenorphine in hospital should, however, not be commenced until consideration has been given to the impact on analgesia. The partial agonist properties and strong binding to the μ receptors complicate analgesic use where patients have a condition requiring potent analgesia. Alternatives for these patients include methadone or medications to treat withdrawal symptoms such as clonidine, antiemetics and anti-diarrhoea agents.

The treatment of opioid withdrawal using buprenorphine in the hospital setting should be consistent with the clinical guidelines contained in the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 4.

Analgesia

The strong affinity of buprenorphine for μ opioid receptors and its partial agonist properties reduce the response of patients on buprenorphine to analgesia. People who have pain will require treatment with alternatives to opioids where indicated, or higher doses of opioid analgesia. Refer to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 5.7 for information on the management of pain.

The options described are:

1. use of non-opioid analgesics
2. brief increase in buprenorphine dose
3. titrate the dose of opioid where indicated against clinical response. Care should be taken to avoid overdose if buprenorphine is reduced while the patient is on high doses of opioid analgesia.

Pregnancy and breast feeding

Risks

Pregnant women who use opioid drugs such as heroin are at an increased risk of developing complications in pregnancy, including:

- premature labour
- intrauterine growth retardation
- miscarriage
- intrauterine infection
- antepartum and postpartum haemorrhage
- intrauterine hypoxia or anoxia.

The newborn from these pregnancies are at risk of experiencing:

- neonatal abstinence syndrome
- sudden infant death syndrome.

Opioid withdrawal in pregnancy

Acute opioid withdrawal during pregnancy carries particular risks including miscarriage, premature labour and foetal hypoxia and distress. Specialist care by an obstetrics team in combination with drug and alcohol specialists is required to manage opioid withdrawal in pregnancy.

Pharmacotherapy in pregnancy and breast feeding

Buprenorphine is at this time, contraindicated for pregnant women and breast feeding women. There is insufficient evidence to state it is safe in these circumstances.

Methadone is the treatment of choice for women assessed as appropriate for pharmacotherapy during pregnancy.

Issues to be addressed during the initial assessment

As most opioid dependent women are in the child bearing years when they present for buprenorphine treatment, the following should be explored:

- might they be pregnant?
- are they breast feeding?
- if pregnant, their plans for the pregnancy
- if not pregnant, their intentions to become pregnant
- the benefits of treatment to pregnancy outcomes
- if not wishing to become pregnant, contraception
- the risks and unknowns associated with buprenorphine in pregnancy and breast feeding
- methadone as the preferred maintenance treatment option in pregnancy.

Pregnancy and breast feeding

Written information

Patients undergoing assessment for buprenorphine treatment should be provided with written information about the issues of buprenorphine in pregnancy and breast-feeding. Written informed consent for buprenorphine treatment should include acknowledgment by the patient of understanding of these issues.

Women on buprenorphine who become pregnant

Women who are on buprenorphine and become pregnant should be advised to transfer to methadone if continuing maintenance pharmacotherapy. The transfer should be undertaken carefully to ensure an opioid withdrawal syndrome is not precipitated. The transfer to methadone from buprenorphine in pregnant women should be undertaken under the supervision and monitoring of a specialist obstetrics service.

Neonatal abstinence syndrome

Babies born to women taking buprenorphine are at risk of developing a neonatal abstinence syndrome. Hospitals that care for neonates should have in place protocols for the monitoring and treatment of neonates at risk of developing an abstinence syndrome.

14

Completing buprenorphine treatment

An important objective of buprenorphine treatment is the successful withdrawal from buprenorphine combined with continued good functioning, including good health and social functioning. Planning for successful withdrawal from buprenorphine should commence from the initiation of treatment. The case management approach should include work towards goals, that when achieved, prepare a patient to live well without buprenorphine.

The decision to withdraw voluntarily from buprenorphine should be made collaboratively between the patient, the prescribing doctor and the case manager, with information contributed by the pharmacist/dispensing staff. When all agree about the timing and method of withdrawal from buprenorphine, patients tend to be more successful in their buprenorphine reduction. It remains, however, the patient's right to withdraw from buprenorphine at any time.

