
Community treatment of drug misuse: more than methadone

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Methadone maintenance: a medical treatment for social reasons?

Introduction

Methadone occupies a position of huge prominence in drug misuse treatment. As a synthetic opioid drug, it not only provides direct and effective relief of opiate withdrawal symptoms, but it is accepted as a long-term treatment option in those with a significant history of opiate dependence. Its selection as the main treatment drug in these indications is largely based on three properties, as shown in Table 1.1.

The first two properties are fundamental to the use of methadone, ideally allowing a heroin user, for instance, to switch from injecting a drug in a rapid cycle of relieving withdrawal symptoms, to taking a medication by mouth which will keep him or her well all day. The noneuphoriant property is relative, and we will see in further discussions on response to methadone, rationales for alternative medications and safety of treatment, that this is the least straightforward of the benefits of methadone. Overall, however, the effect of methadone is to enable an opiate misuser to 'just feel normal', and in individuals who accept this, the treatment routinely produces excellent results, in reducing other drug use and in a wide range of health and social outcomes (Farrell et al. 1994, Bertschy 1995, Marsch 1998). The effectiveness of maintenance treatment makes up for the big relapse rates after detoxification from drugs, and is a major factor in the selective presentation of opiate users to drug services. The promotion of methadone maintenance at the time when HIV began spreading among drug misusers was testament to this effectiveness: methadone has nothing directly to do with HIV, but it engages drug misusers so that other harm reduction work can be done, and it is the simplest way of quickly reducing an individual's other drug use and injecting.

But what exactly are we doing when we prescribe methadone? Given the strong social basis of drug misuse, and the commonality of personal factors across misuse of the various drugs, it seems highly unlikely that there can be a definitive pharmacological treatment in the case of one, and only one, drug type. Is methadone a treatment, as such, which

Table 1.1. *Properties of methadone and resultant benefits in clinical treatment*

Property	Benefit in treatment
Effective orally	Oral preparations, preferably liquid, enable cessation of injecting
Long acting	Avoids frequent withdrawal symptoms, may be taken once per day
Noneuphoriant	Stabilizing effect, relatively little temptation to over-use supply

normalizes the behaviour and personal functioning of an addict, or is the media term ‘heroin substitute’ more appropriate? Is it simply that opiates are the most addictive drugs, *therefore* the method of substitution treatment is approved, *therefore* many indirect benefits occur as individuals are removed from the lifestyle of using illicit drugs? Whatever the mechanism by which methadone produces its results, further questions also arise. In so far as we are treating health problems, are they those of individuals or, since the approach aimed at HIV prevention, is the provision of methadone in effect a public health measure? Many of the most obvious benefits of methadone treatment in practice are firmly social, such as improved relationships, stopping crime or getting out of debt – how appropriate is a doctor’s role in such circumstances?

This chapter considers different models of providing long-term methadone, and what they suggest about the nature of this treatment approach. There is a short review of studies of effectiveness, the most systematic of which mainly date from the early days of such treatment. The reasons which lie behind the gradual departure from the original model of methadone programmes are discussed, as are some of the limitations of the medication which have become apparent, particularly in its use in wider populations. The main practical issues which arise in current usage of methadone, and the prescribing of alternative forms, including injectable methadone, are also considered.

The term ‘methadone maintenance’

This term is used increasingly casually to refer to ongoing prescribing of methadone over any reasonably lengthy time period. Usually a constant dose is implied, but sometimes slowly reducing courses are also described

in this way. Strictly speaking, however, the term refers to the highly structured programme approach which was originally devised for the delivery of methadone treatment in the USA, and is described next. This is not just a matter of semantics since, as we shall see, most of the systematic evidence for methadone's effectiveness relates to treatment as carried out in structured programmes, and the inference that any long-term prescribing amounts to approximately the same thing can lead to false assumptions about the process and its possible benefits.

Formal methadone maintenance programmes

It is well known that the concept of formalized methadone maintenance originates from the work of Dole & Nyswander (1965). The treatment was devised for established opiate 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 which required corrective treatment indefinitely. The fundamental aspect of methadone treatment was seen to be not simply the 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 that were taken (Dole et al. 1966). This effect was considered to be due to cross-tolerance, and it was observed that methadone doses of at least 80 mg per day were necessary to achieve it. This relatively high dose was therefore prescribed on a long-term basis, with no intention that patients should attempt to reduce. The first clinical programmes were for recidivist addicts, with the related aims of reducing heroin use and crime.

