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Entry into buprenorphine treatment

2.1 Suitability for treatment with buprenorphine

There is no good evidence indicating who is better suited to methadone or buprenorphine maintenance treatment or detoxification.

The following guidelines should be taken into account when considering a person's suitability for treatment with buprenorphine for either maintenance or withdrawal.

2.1.1 Indications

(1) Buprenorphine treatment is only indicated for those who are opioid-dependent (see box at right).

Note: Neuroadaptation is not a prerequisite for the diagnosis of drug-dependence. However, in the absence of neuroadaptation, the prescribing medical practitioner must clearly demonstrate potential benefits to the individual's health and well-being that outweigh the potential disadvantages of buprenorphine treatment, and alternative treatment options should be carefully considered.

Evidence of neuroadaptation (or physical dependence) is indicated by:

- tolerance to the opioid;
- onset of withdrawal syndrome on stopping or decreasing use.

Diagnostic Definition of Opioid Dependence (DSM IV)

'A maladaptive pattern of substance use leading to clinically significant impairment or distress as manifested by three or more of the following, occurring at any time in the same 12 month period.'

- **Tolerance** as defined by either of the following:
 - A need for markedly increased amounts of opioids to achieve intoxication or desired effect;
 - Markedly diminished effect with continued use of the same amount of opioids.
- **Withdrawal** as manifested by either of the following:
 - The characteristic withdrawal syndrome for opioids;
 - Opioids, or a closely related substance, being taken to relieve or avoid withdrawal symptoms.
- **Impaired control over use:** Opioids often taken in larger amounts or over longer period than intended.
- **Wish to quit:** A persistent desire or unsuccessful attempts to cut down or control opioid use.
- **Time factor:** A great deal of time regularly spent in activities necessary to obtain opioids, use opioids, or recover from their effects.
- **Life-style changes:** Important social, occupational, or recreational activities given up or reduced because of opioid use.
- **Continued use despite awareness it is causing harm:** The opioid use continued, despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.

(2) The patient must be at least 16 years of age.

Buprenorphine has been registered for administration to people aged 16 and over. Nonetheless caution should be exercised in prescribing a drug of dependence for anyone in the 16–17 age group and a second or specialist opinion should be sought before treating anyone under 18 years of age. However, positive results have been reported from the combination of buprenorphine with behavioural interventions for the treatment of opioid-dependent adolescents (Marsch *et al* 2005).

(3) It is good practice to ensure that the patient can provide proof of identity — check the requirements in your jurisdiction regarding treatment with an S8 medication (see Appendix 2 for useful contacts).**(4) The patient must be capable of giving informed consent to treatment with buprenorphine.****Suitability for Buprenorphine Treatment**

opioid-dependent
16 years or older
proof of identity
capable of informed consent

2.1.2 Contraindications

- (1) Anyone with known hypersensitivity and/or severe side-effects from previous exposure to buprenorphine or the combination product is ineligible for buprenorphine treatment.
- (2) Pregnancy and breast-feeding are listed as contra-indications for the use of buprenorphine in Australia, principally due to the lack of robust data on the safety and effectiveness of buprenorphine. For further information refer to section 5.8 on pregnancy and lactation.
- (3) Severe respiratory or hepatic insufficiency.

2.1.3 Precautions

Particular caution should be exercised when assessing the suitability of buprenorphine treatment for anyone with any of the following clinical conditions.

- (1) *Polydrug use.* All opioid substitution treatments should be approached with caution in individuals using other drugs, particularly sedative drugs such as alcohol, benzodiazepines, antipsychotics or antidepressants. Particular emphasis should be given to assessing the level of neuroadaptation to opioids, the likelihood of continued use of other sedative drugs, and overdose risk.
- (2) *Concomitant medical conditions.* Buprenorphine is an opioid medication and caution should be exercised in using it in the following situations:
 - *Recent head injury or increased intracranial pressure.*
 - *Compromised respiratory function.* Buprenorphine, like other opioids, should be used with caution in patients with a sustained decrease in respiratory reserve, pre-existing respiratory depression, hypoxia, or hypercapnia such as in chronic obstructive airways disease or cor pulmonale, or sleep apnea. **In such patients, even normally safe therapeutic doses of opioids may decrease respiratory drive.**