Forcing a patient off buprenorphine when they do not feel capable of coping without the treatment may result in return to opioid use and related problems. Unless there is a specific reason for involuntary discharge from treatment, this approach is not encouraged.

The elements of treatment that assist patients to complete withdrawal successfully are:

1. Dose

- a flexible approach to dose reduction, individualising reduction regimens to best suit each patient
- slower rates of reduction
- if relapse is likely, or the patient is not coping, reductions in buprenorphine dose may need to be suspended or an increase in dose considered

2. Increased psychosocial support during withdrawal

- more frequent supportive, skills oriented and relapse prevention counselling
- more frequent monitoring and review
- access to residential programs if necessary (residential withdrawal or rehabilitation programs)
- involvement of significant others (including family) in providing support should be explored.

3. Aftercare

- services, including counselling, continuing case management and structured group programs are all likely to assist outcome after completion of withdrawal from buprenorphine
- case managers should remain involved in the care of patients who have voluntarily withdrawn for three months after completion of withdrawal.

For details about the rates of dose reduction and other clinical considerations in withdrawal from buprenorphine maintenance, refer to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 3.9.

Completing buprenorphine treatment

Readmission to treatment

Easy access back into treatment if needed, is an important element of buprenorphine treatment. If relapse occurs within two weeks of leaving treatment and the patient seeks readmission, treatment should be offered expeditiously and without recrimination, provided that the available treatment options are considered and the person is clinically suitable for buprenorphine.

Transfer to naltrexone

Naltrexone has the potential to assist people to remain abstinent from opioids after withdrawal from buprenorphine. For the procedures to transfer patients after buprenorphine to naltrexone refer to the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, Section 3.9.

Involuntary termination of treatment

At the beginning of treatment, patients sign a treatment agreement that provides in writing the conditions under which they may be involuntarily discharged. Situations that may warrant this action include:

- violence or threat of violence against staff or other patients
- property damage or theft from the service centre
- drug dealing on or near the service premises
- diversion of buprenorphine
- unacceptable disruption to the local amenity.

It may be appropriate to transfer the patient to another service provider instead of withdrawing buprenorphine treatment.

If the patient is to be involuntarily withdrawn from buprenorphine treatment, reduction in dosage should be gradual. Rapid dose reduction or abrupt cessation of treatment is warranted only in cases of violence, assault or threatened assault. In general, involuntary withdrawal from buprenorphine should not take less than 14 days.

Advise the patient who is to be discharged of other treatment options, including detoxification. Warn the patient of the increased risk of overdose after completion of withdrawal. Assist the patient to reduce risks associated with resuming drug use and offer training in strategies to prevent relapse. Develop a management plan regarding subsequent readmission for each patient involuntarily withdrawn from the program and document it in the patient's case record.

Complaints mechanism

All patients should have access to procedures for response to conflicts between themselves and the treatment providers.

All patients should have a fair opportunity to present their case. If possible, patients should be retained in the current treatment program pending the resolution of the complaint.

Completing buprenorphine treatment

The *Methadone Advice and Complaints Service* (MACS phone 1800 642 4280) and *The NSW Users and Aids Association* (NUAA phone 1800 644 413) are available to assist patients with complaints associated with buprenorphine and methadone treatment.

Exiting and transferring patients

Treatment Exit Form

When a patient exits buprenorphine treatment, or transfers between doctors, a Treatment Exit Form (available from the Pharmaceutical Services Branch) must be completed and must be immediately forwarded to the Pharmaceutical Services Branch. Patients must be exited from one prescribing doctor to begin treatment with another. This prevents patients being registered in two programs simultaneously and therefore being double dosed.

Transfer of dosing site

To avoid the potential for double dosing, the prescribing doctor should notify the previous dosing site and have them cancel all scripts. If a patient has not changed prescribing doctor but is to transfer between dosing sites, the Pharmaceutical Services Branch is to be notified by phone immediately of the change.

