

Prescribing heroin

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Prescribing heroin

What is the evidence?

Gerry V. Stimson and Nicky Metrebian

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Contents

Acknowledgements	vi
1 Introduction: the history of the heroin prescription debate	1
The current debate	1
Which countries allow the prescription of heroin to addicts?	3
Who now wants to increase heroin prescribing in the UK?	3
History of prescribing heroin	4
Heroin prescribing in the UK	4
2 Heroin: a brief background	9
Illicit manufacture	9
Using illicit heroin	10
How many people use illicit heroin?	10
What individual and social harms are linked with heroin use?	11
3 Current approaches to heroin problems in the UK	16
Who provides drug treatment services?	16
How many drug users are in treatment now?	17
What are the main treatments for heroin users?	18
Substitution treatments: methadone and heroin	19
Prescribing heroin	22
How many heroin users receive prescriptions for heroin?	22
Current regulations for heroin prescribing	24
Current prescribing practice	25
Why is there so little prescribing of heroin for the treatment of opiate dependence in the UK?	26
4 Effectiveness of prescribing heroin	28
Problems of conducting research on heroin	29
What does the research indicate about the effects of heroin prescribing?	32
Conclusions	38
5 Challenges for expanding heroin prescribing	39
Prescribing heroin: a treatment without a plan	39
Clinical guidance: a necessary but insufficient response	40
Practical issues	42
A vision and a strategy	45
References	46
Appendix: Summary of studies of the effectiveness of prescribing heroin	51

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1 Introduction: the history of the heroin prescription debate

The UK is exceptional internationally because heroin is included in the range of legally sanctioned treatments for opiate dependence.

This chapter:

- outlines the arguments in favour of and against prescribing heroin in the treatment of people who are dependent on it
 - gives a history of heroin prescribing
 - shows how the reasons for prescribing heroin have changed from a primary concern to improve health to a concern to reduce crime.
-

Heroin dependence is increasing in the United Kingdom. It is a major public health problem with an elevated risk of illness and of death. It has high social and criminal costs. The Audit Commission (2002) noted that the total bill to the public purse for all drug problems (including heroin) was between three and four billion pounds in 2001/02, and the Home Office estimates that there may be in the region of 200,000 problem heroin users in the UK (Home Affairs Committee, 2002a).

Providing a medical prescription for pharmaceutical heroin (diamorphine) to heroin addicts has been seen in some countries as a way of solving the 'heroin problem' with potential benefits to the individual addict and to society.

Addiction and dependence describe compulsive use of a drug. Heroin dependence is a *chronic relapsing condition*, meaning that, although people may be able to stop using the drug for short periods, they soon start using again. Treatment often involves substituting – on a short- or long-term basis – a legal drug for the illegal drug. The most common substitution drug for heroin is methadone – a long-acting synthetic opiate which is prescribed in non-

injectable form. However, despite the benefits of oral methadone (Ward *et al.*, 1998), there are people who appear not to want it or benefit from it. It has been suggested, therefore, that pure pharmaceutical heroin (*diamorphine* or *diacetylmorphine*) be prescribed to replace the use of illicit heroin. This proposal remains controversial.

The current debate

The UK is exceptional internationally because heroin is included in the range of legally sanctioned treatments for opiate dependence. In practice, this treatment option is rarely utilised: only about 448 heroin users receive heroin on prescription (Metrebian *et al.*, 2002). Some people would like to see heroin prescribed to more people who are dependent on it. But an increase in prescribing heroin may have benefits as well as risks. Coming to a judgement on the merits of prescribing heroin for the treatment of opiate dependence requires looking at scant research evidence to determine whether heroin prescribing is likely to have an advantage over other treatments for dependence.

Prescribing heroin

Those in favour of prescribing heroin for the treatment of opiate dependence often point to the following in support of their case:

- Current treatments – mainly methadone substitution – are insufficiently attractive or effective for some heroin addicts. Prescribing heroin users their drug of choice might attract more people into treatment and retain them in treatment for longer. More heroin users would get help and there would be fewer untreated heroin users in the community.
- It may help some people to stop or reduce their illicit heroin use; this would undercut the black market in illicit heroin; and ensure that heroin users can use a drug of known quality and strength.
- It may help people avoid health problems (such as overdose) and unsafe injecting practices that can lead to transmission of HIV and hepatitis B and C (HBV, HCV).
- It may lead to less acquisitive crime to support a drug habit and to improved social functioning (work, housing and family life).
- It is a first step that may facilitate a gradual change away from heroin use to methadone, and from injecting to oral use.
- Individual heroin users would benefit – and so would society – by having less drug-related crime, lower criminal justice and prison costs, fewer or less visible drug markets, lower aggregate health-care costs, and lower social welfare costs.

Those who do not favour the medical prescription of heroin, or who are more cautious, often point to the following:

- It might maintain the condition of dependence by removing the motivation to stop using or injecting drugs. It might prolong the time a heroin user is drug dependent and injecting.
- An accumulating population of patients receiving a prescription for heroin prevents others from getting treatment.
- Individuals might suffer adverse health consequences as a result of continued heroin injecting (even though the drug is prescribed), including risk of overdose, infections, abscesses and blood-borne viruses, e.g. HIV and HCV.
- Society would have more heroin users and an increasing burden of ill-health.
- Pharmaceutical heroin is more expensive than methadone. Society has finite resources so needs to allocate them equitably.
- Heroin users presenting for treatment would come to expect heroin and might not accept alternatives such as oral methadone.
- There would be potential for diversion of prescribed heroin onto the illicit market, with the danger that new heroin users would be created.
- It is better to use treatments of known effectiveness such as methadone.

Which countries allow the prescription of heroin to addicts?

Heroin is prescribed in the treatment of opiate dependence in only a few countries.

In the UK, heroin has been prescribed to treat opiate dependence since the 1920s. It was originally adopted to help drug addicts lead normal lives without needing to purchase illegal drugs. More recently, the UK government has proposed the limited expansion of heroin prescribing because of the potential impact of such a strategy on reducing crime as well as improving the health of heroin users.

Scientific trials of heroin treatment have been completed in Switzerland (Uchtenhagen *et al.*, 1999) and the Netherlands (van den Brink *et al.*, 2002). Switzerland has now authorised the prescription of heroin for opiate dependence. Since 1998, heroin can be prescribed in the Netherlands for research purposes.

Scientific trials on the efficacy of heroin prescribing are planned or are taking place in Germany, France, Belgium, Spain and Canada (Fischer *et al.*, 2002). In 1992, Australia undertook research studies on the feasibility of prescribing heroin but the proposed trial did not take place, reputedly because of outside pressure on the Australian government.

Who now wants to increase heroin prescribing in the UK?

The *Updated Drug Strategy* for the UK (Home Office, 2002) states that the medical prescription of heroin will be available for all those who have a clinical need. This policy is part of the

government's aim to break the cycle of drug misuse and crime by providing effective treatment and rehabilitation. In its review of the government's drug policy, the Home Affairs Committee also recommended that a pilot programme of prescribing heroin be conducted, targeted in the first instance at chronic heroin users who are prolific offenders. It also made recommendations for a trial to look at the prescription of heroin to addicts with a long history of addiction who have not yet gained access to treatment or who are not currently in treatment (Home Affairs Committee, 2002a, p. 46). It is interesting to note that, in the UK, prescribing heroin is seen – at least by government – more as a way of reducing drug-related crime than as a public health strategy to reduce the risk of HIV infection or mortality due to overdose.

There is also support for heroin prescribing from the Liberal Democratic party. Its Home Affairs spokesperson Simon Hughes said: 'Heroin should be available on prescription because obtaining it through safe outlets is much safer than forcing addicts back into the hands of dealers' (BBC News Online, 2002). The Association of Chief Police Officers asserted that:

... there is a compelling case to explore further the merits of prescribing drugs of addiction to patients with entrenched dependency problems who have not responded to other forms of therapy ... This should include the wider use of heroin within a menu of treatments.
(Association of Chief Police Officers, 2002, pp. 1–2)

Chief Superintendent John Issac of Devon and Cornwall Police told BBC's *Newsnight*:

There will always be a debate among the medical profession about the ethics of prescribing heroin. But from a police officer's point of view, I have to say that if it reduces crime, reduces the number of victims, that has to be a very serious consideration. And I would support it.
(BBC News, 15 January 2002)

History of prescribing heroin

Worldwide, drug treatments have been influenced by international agreements to control drugs, and by changing ideas about the nature of the 'heroin problem' and how to solve it. As we have already seen, some see prescribing heroin as a way to reduce the problem of drug-related crime and others emphasise the advantages of heroin prescribing as a way of reducing public health problems (e.g. overdoses, infectious diseases).

The international control of heroin began in 1909 in Shanghai at a special commission convened by the USA. A convention signed in The Hague in 1912 limited the manufacture, distribution and use of heroin to medical use. This was as a result of the growing opium trade (heroin is an opiate derived from opium), which had come under increased criticism because of the increasing numbers of individuals addicted to heroin. As a result, in the USA, the 1914 Harrison Narcotic Act restricted the use of opiates to legitimate medical purposes and, by 1919, doctors could be prosecuted for

prescribing opiates to addicts. In the UK, the Dangerous Drugs Act of 1920 restricted the supply of morphine and heroin to registered medical practitioners for the purpose of medical treatment. In 1956, with the Narcotic Drug Control Act, the medical use of heroin was completely withdrawn in the USA and many other countries (although hospitals were allowed to continue using existing stocks of heroin).

Many countries believe (erroneously) that the international drug conventions prohibit the use of heroin in medical treatment. Furthermore, the International Narcotics Control Board (INCB) has exerted great pressure on countries to cease prescribing heroin for any medical purpose. Nevertheless, a few countries, including the UK, Belgium, the Netherlands, Iceland, Malta, Canada and Switzerland, continue to use heroin (diamorphine) for general medical purposes, mostly in hospital settings (usually for severe pain relief). Until recently, however, Britain was the only country that allowed doctors to prescribe heroin for the treatment of drug dependence.

Heroin prescribing in the UK

Prescribing heroin and other opiate drugs has been part of the British response to opiate dependence since the 1920s. While the USA chose to criminalise heroin dependency, Britain chose to medicalise the problem. In the UK, the reasons for prescribing heroin have changed over the last 100 years reflecting different historical contexts and changing perceptions of 'the problem' (Hartnoll, 1993).

The 1926 recommendations

Circumstances in which morphine or heroin may legitimately be administered to addicts:

There are two groups of persons suffering from addiction to whom the administration of morphine or heroin may be regarded as legitimate medical treatment, namely:

- a Those who are undergoing treatment for cure of addiction by the gradual reduction method;*
- b Persons for whom, after every effort has been made for the cure of addiction, the drug cannot be completely withdrawn, either because:
 - i complete withdrawal produces serious symptoms which cannot be satisfactorily treated under the ordinary conditions of private practice, or where:*
 - ii a patient, who while capable of leading a useful and fairly normal life so long as he takes a certain non-progressive quantity, usually small, of the drug of addiction, ceases to be able to do so when the regular allowance is withdrawn.**

(Departmental Committee on Morphine and Heroin Addiction, 1926, p. 33, quoted in Spear, 2002)

1920s–60s: helping addicts lead normal lives

In the early 1920s, the extent of the opiate problem in the UK was very small, with few individuals dependent on morphine and even fewer on heroin. In 1926, the Rolleston Committee was convened to consider and advise as to the circumstances, if any, in which the prescription of heroin or morphine to addicts was medically advised. This report recommended that medical practitioners could prescribe heroin or morphine to addicts if it would enable patients to lead useful lives (Departmental Committee on Morphine and Heroin Addiction, 1926). Thus, from the late 1920s, it was considered *bona fide* medical practice to maintain addicts on their drug of addiction if other treatments had failed and if they were able to live ‘normal and useful lives’ when given a regular, stable dose but were unable to do so when the supply of the drug

was withdrawn (Departmental Committee on Morphine and Heroin Addiction, 1926). Until 1968, any doctor could prescribe heroin or other opiate drugs in the treatment of opiate dependence. The majority of doctors who prescribed heroin were general practitioners.

This approach worked reasonably well with the addict population of the time, most of who were in the medical and nursing professions and who became addicted because they had access to opiates; others were individuals who had become addicted in the course of medical treatment (known as therapeutic or iatrogenic addicts).

Mid-1960s: prescribing to contain the black market

In 1961, the Brain Committee was established (Interdepartmental Committee on Drug Addiction) to consider whether the prescribing

Prescribing heroin

policy (based on Rolleston) should be revised and whether there was a medical need to provide special treatment outside the resources already available. It concluded that the drug problem was still small. The Committee saw no reason for any changes in existing practice or procedures.

However, at the beginning of the 1960s, there was a sharp increase in the numbers of heroin users. These were 'hedonistic' heroin users – individuals using heroin initially 'recreationally' and for pleasure, and associated with a 'deviant' or 'underground' culture. The doctors who prescribed heroin thought they were helping to contain an illicit market in heroin. They little realised that some of the heroin that they were prescribing was being sold and therefore they, by prescribing heroin, were helping the black market to expand. Some heroin users received very large prescriptions for heroin and were selling some of it.

Concerns about the increase in numbers of known heroin users led to the establishment of the Second Brain Committee. The Committee (Interdepartmental Committee on Drug Addiction, 1965) blamed the increase in heroin use on the doctors who were overly generous in their prescribing, stating that 'the majority source of supply has been the activity of a very few doctors who have prescribed excessively for addicts' (Ministry of Health and Scottish Home and Health Department, 1965). At the time of report, several doctors were prescribing heroin and cocaine in very large quantities. The Brain Committee recommended that restrictions should apply to the prescribing of heroin and that 'treatment centres be set up, mainly in London and might form part of a psychiatric hospital or the psychiatric wing of a general

hospital'. In effect, the report recommended that, to control the problem, the right to prescribe heroin for the treatment of addiction should be restricted to psychiatrists working at special drug clinics. This report informed new legislation.