A structured programme approach to the delivery of methadone treatment was considered essential. Addicts were stabilized on high-dose methadone in 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. Along with the provision of methadone, the addicts entered not only counselling, but also placements in education or employment. Relaxation of the daily attendance for methadone or urine screening was only for individuals deemed to be making excellent progress, although take-home doses for part of the day were also necessary for those who had difficulty spanning a 24-hour period with one dose. Programmes along these lines developed across the USA, with inevitably some differences in provision

emerging over the years. Ball & 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 was considered to support strongly methadone treatment as it had been originally devised, with the most successful programmes characterized 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.

Other long-term methadone prescribing

Since methadone was introduced it has, in practice, been provided according to a very wide range of treatment models and policies. There are major differences in treatment internationally, which are mainly beyond the scope of this book but have been the subject of reviews (Gossop & Grant 1991, Farrell et al. 1995). Notwithstanding the strong evidence for the original approach, which is discussed further below, there has generally been a gradual departure from this, for various reasons which are inter-related. 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 USA has been partly due to financial and political considerations (Rosenbaum 1995), but many other influences have also affected services. As with other psychiatric conditions, ideologically there has been less acceptance of the medical model, and therefore, in the case of methadone, of the implicit need for life-long treatment. In the meantime, heroin has become more and more available, with a wider range of individuals presenting, who may require a long-term approach but not necessarily a universal high-dose policy. Also, elements such as special employment schemes have become much less common and, without these, routine daily attendance at a treatment centre has gradually been considered less acceptable, for those who are attempting to normalize their lifestyle in other ways.

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 (e.g. Advisory Council on the Misuse of Drugs 1988), but it was recognized that the delivery of treatment needed

to be substantially altered if it was to make an impact in public health terms (see Chapter 7). There was much emphasis on engagement in treatment, with methadone in effect attracting users into services so that other HIV-preventive work could be undertaken, and also on subsequent retention, with routine discharge from treatment for additional drug use considered inappropriate. This use of methadone for individuals who would in many cases not previously have qualified for definite maintenance produced more instances of ongoing low-dose treatment, and the retention aspect meant that there was more recognition of those who do not successfully modify their drug use to taking methadone alone. Rigid approaches have been considered undesirable primarily because they may deter those individuals who pose some of the highest risks, while ideological considerations have been important in generally taking more account of individuals' views on their own treatment. In this way many 'low threshold' programmes have grown up (e.g. Buning et al. 1990, Klingemann 1996, Plomp et al. 1996) with the over-riding philosophies of easy access to treatment, harm reduction policies and individualized dosing.

Lower average doses of methadone have resulted not only from the drug being given to a broader population, but from heightened awareness of its side-effects and particular addictive potential. The addictiveness does not so much matter if treatment is conceived as being life-long, but relatively few patients in current treatment wish this to be the case. With abstinence often the ultimate aim, many individuals elect to be on the lowest comfortable dose of methadone with a view to gradual reduction, and something of a hybrid between maintenance and detoxification has emerged, variously referred to as short-term maintenance, 'maintenance to abstinence' (Department of Health 1991) or 'abstinence-orientated maintenance' (Capelhorn 1994). Outcomes in time-limited methadone treatment have generally been found to be very poor in comparison with maintenance (McGlothlin & Anglin 1981, Rosenbaum et al. 1988), but studies have typically been in established maintenance candidates who have had treatment restricted, rather than individuals who have chosen to reduce as an option within a flexible policy. For our purposes this intermediate duration of treatment is classed as slow detoxification, and is discussed in the section on methadone detoxification in Chapter 3.

The elements of counselling and urine testing remain integral to long-term methadone provision in many services, although both to a lesser degree than in formal maintenance programmes. Both are discussed below, but we should first consider a little further the nature of methadone treatment itself.

Table 1.2. *Medical model and substitution model of methadone treatment*

	Medical model	Substitution model
Rationale	To correct metabolic disturbance caused by opiate dependence	To provide a reasonably satisfying drug effect
Mechanism	Reduces craving and blocks effects of other opiates	Reduces need to use other drugs
Explanation for improvements in health and well being	Primary, due to methadone	Secondary, due to removal from street drug use
Dose	High	Minimum comfortable dose
Duration	Indefinite	Should be able to gradually withdraw

The nature of methadone treatment

Specific treatment or heroin substitute?

A comparison between the medical model of methadone treatment and a model of methadone as a so-called heroin substitute is outlined in Table 1.2, and these concepts will now be considered.

