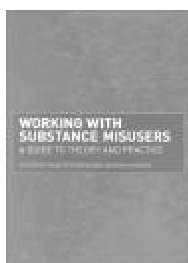
**SUBSTANCE MISUSE**
**OPTION LECTURE 15**

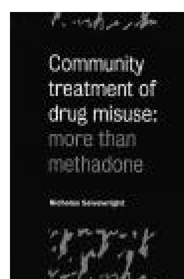
**SUBSTITUTE PRESCRIBING FOR**
**OPIATE ADICTION**

- "The Methadone Briefing" was written and edited by Andrew Preston (1996)
- It has kindly been made available on the web at:

  http://www.drugtext.org/library/books/methadone/default.htm




"Working With Substance Misusers: A Guide to Theory and Practice" by Trudi Petersen and Andrew McBride (2002)




"Community Treatment of Drug Misuse: More than Methadone" by Nicholas Seivewright (2000)

## SUBSTITUTE PRESCRIBING: MAINTENANCE

- Many individuals are unwilling or unable to undergo abstinence-orientated treatment.
- An option for helping these people is to prescribe a substitute drug in non-reducing doses.
- This substitute may be the actual drug to which dependence has developed but, more often, a drug that is considered a better and safer alternative.
- The rationale for prescribing the same drug is that for some illicit drugs there is no suitable to prescribe.

## SUBSTITUTE PRESCRIBING: MAINTENANCE

- Giving the same drug as a prescription at least ensures that the person is avoiding the risks associated with the adulterants that are often present in street drugs.
- Moreover, the person does not need to become involved in the usual acquiring of money and drugs, and taking of drugs, associated with their usual illicit use.
- Maintenance treatment with a substitute drug eliminates withdrawal symptoms and allows the person to address concurrent issues.

## SUBSTITUTE PRESCRIBING: MAINTENANCE

- Thus, an individual on maintenance may be able to stop injecting, stop illicit drug use, reintegrate with their family and non-drug using friends, obtain stable accommodation, and resume education or gain employment.
- For some, the period of maintenance may be short and precede detoxification.
- For others, maintenance may be indefinite or even life-long.

## OPIATE WITHDRAWAL

- Withdrawal syndrome from heroin and other opiates consists of physical, subjective and behavioural signs or symptoms.
- The prevalence and intensity of these withdrawal signs depends on the particular opiate, the dose, the time the dose is postponed, the duration of use, and the state of health of the user.
- The onset of withdrawal generally occurs at the time of the next habitual dose, which ranges from 4-6 hours for heroin.
- Although unpleasant, withdrawal is not life-threatening.

## OPIATE WITHDRAWAL

Users withdrawing from opiates may experience the following:

- Nausea, vomiting, diarrohea, stomach cramps
- Restlessness, anxiety, irritability, sleeplessness
- Pains in muscles, bones and joints
- Running nose and eyes, sneezing, yawning and sweating
- Dilated pupils
- Gooseflesh, flushing

Loss of fluids and failure to eat can leave the addict totally drained.

## OPIATE WITHDRAWAL

- The physical signs gradually decrease in intensity and are usually greatly reduced by the fifth to tenth day.
- In addition to these physical problems, a person experiences a strong craving for drug. This craving may continue for many months.
- There may also be a protracted phase of physiological changes - mild increases in blood pressure, temperature, respiration and pupil size can last for 4-10 weeks or even longer.

## OPIATE WITHDRAWAL

- "I was waking up in the morning with stomach cramps, muscle pains and it's just a horrible feeling when you wake up in the morning and you really need to get a bit of kit ..."
- ""And 'cos I was [vomiting] up all over the place and had sickness and diarrhoea and one minute I was sweating and the next minute I was freezing and my legs were all jittery and there was pains in ma stomach. I felt as if someone had kicked fuck right out of me ..."

From "Beating the Dragon" by James McIntosh and Neil McKeganey

## INTRODUCING METHADONE

Methdone is a synthetic opiate, which has been used as as substitute treatment for over thirty years. It has several properties that make it an excellent substitute for heroin and other opiates. These include:

- A long duration of action so that it can be taken once daily
- Being available in liquid form which deters injecting
- Having little euphoriant effect, thus eliminating withdrawal symptoms without reinforcing continued use.