In 1967, the Dangerous Drug Act restricted the prescribing of heroin and cocaine in the treatment of addiction to doctors holding licences from the Home Office. Prescribing heroin in the treatment of other medical conditions was unaffected. In 1968, new specialist drug dependency units (DDUs) were established by the Ministry of Health – mainly in London. The licensed doctors were mostly NHS psychiatrists in charge of the DDUs – thus effectively excluding general practitioners from prescribing heroin for the treatment of opiate dependence.

One reason for prescribing heroin – given by the Ministry of Health at that time and some of the doctors in the clinics – was to contain the spread of the 'epidemic'. Doctors tried to prescribe just enough to tempt people into

Medical care and social control

The establishment of the drug clinics in 1968 brought to the fore that doctors were now working both for the patient and on behalf of society to control a social problem. The tension between treatment and care on the one hand and social control on the other has since been a continuing feature of drug policy and medicine's involvement in this field. It begs the question of 'who benefits from heroin prescribing?'

treatment, but not too much because this might feed the illicit drug market. Some described this as ‘competitive prescribing’ – doctors competing against the illicit drug market by maintaining heroin users on just the right dose. Too much and they might sell it, too little and they might turn to the illicit drug market.

1970s: the shift from heroin to methadone, and from maintenance to abstinence

After 1970, prescribing heroin went out of favour and doctors at the clinics started to persuade patients to change to methadone as a substitute drug.

This shift was influenced by a number of reasons. These included concerns over the potential threat of the diversion to the black market of prescribed heroin, growing optimism about the positive therapeutic effects of methadone and its advantages over heroin, and concerns with the safety of continued injecting of heroin. Many doctors considered that prescribing heroin was ‘feeding a habit’ while prescribing methadone was a ‘medical treatment’. Steadily accumulating clinic caseloads of patients maintained long term on heroin, and drug workers’ disenchantment with maintaining heroin users on heroin, also contributed to the shift of opinion. Moreover, doctors became more interested in abstinence than maintenance as a treatment goal.

There was little conclusive research evidence to support this change away from prescribing heroin and no formal change of drug policy. Rather, it was as a result of doctors’ decisions and peer pressure within the medical profession. Contributing to the support for this change in treatment were the results of a randomised controlled trial conducted by

Richard Hartnoll and Martin Mitcheson (Hartnoll *et al.*, 1980) comparing heroin maintenance with oral methadone maintenance. The results of the trial were inconclusive and the authors’ conclusions cautious.

Hartnoll and Mitcheson found that those receiving a prescription for heroin tended to stay in treatment but continued to inject and use illicit drugs, although in smaller amounts than before entering treatment. Those receiving oral methadone went to one extreme or another: either they stopped using illicit drugs completely or they continued to be heavily involved in drugs and dropped out of treatment.

The results identified advantages and disadvantages of both treatments. But the results were interpreted by many to show that

The shift from heroin to methadone, and from maintenance to abstinence

It [the Hartnoll and Mitcheson study] has been widely credited with changing treatment policies in the newly established Drug Dependence Units away from heroin maintenance to policies focused on short-term methadone prescribing, and towards abstinence as a goal. It formed the basis of guidelines on good clinical practice issued in 1984. This was certainly not the aim of the researchers. Despite the authors’ reservations about the results, the research was taken to show that oral methadone maintenance treatment was preferable.

(Berridge and Thom, 1996, p. 25)

oral methadone was preferable, and that heroin encouraged continued drug use and led to steadily accumulating clinic populations. The research provided a justification for a change already under way.

This is the only randomised controlled trial of heroin versus methadone treatment that has ever been attempted in the UK.

Mid-1980s: control of HIV/AIDS – maintenance back on the agenda

The advent of HIV / AIDS in the mid- to late-1980s saw another shift in views on maintenance prescribing. Methadone maintenance was increasingly seen as an intervention that could reduce the harm from injecting drug use. The main aim became helping injectors change their behaviour by assisting them to stabilise their drug use and reduce HIV risk behaviour (e.g. the sharing of needles and syringes). It was now seen to be a public health imperative to get heroin users into treatment and to retain them in treatment for as long as possible, thus providing the opportunity to impact on risk behaviours. But, although maintenance was back on the agenda, it was mainly with oral methadone rather than heroin.

Mid-1990s: drugs and crime – prescribing heroin to reduce crime

More recently, the perception of the problem has changed again. Problem heroin use is now seen by the UK government mainly as a drug-related crime issue.

The policy shift began during the first term of the Labour government after the 1997 general election. In his introduction to the White Paper *Tackling Drugs to Build a Better Britain*, the Prime Minister Tony Blair wrote of the need to 'break

once and for all the vicious cycle of drugs and crime which wrecks lives and threatens communities' (Home Office, 1998, p. 1). The UK's first Anti Drug Coordinator (or 'drug czar'), appointed in 1997, echoed the theme in his *First Annual Report and National Plan* – the aim of which was 'to rid our society of the cycle of drugs and crime'.

The policy had several premises: crime is a key concern for communities – and a key issue for the government; a lot of crime is drug related; treatment of addicts works to reduce criminal behaviour; and drug-using criminals can be persuaded to enter treatment. Therefore, getting drug users into treatment will reduce crime. The case for expanding heroin treatment is now argued by government as one of the means for reducing drug-related acquisitive crime.

The drugs–crime focus has mellowed somewhat in the Labour government's second term – but still underpins the *Updated Drug Strategy* (Home Office, 2002). Drug treatment provision is set to double between 2001 and 2008. Much of this new provision will be for methadone substitution treatment.

However, the *Updated Drug Strategy* (Home Office, 2002) also sets out the aim to improve access to prescribed heroin. The strategy proposes that 'all those with a clinical need for heroin prescribing will have access to it under medical provision safeguarding against the risk of seepage into the wider community'. It acknowledges the current inconsistency in providing this treatment and pledges to spend money on it. Subsequently in May 2003, the National Treatment Agency for Substance Misuse (NTA) issued guidance on prescribing injectable heroin (National Treatment Agency, 2003).

2 Heroin: a brief background

This chapter describes:

- what heroin is
 - how and where it is manufactured
 - how it is used
 - how many people use it
 - the harms associated with its use.
-

Heroin is one of a number of drugs – called opiates – derived from opium. It was first synthesised at St Mary’s hospital in London in 1874 and, in 1898, it was produced as a new drug by the German pharmaceutical company Bayer. Heroin was initially introduced into the medical world as a respiratory stimulant (particularly for tuberculosis), though later it was found to be a respiratory depressant. It was also widely used as an analgesic. Subsequently, it was suggested that it might be an effective cure for morphine addiction but it was soon found itself to have addictive properties.

Heroin is a strong analgesic and is highly effective in the treatment of pain. It is mainly injected. In the UK, it is used to relieve the severe acute pain caused by injury, surgery, or heart attack and is used in palliative care for severe chronic pain experienced by patients with terminal illness such as cancer.

Heroin also has strong euphoric effects, produces an intensive feeling of well-being and can lead to a trance-like sedation – in addict parlance, ‘nodding off’. The euphoric effect is more marked when the drug is injected or smoked than when it is swallowed. Side-effects can include nausea, dry mouth, reduced frequency of breathing, reduced appetite and slowed function of the colon leading to constipation. In women, regular consumption can lead to menstrual disorders.

Illicit manufacture

Heroin is derived from the opium poppy. The largest centres for opium cultivation are in Afghanistan and Myanmar (formerly Burma), which together account for over 90 per cent of global production of illicit heroin. However, cultivation also takes place elsewhere, for example, Pakistan, India, Lao PDR, Thailand, Colombia and Mexico. Many other countries around the world have suitable climatic conditions for cultivating opium.

There are various grades of illicit heroin. The main distinction is between smokeable and injectable grades. The pinkish brownish ‘base’ heroin volatilises when heated and is most suited to being ‘smoked’. The whitish water-soluble powder – heroin hydrochloride – is most suited to injection.

The refining of illicit heroin takes place in clandestine ‘laboratories’. It entails converting opium to morphine using lime and ammonia, then converting this into heroin using acetic acid. Water and chloroform are then used to reduce impurities. Heroin in this form is smokeable. A further step in the laboratory involves conversion of heroin to a water-soluble powder using ether and hydrochloric acid to produce an injectable grade of heroin.

It is fairly easy for heroin users to convert brown heroin into an injectable form using an acid (e.g. citric acid).

On average, the illicit heroin that is available in the UK is about 40–45 per cent pure heroin and this has been so for some years (Home Office, 2001a). The myth that dangerous contaminants are often present is largely untrue (Coomber, 1997). However, other substances are often added to increase the effect or alter the taste and give it a distinctive flavour. These are usually added at the time of manufacture and include procaine, barbiturates and caffeine. During the distribution process, relatively neutral bulking substances such as mannitol, lactose and powdered sugar are sometimes added (Carnwath and Smith, 2002).

Using illicit heroin

‘Smoking’ heroin – ‘inhalation’ is the more accurate term – entails vaporising the heroin without burning it and then inhaling the fumes. One method is to ‘chase the dragon’, in which the heroin is placed on some aluminium foil and then heated from below using a flame to make it vaporise rather than burn. The resultant fumes are inhaled through a tube. The melting heroin looks a bit like the wriggling of a dragon’s tail as the heroin user chases the vapour round the foil. ‘Chasing the dragon’ originated in Hong Kong and spread to other countries in South East Asia in the 1960s and 1970s. It is the predominant mode of administration in the Netherlands (where it is also called *Chinezing*).

Heroin base is effectively vaporised at between 200 and 300°C. Chasing is an effective means of heroin administration producing rapid effects, with about 35–45 per cent of the drug actually delivered into the body (Hendriks *et al.*, 2001) but it requires some skill. Heating the

heroin to a higher temperature, as when burning it with tobacco in a cigarette (at 700–800°C), decomposes the heroin and results in much less of the heroin (10 per cent) being delivered in the smoke.

If heroin is to be injected, the powder has to be diluted with water. Heating heroin with an acid helps make it soluble and some impurities can be removed using a makeshift filter made from either cotton wool or a cigarette filter. Heroin hydrochloride, being water soluble, can also be inhaled and absorbed through other mucous membranes. In some parts of South East Asia, it is rubbed into cuts in the skin. Injectable grade heroin is not very suitable for smoking – when heated, the amount of heroin that is delivered is under 20 per cent. Heroin is not very effective when swallowed and is converted by the body into morphine.

How many people use illicit heroin?

The proportion of the UK population who have taken illicit heroin is small. In 2000, the British Crime Survey (BCS) found that 2 per cent of men and 1 per cent of women had taken heroin at some time, and 1 per cent of men had taken it in the last year (Home Office, 2001a, p. 81).

Most people who have tried heroin probably do not go on to become regular users (see Table 1), but no studies have been conducted to confirm this hypothesis. However, some will become ‘problematic’ or ‘dependent heroin users’. The total number of problematic heroin users in the UK is thought to be in the region of 200,000 (quoted in Home Affairs Committee, 2002a, p. 37) but such estimates are acknowledged to be imprecise.

Table 1 Many more people have tried heroin in the UK than have problems with it or are dependent on it – but the exact numbers are not known

	Numbers
People who have tried heroin at some time	1–2% of the adult population = 440,000–880,000
People who are currently using heroin	Not known
Problematic and dependent heroin users	200,000 estimated

Various indicators suggest that the number of heroin users has increased. For example:

- the number of heroin addicts in the UK notified to the Home Office between 1990 and 1996 increased from 14,497 to 30,573 (Home Office, 1995, 1996)¹
- in England, in 1993, 7,700 clients new to drug agencies, or returning after a six-month gap, said heroin was their main drug of use (in the six months to end of September 1993), rising to 22,431 (in the six months to March 2001) (Department of Health, 2002a).

The overall popularity of smoking and injecting changes over time, and differs in locations around the UK. For example, in Scotland, the percentage of new clients at drug agencies who were injecting dropped from 60 per cent in 1999/2000 to 53 per cent in 2000/01, and the proportion reporting smoking increased.

What individual and social harms are linked with heroin use?

Heroin use can affect a drug user’s psychological health, physical health, social functioning and legal situation. An individual’s drug use can have a harmful impact on other

individuals, on their family, or on their community or society.

Not all heroin users suffer problems, or suffer them to the same degree. The health consequences of heroin use will depend on:

- 1 how the drug is used – including the route of administration (injecting heroin is riskier than smoking it), whether it is taken alone or with other drugs (such as cocaine) or alcohol, the level of purity and dose level
- 2 the characteristics of the drug user – including pre-existing or co-existing health, social and economic circumstances. Harms appear to be greater when heroin and other drug use is associated with social deprivation and poverty.

Risks to health

Dependence

Prolonged use can lead to dependence that is both psychological and physical. The physical basis of dependence is the adaptation of cells to the presence of heroin. When drug consumption is reduced or ceases, the resulting withdrawal symptoms are uncomfortable and include flu-like symptoms such as fever, sleep disorder, lachrymation, muscular pain and diarrhoea.