The medical model of methadone treatment, as proposed by Dole & Nyswander (1965), has been reviewed more recently by their co-worker Kreek (1992). The initial studies pre-dated the discovery of the opiate receptors and endogenous opioids, and methadone was selected largely on the basis of careful clinical observation in pain patients and in addicts. The clinical properties of long duration of action (24–36 hours) and effectiveness by mouth were considered highly advantageous, and in addicts the drug appeared to reduce craving and produce a ‘narcotic blockade’, referred to above. This approach to opiate addiction was widely taken up in the USA and elsewhere, and in this original concept methadone is seen as a purely medical treatment, resembling the use of insulin in diabetes or antihypertensives in high blood pressure. The early proponents stressed that in cases where dependence had become clearly established over a significant period, the treatment should be continued for as long as the patient wished, and while it was producing benefit, with Dole (1973) asserting that ‘each withdrawal [from methadone maintenance] is an experiment with the life of a patient’. It has frequently been

pointed out that the portrayal of methadone as a straightforward medical approach has been particularly necessary in the USA politically, where the concept of a substitute drug would fit uneasily with the strong emphasis on enforcement. The suggestion in this version of treatment is that it is the medication itself which produces the behavioural changes, but the substitution process is still implicated, if methadone acts to reduce craving for other opiates and to deter such usage through its blockade effect.

Alternatively, the substitution principle may be spelt out rather more directly, as it tends to be in European countries. (In the UK we are often considered to have a specific 'British system', but this is largely a separate matter relating to drug legislation and prescribing before the modern era of recreational drug misuse, although the concept does include our use of some injectable medications (Strang & Gossop 1994).) Broadly, the 'heroin substitute' view of methadone regards the provision of a guaranteed supply of legal pharmaceutical opioid as leading to a range of secondary benefits, as the activity of illicit drug taking is reduced or stopped. Improvements in general health, mood and personality are therefore seen as indirect rather than direct effects of methadone, more related to avoiding the complications of other drug use. Indeed, methadone is truly a substitute for the preferred drug, heroin, and although the long-acting property and oral route are acknowledged as beneficial, in this view of methadone there is also more acceptance that individuals will actually vary greatly in their ability to adjust to methadone's much more limited subjective effects.

Although the concept of substitution is quite compatible with ongoing treatment, the issue of duration of methadone to some extent becomes tied in with treatment models. Thus, long-term maintenance is sometimes referred to as 'medical maintenance', and short-term treatment as 'psychotherapeutic maintenance'. The implication of the latter term is that with additional therapy and support it ought to be possible for an addict to be 'weaned off' opiates using a reducing course of methadone. This presupposes that opiate tolerance gradually reduces during withdrawal, in an opposite process to the increase which occurs as opiate dependence develops, whereas the medical model does not accept that the various neurobiological and neuroendocrine abnormalities in opiate dependence can in fact be reversed (Kreek 1992). This issue is far from clear-cut, as the medical model view is based substantially on the high relapse rates after detoxification, to which many kinds of factors may contribute, as well as on biological changes of uncertain clinical importance.

Such contrasting views of methadone treatment were encapsulated in a brief joint article in *Addiction* journal, which was followed by a series of commentaries (Ball & van de Wijngaart 1994, Wodak et al. 1994). On a visit during a harm reduction conference, Dr Ball, who has carried out some of the main work on beneficial elements of methadone maintenance programmes, and Dr Wijngaart, an expert on Dutch drug policy, had interviewed a client at the methadone clinic in Utrecht, The Netherlands. In a frank discussion with the programme director and other visitors, the client described his many previous attempts to come off drugs, and related that he had reduced his methadone to 12.5 mg per day. He was not hopeful of completing his methadone reduction, but said that he was 38 years old and he wanted to be changing his life and seeing more of his two children. Unfortunately, as well as his methadone, he was still taking a wide range of other drugs by injection, and he believed that many other clients in the programme did the same. The two authors gave their different views of this situation, with Dr Ball regretting that 'somewhat surprisingly, [the client] seems uninformed about the pharmacology of methadone maintenance and the need for long-term treatment'. Dr Wijngaart observed that the client was 'a typical Dutch methadone client', from a background of using many different kinds of drugs and probably quite unable to adhere to only methadone. Habitual drug users were entitled to 'seek detoxification to regain their health temporarily or because they really want to stop their drug dependence', but the main purpose of methadone was to keep a wide range of clients in contact so that other harm reduction measures could be deployed.

The issue of whether it is inadvisable to attempt to detoxify from methadone maintenance is a major and controversial one, but the study by Eklund et al. (1994) neatly illustrates some salient points. It was carried out in Sweden, within a USA-style methadone policy where there was no requirement to detoxify from established maintenance treatment. However, 59 out of 600 patients had voluntarily done so, and their outcomes were investigated, at an average follow-up of seven years. The high number of seven had died, and two were untraceable. Of the remaining 50, 25 had successfully withdrawn from methadone, 19 at the first attempt. Of those, however, five had current substance misuse problems, mainly with alcohol. Twenty-five had resumed methadone maintenance and had usually achieved good stability, but quality of life measures were generally better in those who had succeeded in withdrawing from methadone. In this group who were very long-term drug users, therefore, it appeared that attempting to withdraw from maintenance treatment was

risky, with a tendency to substitute with other substances, but that if it could be achieved, it resulted in a better quality of life.