Refusal to exit a patient

No prescribing doctor may refuse to complete exit procedures for a patient. Such an action would place the prescribing doctor in breach of a condition of the authority to prescribe buprenorphine.

Refusing to exit patients has occurred in the past when money is owed to the service at which the patient has been dosed. A service in this position may pursue such civil remedies as are open to them to recover the debt. However, the patient must still be promptly exited to ensure further treatment is not blocked.

Persistent failure to exit patients may result in a review of approval to prescribe and where relevant, review of a clinic's licence.

Temporary transfers - interstate, intrastate and overseas travel

The transfer of a patient's buprenorphine treatment within New South Wales, between states and overseas should be carried out by the treating medical practitioner (or delegate). The provision of necessary documentation for a transfer should be made between the treating clinician and clinicians from the transfer destination. Pharmaceutical Services Branch do not require notification of temporary changes in administration point.

Where overseas travel requires the patient to carry takeaway doses, the prescriber, in addition to adherence with the NSW policy regarding takeaways, must clarify with the consulates of the intended destinations their position on a foreigner entering in possession of buprenorphine. Where approval is given for the possession of buprenorphine the medical practitioner must then comply with any special condition on the entry of a person possessing buprenorphine. A letter written by the prescribing doctor stating that the person is in possession of the drug to treat a medical condition in accordance with Australian laws is usually adequate. If the destination requires a letter from the Australian Government this must be obtained from the Therapeutic Goods Administration (TGA phone 02 6270 4321).

Prisoners

Detoxification

There is a dearth of evidence to guide the use of buprenorphine in the prison setting. Consequently, buprenorphine should be trialed as a withdrawal medication for prisoners carefully assessed as experiencing an opioid withdrawal syndrome on entry to prison.

Maintenance

Until more evidence is available on the application of buprenorphine to the prison setting, buprenorphine should not be the first line maintenance pharmacotherapy treatment in the prison setting.

Prisoners who enter jail on buprenorphine should have their treatment continued until review by Corrections Health Service and a treatment plan developed.

Pre-release commencement of buprenorphine should be available as one option for those assessed as suitable due to high risk of heroin related problems, including overdose, upon release from jail. There is no evidence to suggest buprenorphine should be preferred to methadone maintenance treatment in the pre-release population.

Prisoners released on buprenorphine

Prisoners released on buprenorphine should have had continuation of buprenorphine treatment arranged prior to release. Corrections Health Service should negotiate with other Area Health Services to ensure continuity of care for prisoners released on buprenorphine.

If a person was treated in a specific buprenorphine program before incarceration and chooses to return to that program, that program should take the person back into treatment after release. If this results in that program temporarily exceeding its authorised limit of patients, then the program should return to the numbers for which they are authorised by attrition from the program over time.

If a prisoner is to be released to an area where they were not previously treated and buprenorphine services are not available, an alternative treatment for opioid dependence should be considered. Renegotiation with the prisoner and the Corrections Health Service over the area to which the prisoner will be released should be undertaken if buprenorphine is an essential component of the persons post release plan.

Comprehensive treatment plans

The treatment team in the prison system should, where possible, consult with the relevant community treatment program prior to release of a prisoner on buprenorphine maintenance treatment. A Comprehensive Treatment Plan (see page 17) should be developed collaboratively between the treating team in prison, the prisoner and community buprenorphine service providers.

16

Quality assurance

The Pharmacotherapy Credentialling Subcommittee

This is a subcommittee of the Medical Committee and is established under Section 30A of the *Poisons and Therapeutic Goods Act 1966 (NSW)*. The primary role of the Pharmacotherapy Credentialling Subcommittee is to make recommendations to the Director-General on the approval of medical practitioners as prescribers of drugs of addiction under the State's Drug Dependence Treatment programs.

The Subcommittee has a membership of seven plus a secretary. The membership comprises:

- three members who are experienced approved prescribers (these include both public and private prescribers and a general practitioner)
- a Ministerial nominee, (who could be a consumer, legal person, nurse or other health professional)
- a nominee of the Medical Board of NSW
- a member or nominee of the Australian Medical Association (AMA)
- the person holding the position of Clinical Director, Drug Programs Bureau, NSW Health Department.