Ten markers of dependence: Leeds Dependency Questionnaire

- 1 Preoccupation: primacy of thoughts about the drug, how, where, when to procure and use it.
- 2 Salience: primacy of activities involved in the procurement and use of the drug over other routine or once important activities.
- 3 Compulsion to start: the perceived inability to refrain from use of a drug in the face of conditioned cues.
- 4 Planning: the way in which the user's day is organised around procurement and use of the drug.
- 5 Compulsion to continue: the perceived need to continue using the drug in order to enhance or prolong the drug effects.
- 6 Narrowing of repertoire: taking the same drug at the same intervals in the same way.
- 7 Maximise effect: use of a drug in a particular way that maximises the desired effect.
- 8 Primacy of effect: achieving any pharmacological effect takes precedence over the use of the preferred drug.
- 9 Constancy of state: maintenance of a drug-induced state (whether of intoxication, avoidance of withdrawal or avoidance of a drug-free state).
- 10 Cognitive set: belief in the need to use the drug in order to cope with everyday life.
(Raistrick *et al.*, 1994)

Dependence is characterised by an overwhelming desire to take the drug, difficulties in controlling its use and a compulsion to take the drug despite harmful consequences. 'Tolerance' to the drug occurs when repeated or long-term use requires higher dosage in order to experience the same effects.

Heroin dependence is aptly described as a 'chronic relapsing condition', meaning that many individuals may be able to stop using it for short periods, but soon start using again.

Mortality

The mortality rate for chronic heroin users is about 1.5 per cent a year, both from causes related to the drug itself (e.g. overdose) and from accidents and violence associated with a drug-using lifestyle. The number of opiate overdose deaths in England and Wales has more than doubled, from less than 400 in 1993 to nearly 1,000 deaths in 2000.

Overdose

Overdose risk is increased when heroin is used in combination with other drugs, in particular

with alcohol and tranquillisers such as benzodiazepines, or when tolerance has fallen (meaning that a person needs *less* drugs than hitherto to achieve the desired effects; for example, after release from prison or interruptions of use while in treatment). Overdose in naive subjects may occur with as little as 20 mg of pharmaceutical heroin. However, with prolonged use, tolerance develops so that larger doses can be consumed without overdose – a few addicts in London in the 1960s were using 1,500 mg a day or more of pharmaceutical heroin. Not all overdoses result in death. However, heroin overdose deaths are more likely to occur among people who inject heroin than among those who ‘chase the dragon’.

Morbidity

Heroin use has been associated with poor physical health, such as liver, renal, pulmonary and cardiovascular diseases, constipation, reduced sexual drive and fertility.

Diseases transmitted through sharing needles and syringes

Heroin injectors are at risk of contracting and transmitting blood-borne viruses through the sharing of needles and other injecting equipment. Most significant are HIV and hepatitis B and hepatitis C. The UK has been fortunate in avoiding a major epidemic of HIV among injectors, with less than 1 per cent of injectors HIV positive. This is due to harm-reduction services, such as syringe exchange, methadone treatment, outreach and social marketing of ‘safer injecting’ messages. There are many cities around the world that have had uncontrolled epidemics of HIV and where 40 per cent or more injectors became HIV positive,

for example Bangkok and New York (Stimson *et al.*, 1998). As a result of harm reduction, the UK also has relatively low levels – by international standards of hepatitis B (around 20 per cent) and hepatitis C (around 38 per cent) – but these levels are still too high (Hope *et al.*, 2001).

Other injecting-related health problems

Injecting heroin and other drugs also brings with it the risk of developing abscesses and infections, and of causing vein damage, vein blockage and collapse, and deep vein thrombosis. Injecting heroin is implicated in other physical complications including pulmonary embolism (a blood clot in the lungs, which can cause death), septicaemia (a generalised bacterial infection of the blood) and endocarditis (an inflammation of the valves and lining of the heart). Rarely – but with tragic consequences – contaminated heroin may lead to severe infection and death. In Glasgow, Dublin, Manchester and Liverpool, in 2001, an unusual and often fatal infection among drug injectors was caused by batches of heroin contaminated by the bacterium *Clostridium novyi* type A.

Co-morbidity

Mental health problems including affective disorders (depression) and anxiety or personality disorder are common among individuals being treated for heroin dependence. A recent study found that a majority of drug users attending drug treatment agencies had at least one psychiatric disorder. It is often impossible to determine whether the mental health problem predates the drug problem or vice versa (Weaver *et al.*, 2001). Mental health problems often go unrecognised by drug services staff.

Prescribing heroin

Table 2 Health and social problems associated with problem heroin use

	Inject	Smoke
<i>Health</i>		
Overdose	Yes	Less common than with injection
Infectious disease, e.g. HIV, hepatitis B and C	Yes	No
Endocarditis	Yes	No
Abscesses	Yes	No
Dependence	Yes	Yes
Mental health problems	Yes	Yes
<i>Social</i>		
Dysfunctional family and social relationships	Yes	Yes
Income-generating crime	Yes	Yes
Work and employment	Yes	Yes

Table 2 summarises the wide-ranging problems associated with problem heroin use. It clearly shows that the most serious physical harms are associated with injecting.

Poor health inevitably leads to high levels of contact with Accident and Emergency (A&E) departments and with general medical services. The National Treatment Outcome Research Study (NTORS) – a large-scale study of drug users receiving treatment at opiate treatment services in the UK – found that almost half the patients had received treatment in an A&E department and a quarter had been admitted to a general hospital bed (Gossop *et al.*, 1998).

Social problems

Many heroin users experience relationship difficulties with sexual partners, friends and family as a result of their drug use. They may also have difficulties in holding down jobs and have financial and legal problems. Many may become involved in criminal activity to help fund their drug use.

Crime

There has been much discussion about the causal relationship between crime and drugs, and the extent to which heroin or other illicit drug use leads to law breaking or whether those committing crimes would do so regardless of drug use. Indeed, some drug users never commit any serious crime, other than possession of an illicit substance, while others commit large numbers of crimes to pay for their drug use. Given the high price of heroin – for example, at an average price of £65 per gram in the UK (Home Office 2001a, Table 2.8), the only way many drug users can afford to buy drugs is to commit crimes.

The drug–crime nexus was investigated in the UK in a study of 506 people arrested for a variety of offences. Drug tests found that 29 per cent were positive for opiates (including heroin) and 20 per cent were positive for cocaine (including crack) (Bennett, 2000). Some 145 of the 506 arrestees had injected heroin in the previous year. In this study, on average, heroin

users had spent over £16,000 a year on drugs, of which, on average, about £13,000 came from illegal sources.

The large UK research study NTORS found high rates of criminal behaviour among their treatment sample of drug users, with 61 per cent reporting 70,728 separate crimes during the three months prior to entering treatment (Gossop *et al.*, 1998) – an average of about one crime a day each. Although shoplifting was the most commonly reported offence, more serious crimes such as burglary and robbery were reported by 12 per cent and 5 per cent respectively.

The relationship between drugs and crime was also found in a recent survey of the prison population. Fifty per cent of people in custody

and awaiting trial admitted they were dependent on a drug (Home Office, 2001a, Tables 4.3 and 4.4).

There is still little understanding of the complex relationship between drugs and crime, whether using drugs leads to crime (and, if so, whether it is only to acquire money to pay for the drugs) or whether those committing crimes would do so whether they were using drugs or not.

Note

- 1 The regulation under the Misuse of Drugs Act requiring doctors to notify their addict patients to the Home Office was revoked in May 1997.

3 Current approaches to heroin problems in the UK

This chapter:

- outlines the current treatments for heroin dependence
 - shows the limitations of current treatments
 - explains maintenance and substitution treatment with methadone and heroin
 - describes current regulations for prescribing heroin and how it is prescribed
 - shows who prescribes it and how many people get it on prescription
 - asks why prescribing heroin is so uncommon in the UK.
-

The UK has a wide range of services aimed at reducing or ameliorating drug problems. The government estimated that around £3.5 billion was spent on the direct and indirect costs of drug problems in 2001/02, channelled through a large number of government departments (Audit Commission, 2002). About £1,900 million was spent by the Home Office on enforcement and prisons, about £265 million on the courts, £200 million on customs, £738 million on benefits – and £217 million on treatment. Spending on treatment in the community and in prison is set to rise to £573 million by 2005 (Home Office, 2002) as the government plans to double treatment provision.

Who provides drug treatment services?

The current pattern of treatment provision is complex and patchy, reflecting uneven growth and different philosophies of care.

- *Community drug teams* (CDTs) are NHS community-based services which generally aim to provide easy access to information, advice and counselling, and

general health care. Community detoxification (see below) and substitute prescribing are provided by medical staff or through shared-care schemes with general practitioners. Some CDTs offer structured day programmes.

- *Street-based agencies* are usually run by the independent sector. They generally aim to provide easy access to information, advice and counselling, and outreach (a community-based activity which attempts to contact drug users out of contact with existing services).
- *Drug dependency units (DDUs)* are usually situated within NHS hospitals. They provide assessment and medical treatment on an out-patient basis. They characteristically offer treatment to opiate-dependent drug users and are staffed by multidisciplinary teams (nurses, doctors, psychologists and social workers) led by a consultant addiction psychiatrist. They provide out-patient community detoxification, substitute

prescribing, counselling, group work and structured day programmes. Many DDUs have access to hospital in-patient facilities for detoxification.

- *General practitioners (GPs)* are a common point of first contact for people with drug problems. The Department of Health has recommended that GPs provide general health services to drug users, assessment and referral, and where possible – and with the support of specialist services – detoxification and substitute prescribing.
- *In-patient detoxification units* are in-patient units in NHS hospitals or private clinics. They are either specially designated units for drug detoxification or have allocated beds within an in-patient psychiatric ward.
- *Residential rehabilitation units* are usually provided by the independent sector. Individuals are required to be drug free and have usually undergone detoxification before entry. They may be at the ‘rehab’ for between 12 weeks and six months, during which time they are encouraged to explore the reasons for their drug use and ways to stay abstinent through counselling and other non-medical therapies. Residential facilities are based on different philosophies (e.g. the 12-step structured programmes, Christianity-based programmes and therapeutic communities using a behavioural model). Residents are expected and encouraged to support each other in order to facilitate behaviour change and remain drug free.

- *Crisis intervention units* are usually provided by the independent sector. They are short-term residential units and provide counselling, intensive structured day programmes and sometimes substitute prescribing to very traumatised or vulnerable drug users needing immediate help. Wherever possible, they refer clients to agencies that can offer longer-term assistance.
- *Self-help groups* provide support and encouragement to individuals with drug problems. Narcotics Anonymous (NA) follows the 12-step abstinence-based approach initially developed by Alcoholics Anonymous (AA).

How many drug users are in treatment now?

The precise number of people in treatment for their drug problems in the UK is not known. The Department of Health recently reported that 118,500 drug users were in treatment with drug services and GPs in England in 2000/01 – based on a survey of all drugs agencies (Department of Health, 2002b).

The following are estimates based on a number of different sources of new treatment ‘episodes’:

- During the six-month period ending 31 March 2001, in England, there were 33,200 new treatment ‘episodes’. Heroin was the most frequently reported main drug in 22,431 of these, accounting for two-thirds of users (67 per cent). Fifty-five per cent of heroin users were injecting.

- During the same six-month period, there were, in Scotland, 3,035 new 'episodes' involving heroin and, in Wales, 958. In Scotland, 52 per cent of those where injecting status was known were injecting heroin. In Wales, it was 45 per cent.
- There is no information from Northern Ireland.

What are the main treatments for heroin users?

There are a number of treatment options available to people with drug problems. These include different modalities and encompass different treatment goals (e.g. counselling, maintenance, abstinence, etc.). Furthermore, treatments are delivered in a variety of settings (e.g. NHS drug dependency clinic; private clinic; general practice, residential rehabilitation centre). Many treatments are a mixture of interventions and approaches – for example, methadone maintenance is usually accompanied by counselling. Besides, goals for a patient may change over time – for example, treatment may commence with stabilisation on methadone but with a long-term aim of abstinence.

- *Detoxification* is the process by which an individual dependent on a drug is given gradually reducing doses of the drug (or a substitute drug) to eliminate physical dependence with minimal physical discomfort from withdrawal symptoms. This may be achieved by reducing the dose over days or weeks, either as an in-patient or as an out-patient in the

community. There are also forms of rapid detoxification available where withdrawal may be achieved extremely rapidly – over 24 hours or so. Clinical experience and research evidence show that detoxification alone is normally insufficient to cope with the range of problems experienced by people dependent on heroin. While immediate withdrawal is relatively easy to achieve, many people rapidly relapse back to heroin use.

- *Counselling* aims to help and support individuals to bring about personal change, control their drug use, or prevent relapse once abstinence has been achieved. A number of different counselling techniques are used in the treatment of drug problems. These include 'person-centred counselling' (derived from Carl Roger's approach), cognitive behavioural counselling (often used in relapse prevention) and motivational interviewing (helping individuals to recognise and do something about their drug problem). Help in relapse prevention is usually provided either when an individual is taking methadone to prevent relapse into illicit drug use or after an individual has completed detoxification to help them avoid taking drugs again.
- *Alternative or complementary therapies* include auricular acupuncture, homeopathic teas and shiatsu massage. Most remain unevaluated.

- *Structured day programmes* aim to rehabilitate drug users by promoting life skills and vocational training, building personal independence and responsibility, and helping drug users maintain links with family and friends.
- *Twelve-step programmes* are based on the 12 steps used by Alcoholics Anonymous. Problem drug use is viewed as a disease which the individual has no power to overcome. Recovery is thought possible only if the drug user remains completely abstinent from all drugs and adheres to the recovery programme. The goal of treatment is continued abstinence. Twelve incremental improvements or steps are made for changing problem behaviours.
- *Substitution treatment* is a form of medical care for heroin addicts, where a similar but safer pharmaceutical drug is prescribed to replace the one that is being used illicitly. The idea is to improve health and social functioning. We deal with this in more detail in the next section.