In this book methadone is referred to as a substitution treatment, and that concept is generally employed rather than the purely medical model. It is considered that one of the main reasons why long-term methadone treatment produces such good results is that it does not require those who have risk factors for ongoing drug misuse, such as personality disorder or an adverse social situation, to be completely without the effects of a mood-altering drug, albeit that those effects are limited in the case of methadone. Further, it is relatively easy to avoid other substances of misuse, given that a drug is provided, and so there are consequent reductions in many other indices of drug use such as injecting or HIV-risk behaviours. Methadone is seen as being somewhat nonspecific in its impact on drug-taking patterns, but as a good starting point in attempts to convert individuals from street drug use to the clinically more desirable effects of a prescribed regime. It is clear that many opiate misusers cannot make this transition fully, and there need to be alternatives to simply discharging them from treatment, including other long-term prescribing options in some cases (see Chapter 2).

The nature of methadone treatment makes it unsurprising that retention rates are typically much higher than in other kinds of treatment for drug misuse. Methadone is a desirable commodity, and it must be acknowledged that this is not always for straightforward clinical reasons. Of course, well-motivated patients may routinely value all the various clinical benefits, but at the other end of the spectrum an individual may sell all their methadone to buy heroin, if given the chance. If this occurs the clinic is in effect giving currency, and there should be no surprise when such a patient reacts badly to this opportunity being curtailed if their 'medication' is reduced or stopped. Prevention of the abuse of services and medication ties in with the delivery of treatment, patient selection and the adequacy of monitoring, but the concept of methadone as a substitute drug helps explain the wide range of favourable responses on the part of patients towards this treatment approach. It is to be hoped that the extreme situation of a user diverting all their methadone is rare, but as security of treatment has generally been relaxed, we may hear of patients reserving their methadone for days on which they cannot get heroin, or selling a proportion of their prescription, the latter being most likely if there is a combination of high dosage but no supervision. The necessary security in treatment, and the difficulties in balancing this against making treatment accessible, are discussed in detail in Chapter 7.

The following case history illustrates several features which are reasonably characteristic of progress in treatment with methadone, as delivered in a community setting.

Case history

Chris was a 24-year-old man who was single, but with a child from a previous relationship. He had an eight-year history of drug misuse, including cannabis, ecstasy, LSD and amphetamines, with heroin misuse for the past three years. He had initially smoked heroin, but progressed to injecting as he became more dependent, and at the time of referral was using 1–1.5 g per day. He had tried stopping several times himself, but had been unable to tolerate the withdrawal symptoms. He had had one methadone course from his general practitioner, but complained that this had reduced 'too quick', with heroin use restarting after the early stages.

It was agreed that Chris needed methadone treatment on a more prolonged basis. He was started on 60 mg per day, but an increase was required to 70 mg per day, on which he claimed to be entirely comfortable. He indicated that he did not want to be on methadone very long term, as he did not really see it as a solution, and believed it to be 'worse to get off than heroin'. There was no pressure from us to reduce quickly, and it was felt that an initial stabilizing period on the same dose was required.

At the first few appointments Chris' progress seemed excellent, with improvements in mood and general health. He was very pleased, and showed us the new clothes he had been able to buy with money which he said would have previously gone on drugs. While continuing at the same dose, however, his urine drug screens still showed heroin and, on one occasion, amphetamine, in addition to methadone. He told us his heroin use had dramatically declined, so that while he used to raise money illegally to buy heroin every day, he would now only have it if it was offered when somebody came round to his house. To his counsellor he admitted that although the methadone enabled him to avoid feeling ill, and he did not really crave heroin, there was something missing with the effect of methadone and he could not resist having different drugs on an occasional basis as a 'treat'. He retained a desire to change his lifestyle so that he was not involved in the drug scene, and he was sceptical of the idea that an increase in methadone would help him stop his other drug use.

It was agreed that Chris' situation had greatly improved on methadone treatment, but he was advised that for his methadone to continue, we would need to see his urine become free of nonprescribed drugs. Chris felt that such a requirement would actually help him in his own efforts to avoid other usage. Three out of four urine samples since have shown only methadone, and while one showed heroin, he emphasized that this was an isolated occasion and that

he managed to smoke the drug rather than inject it. Overall, the reduction in Chris' drug use and criminal behaviour has been evident enough for his ex-girlfriend to allow him to have contact again with his young son. So far he has wished to remain on the same dose of methadone, and given the gains and the previous difficulties, this is considered appropriate at present.

Individual treatment or public health policy?