Credentialling of prescribers

Approval to prescribe methadone and buprenorphine is granted by the Director-General of the NSW Health Department.

Medical practitioners will be required to successfully complete:

- the Pharmacotherapy Accreditation Course for medical practitioners, either through attendance at a workshop or through the web-based course
- an examination,
- a workplace assessment (a 2-3 hour clinical placement), or alternatively submitting a written clinical case discussion that is assessed as satisfactory,
- assessment of the above and the professional record of the medical practitioner by the Pharmacotherapy Credentialling Subcommittee.

Limits on the number of patients able to be treated

Initially prescribers are granted approval to treat up to 25 patients with methadone or buprenorphine. An approved prescriber may, after a period of 6 months, apply for an increase in patient numbers. Application should be made in writing to the:

Director-General NSW Health Department c/o Secretary, Pharmacotherapy Credentialling Subcommittee, Drug Programs Bureau, NSW Health Department, Locked Mail Bag 961, North Sydney 2059.

Quality assurance

The Pharmacotherapy Credentialing Subcommittee review applications for increased numbers. The Subcommittee deliberations include review of:

- a short case study or de-identified patient record provided by the applicant that demonstrates clinical competence
- the context in which prescriber works (eg. clinic, solo general practice)
- the time allocated by the prescriber for treatment and care of patients in pharmacotherapy treatment
- the drug and alcohol clinical knowledge and skills of the prescriber.

Specific items to be addressed in the written application to the Subcommittee can be obtained by contacting the Principal Pharmaceutical Adviser, Drug Programs Bureau on (02) 9391 9261.

Locums

Prescribing doctors who are going on leave and will not be available to their patients on buprenorphine must arrange for a locum medical practitioner. Locum medical practitioners require the approval of the Director-General through the Pharmaceutical Service Branch. A locum will ideally be experienced in the management of drug dependent people. If possible, the locum should be an approved methadone and buprenorphine prescriber. Locums should not commence patients in buprenorphine treatment, but may make any necessary alterations to treatment in accordance the guidelines set out in the *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*.

Accreditation of clinics

An important quality assurance and improvement mechanism is accreditation of services against agreed standards. Services that hold a licence to supply buprenorphine or methadone under the *Poisons and Therapeutics Goods Act 1966 (NSW)* will, as a condition of their licence, be required to achieve accreditation with an approved organisation. Methadone and buprenorphine clinics operated by Area Health Services will be required by the Director-General, NSW Health Department, to achieve accreditation in accordance with the requirements placed on licensed services.

The Methadone Accreditation Standards will be adapted to apply to buprenorphine and methadone.

Authorisation to treat individual patients

Pharmaceutical Services Branch of the NSW Health Department administers the *Poisons and Therapeutic Goods Act 1966* and *Poisons and Therapeutic Goods Regulation 1994 (NSW)* and is responsible for issuing the authority to approved prescribers to treat individual patients.

- A prescribing doctor must obtain authority for each buprenorphine patient by completing an Application for authority to prescribe buprenorphine form and faxing it to the Pharmaceutical Services Branch (PSB) of the NSW Health Department Fax. (02) 9859 5170.

- A patient must not begin buprenorphine treatment until approval has been given by PSB.
- The authorised maximum dose should not be exceeded except by a further application to do so.
- An authority to prescribe is valid for a maximum of 1 year.
- The Treatment Exit Form also available from Pharmaceutical Services Branch must be completed and faxed to Pharmaceutical Services Branch for each patient discharged from a program or transferred from the care of one prescribing doctor to another.

Medical practitioners should be aware that Clause 81 of the *Poisons and Therapeutic Goods Regulation 1994 (NSW)* states that it is offence for a prescriber to prescribe a drug of addiction “in a quantity or for a purpose that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.”