Substitution treatments: methadone and heroin

Because heroin dependence is a chronically relapsing condition, and affects multiple dimensions such as physical dependence and psychological and social well-being, abstinence is difficult and often unachievable for many drug users, at least in the short to medium term. Prescribing methadone or other alternative drugs such as pharmaceutical heroin is a form

of substitution treatment where methadone or pharmaceutical heroin is substituted for illicit heroin.

Substitution treatment aims to attract drug users into treatment by offering a prescription for an opiate substitute, helping them reduce their risk behaviours, treating and stabilising health and social difficulties, and then focusing on treating their physical and psychological dependence on drugs.

Methadone

Methadone is a synthetic opioid – with a similar action to the opiates that are derived from heroin. It is considered by many to be the best substitute drug for opiate-dependent drug users because it is easy to administer (usually prescribed for oral use), it is long acting which means that it needs to be taken only once a day, and it is both safe and effective. Treatments using other opioid drugs (synthetic opiate type drugs) such as buprenorphine and LAAM (levo-alpha-acetylmethadol) are also used, but to a lesser extent.

Substitution treatment with methadone delays or eliminates heroin withdrawal symptoms, reduces the frequency of drug consumption and changes the route of administration away from injecting (see Table 3). By providing a safe and regular opiate substitute, it aims to eliminate or at least reduce risk behaviours (injecting illicit drugs) and thus the risks of drug-related harms, including transmission of blood-borne viruses (HIV, HBV and HCV) and overdose. By reducing the need for illicit drugs, this treatment aims to diminish activities involved in obtaining and administering illicit drugs including criminal

Prescribing heroin

Table 3 Heroin and methadone compared

	Heroin injected	Oral methadone
Maximum effect	Within minutes	After 4–5 hours
Duration of effect	6 hours	12–55 hours
Administration	3–4 times a day	Once a day

activities, involvement in the drug scene, injecting and sharing of injecting equipment. In the UK, methadone is usually prescribed for oral use. However, it should be noted that methadone is also available in injectable form (in small glass ampoules) and that 10 per cent of methadone prescriptions in the UK are for injectable methadone – in such cases, injecting will continue (Strang *et al.*, 1996) but patients should experience the other benefits from receiving methadone treatment.

The evidence suggests that oral methadone substitution treatment can help reduce the consumption of illicit drugs, improve the health

of drug users, help them avoid risks of overdose and infection such as HIV and hepatitis C, improve social skills and functioning, and reduce criminality (Farrell *et al.*, 1994; Gossop *et al.*, 2001; Hall, 1998; Ward *et al.*, 1998).

Methadone maintenance attracts more opiate injectors than any other form of drug treatment commonly provided, presumably because drug-free approaches offer drug users fewer choices about their drug use and the changes they would like to make. Also, it is less resource intensive and therefore less expensive than many drug-free alternative treatments.

Methadone treatment is generally more

A brief history of methadone substitution treatment

Methadone substitution treatment was pioneered in the USA in the 1960s. Methadone maintenance was originally designed to be a long-term treatment for opiate dependence in order to reduce illicit drug use and criminal activity. Later, it was seen to be important for HIV prevention by helping people reduce or stop injecting. In the USA, lack of public funding at a local and state level has resulted in limited comprehensiveness of methadone maintenance treatment. It is estimated that approximately 110,000 people receive substitution treatment in the USA.

Substitution treatment first appeared in some European countries in the late 1960s, but became more important from the late 1980s as a response to the HIV epidemic and became widely available in some EU countries only in the 1990s. All EU countries provide substitution treatment. Methadone is still the drug most commonly used, accounting for 90 per cent of substitution treatment in the EU. It is estimated that about 300,000 people receive substitution treatment in EU countries and 500,000 worldwide.

(European Monitoring Centre for Drugs and Drug Addiction, 2000)

successful than other approaches in retaining clients – drop-out rates are lower in methadone treatment than in drug-free programmes. The two most recent observational studies – the Drug Abuse Treatment Outcome Study (DATOS) in the USA and the National Treatment Outcome Research Study (NTORS) in the UK – have found significant reductions in illicit drug use and criminal activity in methadone maintenance patients (Fletcher and Battjes, 1999; Gossop *et al.*, 2001).

However, despite encouraging results, there are some cautionary points to be made about methadone treatments. Significantly, there are in fact substantial variations in effectiveness between programmes in retaining drug users in treatment, and in reducing illicit drug use and criminal activity. The quality of the treatment programme – including the quality of the clinical staff who work in the treatment agency – are important in determining the success of methadone maintenance (Hall, 1998). Overall, methadone maintenance programmes lose about a third of their patients in the first 12 months and another third in the following 24 months. The benefits of methadone maintenance continue only as long as the drug user stays in treatment – hence, retention is important (Hall, 1998). While methadone maintenance can be effective in reducing risk behaviour, it does not completely eliminate

illicit drug use or crime. Many of those who are retained in treatment continue to use illicit drugs albeit in smaller quantities and continue to commit crimes (but less frequently) (Hall, 1998).

There is no central record of the number of problem heroin users in methadone treatment in the UK. A recent estimate suggests that there are probably in excess of 40,000 drug users in methadone treatment (see Table 4) – about 20 per cent of the estimated 200,000 problem heroin users (Matt Hickman, personal communication, 2003). More heroin users could probably be drawn into methadone with an expansion of the service (the government plans to double the number of treatment ‘slots’). But not all heroin users want methadone treatment. Some continue to want their drug of choice, usually heroin, rather than methadone. Others may have tried methadone treatment, disliked it, or found it ineffective. Some patients are unable to manage on the prescribed dose and use illicit heroin to ‘top up’ their prescription, or may dislike the clinic rules and regulations. Some injectors are unable or unwilling to give up injecting. The ritual of injecting is an experience that sometimes becomes a focus for addiction (Carnwath and Smith, 2002). Some heroin users do not want any treatment at all – they may decide that they do not have a problem, that they do not want to stop using

Table 4 Only a small proportion of heroin users in the UK are in treatment with methadone

	Numbers
People who have tried heroin at some time	1–2% of the adult population = 440,000–880,000
People who are currently using heroin	Not known
Problematic and dependent heroin users	200,000 estimated
In methadone treatment	40,000–80,000
Prescribed heroin	448

Prescribing heroin

heroin, or that they do not like treatment services.

Prescribing heroin

There is no central record of the numbers of doctors prescribing heroin or of the numbers of drug users receiving a prescription for heroin. Previous research studies have provided only an indication of the extent of heroin prescribing. Therefore, in 2000, the Centre for Research on Drugs and Health Behaviour conducted postal surveys of:

- 1 all doctors holding a licence from the Home Office to prescribe heroin, in order to determine the scale and practice of heroin prescribing in the UK
- 2 all consultant psychiatrists or clinical directors of drug clinics not holding a licence to prescribe heroin, in order to determine their reasons for not requiring such a licence.

This study will be referred to as 'our survey' (Metrebian *et al.*, 2002).

Our survey found that, in the year 2000, there were 70 doctors holding a Home Office licence to prescribe heroin. Not all were using their right to prescribe and only 46 were currently prescribing heroin. The majority of doctors who prescribed (28) were consultant addiction psychiatrists, nine were consultant general psychiatrists with an interest in addiction, six were junior doctors and two were general practitioners.

For most of these doctors, methadone was the main drug prescribed and they had only a small number of patients to whom they

prescribed heroin. Most of the doctors prescribed heroin to between one and nine patients, 14 doctors prescribed to between ten and 50 patients, five of the 14 doctors were prescribing heroin to between 30 and 50 patients.

There was very uneven geographic distribution of heroin prescribers, with the majority living in London (nine), the South East (nine) and the North West (seven), three in Wales and none in Northern Ireland and Scotland. Consequently, there were regional variations in the number of drug users receiving a prescription for heroin. The majority of patients were in the North West of England.

The history of the service, the personal preferences of the prescribing doctors and individual NHS trusts' policies on prescribing heroin determine the current level of heroin prescribing. In our survey of doctors who prescribed heroin, nearly half (21/46) had not themselves initiated the prescription for heroin, but had 'inherited' these patients from a previous physician and continued to prescribe heroin. Many were reluctant to prescribe. About 40 per cent (18/46) of doctors said that they prescribed heroin because it provided an opportunity for clinical improvement. Three prescribed heroin to help attract and retain in treatment hard-to-reach drug users.

How many heroin users receive prescriptions for heroin?

Heroin does not figure prominently in the treatment of opiate dependence. Our survey identified that there were about 448 patients on heroin, compared with about 40,000–80,000 on

methadone. In 1995, prescriptions for heroin accounted for under 2 per cent of all prescriptions given for the treatment of opiate dependence compared with prescriptions for methadone which comprised 96 per cent of the total (Strang and Sheridan, 1997). Despite an increase in the volume of methadone prescribing in recent years, the numbers receiving heroin are small and relatively stable, probably not exceeding about 448 since 1975. This is a decline from the late 1960s when there were probably about 1,000 patients on prescribed heroin.

The numbers of patients receiving heroin is not necessarily dependent on the number of doctors prescribing it (see Table 5). In the North West, seven doctors were prescribing to 128 patients compared with nine doctors prescribing to 42 patients in the South East.

Neither does the distribution of patients approximate to need. A rough comparative measure of need is the number of new treatment episodes where the patient said that heroin was their main drug. Assuming that roughly the same proportion of patients would be eligible for heroin in each region, our crude measure is the ratio of patients getting heroin to the total number of new heroin patients. This varied from 0 per cent in Scotland to 4.9 per cent in the North West.

We do not know how many people are started on a prescription for heroin for the first time each year, but many patients have been receiving prescriptions for heroin for a long time. It is reasonable to assume that very few heroin users are started on a heroin prescription for the first time each year.

Table 5 Doctors prescribing heroin and patients receiving heroin in 2000, and number of new treatment episodes with heroin as the main drug

	Doctors prescribing heroin	Patients receiving heroin (a)		Number of new treatment episodes involving heroin (b)	Comparative index of 'need' (a) as % of (b)
		N	% of total		
<i>England</i>	43	419		26,424	1.7
Northern and Yorkshire	5	27	6	5,021	0.5
Trent	6	46	10	3,261	1.4
Eastern	1	5	1	1,381	0.4
London	9	93	21	3,408	2.7
South East	9	42	9	1,767	2.4
South West	4	56	13	2,530	2.4
West Midlands	2	22	5	2,035	1.1
North West	7	128	33	3,028	4.9
<i>Scotland</i>	–	–		3,035	0.0
<i>Wales</i>	3	29	2	958	0.9
<i>Northern Ireland</i>	–	–			

Prescribing heroin: a system without a plan

The current provision of heroin is not part of any plan on the part of local health services, rather something that has developed in a rather haphazard way. This lack of a plan means that there are large parts of the UK where the option of a heroin prescription is not available. The arbitrary way in which treatment with heroin has developed is typical of drug service development – as noted by the Audit Commission (2002, p. 34).

Current regulations for heroin prescribing

Heroin is controlled under the Misuse of Drugs Act 1970, which covers offences of possession, possession with intent to supply and supply. Heroin can be prescribed by any medical practitioner in the treatment of medical conditions but, in order to prescribe it in the treatment of addiction, a doctor needs a licence from the Home Office. Licences are generally given only to consultant addiction psychiatrists working from NHS drug dependency units. Licences are valid only for a specific address and are renewed every three years. Applications for licences require a recommendation from the doctor's health authority and from a senior medical officer in the Department of Health. There are requirements about how prescriptions are written.

Pharmacists dispensing prescriptions for heroin must record details of the prescription in their controlled drugs register. These registers are open to inspection by the Home Office inspectors and police.

Many people – especially from countries with a tradition of tight control of opiates – are surprised that the UK has relatively few restrictions and regulations for heroin prescribing to addicts. For example:

- There are usually no restrictions on the amount of heroin that licensed doctors may prescribe, nor on how many patients they may prescribe heroin for. However, the Home Office can impose any restrictions they wish on a doctor (for example, a doctor may be restricted to prescribe heroin for one named patient only, for a limited number of patients, or a doctor – usually a clinical assistant – may be restricted from initiating prescriptions).
- There is no requirement for doctors to get permission to prescribe for particular individuals or to report details of patients for whom they prescribe.

Until 1997, all doctors were required to 'notify' their addict patients to the Chief Medical Officer at the Home Office (i.e. provide information about their addiction treatment). However, this requirement has since ceased. One consequence is that there is now no central database recording the number of drug patients, their characteristics or the treatment they are receiving.

There has also, until recently, been very little in the way of guidance for doctors. For most of the period under discussion there were no national treatment guidelines on prescribing heroin, and no agreed treatment protocols. In 1999, the Department of Health issued guidelines on the clinical management of drug dependence, but the section on prescribing heroin is extremely brief.

Department of Health 1999 guidelines on prescribing heroin

Diamorphine (heroin):

A short-acting opiate agonist, mainly used intravenously, but can also be taken in oral form and inhaled. It is used as part of a maintenance regime in a minority of patients. A Home Office licence is required for such prescribing, which is the preserve of specialists. Diamorphine should only be prescribed in situations of rigorous monitoring and where use in the initial stages can be supervised. With the availability of injectable methadone, there is very little clinical indication for prescribed diamorphine. All the caveats and criteria discussed with regard to injectable methadone apply to diamorphine.

(Department of Health, 1999, p. 57)

These guidelines are not legally enforceable but their breach can be taken into account in professional disciplinary cases brought before the General Medical Council.

There are few safeguards to ensure that drugs are used by the individual for whom they are prescribed and not sold or diverted onto the illicit market. Some prescribers may ask patients to return their used ampoules before receiving another prescription, but this is not done routinely.

The Home Office Drugs Branch monitors aberrant heroin prescribing through information received from pharmacists, the police and others, and this sometimes identifies doctors who are self-medicating with heroin. Indications are that there is not a major illicit market in pharmaceutical heroin.