The issue in considering this dimension is not so much whether benefits to individual health or public health accrue with methadone treatment, as clearly both do, and both are important in different ways. Partly the difficulty is whether, if we have one eye on the public health agenda of reducing HIV transmission from drug misusers, we can still apply the treatment that is best at any time for each individual. Since awareness of the risks of this particular infectious complication has been heightened, opiate misusers have in effect been 'cushioned' by the use of methadone treatment. They are already unlike all other types of drug misuser in being prescribed a closely related drug and, depending on treatment policies, in not being required to work towards abstinence; now methadone is also relied upon for engagement purposes, and to protect against relapses which might increase risk behaviours.

In relation to individuals and treatment populations, methadone has been shown not only to reduce other drug use and injecting, but specifically to reduce HIV risk behaviours (Darke et al. 1990, Capelhorn & Ross 1995, Marsch 1998), and sero-conversion rates (Metzer et al. 1993). Because of these impressive aspects, access to methadone treatment is generally encouraged, and in a low-threshold programme relatively few demands may be made. Criteria for receiving methadone are often not rigorous and, once in treatment, if it broadly appears that the harm-reduction aims are being met, there is a tendency for prescribing to 'drift' into the long term in individuals who are not definite maintenance candidates. This situation is compounded by the fact that public health-orientated treatment means maximum number of methadone patients, shorter appointments, less attention to individual drug-using situations, and less associated counselling to consider alternative management possibilities.

Even in undoubted long-term treatment, there is an uneasy mix between individualized treatment and the wider health and social aspects, as Raistrick (1997) points out in a thoughtful article on the subject. Although he acknowledges that 'prescribing methadone as a public health or social policy measure is not necessarily incompatible with prescribing for individual treatment', he envisages a situation where different

purchasers of health care might have different desired outcomes, which would in turn influence the nature of substitution treatment. A criminal justice system purchaser might fund some places with the express aim of reducing the harm caused by criminal activity, and so to maximize that outcome prescribing would probably be high dose, long duration and include the possibility of injectable drugs or diamorphine if they were more effective for individuals in that regard. Furthermore, if an individual was failing on treatment there would be a tendency to go 'up the tariff' or, at the very least, retain them in the programme. By contrast, a patient on an individual treatment 'ticket' could face discharge from the programme for similar lack of progress, if the goal was more to encourage progressive reduction of dependency. At present 'in the real world prescribing doctors are pragmatists, and the circle is squared behind the closed door of the consulting room' (Raistrick 1997), but increasingly 'a transparency of objectives' is required in our understanding of the various purposes of methadone treatment. The irony is pointed out that methadone is usually paid for solely by health services, whereas the benefits extend widely into other areas, and it is rightly suggested that the criminal justice system and social services should also shoulder the financial burden, even if differential objectives would mean some adjustments in treatment methods.

Of the various possible roles of methadone treatment, the public health role which has been so strongly emphasized in the era of the HIV threat is requiring reassessment in the light of high prevalence rates of hepatitis C among injecting drug users (Wodak 1997, Serfaty et al. 1997). Although there have been many demonstrations of benefits of methadone maintenance in relation to indicators of HIV risk, the hepatitis C rates suggest transmission of this agent has still occurred and this is much more transmissible than HIV through blood (although less so through sexual contact). Different kinds of injecting equipment sharing are implicated, and it seems that some of the behaviour changes advised to reduce HIV risk are not sufficient to avoid hepatitis C (Wells 1998). In a study giving cause for concern, Crofts et al. (1997) found that methadone maintenance treatment failed to protect against new acquisition of hepatitis C in a significant proportion of cases, and further similar investigations will be required to judge the impact of methadone on this additional serious health problem.

Effectiveness of methadone

Comprehensive reviews of the effectiveness of methadone have been provided by several authors (Hall et al. 1998, Farrell et al. 1994, Bertschy 1995, Marsch 1998). Here, we will examine the subject enough to gauge the overall importance of methadone for services, and to make some links with the discussions of the nature of the treatment and its practical provision.

It is extremely problematic adequately to undertake randomized controlled trials of substitution treatments in this specialty. Drug misusers are not going to have neutral views as to whether they receive methadone or no treatment or, say, methadone or intravenous diamorphine. Apart from the issues of consent, methadone is now of a status such that it would usually be considered unethical to withhold it from users who had a clinical need. Because of the difficulties, the evidence which so strongly supports methadone maintenance is largely from observational studies which back up a small number of early randomized trials.