## INTRODUCING METHADONE

- Marie Nyswander and Robert Dole first developed "Methadone Maintenance Treatment" in the mid-1960s.
- The treatment was devised for established addicts and was based on the principle that, following the physiological changes which occurred through prolonged taking of opiates, the state of dependence represented a metabolic disorder (similar in principle to metabolic disorders such as diabetes) which required corrective treatment indefinitely.

## INTRODUCING METHADONE

- The fundamental aspect of methadone treatment was viewed not simply as a relief of withdrawal symptoms and craving, but a 'narcotic blockade', whereby an individual on methadone would fail to experience the euphoriant effects of heroin if it was taken.
- A dose of at least 80 mg per day was recommended and it was suggested that this dose be prescribed on a long-term basis with no intention that patients should attempt to reduce the dose.

## INTRODUCING METHADONE

- In these first studies, a structured programme approach to the delivery of methadone treatment was considered essential.
- Addicts were stabilised on high-dose methadone on a hospital ward, following which they returned on a daily basis for supervised consumption of medication and urine testing.
- There was an initial comprehensive assessment of medical, psychiatric and social problems, with facilities to address these on an ongoing basis as necessary.

## INTRODUCING METHADONE

- Addicts were also provided with counselling and also placements in education and employment.
- Relaxation of the daily attendance for methadone and urine screening occurred for those who were deemed to be making excellent progress.
- Many of the addicts in this study derived great benefit from this programme.
- Dole and Nyswander produced an influential paper in 1965 showing huge decreases in criminal activity in heroin addicts treated with methadone over a one year period.

## SPREADING OF METHADONE TREATMENT

- This new form of treatment spread rapidly in the USA but was often implemented in a rigid way that lost some of the characteristics of Nyswander and Dole's original work.
- Consequently few programmes have produced such good results as their early work.
- The ways in which it was implemented in the early 1970s were strongly affected by political and other factors, with extensive government regulation.

## SPREADING OF METHADONE TREATMENT

- The medical treatment was - and is - encased in a rigid delivery system.
- In most programmes, patients attend the programme daily to drink their methadone and are regularly monitored through testing of urine samples (the collection of which is supervised) and counselling.
- Some programmes offer a variety of help and psycho-social treatment from group therapy to help in finding jobs.
- Once patients are stabilised they are able to earn the 'privilege' of taking home doses of methadone for one or more days.

## SPREADING OF METHADONE TREATMENT

- The numbers of patients receiving Methadone Maintenance Treatment in the USA rose: in 1992 there were about 120000 patients served by around 800 programmes.
- There is a great deal of variation in the rehabilitation and psycho-social services that are offered in addition to methadone and also in the dosage levels employed.
- Over half of patients receive below 60mg daily - which is accepted in the USA as the therapeutic minimum - well below the level recommended by Nyswander and Dole's research.

## FEELINGS AGAINST METHADONE

- There are strong feelings against methadone in many parts of the US.
- "But methadone has been handicapped by restrictive government regulations, by misinformation - among treatment providers and drug users alike - and by prejudice against methadone treatment. Methadone is the most tightly restricted drug in the U.S. Doctors in general medical practice can't prescribe methadone, and regular pharmacies don't distribute it."

Drug Policy Alliance

## SUBSTITUTE PRESCRIBING IN THE UK

- In the UK, the Rolleston Committee of 1926 had allowed maintenance prescribing of heroin and other opiates, unlike the situation in the US.
- A few physicians continued to prescribe heroin, morphine and cocaine to a small number of addicts until the mid-1960s.
- In the 1970s, clinic prescribing practice in the UK moved away from predominantly prescribing injectable heroin towards prescribing oral methadone, on the basis that it was more therapeutic to prescribe a non-injectable drug and because its long half-life meant it could be taken once daily rather than every few hours.

## METHADONE IN THE UK

- In a landmark study conducted by Mitcheson and Hartnoll between 1971 and 1976, the effects of randomly allocating heroin users to either substitution heroin or methadone were studied.
- The methadone treatment produced more polarised results than the heroin group.
- Whilst the methadone group were more likely to leave treatment, they were also more likely to achieve abstinence.
- The heroin group were more likely to stay the same.