Consequent to the new interest in prescribing heroin expressed by the government, the National Treatment Agency for Substance Misuse issued guidance on prescribing injectable heroin in May 2003. This guidance was not effective during the period described in this chapter. The new guidance will be discussed in Chapter 5.

Current prescribing practice

Heroin is usually prescribed by a doctor working in a drug dependency clinic and dispensed from a community or hospital pharmacy for unsupervised injection at home.

On entering treatment, the initial dose of heroin may be supervised to check tolerance and injecting practices. However, regular and ongoing supervision of injecting is rare. Injecting equipment such as needles, syringes, antiseptic swabs for cleaning the skin and disposal bins for used injecting equipment are either supplied by the clinic or obtained from community pharmacies or a syringe exchange. Patients can bring their full disposal bins back to the drug clinic or to a syringe exchange. Sterile water for injecting purposes requires a prescription and is dispensed with the drugs.

Most doctors prescribe heroin as a freeze-dried powder contained in ampoules for injection (about 75 per cent of prescriptions). These must be mixed with sterile water in order to be injected. Some doctors prescribe heroin in other forms, e.g. in tablet form to be taken orally, as a powder to be mixed with water for

injection (or occasionally for smoking), as a solution to be taken orally, or as heroin-impregnated cigarettes (reefers) to be smoked (Metrebian *et al.*, 2002).

Daily doses of heroin range between 5 and 1,500 mg, with the minimum average (median) daily dose of 90 mg and the maximum daily dose averaging 460 mg (Metrebian *et al.*, 2002). In a survey of pharmacists, the mean dose of prescribed heroin was 175 mg (median 130 mg) (Strang and Sheridan, 1997).

There is a lack of consensus about the equivalent doses of methadone and heroin. Knowing how a dose of heroin equates with a dose of methadone helps the doctor prescribe the correct dose of heroin to a patient who wishes to transfer from a methadone prescription to heroin. In our survey, we asked doctors to estimate the equivalence dose of heroin for 100 mg injectable methadone. The doctors' estimates varied widely: from 50 mg of heroin to 900 mg of heroin (Metrebian *et al.*, 2002). However, the Department of Health clinical guidelines (Department of Health, 1999) report that 60 mg of methadone is equivalent to a 30 mg ampoule of pharmaceutical heroin.

Heroin – like other controlled drugs – can be dispensed in instalments by community pharmacists, following the prescribing doctor's instruction (under the Misuse of Drugs Regulations 1973). Heroin is usually dispensed daily (though generally not on Sunday) or a few times a week. Heroin prescriptions are more likely than methadone to be dispensed on a daily basis (74 per cent) compared with methadone (38 per cent) (Strang and Sheridan, 1997).

There is little consensus among doctors about who is eligible to enter heroin treatment. Most agree that it is a treatment for entrenched heroin injectors who have not been helped by other treatments. In our survey of prescribing doctors, half reported that, to be prescribed heroin, patients needed to have failed previous treatments with oral methadone – either detoxification or maintenance, and some doctors mentioned that the patient should also have previously tried injectable methadone. Many indicated that patients should have a long history of opiate dependence and injecting – but long meant anything from between two and ten years (Metrebian *et al.*, 2002).

Beyond these indicators, there were few other factors that were consistently mentioned. Some doctors said that patients must be generally compliant, not dependent on other drugs, be able to inject safely in either arms or legs with no injecting in the groin or neck, have no history of severe mental disorder or active psychosis, be socially stable, or have physical complications such as HBV, HCV or HIV. There were others, however, who took a different view and said it was the unstable patients who were most likely to benefit from heroin treatment.

Why is there so little prescribing of heroin for the treatment of opiate dependence in the UK?

It is striking that, while the UK has few restrictions on prescribing heroin for the treatment of opiate dependence, few doctors actually prescribe it, and only to a few patients. Among those doctors who prescribe heroin are

some who think heroin has an important treatment utility and others who do so reluctantly and only because they have inherited patients from others.

Our survey of licensed doctors (Metrebian *et al.*, 2002) and of doctors eligible for licences but who had not sought a licence found that the main reasons given for not prescribing heroin were:

- *not good clinical practice* – due to the possibility of diversion of the drug to the black market; that it encourages dependency; that it encourages injecting and increases the risk of infection, overdose and respiratory problems
- *lack of need* because most patients could be made comfortable with oral methadone
- *lack of demand* – few drug clinic patients ask for a heroin prescription

- *potential for high demand* – which may be generated if heroin becomes easily available: ‘honey-pot effect’
- *lack of evidence* for effectiveness, or for its superiority over oral methadone
- *disadvantages compared with methadone* – short half life; that only injectable forms are readily available
- *lack of guidelines to best practice*
- *lack of financial resources* – its high cost compared with methadone; financial pressure to keep costs to a minimum; no budget for prescribing diamorphine
- *lack of facilities* – e.g. for supervised injecting.

Resources for prescribing heroin

Many respondents cited lack of appropriate resources as a reason for not prescribing diamorphine to more patients. This included inadequate funding and the unavailability of facilities for supervised injection. To prescribe for more than a handful of patients is therefore beyond the budget of most drug teams, whatever the arguments about cost-effectiveness might be in terms of health and forensic gains. Supervised injection would require attendance at special injecting rooms two or three times a day, and would therefore increase the cost of the treatment.

(Metrebian *et al.*, 2002, p. 1160)

4 Effectiveness of prescribing heroin

Questions about prescribing heroin are easier to ask than to answer. The key issues are:

- Is prescribing heroin feasible? How is the treatment delivered and are there any problems with delivering it?
 - Do heroin users want heroin? Does prescribing heroin attract and retain heroin users in treatment?
 - Is prescribing heroin effective? Does the treatment work and is it better than the other treatments?
 - Who benefits most from the treatment? Who should receive it?
 - Is it cost-effective? Do the benefits of the treatment outweigh the additional cost of the treatment when compared to other treatments?
-

The evidence base for the effectiveness of heroin as a treatment is rather limited – four small-scale studies in the UK, one large study with multiple components in Switzerland (hereinafter referred to as the Swiss trial) and two large trials in the Netherlands. One reason for such a dearth of research is that heroin is prohibited for use in the treatment of opiate dependence in many countries, and pressure has been brought to bear from the International

Narcotics Control Board against countries wanting to conduct research trials on this topic. Another is the cost of trials. The Canadian trial is expected to cost \$CAN 8.1 million.

There have been four randomised controlled trials – one in the UK (Hartnoll *et al.*, 1980, one in Switzerland (Perneger *et al.*, 1998) and two large trials to assess the efficacy of both injectable and smokeable heroin treatment in Holland (van den Brink *et al.*, 2002).

UK studies of heroin prescribing

Stimson and Ogborne (1970); Stimson and Oppenheimer (1982). A follow-up study, started in 1969, of a randomly selected sample of one in three heroin users attending the first London drug clinics and being prescribed heroin. Patients were followed up at seven (Thorley *et al.*, 1977), ten (Wille, 1981) and 22 years (Tobutt *et al.*, 1996).

Hartnoll *et al.* (1980). Ninety-six opiate-dependent injecting drug users randomly allocated to receive either injectable heroin maintenance or oral methadone maintenance and followed up at 12 months.

McCusker and Davies (1996). Twenty-seven drug users receiving a prescription for heroin (injectable and smokeable) at one drug clinic compared with 39 receiving oral methadone at two other clinics in one regional health authority.

Continued

Metrebian *et al.* (1998, 2001). Fifty-eight long-term opiate-dependent drug injectors who had previously tried and failed oral methadone treatment were offered the choice to receive either injectable heroin or injectable methadone and followed up for 12 months.

The Swiss heroin trials

Uchtenhagen *et al.* (1997, 1999). Five linked studies to evaluate heroin prescribing were undertaken between 1994 and 1996 involving 1,000 subjects. Eight-hundred chronic heroin addicts who had failed in drug-free or methadone-substitution treatments were prescribed heroin and provided with psycho-social interventions at a number of treatment centres throughout Switzerland (as part of these five studies) and followed up at 12 and 18 months. While this was not a randomised controlled trial, this study is usually referred to as a trial and will be referred to as such hereinafter.

Perneger *et al.* (1998). A randomised controlled trial in Geneva of 46 long-term dependent heroin users who were randomised to either receive a prescription for heroin or were put on a waiting list where most received oral methadone.

The Dutch heroin trial

van den Brink *et al.* (2002). Two large multicentre randomised control trials were undertaken involving 625 patients from eight treatment units located in the Netherlands. The trials were designed to assess the effectiveness of heroin, co-prescribed with methadone – i.e. all patients were on methadone and some, in addition were given inhalable or injectable heroin. These were compared with people who got only methadone.

Further details of these studies can be found in the Appendix.

Problems of conducting research on heroin

Before looking at what can be concluded from the evidence, we highlight some of the problems in conducting research and interpreting the evidence.

Complexity

Randomised controlled trials, comparing one treatment against either no treatment, minimal treatment or a comparison treatment, are

considered the ‘gold standard’ for measuring effectiveness, but are difficult to undertake with problem drug users. Randomly allocating patients to different treatments ensures that patients in each treatment are similar, so that any differences found between the two groups can be attributed to the differences in treatment rather than differences in the patients. The complexity and logistics of such trials can be seen in the example of the Dutch heroin trial, summarised in the box overleaf.

Clinical trials are complex and difficult to set up and run – the Dutch example

- *Lead time of three years (1995–98)*: study design and feasibility, establishing collaborations, finding treatment sites, drafting treatment protocols, recruiting and training staff, obtaining heroin and providing for its safe keeping, building rooms where patients can smoke or inject, getting permissions from government, health and local authorities, pharmaceutical regulatory bodies and trials ethics committees.
- *Collaborations*: the Ministry of Health, Welfare, and Sports commissioned the study. The Central Committee on the Treatment of Heroin Addicts was responsible for the development, conduct and scientific quality of the study. The National Research Board was responsible for technical and scientific aspects. The Inspectorate of Health Care examined the quality of the care. The National Safety Committee advised on the evaluation of severe adverse events and the National Committee on Public Order and Controllability advised on public order and public safety. The Central Committee on Medical Ethics vetted the trial protocol. Each city developed a protocol with respect to public order.
- *Eligibility*: the trial had ten ‘inclusion criteria’. ‘Treatment refractory’ was defined as treatment-resistant heroin dependency of at least five years; minimum 60 mg of methadone per day for an uninterrupted period of at least four weeks in the previous five years; in the previous year, registered in a methadone programme and, during the previous six months, in regular contact with the methadone programme; chronic heroin addiction and unsuccessfully treated in methadone maintenance treatment; daily or nearly daily use of illicit heroin; and poor physical and/or mental and/or social functioning. There were also 14 ‘exclusion criteria’.
- *Randomisation*: eligible patients were divided into injectors and smokers, and randomly assigned to receive standard oral methadone treatment (Group A) or to receive heroin (Groups B and C). Group B were assigned to methadone and heroin for 12 months, while group C continued on methadone for six months and then switched to heroin.

(van den Brink *et al.*, 2002)

Measures of effectiveness

There are at least two stakeholders who might or might not benefit from prescribing heroin: the drug-using patient and the community.

Research has to take into account the varying and sometimes contradictory aims of

prescribing. The reasons for prescribing heroin might focus more on health gain, or on reducing crime – depending on the political context of the research and who is paying for it. It cannot be assumed that positive outcomes will be seen in all areas. Typically, individual outcome

measures include: health and psychological well-being, illicit drug use, HIV risk behaviour, criminal behaviour and social functioning.

Community outcomes might include: levels and types of crime occurring in the community linked with heroin use; overall availability of illicit drugs and diversion of prescribed drugs onto the illicit market; heroin users migrating to the area to get treatment; public safety and sensitivity (e.g. patients loitering around the clinic, used injecting equipment left in public places); and effects on other health and social services in the area (e.g. emergency hospital admissions, additional burden on law enforcement and social services).

Cost-effectiveness

Prescribing heroin is more expensive than oral methadone. It is necessary, therefore, to demonstrate that heroin prescribing provides added advantage over standard treatment in order to justify its use. Thus, a health economic assessment needs to be conducted to establish whether prescribing heroin results in greater economic benefit per extra unit of resource invested in the treatment, compared with prescribing oral methadone.

Treatment components

Treatment components provided in addition to the prescription for heroin may affect outcome. All research studies have evaluated the effectiveness of prescribing heroin with additional psycho-social services. In Switzerland, the large research study evaluated the prescription of heroin with additional social and psychological interventions. Because there was no comparison treatment group in the main

study, it is impossible to say whether treatment success was due to the pharmacological effects of heroin, the social and psychological interventions, or the fact that treatment was given in well resourced clinics with motivated staff offering both pharmacological and psychological treatment (Farrell and Hall, 1998).

Recruitment and eligibility

Studies recruit different types of patients. In the Netherlands, heroin was offered to people already in methadone treatment and offered in addition to methadone. In Switzerland, heroin was offered to drug users newly presenting for treatment. All treatment trials have a high level of control over the treatment delivered – essential because of the requirements of scientific measurement. However, ‘real-life’ treatment is rarely delivered in the same rigorous way as in a clinical trial – this is true of all of medicine.

Generalisability

Studies in other countries may provide useful information, but, since the treatment context differs, it is unclear how far results from these studies are generalisable. For example, patient interest in participating in a trial will be influenced by the history of treatment in that country (e.g. in Switzerland, heroin was not available before; in the UK, it is currently available). It will also be influenced by the accessibility, availability and quality of other treatments. Recruitment of patients and their response in a heroin trial may well be different between the Netherlands, where there is good methadone coverage (methadone is generally available to those who need it) and Canada,

where coverage is poor. Other factors will also be important – for example, in the Netherlands, there is good provision of housing and welfare services, while, in Canada, this provision is poor. Legal penalties might make treatment more or less attractive to patients.