The reviews mentioned above make it clear that the majority of studies demonstrating the effectiveness of methadone are of ongoing maintenance treatment. The evidence generally becomes weaker as duration of treatment shortens, through to detoxification treatments. In services we may choose to do short-term treatment and, importantly, users themselves will often choose it, but it cannot be considered to be supported by much systematic evidence. Furthermore, the evidence also weakens as there is departure from the original model of formal methadone maintenance programmes, no doubt confirming the worst suspicions of those who feel that current models of providing methadone are misguided. In defence of the various relatively unstructured treatment methods, it should be pointed out that the major 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. Although the importance of additional programme elements is often stressed (Ball & Ross 1991), the provision of the drug itself has been seen as the single most important aspect ever since the first trials of structured methadone treatment (Dole & Nyswander 1965), and the outcomes in studies most strongly relate to direct drug factors, such as duration or dosage. Studies of methadone detoxification, mainly in the UK context, are discussed in Chapter 3, but the following are some important studies of maintenance treatment.

Randomized controlled trials have necessarily been carried out in

rather atypical situations where methadone treatment was not otherwise available, so that those randomized to no treatment would not receive the drug elsewhere. The first was by Dole et al. (1969) in recidivist opiate addicts who were due for release from prison. Entry criteria included at least a four-year history of opiate addiction and at least one previous unsuccessful rehabilitation attempt. Twelve individuals started methadone treatment, with 16 randomized to no treatment, and at 12 months the findings were overwhelmingly in favour of methadone maintenance. Indeed, all of the control sample had returned to daily heroin use and prison, while none of the methadone patients was using heroin daily and only three had been imprisoned. A larger study in a broader population was carried out in Hong Kong, where methadone treatment was not otherwise available (Newman & Whitehill 1979). The same entry criteria were used, with evidence of daily opiate use, and 100 male addicts were included. All subjects were stabilized in hospital on 60 mg of methadone per day, and were randomly assigned either to be withdrawn from methadone under double-blind conditions and then receive placebo maintenance, or to receive methadone maintenance, both groups also having additional counselling treatments. Methadone maintenance dose was determined by the patients and averaged 97 mg per day, and those who had more than six urine tests positive for heroin during the follow-up, or who missed six daily doses, were discharged from the programme. At 32 weeks only 5 of the 50 placebo subjects were still in treatment, as against 38 of the 50 methadone subjects, the pattern continuing to produce figures of 1 and 28 respectively at three years. A significantly greater proportion of the placebo group than the methadone group had been discharged for heroin use, but three deaths had all been in the methadone group.

A study in Sweden used similar entry criteria (Gunne & Gronbladh 1981), but added a period of intensive inpatient vocational rehabilitation to the methadone maintenance programme, and employed a sequential design. Once again, at follow-up after two years almost none of the control group had ceased drug use or made other satisfactory progress, while in the treatment group there were high levels of cessation of other drugs and gaining employment or further education. A further randomized controlled study by Yancovitz et al. (1991) is interesting in that it tested the effects of 'interim' methadone treatment, involving limited other services, in those awaiting treatment in comprehensive methadone programmes. Treatment subjects received high-dose oral methadone by daily dispensing, but no counselling or structured social rehabilitation. A

total of 301 heroin addicts were recruited, and in the period of interim treatment the proportion of subjects receiving methadone who were shown by urinalysis to be using heroin declined from 63% to 29%, with no corresponding decrease in the control sample. There was, however, no change in cocaine use in either group.

The Treatment Outcome Prospective Study (Hubbard et al. 1984, Hubbard et al. 1989) included over 11 000 drug misusers who had applied for treatment programmes in the USA over a three-year period. The treatment approaches were grouped into methadone maintenance, residential therapeutic communities, and outpatient drug-free counselling, and there was an extensive series of follow-up interviews, some on selected subgroups of clients. The outcome measures in the study were illicit drug use, criminal activity, employment, depression and suicide, and statistical techniques were used to control for various confounding factors such as educational level and extent of previous treatment. This study forms some of the basis for the often-quoted view that results of treatment are generally better the longer that individuals stay in the treatment, as that applied to various outcomes in this research. Retention rates were significantly better in methadone maintenance than the other modalities, and regular heroin use and crime in that group both dropped from high levels to less than 10% of individuals, 1–3 months into treatment.

Higher methadone dosages have been found in various studies to be associated with less heroin use and improved retention in treatment (e.g. Ling et al. 1976, Ball & Ross 1991, Joe et al. 1991). In an Australian maintenance programme, Capelhorn and colleagues have demonstrated a greatly increased risk of leaving treatment among those prescribed less than 60 mg per day compared with those prescribed up to 80 mg per day (Capelhorn & Bell 1991), and an inverse relationship between additional heroin use and methadone dose, between 40 mg and 80 mg per day (Capelhorn et al. 1993). However, the contradictory results of Seow et al. (1980) suggest that benefits of high dosage are not necessarily demonstrable where that is reserved for individuals who have failed on low dosage, since they may to some extent represent a more difficult group who are prone anyway to additional drug use. Hartel et al. (1995) found that heroin use was generally greater in those who were maintained on less than 70 mg of methadone per day, but that patients who used cocaine were more likely than others to use heroin at all methadone dosage levels.