- *Acute abdominal conditions.*
 - *Severe hepatic disease.* Caution needs to be taken in considering buprenorphine treatment for people with clinically significant liver disease (i.e. acute hepatitis or cirrhosis). Severe hepatic disease may alter the hepatic metabolism of the medication. However, the presence of elevated enzyme levels on liver function testing, in the absence of clinical evidence of liver failure, does not exclude someone from treatment with buprenorphine although they will require more frequent hepatic monitoring.
 - *Special risk patients.* Opioids should only be given with caution, and at a reduced initial dose, to patients with any of the following conditions:
 - advanced age or debilitation;
 - prostatic hypertrophy or urethral stricture;
 - severe renal disease (pharmacokinetic studies have not been conducted on this group, so methadone should be the first option).
- (3) *Concomitant psychiatric condition.* Opioid substitution treatment should not be initiated in anyone with a psychiatric condition likely to severely compromise the capacity to give informed consent, such as acute psychosis or severe depression. The first priority should be an attempt to manage and stabilise the psychiatric condition. People at moderate or high risk of suicide should not be commenced on buprenorphine without adequate supervision, and specialist advice should be sought.
- (4) *Chronic Pain.* Buprenorphine can be used as an analgesic in the management of acute and chronic pain conditions. Ideally, chronic pain is best managed under the supervision of a specialist multidisciplinary team, and appropriate referral or consultation should be considered (see section 5.7 for details of the management of patients who require analgesia while taking buprenorphine)
- (5) *Transfer from methadone maintenance.* Patients taking methadone can safely transfer to buprenorphine but special precautions must be taken during dose induction in order to avoid precipitating withdrawal with the initial buprenorphine dose (see Section 3.3.2).
- (6) *Low or uncertain levels of neuroadaptation to opiates.* Commencing buprenorphine in someone who is opioid dependent but not currently tolerant to opioids is justified in some circumstances where that person is likely to develop a tolerance in the near future or whose use of opioids is likely to cause them harm (prior to release from prison, for example). At other times, the degree of neuroadaptation to opioids may be uncertain. Even low doses of buprenorphine can cause sedation and respiratory depression in these circumstances. The use of concomitant sedating medications such as benzodiazepines, neuroleptics, and tricyclic antidepressants further increase this risk.

EXERCISE CAUTION WITH PATIENTS IN ANY OF THE FOLLOWING CATEGORIES

- polydrug use**
- concomitant medical conditions (see list above)**
- concomitant psychiatric conditions**
- suffering chronic pain**
- transfer from methadone maintenance**
- uncertain neuroadaptation**

2.2 Assessment procedures

A comprehensive assessment should be conducted at the outset of buprenorphine treatment. The aims of assessment are to focus on important issues and thereby start the process of patient education about risk behaviours and to start to develop a treatment plan. A comprehensive assessment can rarely be completed at the initial appointment, and generally needs to be conducted over several sessions. Initially, clinicians should target key issues important in the selection and initiation of treatment, and assess indications, contraindications and precautions. Referral or consultation with a specialist is recommended for patients with complex presentations.

2.2.1 History

(1) Drug use and treatment

- Heroin and other opioid use:
 - quantity and frequency (amount, cost, number of times used per day);
 - duration;
 - route of administration (injected/non-injected);
 - when last used;
 - features and severity of dependence.
- Use of other drugs (including benzodiazepines, alcohol, cannabis, psychostimulants) and assessment of degree of dependence on each drug class.
- History of prior attempts at withdrawal, maintenance and other treatment — what has worked and not worked before.

(2) Risk factors

- Presence of risk behaviours, particularly overdoses, self-injury, or polydrug intoxication.
- Medical and psychiatric history, with particular attention to unstable or active conditions which might potentially complicate treatment.
- Pregnancy and contraception.

(3) Social circumstances

- Home environment, social supports, employment, and barriers to change.
- Motivations and goals for treatment. Finding the right approach requires an understanding of the **reasons for seeking treatment** and of **patient goals and expectations**.

2.2.2 Examination

- Vital signs (blood pressure, pulse, respiratory rate).
- Evidence of intoxication or withdrawal from heroin or other drugs.
- Evidence of complications of injecting drug use, including injection site problems, hepatic disease, lymphadenopathy, systemic infections.
- Evidence of injection marks consistent with the stated history.

2.2.3 Investigations

- **Urinary drug screens** can be helpful in clarifying or confirming an unclear drug use history. While delays in getting the results of routine urine tests often limit their usefulness at initial assessment, conducting a urine drug screen prior to the commencement of opioid substitution therapy provides supportive evidence of opioid use that can otherwise be difficult to obtain.
- **Tests of viral serology** (HIV, Hepatitis B and C) should be considered at some stage with appropriate pre- and post-test counselling. (This is advisable after stabilisation, when the patient is better able to understand the significance and consequences of testing).
- **Liver function tests** are recommended at the commencement of treatment to establish a baseline. Periodic monitoring of liver function is also recommended.

2.3 Informed consent and patient literature

The participation of an informed patient in the clinical decision-making process is essential in the treatment of all opioid dependence. It is particularly important when incorporating opioid medications — such as buprenorphine or methadone — as part of the treatment plan. In considering the commencement of buprenorphine for maintenance or withdrawal treatment, the service provider should also explore alternative treatment options with the patient (including alternative approaches to withdrawal or substitution maintenance treatment, self-help, residential rehabilitation programs, counselling, and naltrexone).

All patients commencing treatment with buprenorphine must give their informed consent to treatment. This process requires that patients are fully informed and given an opportunity to discuss with the service provider the following topics:

- what is buprenorphine, how is it administered, how does it work, and what are its advantages and disadvantages?
- what is the duration of treatment; its cost; its associated 'routines', including urine-testing, "take-aways", transfers?
- what are the known side-effects?
- what about pregnancy and contraception issues?
- what are the dangers of additional drug use, overdose?
- what is the potential impact on driving, and on employment?
- what are the circumstances in which the doctor or pharmacist may withdraw their services and treatment may be ceased?

Specific patient literature should be provided prior to the commencement of treatment. It is recommended that consent be documented and that patients be given their own copies of the documents they have signed.

2.4 Permits and Registration of Patients

Buprenorphine is registered as a Schedule 8 medication. Each jurisdiction (See Appendix 2) is responsible for a system of authorising medical practitioners to prescribe buprenorphine to a particular patient for the management of opioid dependence within a framework of medical, social and psychological treatment.