Comparing the UK, Swiss and Dutch evidence shows up differences in the way in which heroin treatment is delivered. The question ‘does prescribing heroin work?’ has to consider whether it works when it is delivered in a particular manner, in a particular treatment modality, in a particular treatment and country context.

What does the research indicate about the effects of heroin prescribing?

1 Implementation and feasibility

Prescribing heroin is practical in specialist treatment settings

Practical considerations include drug storage and security, dispensing and supervision of the consumption of heroin ampoules and powder for smoking. Studies conducted in the UK have not involved supervised consumption; however, they suggest that the storage, control and dispensing of heroin is practical. Studies in the Netherlands (van den Brink *et al.*, 2002) and Switzerland (Uchtenhagen *et al.*, 1999) where the prescription was supervised have found the prescribing of heroin to be practical in specially established drug treatment clinics.

Heroin is as safe for patients as other comparable treatments where injectable drugs are prescribed

No serious side-effects were reported in toxicology studies in Switzerland (Brenneisen,

1997; Uchtenhagen *et al.*, 1999). Fewer mild side-effects were reported by patients receiving injectable or oral heroin compared to those receiving methadone or morphine (Uchtenhagen *et al.*, 1999). The Dutch trial found that the incidence of serious side-effects was comparable to patients receiving oral methadone (van den Brink *et al.*, 2002).

Prescribing is safe for clinic staff

Incidents of negative behaviour by patients directed at clinic staff (e.g. disputes, aggression, violence) are no different from other treatments (Uchtenhagen *et al.*, 1999; van den Brink *et al.*, 2002).

Prescribing heroin does not pose problems for the community

Neither the Dutch nor the Swiss trials experienced any serious public order or safety problems in the surrounding neighbourhood (Uchtenhagen *et al.*, 1999; van den Brink *et al.*, 2002). Studies in the UK found little or no public order problems. A few patients were found to be injecting their drugs in the local vicinity and were then given the opportunity to inject at the clinic (Metrebian *et al.*, 2001).

Prescribed heroin is not diverted to the black market

In the UK, heroin is prescribed for take-home consumption. To date, there is little evidence that prescribed heroin is diverted onto the illicit market. However, with unsupervised consumption, diversion might become a problem if the provision of prescribed heroin is substantially increased. In Switzerland and in the Netherlands, consumption is supervised and diversion is not a major issue.

Patients can be maintained on a stable dose of heroin

It appears that most patients can be maintained on a stable non-increasing dose. The Swiss trial showed that, after the first few months, doses were more likely to decrease than increase and that patients were stabilised on between 500 and 600 mg a day (Uchtenhagen *et al.*, 1999). In the UK (Metrebian *et al.*, 1998) and in the Dutch and Swiss trials, additional oral methadone was generally prescribed to stop night-time withdrawal and reduce the number of times patients needed to inject heroin. Overall, doses of heroin prescribed are much lower in the UK than in Switzerland and the Netherlands (see Table 6).

2 Attraction and retention of target group

It is uncertain whether heroin prescribing attracts more drug users into treatment

There has been no research to examine whether prescribing heroin attracts patients into treatment. Metrebian *et al.*'s study (1998) and

the Swiss randomised controlled trial (RCT) (Perneger *et al.*, 1998) both took some time to recruit patients to participate in the trials, suggesting that there was no 'honey-pot' effect. In Switzerland, the regime of supervised consumption may have discouraged some patients from applying for the trial.

It does not appear to discourage patients from accepting oral methadone treatment

Metrebian *et al.* (1998, 2001) found that, offered the choice between receiving injectable methadone or heroin, one-third of patients chose methadone, indicating that heroin is not always the drug of choice. The 200 mg per day upper limit imposed on both methadone and heroin prescriptions resulted in a potentially greater dose of methadone being offered than for heroin (it is usually in the region of 60 mg) and this may have influenced patient choice. Many patients who chose methadone reported that they did not want to inject frequently (which they felt they would have to do if they were receiving a prescription for heroin due to

Table 6 Daily doses of heroin

	UK	Switzerland ³	Netherlands ⁴
Regulation or guideline	No upper limit	None	1000 mg daily and no single dose greater than 400 mg
In practice	Range 5–1,500 mg ¹ Mean 175 mg ²	500 mg for injectable heroin 1,000–1,850 mg for smokeable heroin	Mean 549 mg for injectable heroin Mean 539–47 mg for smokeable heroin

Notes:

¹ Metrebian *et al.* (2002)

² Strang and Sheridan (1997)

³ Uchtenhagen *et al.* (1999)

⁴ van den Brink *et al.* (2002)

heroin's shorter half-life). Research from Switzerland found that, of those discharged from treatment after one year, 37 per cent left to receive oral methadone (Rehm *et al.*, 2001).

Patient retention in treatment is equal to or better than for methadone treatment

UK research indicates that prescribing heroin helps retain more drug users in treatment than oral methadone. Hartnoll *et al.* (1980) in a randomised controlled trial found at 12 months that a greater proportion of patients were retained in heroin treatment than in oral methadone treatment (74 vs. 26 per cent). Similarly, McCusker and Davies (1996) found that only one of 27 patients in a heroin group left treatment during the six-month follow-up period compared to 14 of 39 in the methadone group. However, the groups were receiving treatment from different drug clinics, thus differences may have been due to the differences in the way treatment was delivered, rather than to the drug prescribed. Metrebian *et al.* (1998, 2001) found that those prescribed heroin were more likely to remain in treatment at 12-month follow-up than those on injectable methadone (59 vs. 48 per cent). However, the number of patients studied was small and, while both groups received similar treatment, drug users were able to choose their treatment rather than being randomly allocated to treatment. Thus, it is possible that any differences in outcome between the two treatment groups may be attributable not merely to the differences in their treatment regimes but also to other factors (e.g. differences in personal characteristics, previous drug history, etc.). Moreover, the overall retention rate at 12 months was higher than that reported

by the National Treatment Outcome Research Study of oral methadone maintenance programmes at 12 months (59 vs. 38 per cent).

None of the UK studies required supervised consumption of heroin. Trials that had supervised consumption provide conflicting results.

The Swiss heroin trial found that 70 per cent were retained in treatment at 12 months, but there was no comparison oral methadone treatment (Uchtenhagen *et al.*, 1999).

The Dutch heroin trial found that those prescribed injectable heroin were only marginally less likely to be retained in treatment than the methadone group and those who were prescribed heroin for inhalation were less likely to remain in treatment than the methadone group (van den Brink *et al.*, 2002).

3 Effectiveness – at an individual level

Illicit use of heroin and other drugs decreases but is not eliminated

All studies found that illicit drug use (reported by urinalysis and self-report) reduces during treatment and (where available) by comparison to controls, but was not eliminated in all patients. Both Hartnoll *et al.* (1980) and Metrebian *et al.* (1998) found that illicit drug use was reduced but not eliminated. The Swiss trial showed significant reductions in illicit drug use among those still in treatment but there was no control group to assess whether similar findings would have been found with oral methadone. However, the RCT (Perneger, 1998) conducted in Switzerland found that, at six months, none of the study patients receiving heroin was using illicit heroin on a daily basis, compared to nearly half of those on the waiting list (many

receiving oral methadone). The Dutch trial (van den Brink, 2002) found similar results; at 12-month follow-up, only half the study participants receiving heroin were using illicit drugs.

Health improves

Hartnoll *et al.* (1980) found no evidence of improved health with heroin prescribing, although HIV was not an issue at the time the study was conducted. Recent studies have measured physical health symptoms, mental health, overdose and risk of infection with blood-borne viruses (HIV, HBV, HCV). Most find health improvements but the lack of controls makes definitive conclusions difficult. Metrebian *et al.* (1998) found significant improvements in health but the lack of control group makes it impossible to know whether similar gains would have been made had study participants been receiving oral methadone. The Swiss trial found improved health but, again, had no control group receiving oral methadone (Uchtenhagen *et al.*, 1999). However, the Swiss RCT did find health improvements (Perneger *et al.*, 1998). The Dutch trials found that, at 12 months, health had improved significantly more in the heroin group than in the methadone group (van den Brink *et al.*, 2002).

Social functioning improves

Findings from the Swiss trial showed that, at 18 months, patients' accommodation situation had improved, there was a nearly twofold increase in number of patients achieving permanent employment and a decrease in the numbers of patients regularly in contact with other drug users (Uchtenhagen *et al.*, 1999). The Dutch trial and studies in the UK found similar results. However, substantial numbers of patients

remained unemployed (Metrebian *et al.*, 1998; van den Brink *et al.*, 2002).

Patients commit less crime than before being prescribed heroin

Hartnoll *et al.* (1980) and Metrebian *et al.* (1998) found that crime reduced but was not eliminated. The Swiss trial (Uchtenhagen *et al.*, 1999) showed that self-reported criminal activity progressively reduced and, 12 months after entering treatment, the majority of patients had no convictions while in treatment. The Dutch trial found similar results; at 12-month follow-up, only half the study participants receiving heroin were involved in crime (van den Brink *et al.*, 2002). Again, those in the heroin group had reduced their criminal behaviour, but criminal behaviour remained high among the control group. All studies found crime had reduced compared to levels at entry to treatment and where available to controls.

Patients tend not to switch to methadone or oral routes of administration particularly when injecting is unsupervised

There is little evidence to suggest that prescribing heroin will help change drug users' route of administration from injecting to oral routes. Hartnoll *et al.* (1980) found that the majority of the heroin group continued to receive a prescription for an injectable drug. Similarly, Metrebian *et al.* (1998) found that only a few patients changed from injecting to oral methadone use. Other UK research found that one-third of a sample of drug users prescribed heroin by the early London drug clinics were still receiving a prescription for heroin seven years later (Thorley *et al.*, 1977). These UK studies suggest that prescribing heroin without regular supervised injection might reduce the

motivation to stop injecting. However, research from Switzerland found that of those discharged from treatment by one year, 30 per cent moved on to other treatments.

It is not clear who does best on the treatment

The research evidence comes from patients with long injecting careers who have previously tried and not been significantly helped by oral methadone treatment. It is not known which problem drug users would most benefit. Most studies have not been designed in a way that can answer this question.

4 Effectiveness – at a community level

There is no evidence that the current extent of heroin prescribing undercuts the illicit market in drugs or reduces drug scenes

Studies have used only individual measures of illicit drug use and have shown that prescribing heroin reduces illicit drug use; there is thus a potential impact on drug markets and drug scenes. However, as the number of patients prescribed heroin remains small, the overall effects on the drug markets is likely to be difficult to measure.

5 Costs and cost-effectiveness

Prescribing heroin is more expensive than methadone

Assuming that other services continue at the same level, i.e. that a person on heroin needs the same amount of staff time and other resources as a patient on methadone, then the main costs that vary are those of the drug itself and the extra costs for the supervision of injecting or smoking the drug. Current information suggests that the price range for prescribing methadone per patient, per year ranges from £1,320 to

£3,550 in developed countries (Centre for Addiction and Mental Health, 2002; Ministry of Health, 1996; National Evaluation Data Services, 1999; National Institute on Drug Abuse, 1999; Netten and Curtis, 2001; Substance Abuse and Mental Health Services Administration, no date). In the UK, the total costs per patient per year of £2,800 include capital and revenue costs of £36 per patient per week and methadone costs of £18 per patient per week. Figures are not available separately for oral and injectable methadone.

In the Swiss trial, the annual patient cost for a patient receiving heroin was £8,030 (Gutzwiller and Steffen, 2000) and, in the Netherlands, between £9,775 and £17,109 (van den Brink *et al.*, 2002). These costs included labour, medical material, substitute drugs, laboratory costs, rent, maintenance, energy and administration, including depreciation. This is substantially higher than costs for methadone, but the trials required special facilities (e.g. in the Netherlands, separate heroin injection and inhalation rooms, each with specific technical requirements), which were resource intensive with daily visits by patients for supervised consumption.

In the Dutch heroin trial, the main costs were for nurses (around 30 per cent of costs). Nurses were required to be present to supervise the self-administration of heroin by the patients. Based on a minimum presence of two nurses during the opening hours of a treatment clinic, with working hours from 7.30 a.m. to 8.30 p.m., and taking into account weekends, leave/holidays and sick-leave, a minimum of seven full-time nurses is required for a small treatment clinic. The costs of heroin itself were relatively low, at £1,200 per person per year.

What might it cost to prescribe heroin in the UK?

The additional cost of prescribing heroin over the standard treatment – methadone – comprises two components, the additional price of the drug and the additional cost of supervised consumption. Current drug costs could be misleading if heroin provision were expanded. In the UK, heroin is available from a sole supplier. The Department of Health could negotiate a better price from the manufacturer. Heroin is not covered by patent, there are no pharmaceutical research costs to recoup and it is derived from a plant product that is itself cheap (see Table 7).

Is it cost-beneficial?

The Swiss trial suggests that the benefits of heroin on prescription outweigh the treatment costs. For every franc invested, there was a benefit of CHF1.75. However, as cost data were easy to obtain and benefits were often estimated, it considers that the programme might have a higher cost benefit ratio of

between three and five. The cost of prescribing heroin is counterbalanced by savings for the health sector in general (decrease in medical and hospital costs), as well as the criminal justice and employment sectors. Findings from the Swiss trial show that the number of offences committed while receiving heroin decreased leading to a reduction in crime rates. In turn, this led to cost savings to criminal justice (fewer judges, policemen and prison wardens were required). The number of days in employment increased while receiving a prescription for heroin, leading to an increase in the amount of productivity and wages received.