In the reviews cited at the start of this section there is some breakdown

of findings into those relating to heroin use, criminality, HIV-risk behaviours, social rehabilitation and nonopiate abuse. We have noted that crime was one of the earliest indicators in methadone treatment, while the wider range of outcomes is formalized in current drug misuse rating instruments such as the Opiate Treatment Index (Darke et al. 1992a). The main areas in which methadone treatment has been found to be of substantial benefit are indicated in Table 1.3.

The list gives the approximate order in which effects have been demonstrated in systematic studies, according to reviews of studies and a recent meta-analysis (Marsch 1998). There is clearly a very substantial social component to beneficial treatment outcomes, with quality of life, for instance, including family and personal relationships, social stability, finances and other aspects of social functioning. These are commonly among the main areas of improvement seen in clinical practice, behind the most direct effects of reduced opiate misuse and drug-related crime. The demonstration in studies of methadone patients gaining employment has generally decreased over time, probably due to fewer special schemes and the wider unemployment picture, with some differences found between countries. Reduction in use of nonopiate drugs by individuals on methadone is undoubtedly very variable, with studies in general suggesting overall benefit, but in practice some problematic combinations with alcohol, benzodiazepines, cocaine and other drugs which are discussed elsewhere in this book. The data on mortality partly relies on comparisons with out-of-treatment drug misusers, including those refused treatment or discharged, who may differ in important ways from those who are retained; this subject is discussed in detail in Chapter 7. More limited is the evidence of an impact of methadone on HIV-risk sexual behaviours, as opposed to injecting practices (Stark et al. 1996). This discrepancy, found in many studies, is unsurprising, but needs to be acknowledged in view of the emphasis on methadone as an HIV-preventative measure. Also, there are many subgroups of drug misusers who are relatively unlikely to adopt even the safe injecting practices, such as those with antisocial personality disorder, other psychiatric problems, benzodiazepine abuse or various characteristic patterns of drug using with peers (Darke 1998).

In Table 1.3 I have included the areas of physical and psychological health, which often do not feature in reviews. Methadone has significant adverse effects, as discussed below, and by no means do all patients report subjective improvements in health on the drug, as opposed to when taking street heroin or other opiates. However, if methadone treatment is

Table 1.3. *Main areas 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 nonopiate misuse
Employment, college
Reduced death rate
Reduced HIV risk behaviours (sexual)

adhered to, there is normalization of various circadian rhythms and endocrine effects including menstruation (Kreek 1992, American Psychiatric Association 1994), and improved immunological function, possibly relevant in delaying progression of HIV disease (McLachlan et al. 1993). In addition, the various complications of injecting and of erratically using street drugs can be avoided. Improvements in psychological functioning, such as reduced anxiety, depression and other mood disturbances, have also been reported (Musselman & Kell 1995).

Before leaving the subject of the general effectiveness of methadone, two further general points should be made regarding the evidence from studies. One is that the cohorts of methadone patients in strict programmes are self-selecting, with discharge from the programme if there is persistent use of other drugs. Some studies make adjustment for this, but in many, the improvements seen are in the subgroups who were able to adhere to the desired position of taking methadone only. Also, the influential early studies often excluded those with a significant history of polydrug use (Dole et al. 1969, Gunne & Gronbladh 1981). In many areas polydrug use is the norm in those presenting for treatment, including those accepted for methadone, because of the extent of predominant opiate use (Bell et al. 1990a). Such individuals are likely to differ substantially from those in the original studies in terms of treatment needs and response to standardized methadone treatment.

Associated counselling

Counselling is one of the main aspects of process which has been examined in studies of methadone treatment. In general, once again, the

most positive evidence is in favour of a systematic and comprehensive approach. McLellan et al. (1993) randomly assigned 92 methadone patients to three groups which differed in levels of psychosocial services, with the actual methadone treatment remaining the same. Some 69% of subjects who received virtually only the methadone prescription continued to use other opiates or cocaine, with lower levels in groups who received additional counselling (41%), or counselling plus on-site medical and psychiatric services, workshops on employment skills and family therapy (19%). There is also some evidence supporting the addition to methadone maintenance of motivational interviewing (Saunders et al. 1995), and a therapeutic community-orientated day programme (De Leon et al. 1997). The low acceptability of formal psychotherapy in drug misusers has been recognized (Seivewright & Daly 1997), and was strikingly illustrated in a controlled trial of short-term interpersonal psychotherapy by Rounsaville et al. (1983). Only 5% of eligible patients agreed to participate in that trial, with around half of subjects completing the study treatment. Better results were shown in a study where the therapy was cognitive-behavioural in nature rather than dynamic (McLellan et al. 1986).