Data collection and reporting

Accurate data is required to monitor and evaluate the introduction of this drug for treatment of opioid dependence. Prescribers must comply with reporting requirements of the NSW Health Department as a condition of authority to prescribe buprenorphine. This includes providing the full details on the authority to prescribe and prompt submission of changes in details included on this form as well as prompt notification of treatment cessation.

Prescriptions

Buprenorphine prescriptions must be written in accordance with the requirements for S8 prescriptions (including methadone prescriptions) set down under the *Poisons and Therapeutic Goods Act 1966 (NSW)*.

The prescriptions should not be handed to patients. They should be sent directly to the dispensing point to avoid any risk of alteration.

Storage and administration of buprenorphine

All stocks of buprenorphine must be stored in a manner approved by the Pharmaceutical Services Branch of the NSW Health Department.

Records must be maintained in good order in a drug register, showing all doses given each day and the balance at the end of the day. Entries are to be made in the drug register on the day the pharmacist or clinic receives, dispenses or administers buprenorphine.

Nurses, pharmacists and medical practitioners are able to administer buprenorphine to a patient, but only a pharmacist, an assistant under the direct supervision of a pharmacist, or a medical practitioner can dispense buprenorphine takeaway doses.

Chief sources

The *NSW Methadone Maintenance Treatment Clinical Practice Guidelines*, NSW Health Department, Sydney 1999.

The *NSW Drug Treatment Services Plan 2000-2005*, NSW Health Department, Sydney, June 2000.

The *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence*, National Drug Strategy, Commonwealth Department of Health and Aged Care, 2001.

The *National Buprenorphine Policy*, *National Drug Strategy*, Commonwealth Department of Health and Aged Care 2001.

Appendix A



Further reading

National Buprenorphine Policy, National Drug Strategy, Commonwealth Department of Health and Aged Care, 2001. Available on the Commonwealth Department of Health and Aged Care web site www.health.gov.au

National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence National Drug Strategy, Commonwealth Department of Health and Aged Care, 2001. Available on the Commonwealth Department of Health and Aged Care web site www.health.gov.au.

The NSW Methadone Maintenance Treatment Clinical Practice Guidelines, NSW Health Department 1999. Available on the NSW HealthWeb www.health.nsw.gov.au.

NSW Health Frontline Procedures for the Protection of Children and Young People, NSW Health Department. Available on the NSW HealthWeb www.health.nsw.gov.au.

B

Appendix B

Further information and advice

ADIS (Alcohol and Drug Information Service) provide a 24 Hour and 7 days confidential service for the public and for health practitioners which includes information and referral. Tel. (02) 9361 8000
or toll free for country areas – 1800 42 25 99.

MACS (Methadone Advice and Complaints Service) provide a confidential service for patients 9-5pm Monday-Friday. Tel. 1800 642 428.

The State-wide Specialist Drug and Alcohol Advisory Service can be contacted 24 hours a day by health practitioners for advice from a drug and alcohol medical specialist. Tel. 1800 023 687.

The Drug Programs Bureau, NSW Health Department. Tel. (02) 9391 9244

Appendix C



Example of an assessment module for buprenorphine treatment

This assessment module is designed to document the key stages of the assessment of a patient being considered for treatment. The form provides for a structured assessment that covers all the essential stages of information gathering, examination and counselling. It is designed to be used by ticking boxes to record key findings and writing the details in the lines nearby.

The 10 page assessment module can be photocopied for use in any clinical setting.

Record No.

Patient Assessment

Surname

Given names

.....

Aliases

Address

.....

.....

Telephone ()

General practitioner Telephone ()

Sex Male Female

Date of birth / /

Country of birth

First language

Marital status

Medicare No

Health care No

Emergency contact

Name

Address

.....

.....

Telephone

Relationship

PHOTOGRAPH

Presentation

Reason for presentation at this time

Presenting date / /

Assessed by
(list all)

.....
.....
.....

Referred by

.....

Drug use history (brief outline)

.....
.....
.....
.....
.....