It is uncertain if it is more cost-effective than methadone

There are no data on comparative cost-effectiveness of heroin compared to methadone. But, at an estimated cost of £7,717–£9,691 per patient per annum compared to £2,800 for methadone (excluding supervised consumption), its advantages need to outweigh the additional cost.

Table 7 Estimated annual cost of prescribing heroin per patient in the UK

Cost	Per annum (£)
Capital and revenue buildings and land, equipment, staff, supplies and services, site and agency overheads) ¹	1,872
Supervised consumption for first 3 months ²	987–2,961*
Drug costs – assuming 175 mg per day	4,858
Total	7,717–9,691

Notes:

¹ Netten and Curtis (2001)

² Strang *et al.* (2000)

* Lower cost based on cost of supervising one injection of methadone a day; upper cost inflated pro-rata for three injections of heroin a day

Conclusions

The evidence base is relatively weak – with only a few studies, and only four with control groups for comparison. Therefore, only cautious conclusions can be drawn about the merits of prescribing heroin.

That said, it appears that prescribing heroin is feasible in specialist clinical settings, that it succeeds in retaining people in treatment and that there are health and social gains. Patients improve in most areas – physical and mental health are noticeably better, illicit drug use and crime are reduced, and employment increases. But problems are not eliminated. Individual benefits have been identified in most studies, but there are no data on community impact (e.g. the overall effect on crime and drug scenes).

This evidence is based on information about long-term injectors and smokers for whom other treatments have failed. There are no data on what benefits would be found with other patients, or about who would most benefit from

this treatment. There is no information on whether the availability of a heroin treatment attracts more people into treatment.

Prescribing heroin costs more than prescribing methadone but it may be cost-beneficial. However, it is unclear whether the benefits of prescribing heroin outweigh the additional costs when compared with methadone.

A cautious assessment of the evidence suggests that heroin is potentially an effective treatment for some patients, but that this has not yet been conclusively proven. Any expansion in the provision of heroin prescribing must be monitored and properly evaluated. The government interest in expanding the provision of heroin provides the opportunity to do this. We have lost many opportunities to conduct research on the effectiveness of prescribing heroin in the UK – and it would be unfortunate if we lost this new chance to do some definitive work.

5 Challenges for expanding heroin prescribing

If heroin prescribing were to increase, how could this be done?

This chapter:

- shows that heroin prescribing in the UK lacks a clear plan
 - examines who would want to prescribe it, what kinds of heroin would be prescribed and how it would be prescribed
 - argues that it is essential that any government plan to increase heroin prescribing has to be accompanied by rigorous evaluation and assessment.
-

Prescribing heroin: a treatment without a plan

The current prescribing of heroin in the UK is inconsistent and arbitrary. In spite of 80 years of prescribing heroin to opiate addicts, no consensus exists about who should be treated and what benefits heroin prescribing might be expected to achieve.

Despite the UK being one of the few countries where heroin can be prescribed for the treatment of opiate dependence, most doctors don't want to prescribe it. Few people dependent on illicit heroin receive prescriptions for it. Even doctors with Home Office licences to prescribe heroin are, with a few exceptions, reluctant to initiate prescriptions for heroin. For dependent heroin users, the odds of getting a prescription for heroin are low, and are often determined by place of residence and the inclinations of the doctor providing treatment at the local drug service.

Furthermore, heroin as a treatment for opiate dependence has not been properly researched or evaluated in the UK; as the Audit Commission (2002) concluded, the current provision of

heroin has grown up in a haphazard way and is not part of any plan. In the past, this typically British way of muddling along may have had the merits of flexibility and innovation, and of being a welcome counterbalance to an over-bureaucratized health service. But the current muddle reflects a lack of vision and direction. In the twenty-first century, both heroin-dependent patients and the public deserve high quality, accessible and equitable drug treatment services. The costs to society – both in terms of public health and crime – are too great to ignore this challenge.

The *Updated Drug Strategy* aims to improve access to prescribed heroin for those with a clinical need for it (Home Office, 2002, p. 11).

While the willingness of the government to favourably consider the idea of prescribing heroin is to be welcomed, a major stumbling block is the lack of evidence of what might constitute 'clinical need'. It appears that doctors have one goal of treatment (the health of the drug user and their freedom from addiction) and policy makers hold different goals (the needs of society as a whole), hence their interest

in providing heroin as a risk-reduction strategy and more recently to reduce crime. In order to persuade the doctors to prescribe heroin, the policy makers need to make a strong argument for its clinical efficacy. Because of the dearth of research in this field, the questions of who might benefit, and in which circumstances, remain unanswered. Without this evidence, doctors may remain reluctant to prescribe heroin.

Unless there is a clear strategy for increasing the provision of heroin across the UK to ensure that all eligible drug users have access to this treatment, the inconsistent and haphazard nature of prescribing will continue. If heroin on prescription is to be made available to all those who need it and if it is to play a role in the way we treat drug problems, it has to be done well. That means that it has to be introduced, where now unavailable, and expanded, where currently available, in a systematic manner, and subject to scrutiny and evaluation.

There must be some clear plan of action. This should include objectives that specify:

- the aims of prescribing heroin (what it hopes to achieve)
- patient eligibility criteria (those who are most likely to be in need and to benefit)
- outcome criteria against which such a plan can be assessed – objectively verifiable indicators that indicate whether the plan is on track.

Clinical guidance: a necessary but insufficient response

The Home Office has indicated that the current guidance on prescribing heroin may be too restrictive (Department of Health, 1999).

Therefore, the National Treatment Agency has developed new clinical guidance on heroin prescribing (National Treatment Agency, 2003).

The new guidance was informed by an expert group including clinicians, researchers, service users and policy advisers. The expert group reached some consensus about good practice based on current experience and the limited evidence from outside the UK.

The guidance – which covers both injectable heroin and injectable methadone – states that ‘The prescribing of injectable substitute opioid drugs for maintenance may be beneficial for a minority of heroin misusers’ (p. 3). It gives guarded endorsement to prescribing heroin, within a range of stepped prescribing options, where optimised oral methadone maintenance treatment should be the treatment for the majority of heroin users. It states the first priority is to improve the effectiveness of oral methadone maintenance.

The NTA recommends that injectable heroin or methadone should be considered only for a minority of patients who do not respond to ‘optimised’ oral methadone maintenance. The eligibility criteria suggest that heroin should be prescribed as a treatment of last resort – patients should have a history of more than three years of heroin dependence and regular daily injecting, have previously received optimised oral methadone treatment for at least six months, and have failed to respond to this treatment.

The NTA states that new maintenance prescribing of injectable drugs should only be undertaken in accordance with eight principles. Pilot centres for new types of injectable maintenance drug treatment will be established in line with these eight principles.

The guidance does not cover non-injectable forms of heroin, does not give guidance on doses, and does not advise on the choice between injectable heroin and injectable methadone.

National Treatment Agency for Substance Misuse – principles for prescribing heroin and injectable methadone

- 1 Drug treatment comprises a range of treatment modalities which should be woven together to form integrated packages of care for individual patients.
- 2 Substitute prescribing alone does not constitute drug treatment. Substitute prescribing requires assessment and planned care, usually with psycho-social interventions. It is one element within wider packages of planned and integrated drug treatment.
- 3 A range of substitute prescribing options are required. Patients should be offered options in a series of steps, including optimised oral methadone, before injectable methadone or injectable heroin maintenance treatment is tried.
- 4 Injectable maintenance options should be offered in areas that can provide optimised oral methadone maintenance treatment including adequate doses, supervised consumption and psycho-social interventions.
- 5 Injectable and oral substitute prescribing must be supported by locally commissioned and provided mechanisms for supervised consumption.
- 6 Injectable maintenance treatment is likely to be long-term treatment with long-term resource implications. Clinicians should consider the long-term implications for patients and services.
- 7 Specialist levels of clinical competence are required to prescribe injectable substitute drugs. Heroin prescribing also requires a Home Office license.
- 8 The skills of the clinician should be matched with good local systems of clinical governance, supervised consumption and access to a range of other drug treatment modalities.

There is need for further work around identifying the most effective models of delivery.

(Summarised from: National Treatment Agency, 2003, p. 4)

Guidance is necessary, but, on its own, it is insufficient because it is inevitably constrained by the current lack of a good UK evidence base. Moreover, it is, in any case, a poor lever for change, having teeth only when bringing aberrant prescribers into line. It is unlikely in itself to encourage more doctors to prescribe.

Practical issues

Who might be prescribed heroin?

If heroin is to be prescribed to heroin users with a clinical need, there need to be agreed patient eligibility criteria and an agreed rationale as to why and how they would benefit from receiving such a prescription.

The current state of evidence does not help answer the question 'how many people might have a clinical need for heroin?'. A needs analysis should be undertaken to assess how many people might benefit from a heroin prescription under different eligibility criteria.

There is general consensus (as indicated by the NTA) that heroin could be prescribed as a 'treatment of last resort' for those who do not respond sufficiently well to other treatments, i.e. problem heroin users with long injecting careers, who have tried and not significantly improved with other treatments such as oral methadone and who will not stop injecting. To date, all the research evidence is based on this group of heroin users.

The pathway into heroin treatment could be by transferring on to heroin those currently receiving other treatment (e.g. oral or injectable methadone) but who have failed to obtain benefits from it, or by attracting back into treatment those who have tried previous

treatments and not been significantly helped by them.

Consideration could also be given to heroin being prescribed in order to attract heroin users into treatment for the first time. There is a considerable time lapse between developing a drug problem and seeking help, and there are heroin users who have never presented for or received treatment but who have a long history of illicit heroin use and/or injecting. Prescribing heroin might attract people into treatment for the first time sooner than hitherto. It would be a 'bait' to establish first contact – and could perhaps be used as a prelude to other treatments (e.g. methadone). So far, however, there is little support for this idea of a 'treatment of first resort' among doctors in the UK. To date, there is no research evidence about the potential efficacy of this treatment for this group of heroin users. However, the heroin trial currently being conducted in Germany (Krausz, 2001) plans to include heroin users who have been using heroin for many years but who have not had any previous treatment experience.

Who would prescribe it?

How could the numbers of patients receiving a prescription for heroin be increased as part of a monitored and evaluated strategy? This is likely to present a human resources problem.

There are about 85,000 doctors practising in the NHS in the UK, of which about 30,000 are general practitioners. There are 2,861 consultant psychiatrists, but, in 1999, there were only about 90 consultants in the UK with a primary or secondary interest in substance misuse (Royal College of Psychiatrists, 2002).

The Dutch heroin trial – the need for training

Supervised co-prescription of heroin to chronic, treatment-resistant heroin-dependent patients is a complex treatment with potent pharmacological compounds in patients with high levels of somatic and psychiatric co-morbidity. Therefore, a state-of-the-art treatment requires adequate medical and addiction training, and an adequate medical staffing in terms of both physicians and nurses. In addition, adequate drug accountability has to be secured. Finally, adequate possibilities for counselling, psychotherapy and rehabilitation should be available.

(van den Brink *et al.*, 2002, p. 154)

In 2000, only 70 doctors had licences to prescribe heroin, and only 46 prescribed heroin. Our survey (Metrebian *et al.*, 2002) found that many doctors with licences were reluctant to prescribe heroin, and many who were eligible for a licence did not want one.

There are several options.

- *Increase the numbers being treated by those doctors who currently prescribe. But, as we have shown, only half of these have initiated prescriptions for heroin, and the rest are reluctant to prescribe to new patients and restrict themselves to prescribing to those whose heroin regime was initiated by others. More of these doctors would need to agree to initiate prescriptions for heroin. Geographical variations in prescribing would continue to persist.*

- *Increase the number of doctors with licences who actually prescribe heroin. Only 46 out of 70 licensed doctors were prescribing heroin in 2000. But, given their current reluctance to prescribe heroin, it is unclear what would persuade them to change.*
- *Increase the number of consultant psychiatrists who can prescribe heroin, which would require expanding the number of psychiatrists with a specialist interest in substance misuse.*
- *Extend the licensing system to include general practitioners. About 50 per cent of GPs in England have seen a drug user in the last month and 25 per cent have prescribed methadone (Home Affairs Committee, 2002a, p. 50). The Home Office has indicated that it sees the expansion of heroin prescribing occurring through the expansion of the number of doctors licensed to prescribe it, including general practitioners (Home Affairs Committee, 2002a). However, a problem with this option is that the Royal College of General Practitioners has already come out against GPs doing this.*

Doctors clearly have the right not to deliver treatments on ethical or religious grounds: the problem for equity of NHS provision arises when doctors have a local monopoly of treatment – as is usually the case in addiction services. Mechanisms would need to be found for the NHS through the National Treatment Agency to ensure that heroin prescribing is one of the treatments available in each area.

How would prescribing it be monitored?

There are currently no monitoring mechanisms to generate useful information on current prescribing of heroin. Expanding the provision of heroin prescribing would need to be accompanied by routine information gathering on who is prescribing what to whom, perhaps as part of a regulatory framework.

What kinds of heroin would be prescribed?

The debate about heroin prescribing in the UK has been confined mainly to injectable heroin. But nearly half of the drug users coming to treatment do not inject. It seems perverse to discuss making heroin available only to injectors, given that the risks to health of using heroin are greater when heroin is injected than when smoked. There are also good grounds for encouraging current smokers not to switch to injecting, and to persuade current injectors to stop injecting and switch back to smoking heroin.

Individual and public health gains might therefore come from prescribing smokeable and inhalable heroin. But how could pharmaceutical-grade smokeable heroin be made available and consumed? Some doctors prescribe heroin reefers using diamorphine hydrochloride dissolved and injected into cigarettes. These are inefficient with low bio-availability of heroin. In the Dutch trials, powdered heroin was offered for smoking ('chasing') using diamorphine base mixed with caffeine. This was found to be feasible and effective. A further option is to try other delivery systems such as an aerosol inhalation.