A study which appears important in demonstrating that intensive treatment is not necessary for all methadone patients is that by Senay et al. (1993). In a controlled comparison, some individuals who had progressed very well in methadone treatment were switched from a conventional intensive regime to a system of having medical and counselling appointments only monthly, with other relaxations in programme elements. Not only was stability maintained, as demonstrated by a range of outcome measures and urine testing, but the new approach was so much preferred that it was considered unethical to return those users to the more demanding regime. The authors observed that, for well stabilized patients, 'the time spent in travelling to a clinic two or three times a week and then waiting in lines for methadone and/or for counselling . . . creates problems in getting or holding a job and significantly limits their ability to relate to their family. In addition, they are exposed constantly to non-recovering patients and experience this as additionally burdensome, as these are the very people they are trying to avoid.'

Following the evolution of methadone treatment internationally, as summarized earlier in the chapter, in many clinics medical and counselling appointments are at about that monthly frequency, with counselling mainly on an individual basis. In our experience it is preferable to have the two kinds of appointments as separate, with the counsellor spending

some of his or her time discussing the methadone treatment, but also looking at wider personal and lifestyle aspects. The actual combination of appointments depends on staffing and other considerations, and often it is not possible for all patients to have a counsellor as well as a prescriber. Having only a prescriber risks neglect of aspects such as lifestyle planning, family support or consideration of other treatments; but, at the same time, if resources are limited, counselling needs to be targeted for those who will derive most benefit. The worst scenario, which needs to be guarded against, is where a methadone patient fails to attend for organized counselling, and uses the counsellor only as a contact at other times over specific and possibly manipulative prescription-related requests.

Practical management

In common with many other clinics in the UK, in our own services we tread something of a middle path between the formalized programmes and the low-threshold, low-demand approach to methadone treatment. There is no establishment of a structured programme with the various additional on-site services and, even if that were advocated, the funding climate generally is such that it could not realistically be provided. Ours are community-orientated services, with treatment mainly delivered through our specialist multidisciplinary clinical team and associated staff. The services are described further in Chapter 5.

Approximately 25% of our patients are on long-term methadone, with criteria for its use based on broad general guidance (Department of Health 1991, American Psychiatric Association 1994): 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), and preferably aged 18 years or over, although exceptions are necessary to this. Usually methadone mixture is used, in dosages of 40–120 mg per day, with dispensing at community pharmacies. We emphasize that methadone should replace heroin use rather than be additional to it, and encouragement, counselling and monitoring are provided with that aim. To some extent the requirements on patients depend on the nature and extent of their prescribed medication, which principle is discussed at various stages in this book, and outright discharge from treatment for additional drug use is relatively rare.

In such treatment there are various important practical considerations, and some of the main principles are examined here. More detail is

provided on practical aspects in the discussion of the use of methadone as a detoxification treatment in Chapter 3.

Treatment contracts

The nature of methadone treatment makes some kind of contract between patient and clinic essential. These may be in standard form for everybody, or individualized according to the particular circumstances of cases. Many services prefer contracts to be in writing and signed, although an unambiguous verbal agreement with recording in the case notes is basically as satisfactory. The most fundamental aspect is the required abstinence from other drugs of misuse which, as we have noted, varies to some extent in different approaches to methadone treatment. In practice we find it suitable to operate something of a hierarchy in contractual obligations depending on the prescribed medication: an individual on high-dose methadone or injectable drugs is required to be completely abstinent from other drugs, and has a generally stricter contract in matters such as frequency of dispensing, whereas there may not be quite the same expectations in someone who has elected to be on low-dose oral methadone.

The other elements which need to be included in contracts, and approaches to contract breaches, are outlined on page 94, and mainly apply to both maintenance and detoxification treatment. Although it can seem paradoxical, sanctions should include reductions in methadone dose where this appears the only way of making an impact on additional drug-taking or other problematic behaviours. In our long-term treatment we consider it inadvisable to specify exact lengths of time an individual is to be on a certain prescription, as changes may be required for various reasons, but it should be made clear that treatment will continue provided the contract is adhered to.

Urine testing

It can correctly be said that the evidence from studies regarding benefit of urine testing over patient self-reporting of drug use is not very convincing (Ward et al. 1998a). However, it must be noted that the comparisons were mainly carried out in the early maintenance programmes where patients were observed every day when presenting for their methadone, a far cry from a modern clinic where there may only be contact monthly. In our view urine testing is essential at every appointment, simply because it usually provides the only objective evidence of progress. In the early days 'random' urine testing meant that the patient still provided a sample