Drug use summary

Drug used	Days used in last month	Amount/ times daily	Route	Date/time of last use	Age at start of regular use	Longest abstinence date
.....
.....
.....
.....
.....
.....
.....
.....
.....

Medical history

Gastrointestinal (infectious hepatitis, liver disease, peptic ulceration, bowel habit, other current symptoms)

.....

.....

Cardiovascular (hypertension, endocarditis, other current symptoms)

.....

.....

Respiratory (asthma, bronchitis, other current symptoms)

.....

.....

Neurological (seizures, head injury, other current symptoms)

.....

.....

Genito-urinary (pregnancy, STDs, sexual dysfunction, menstrual dysfunction, other current symptoms, contraception)

.....

.....

Endocrine (diabetes, thyroid disease, other current symptoms)

.....

.....

Other (chronic pain, musculoskeletal [trauma, arthritis], dermatological)

.....

.....

Prescribed medications

.....

.....

.....

Key conditions checklist
(complete after taking history)

- Pregnant
- HIV Positive
- Hepatitis C positive
- Chronic hepatitis B infection
- Hepatitis B vaccination
- Liver disease
- Cardiovascular disease
- Respiratory disease
- Renal disease
- Chronic pain
- Drug allergies
- Oral contraceptive

Infectious risk behaviour

Frequency of needle sharing in last three months (per day, week or month)

.....
.....

Use of bleach to clean needles before re-use (always, sometimes, never, doesn't re-use needles)

.....
.....

Needle sharing partners in last three months

Number using needle before:

.....

Number using needle after:

.....

Number of sexual partners for unprotected penetrative sex in last three months

.....

.....

Psychiatric history

<input type="checkbox"/> Depression
<input type="checkbox"/> Anxiety
<input type="checkbox"/> Mania
<input type="checkbox"/> Psychosis
<input type="checkbox"/> Suicide attempts
<input type="checkbox"/> Previous psychiatric treatment

Family history

<input type="checkbox"/> Psychiatric disorders
<input type="checkbox"/> Medical conditions
<input type="checkbox"/> Drug or alcohol problems
<input type="checkbox"/> Problem family relationships

Personal/social history

Current stressors (losses, problems with relationships, or financial, legal, employment or accommodation difficulties)

.....

.....

.....

.....

Past significant life events

<input type="checkbox"/> History of abuse
<input type="checkbox"/> Loss of significant other
<input type="checkbox"/> Other traumatic events

.....

.....

.....

Current social situation and significant relationships

<input type="checkbox"/> Single	<input type="checkbox"/> Married/defacto relationship	<input type="checkbox"/> Separated or divorced
<input type="checkbox"/> Supportive friends	<input type="checkbox"/> Abusive partner	<input type="checkbox"/> Children, separated
<input type="checkbox"/> Supportive relatives	<input type="checkbox"/> Drug-using cohabitants	<input type="checkbox"/> Dependent children

.....

.....

.....

Formal qualifications and skills

.....

Income and employment

.....

Legal history

<input type="checkbox"/> Currently facing charges
<input type="checkbox"/> Past conviction
<input type="checkbox"/> Time in gaol

.....

.....

.....

Mental state examination

General appearance and behaviour (attire, grooming, movements [agitated, slowed], speech, attitude to examiner)

.....

.....

.....

Affect and mood (affect - quality, range, appropriateness, mood)

.....

.....

.....

Thought (tempo, form, content, delusions, suicidal or homicidal ideas)

.....

.....

.....

Perception (hallucinations, illusions, perceptual distortions)

.....

.....

.....

Cognition (orientation, memory, attention, concentration)

.....

.....

.....

Insight

.....

.....

.....

Physical examination

BP

Pulse

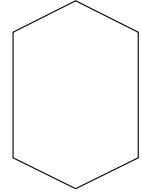
Temp

Head and neck

.....
.....

Abdomen

.....
.....



Cardiovascular

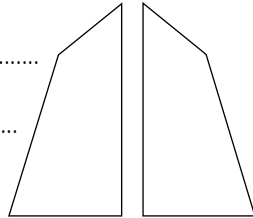
.....
.....