Daily doses prescribed in the UK are lower than those in the Dutch and Swiss trials. This may reflect both a reluctance to prescribe and

the high cost of the drug. Studies need to be conducted so as to arrive at suitable doses. Current evidence indicates that methadone would also need to be prescribed in tandem with heroin in order to prevent night-time withdrawal.

Should consumption be supervised?

The Department of Health recommends that consumption of substitute drugs should be supervised daily for at least the first three months of treatment to ensure treatment compliance, and reduce diversion and overdose. Supervision is relatively easy with oral medications such as methadone. Daily consumption can be observed by clinic staff if the drug is dispensed on site, or by a community pharmacist. This might be inconvenient for a patient in relation to employment and travel, but the ingestion itself takes only a few moments.

Supervising injecting or smoking is more difficult. Both take longer, require privacy and, in the case of smoking, the staff might inhale slipstream smoke. In the Netherlands and Switzerland, special injecting rooms were built and, in the Netherlands, the smoking room had lower air pressure than outside to prevent escape of smoke. In addition to construction and space costs, the main cost is the 30 minutes or so of staff time for observing each patient, and the fact that patients consuming heroin need to come in two or three times a day. The facility needs to be open for longer hours than would be normal in a UK drug clinic, and possibly at the weekends (unless weekends were exempted from daily supervision). If one of the aims of treatment is to facilitate a return to 'normal life', the need for the patient to attend two or three

times a day is likely to be a serious obstacle, at least in the short term).

Illicit heroin is easily available and many drug users are not coming forward for treatment. Any provision of heroin prescribing needs to be delivered with few barriers to treatment to ensure it remains an attractive treatment option that will catch the attention of and retain drug users. Regular supervision of injecting might be a barrier to treatment.

A vision and a strategy

Studies in other countries provide useful information about heroin prescribing but, since the treatment context is different, it is unclear how far this can be applied to the UK situation. It is ironic that undertaking such studies is easier in Britain than in any other country and yet these studies have not been conducted.

Heroin prescribing should not be expanded in an *ad hoc* manner. Evaluating pilot centres might provide some further evidence of feasibility of different models of care, but will not deliver evidence about effectiveness. The priority must be for a multi-centre, randomised, controlled trial comparing heroin against standard treatment. The UK has a poor track record in treatment research – in part, a

reflection of the overall under-funding of research on drug problems. For every £995 spent on responding to drugs, only £5 is spent on research. There can be little benefit from expanding the provision of heroin unless it is monitored and evaluated. We still need answers to questions about who benefits, in what way, at what cost and whether these benefits exceed those of standard substitute treatment (oral methadone).

Implementing this strategy will require clear commitment. It will require a continuation of political will – mainly from the Home Office, clinical and commissioning guidance from the National Treatment Agency, treatment resources from the Home Office and the Department of Health, the enthusiasm and support of the medical profession, support from local Drug Action Teams and commissioners. It will require major research funding to ensure that it is properly evaluated.

An increase in the provision of heroin and an evaluation of the part it can play in treating people with heroin problems is well overdue. It would be a clear failure of vision if, ten years ahead, we still have the same vague system and the same unanswered questions about the effectiveness of prescribing heroin.

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Appendix: Summary of studies of the effectiveness of prescribing heroin

Studies in the UK

Stimson *et al.*

This study was based on a randomly selected sample of one in three heroin users attending the first London drug clinics and being prescribed heroin in 1969 (Stimson and Ogborne, 1970; Stimson and Oppenheimer, 1982). Heroin was then the standard treatment for opiate dependence. Patients were followed up at seven, ten and 22 years. Heroin users' lives and addiction careers, their experiences at the drug clinics and the operational problems of the clinics were examined. Contrary to the belief that heroin addicts were a homogeneous group, great differences between them were found and these characteristics were associated with treatment outcome. A minority of patients were stable on their heroin prescription. They suffered fewer social and physical complications of addiction, were more likely to be legally employed and to avoid other drug users, and were less likely to use illicit drugs or to be involved in any criminal activity. The majority had more chaotic lifestyles. They were often unemployed and had higher involvement in crime, spent more time with other drug users and used more illicit drugs. At six years' follow-up (Thorley *et al.*, 1977), 51 per cent were still in treatment, 40 per cent were alive and not attending treatment and 9 per cent were dead. One-third were still receiving a prescription for heroin.

Hartnoll *et al.*

The first and only heroin trial in the UK was conducted at a London drug dependence clinic in the 1970s (Hartnoll *et al.*, 1980). Ninety-six opiate-dependent injecting drug users

requesting heroin were randomly allocated to receive either injectable heroin or oral methadone maintenance and followed up at 12 months. Heroin and methadone doses ranged from 40 to 80 mg per day. Drug consumption was not supervised. Almost all patients receiving heroin continued to inject regularly and the majority continued to obtain illicit drugs, although usually in small quantities. The majority remained in contact with other drug users and were involved in drug-related activities, although less intensively than before they received heroin. Those receiving oral methadone tended to move to one extreme or another. They had a higher drop-out rate than the heroin group, but they were more likely to become abstinent or near abstinent. On the other hand, those who continued to inject and use drugs were obtaining larger quantities of illicit opiates than those receiving heroin. The methadone group either ceased drug-related activities or were using lots of drugs and were heavily involved in the drug scene. The authors concluded that the results did not indicate a clear overall superiority of either treatment. Both had advantages and disadvantages. Oral methadone discouraged illicit drug use but there were a group of people for whom it failed and they continued to be heavily involved in drugs. Heroin encouraged continued drug use and would lead to larger steadily accumulating clinic populations.

McCusker and Davies

Similarly inconclusive results were found in a case control study of 27 drug users receiving injectable or smokeable heroin and 39 receiving

oral methadone from drug clinics in the North West of England (McCusker and Davies, 1996). The two groups were matched for age, gender, length of time using opiates and length of time receiving their current treatment. The heroin group were first interviewed an average of 11 months after first receiving their treatment and the methadone group after nine months. Both groups were interviewed again six months later. The mean dose was 253 mg per day for heroin and 72 mg per day for oral methadone. The heroin group – compared with those on methadone – were better retained in treatment, used less illicit heroin, shared injecting equipment less often, were less likely to be involved in criminal behaviour, spent less money on illicit drugs and had better psychological health. The heroin group were less likely to have abstinence as a treatment goal and more likely to be using cocaine than the methadone group. There were no significant differences between the groups in their use of illicit non-opiate drugs and physical health.

Metrebian *et al.*

In an observational study of prescribing heroin at a West London drug clinic, 58 long-term opiate-dependent drug injectors who had previously tried and failed oral methadone treatment were offered the choice to receive either injectable heroin or injectable methadone. They were followed up for 12 months (Metrebian *et al.*, 1998, 2001). One-third (21) chose to receive methadone, the other two-thirds (37) opting for heroin. Overall, 57 per cent were retained in treatment at 12 months; with the heroin group better retained in treatment than the methadone group (59 vs. 48 per cent). Significant reductions in illicit drug use,

criminal behaviour and improvements in health and social status were found in the first three months of treatment for both groups. These improvements were sustained between three and 12 months. Two subjects progressed to oral methadone treatment and one became abstinent. There was no significant difference in treatment outcome between the heroin and methadone group. The authors concluded that prescribing injectable drugs was a feasible treatment option. Drugs were dispensed at the clinic daily, with weekend doses taken home for the first few weeks and less frequently thereafter. Patients were not able to inject on site. To reduce the risk of diversion, subjects had to return used ampoules and batch numbers were checked before receiving further ampoules.

Swiss heroin trials

Uchtenhagen *et al.*

Between 1994 and 1996, a series of studies to examine the effectiveness of prescribing injectable and smokeable heroin, injectable methadone and injectable morphine were undertaken in Switzerland (Uchtenhagen *et al.*, 1996, 1997, 1999). The research was conducted as a result of the concern for the high numbers of dependent drug users in Switzerland and the high prevalence of HIV infection. Switzerland has a relatively well equipped and diversified system of treatment for dependent heroin users but a large group of dependent heroin users were either not in contact with drug services or had tried and failed them. The objectives of these studies were to examine the effects of these drugs on the health, social integration and drug-related behaviour of long-term heroin-

dependent drug users who had tried and failed previous drug treatments. The studies included two double-blind studies (so called because the prescribed drug is not known to either the patient or the doctor), two randomised studies (where patients were randomly allocated to treatments) and 11 studies where the patient was allocated to treatment based on clinical assessment and patient choice. Moreover, the viability of prescribing heroin was studied at three methadone out-patient drug clinics and one prison.

The analysis of the effectiveness of heroin was based on a cohort of 800 subjects receiving heroin in a number of treatment centres throughout Switzerland. (While this study was technically not a trial – it did not randomise patients to treatment and had no comparison group – it has always been referred to as a trial.) Heroin was dispensed three times a day, seven days a week, from selected drug clinics for supervised injection on site in designated injecting rooms. The mean daily dose was 500 mg. Multidose ampoules containing 500 mg and higher multidose ampoules of 10 g (10,000 mg) were produced. Injecting equipment was provided by the clinics in the injecting rooms. Treatment involved a prescription for one of the above drugs with psycho-social interventions (counselling, social work, etc.).

At 18 months, 69 per cent of subjects were retained in treatment and the mortality rate was 1 per cent per year. There were significant reductions in illicit drug use and criminal behaviour, and significant improvements in physical and psychological health, and in social functioning. At 18 months, illicit heroin use reduced from nearly all subjects reporting daily use to 26 per cent reporting daily use. Cocaine

use reduced from 85 per cent using at the start of the trial, to 59 per cent at 18 months. At 18 months, criminal behaviour reduced from 69 per cent reporting income from illicit sources to 10 per cent. Police records and official crime statistics verified self-reported criminal activity.

Health improvements included general and nutritional status and injection-related skin diseases, and psychological improvements were most notable in the areas of depressive states and anxiety states and delusional disorders.

There was a lack of control group (receiving oral methadone) for comparison. Therefore, even after this large study, it is not possible to conclusively answer the question of whether prescribing heroin to long-term dependent drug users is more effective than prescribing oral methadone. The researchers recommended a continuation of this treatment for 'chronic and marginalised heroin addicts who failed in other treatment modalities' and that 'similar conditions and safety controls as established for the study should be applied' (Uchtenhagen *et al.*, 1999). Heroin addicts have continued to be prescribed heroin in Switzerland and researchers have continued to collect data on their progress (Rehm *et al.*, 2001).

Perneger *et al.*

In a further study, in Geneva, 46 long-term dependent heroin users were randomised to either receive a prescription for heroin or were put on a waiting list where most received oral methadone (Perneger *et al.*, 1998). After six months, the heroin group showed significant reductions in illicit heroin use and criminal behaviour, and significant improvements in psychological health and social functioning compared with those on the waiting list.

Dutch heroin trial

van den Brink et al.

The Dutch heroin trial started in 1998 and was completed at the end of 2001. The primary objective was to evaluate the beneficial and harmful effects of maintenance treatment with oral methadone when patients were additionally prescribed heroin. Hence, the study is accurately described as a study of 'heroin co-prescription' – the patients continued to receive methadone and in addition were given legal heroin. Those in the heroin arm of the trial were compared with patients who received the standard maintenance treatment of oral methadone. Two randomised controlled trials were conducted, comparing (1) the co-prescription of inhalable heroin with oral methadone and (2) comparing the co-prescription of injectable heroin with oral methadone. This was a multicentre trial in eight centres in six cities. Patients in trial (1) were randomly allocated to receive (a) oral methadone for 12 months, or (b) methadone and inhalable heroin for 12 months, or (c) methadone for six months followed by methadone and inhalable heroin for six months. Patients in trial (2) were randomly allocated to either (a) methadone for 12 months or (b) methadone and injectable heroin for 12 months. All groups were followed up for a further six months. The consumption of heroin was supervised three times a day at the drug clinic. The mean dose of heroin prescribed was between 530 and 560 mg per day.

Heroin was seen as a treatment of last resort for a group of highly problematic heroin users (mainly smokers) within the methadone population. This trial recruited patients who were already in methadone treatment

programmes but who were doing badly, defined as chronic, treatment-resistant heroin addicts. The impact of the medical co-prescription of heroin was evaluated in terms of (a) improvement in the physical and mental status of the patients, (b) improvement in their social integration and social functioning, and (c) changes in their illicit drug use. Further study objectives included (a) a comparison of the effects of co-prescribed heroin given for six months' and 12 months' duration, and (b) an evaluation of the effects of the discontinuation of co-prescribed heroin after six and 12 months of treatment with co-prescribed heroin.

The primary outcome measure was at least a 40 per cent improvement in physical health, mental health or social functioning, and no increase in substance use and no deterioration of 40 per cent or more in any area. Patients with this outcome were called 'responders'.

At 12 months, in Trial 1, 87 per cent of the methadone group had completed treatment compared to 68 per cent of the co-prescribed inhalable heroin group. In Trial 2, 85 per cent of the methadone group completed treatment compared to 72 per cent of the co-prescribed injectable heroin group. However, patients receiving injectable heroin were able to switch to receive inhalable heroin; 33 per cent made this switch. After 12 months, 48 per cent of patients in the co-prescribed inhalable heroin group were 'responders' compared to 25 per cent in the methadone group. Similarly, 57 per cent of patients in the co-prescribed injectable heroin group were 'responders' compared to 32 per cent in the methadone group. Two months after discontinuation of the co-prescribed injectable or inhalable heroin treatment, the majority of 'responders' had deteriorated considerably.