## METHADONE IN THE UK

- 'The provision of heroin maintenance may be seen as maintaining the status quo, although ameliorating the problems of acquiring drugs ... by contrast the refusal to prescribe heroin (and offer oral methadone instead) may be seen as a more active policy of confrontation that is associated with greater change.'
- At the time of this study, clinics were starting to deal with a new and different client group: large numbers of working-class heroin users who were smoking rather than injecting.
- As a result of these factors, clinics defined their role as one of promoting change and increasingly moved towards the use of oral methadone.

## METHADONE TREATMENT OUTCOMES

- It is extremely problematic to undertake randomised controlled trials of substitution treatments.
- Drugs misusers are not going to have neutral views as to whether they receive methadone, heroin or another drug.
- Aside from the issue of consent, it is unethical to withhold a treatment from users who have a clinical need.
- Therefore, evidence is primarily from observational studies which back up early randomised studies.

## METHADONE TREATMENT OUTCOMES

- Ball and Ross (1991) undertook a clinical outcome study across six methadone programmes in the mid-1980s, and found a wide variation in programme elements and effectiveness.
- This research strongly supported methadone treatment as it had originally been devised.
- The most successful programmes were characterised by high methadone doses, definite maintenance treatment (rather than attempts at reduction), more intensive counselling and more medical services, as well as features indicating good relationships between staff and patients.

## METHADONE TREATMENT OUTCOMES

- Reviews reveal that the majority of studies showing effectiveness of methadone are of ongoing maintenance treatment.
- Evidence generally weakens as duration of treatment shortens, through to detoxification treatments.
- Evidence also weakens as there is a departure from the original model of formal methadone maintenance programmes.
- However, in defence of the various relatively unstructured treatment methods (as will be described shortly), it should be noted that the studies were carried out many years ago in highly selected populations, and may be of limited relevance in terms of current heroin usage and the revised purposes of methadone treatment.

## METHADONE TREATMENT OUTCOMES

- In Dole et al. (1969), opiate addicts leaving prison were included in the study if they had at least a four-year history of opiate addiction and at least one unsuccessful rehabilitation attempt.
- At twelve months, all 16 of the no-treatment control group had returned to daily heroin use and prison, while none of the 12 methadone group were using heroin daily and only three were imprisoned.
- A larger study, using the same entry criteria, took place in Hong Kong, where methadone was not otherwise available (Newman and Whitehill 1979).

## METHADONE TREATMENT OUTCOMES

- All subjects were stabilised in hospital on 60 mg methadone, and were randomly assigned either to be withdrawn under double-blind conditions and then receive placebo or methadone maintenance (both groups received counselling).
- Methadone dose was determined by the patients (averaged 97 mg), and those who had more than six positive urine tests for heroin, or missed six daily doses, were discharged.
- At 32 weeks, 5/50 placebo subjects were still in treatment, compared to 38/50 methadone subjects (numbers were 1 and 28 at three years).

## METHADONE TREATMENT OUTCOMES

- The Treatment Outcome Prospective Study involved 11,000 drug misusers in the US over a three year period (Hubbard et al., 1989).
- Treatment approaches were grouped into methadone maintenance, residential therapeutic communities, and outpatient drug-free counselling.
- Retention rates were significantly better in methadone maintenance than the other modalities, and both regular heroin use and crime in that group dropped from high levels to less than 10% 1-3 months into treatment.

## METHADONE TREATMENT OUTCOMES

- Higher methadone doses have been found in various studies to be associated with less heroin use and improved retention in treatment.
- It is generally accepted that better outcomes are obtained with doses of 60 mg and higher.
- Studies have shown methadone treatment improvements in various measures.
- Seivewright (2000) has provided a list in the approximate order "in which effects have been demonstrated in systematic studies, according to reviews and a recent meta-analysis (Marsch 1998)."

## METHADONE TREATMENT OUTCOMES

Main effects of benefit in methadone treatment
- Reduced opiate misuse
- Reduced crime and imprisonment
- Reduced HIV risk behaviours (injecting)
- Improved quality of life
- Improved physical and psychological health
- Reduced non-opiate use
- Employment, college
- Reduced death rate
- Reduced HIV risk behaviours (sexual)

## METHADONE TREATMENT OUTCOMES

- Counselling is one of the main aspects of process which has been studied in methadone treatment.
- In general, the most positive evidence is in favour of a systematic and comprehensive approach.
- For example, McLellan et al (1993) randomly assigned 92 methadone patients to three groups differing in levels of psychosocial services.
- 69% of clients who received virtually only the methadone prescription continued to use opiates and cocaine, with lower levels in groups in groups who received additional counselling (41%), or counselling plus on-site medical and psychiatric services, workshops on employment skills, and family therapy (19%).