Lymph nodes

.....
.....

Respiratory

.....
.....
.....
.....



Central nervous system

.....
.....

Periphery

.....
.....

Evidence of injecting drug use (indicate where)

- Needle marks
.....
- Venous scarring
.....
- Phlebitis
.....

Evidence of intoxication

- Opioids (pinpoint pupils, sedation, low blood pressure, slowed pulse, itching/scratching)
.....
- Benzodiazepines (slurred speech, ataxia, sedation, nystagmus, low blood pressure, drooling, disinhibition)
.....
- Amphetamines (hyperactive, disinhibited, dilated pupils, high blood pressure, tremor, tachycardia)
.....
- Alcohol (ataxia, slurred speech, disinhibited, low blood pressure, smells of alcohol).
.....

Evidence of opioid withdrawal

- History (muscle tension/pain, bone aches, cramps, nausea, sleep disturbances, coldness, shivering, abdominal cramps, palpitations)
-

- Examination (lacrimation, rhinorrhoea, yawning, gooseflesh, piloerection, sweating, dilated pupils, elevated BP and pulse, vomiting, diarrhoea, muscle spasm, twitching)
-

Evidence of opioid dependence

- Tolerance
- Withdrawal syndrome
- Opioids used in larger amounts or for longer periods than was intended
- Persistent desire or unsuccessful attempts to reduce opioid use
- Great deal of time spent in obtaining, using and recovering from the use of opioids
- Important social, occupational or recreational activities are reduced because of opioid use
- Opioid use is continued despite knowledge that it causes or exacerbates physical or psychological problems

.....

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.....

.....

.....

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.....

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.....

Management plan

Suitability for buprenorphine treatment

- Opioid dependent
- Not primarily dependent on another drug
- Aged 16 or more
- Competent to consent
- Not pregnant

.....

.....

.....

.....

.....

- Suitable for buprenorphine treatment**

- Not suitable for buprenorphine treatment. Alternative treatment plan:**
-

Investigations

- Urine test for opioids
- Hepatitis serology
- HIV test
- Liver function tests
-
-
-
-
-
-

Patient information given

- Treatment aims
- Buprenorphine effects and side effects

Warnings

- Overdose
- Control of vehicles

Patient routine obligations

- Appointments/collections
- Report use of other drugs
- Report withdrawal symptoms
- Provide urine tests

- Attend counselling
- Consequences of non-compliance

Involuntary discharge conditions

- Violence
- Buprenorphine diversion
- Failure to collect doses
- Drug dealing

Other

- Support services available
- Review and appeal process
- Reducing infectious risk behaviour

Initial buprenorphine treatment plan

Detoxification

Coping strategies for patients and carers

Dealing with an emergency

Roles and responsibilities

Medication regime

Monitoring procedures

Other medical, psychiatric treatment

Post withdrawal treatment

Communication with other services

Monitoring of parenting and health or children

Maintenance

Dose review and adjustments

Setting and reviewing treatment goals

Medical and psychiatric review and treatments

Monitoring of progress

Assistance in reducing concurrent drug use

Harm reduction interventions

Supportive or skills focussed counselling

Assessment of suitability for retail pharmacy dosing

Assistance with accommodation if required

Assistance with any vocational difficulties

Monitoring of parenting and the health and safety of the children

Plans for discharge

Checklist

- Informed consent to treatment obtained
- PSB form completed
- Patient requested to obtain four ID photos
- Physical description documented
- Treatment agreement signed
- Treatment sheet with doctor's instructions or prescription



Appendix D

Acknowledgements

The NSW Health Department thanks those who contributed to the development of the *New South Wales Policy for the Use of Buprenorphine in the Treatment of Opioid Dependence*.

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Southern Area Health Service	Alliance of NSW Divisions of General Practice
Northern Area Health Service	Pharmaceutical Services Branch,
Mid North Coast Area Health Service	NSW Health Department
Far West Area Health Service	
Corrections Health Service	
Macquarie Area Health Service	
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