## CHANGES IN METHADONE TREATMENT

- Since methadone was introduced it has, in practice, been provided accorded to a wide range of treatment models and policies.
- The overall trends in provision have been towards lower dosage, fewer additional interventions and less acceptance of outright maintenance treatment although, importantly, these do not necessarily apply together.
- The dilution of the original approach within the US has been due primarily to financial and political considerations.

## CHANGES IN METHADONE TREATMENT

- In the UK, there was a dramatic increase in the prevalence of heroin use in the early 1980s. This increase was country-wide and involved many people smoking the drug.
- The substitute prescribing at this time mainly involved the "gradual withdrawal method" suggested by the Rolleston Report.
- The large increase in opiate users resulted in the development of new treatment services, most of which got involved with methadone prescribing.

## CHANGES IN METHADONE TREATMENT

- Some of the changes which have occurred in methadone treatment have come about as a result of the threat posed by the involvement of drug misusers in the HIV epidemic.
- In the UK (and other countries), methadone was seen as an important vehicle for shifting heroin users away from the risks of injecting.
- However, it was recognised that the delivery of treatment needed to be substantially altered if it was to make an impact in public health terms.

## CHANGES IN METHADONE TREATMENT

- Methadone was in effect used to attract users into services so that other HIV-preventive work could be undertaken.
- It was also recognised that users needed to be retained in treatment, and there was an increase in longer-term prescribing.
- The use of methadone for individuals who would not have previously qualified for methadone maintenance resulted in more cases of low-dose treatment.
- There was a recognised need for flexibility, in order not to deter the heavy users who might be at greatest risk, and to listen to the views of the user himself.

## CHANGES IN METHADONE TREATMENT

- Lower average doses of methadone have resulted not only from the drug being given to a broader population, but also from a heightened awareness of its side–effects and addictive potential.
- The latter is of particular relevance to the majority of people who have abstinence as an ultimate aim: they want to be on the lowest comfortable dose of methadone with a view to gradual reduction.
- Many people are now on short-term methadone maintenance, 'maintenance to abstinence' or 'abstinence-orientated maintenance.

## METHADONE TREATMENT TODAY IN THE UK

- Today, there are great variations across health districts in the use of methadone.
- All GPs are entitled to prescribe methadone, but many do not wish to do so. Of those that do, most prefer that users agree a dose reduction programme, with abstinence in mind.
- Users can also be prescribed methadone by Community Drug Teams and Drug Clinics.
- Street agencies refer clients to their GP (often recommending a methadone prescription) or Community Drug Team.

## METHADONE TREATMENT TODAY IN THE UK

- There are now relatively few highly structured methadone programmes, particularly in Europe where there has been an emphasis on 'low-threshold' methadone treatment as a response to the HIV epidemic.
- Low dose is used so much, in part because many users are using relatively small amounts of impure street heroin, and they often want to reduce and then abstain.
- The purely medical model of methadone maintenance sees the drug as a necessary corrective treatment for the metabolic disorder of opiate dependence, a concept based on severely dependent individuals.

## METHADONE TREATMENT TODAY IN THE UK

- Methadone is often used to get people away from impure street drugs and in order to give them some stability to their lives. This is valued by many users, even though some may still use other drugs from time to time.
- Methadone is considered important because it helps attract and retain clients, and it produces reductions in many indicators of drug misuse, raging from injecting to social consequences.
- However, there are accepted problems such as the addictiveness of the drug, and its side effects.

## PRACTICAL MANAGEMENT

There are guidelines for determining who should be prescribed methadone. Full assessment should show the person has:

- Established physical dependence on opiates (usually heroin)
- At least two years of opiate use
- Previous unsuccessful experience of detoxification treatment (or clearly severe history if no such prior treatment)
- Preferably reached the age of 18
- Opiates present in their urine to confirm use (this is not always done).

## PRACTICAL MANAGEMENT

- There are a number of other practical considerations.
- It is essential that there is some sort of contract between client and clinic. Goals must be agreed between client and doctor.
- The client must be motivated and agree to change his use of drugs (preferably abstain from all other drugs, including alcohol).
- He may have to agree to provide urine samples at different times for drug testing.
- He may have to agree to changing dosages (on a reduction programme) at varying times.
- He must behave appropriately when visiting the clinic (aggression and abuse will not be tolerated).

## ADDITIONAL MEDICATION

- As far as possible, methadone treatment should mean just that, not methadone plus other medications of potential abuse.
- The most problematic drugs are the benzodiazepines (BDZs), which are sometimes taken to enhance the effects of methadone.
- The issue of whether to prescribe BDZs in addition to methadone is a difficult one, particularly when the client will frequently be using BDZs and will request to continue, and may alternatively use street BDZs. The relevant issues are discussed in some detail by Seivewright (2001).
- It should be noted that in the majority of cases heroin is not in itself the cause of death in an overdose case – it is often taken in combination with alcohol and tranquillisers.

## PROBLEMS OF METHADONE

Methadone is not an innocuous treatment and inappropriate methadone prescribing can:

- Cause fatal overdose
- Simply increase a person's total drug consumption
- Increase the drug-related chaos in a person's life
- Supply the illicit market
- Demoralise prescribing and other staff
- Reduce respect for the prescribing agency among both drug users and other helping agencies
- Reduce the client's motivation and ability to achieve abstinence
- Create opiate dependence.

## ADVERSE EFFECTS OF METHADONE

- "The most serious direct risks of methadone treatment are from overdose, which is heightened by combined use with other drugs. Otherwise, methadone appears to be remarkable safe for long-term use, causing no recognizable functional deficits or somatic damage" (Seivewright, 2001).
- Deaths from treatment medications must be put in context however, since the treatment is a response to a condition which itself has a mortality rate.
- For example, Gearing (1977) reported a 0.8% mortality rate among 3000 subjects in methadone programmes compared with 8.3% death rate in heroin addicts who were offered detoxification only.

## ADVERSE EFFECTS OF METHADONE

The main adverse effects of methadone are:

- Constipation
- Sweating
- Weight gain
- Dental problems
- Nausea
- Depression/lethargy
- Reduced sexual desire

"These problems can be extremely problematic, variously leading to distress for individuals, limitations in compliance, and requests for alternative treatments ..."

## How to prescribe methadone

"The aim is to prescribe the lowest dose of methadone that will prevent withdrawal symptoms, minimize injecting and reduce the need for additional street drugs. There is evidence that higher doses of methadone (60 mg and above) are more effective than lower doses in reducing the risk of continued use of illicit opiates. As long as the GP can be confident that the user is notoversedated and is not selling the medication, then there is no advantage in keeping the dose down at a level that leaves the drug user feeling uncomfortable. It is important to remember that many opiate users experience psychological withdrawal symptoms before they experience physical withdrawal symptoms."

In "Care of Drug Users in General Practice" by B. Beaumont (1997)

## INITIATING METHADONE TREATMENT

- It is important that care is taken in starting a person on methadone treatment: there is a potential for opiate toxicity at this stage.
- The client's opiate tolerance needs to be determined by discussing their drug-taking history (it is better to underestimate how much they have been taking).
- It is essential to remember the long half-life of methadone.
- The commencement dose should aim to achieve an effective level of physical and psychological comfort, while minimising the likelihood of overdose.

## INITIATING METHADONE TREATMENT

- An initial dose of 10 – 40 mg is generally given and the client attends the clinic daily for the first few days in order that the dose can be titrated against withdrawal symptoms.
- Small increments in dose may be given on these days, and may continue until a stabilisation is achieved (usually complete by end of sixth week).
- It is critically important to provide adequate information regarding the recognition of methadone toxicity and management to clients and their careers.

## OTHER PRESCRIBING FOR DRUG MISUSE

- Other drugs have been used in the treatment of opiate dependence.
- These include buprenophine, dihydrocodeine, LAAM, and injectable heroin.
- A range of non-opiate medications (e.g. clonidine) have also been used for treating opiate withdrawal symptoms.
- In addition, substitute prescribing has been tried for the treatment of stimulant dependence, albeit to a much lesser extent.
- Each of these issues will be discussed in a later lecture.