

Heroin and methadone substitution treatments; Harm reduction and the effectiveness of 'flexible' prescribing for the treatment of opioid dependency.

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ABSTRACT

In the mid 1990's the UK government began to focus on problem heroin use mainly as a drug related crime issue, and so attracting and retaining clients became a treatment priority. The concept of flexible prescribing, matching individual clients to treatment programmes appropriate to their drug using history and circumstances, began to gain support amongst politicians and clinicians. As part of this shift in emphasis, prescribing heroin to heroin addicts re emerged as a treatment option. Injectable (and smokable) diamorphine (pharmaceutical heroin) began to be prescribed in a small number of drug dependency units under the direction of local psychiatrists, including two in North West England.

One hundred and thirty three registered drug users were interviewed between August 1995 and February 1997 using a structured questionnaire. Three key areas and their association with heroin substitution prescribing were addressed; levels of criminal activity, levels of illicit drug use, and a range of client held perceptions and attributions regarding coping/quality of life.

The mean age of the sample was 30 years, and 75% were male. 61% had used illicit heroin in the past month, spending on average £638, on a habit of 4g per week. Clients were subdivided on a number of variables and comparisons were made between groups according to (IV) prescription type (which drug), and form (injectable/smokable/oral mixture). Significant differences were found across each of three key variables, including differing levels of illicit drug use according to prescription form, and differing levels of specific criminal activity according to prescription type. Significant effects included; Clients on prescriptions which included ampoules were significantly more likely to report being able to cope with life, and spent significantly less time on drug taking activities, than those clients receiving other prescriptions. Clients on prescriptions which included 'reefers' (smokable) reported significantly less shop lifting than clients receiving other prescriptions.

It was concluded that the available empirical evidence regarding heroin prescribing is limited, and although some clinicians are yet to be convinced, it seems heroin does have its merits as a viable treatment option. Issues of cost and possible dispersion remain, and are discussed in relation to the continuing development of substitution treatment policy in the UK.

Heroin and methadone substitution treatments; Harm reduction and the effectiveness of ‘flexible’ prescribing for the treatment of opioid dependency.

Abstract	i
Contents	ii
Tables	v
Acknowledgements	vii
1. Chapter one: Introduction	1
1.1 Heroin and heroin use.....	2
1.1.1 Heroin	
1.1.2 Heroin use: Prevalence	
1.1.3 Heroin use: Consumption	
1.2 The British System. Key changes/influences in the approach to substitution treatment provision in the UK.....	7
1.2.1 Substitution treatment 1920-1960’s	
1.2.2 Substitution treatment 1970-1980’s	
1.2.3 Substitution treatment: The impact of HIV	
1.2.3.1 Flexible prescribing	
1.2.3.2 Injecting behaviour	
1.3 Recent developments in prescribing to those with an opioid dependency.....	24
1.4 Evaluating the effectiveness of heroin/diamorphine substitution prescribing.....	26
1.4.1 The evidence base	
1.4.2 Summarising the evidence	
1.4.3 NTORS	
2. Chapter two: Introduction to the Study	40
2.1 Context of the study: National prescription patterns.....	41
2.2 The North West Region.....	43
2.2.1 Prescription patterns 1995-2000	
2.2.2 Client data 1995-1997	
2.2.3 The clinics: Location and services	
2.2.4 The clinics: Prescription trends	ii

2.2.5	Pilot study: Injectable and smokable opiates	
2.3	Research Aims.....	53
3.	Chapter three: Methodology	55
3.1	Design.....	56
3.1	Script type	
3.2	Drug Use	
3.3	Crime	
3.4	Research Questions	
3.2	Participants.....	60
3.3	Procedure.....	61
3.3.1	Pilot Study	
3.3.2	Main Study	
3.4	Research Instrument/Materials.....	63
3.5	Methods of Analysis.....	65
3.6	Ethics.....	65
4.	Chapter four: Findings	66
4.1	Characteristics of the sample.....	67
4.2	Types of prescription.....	67
4.3	Client perceptions.....	71
4.4	Illicit drug use (and nicotine/alcohol).....	74
4.4.1	Total monthly drug cost	
4.5	Criminal activity.....	76
4.5.1	Drug dealing	
4.5.2	Script leaking/Dispersion	
4.5.3	Shoplifting	
4.5.4	Prostitution	
4.6	Crime and Drug use in combination.....	80

5. Chapter Five: Discussion

82

5.1

Overview.....

83

5.1.1

Key findings in relation to criminal activity

5.1.2

Key findings in relation to illicit drug use

5.1.3

Key findings in relation to client perceptions/attributions

5.1.4

Key findings in relation to crime/drug use combined

5.2

Interpretation of findings.....

89

5.2.1

Two dimensions of drug taking consequences

5.2.2

Findings in relation to previous research

5.2.2.1

Prescription factors

5.2.2.2

Client factors

5.2.2.3

Socio-Economic factors

5.3

Critique of methodological approach.....

101

5.3.1

Complexity of design

5.3.2

Representativeness of sample

5.3.3

Measuring and reporting effectiveness

5.4

Implications for prescribing policy and practice.....

105

5.4.1

Government policy for heroin prescribing

5.4.1.1

Potential problems: GP co-operation

5.4.2

Implications for policy and services

5.4.3

Implications for treatment

5.5

Heroin use in the mid 2000's – prevalence characteristics.....

110

5.6

Conclusions

References.....

112

Appendix.....

126

Appendix One: Research Questionnaire.....

126

Appendix Two: Raw Frequency Data.....

137

TABLES

Chapter One - Review of The Literature

Table 1.1: Numbers of drug offenders and notified drug addicts in Britain, 1975-2000	4
Table 1.2: Purity of illicit powder drugs in England & Wales; Police seizures, 1984-2003	6
Table 1.3: Retail price (£) of illicit drugs, UK, 1997-2000	7
Table 1.4: The arguments concerning the prescription of heroin.	15
Table 1.5: Bi-annual number of PDUs, 1993-2001; and (a) percentage of PDUs who are <i>injecting drug users</i> (IDUs); (b) percentage of IDUs <i>sharing injecting equipment</i> in past month (SIE)	20
Table 1.6: Annual number of drug offences, by heroin and methadone – UK, 1973-2002	22
Table 1.7: Summary of Outcome differences between IH and OM clients after 12 months (Hartnoll et al 1980)	28
Table 1.8: Estimated annual cost of prescribing heroin per patient in the UK	37

Chapter Two - Introduction to the study

Table 2.1: Percentage of agencies with Home Office Licences to prescribe opiates, March-June 1995	42
Table 2.2: Mean dose prescribed by UK Community Pharmacies 1995	43
Table 2.3: prescribing action for new clients in north west region, 1995-2000 (drug misuse database)	45
Table 2.4: methadone prescribing regime for new clients in north west region, 1995-2000 (drug misuse database)	47

Chapter Three - Methodology

Table 3.1: Summary of Variables	59
---------------------------------	----

Chapter Four - Findings

Table 4.1: Numbers (%) of clients getting each of 12 types of script, based on combination of three forms and four drug types. 69

Table 4.2: Mean daily doses (mg) involved in each of the six main types of prescription 70

Table 4.3: Number (%) of people on two main specific scripts (MM & HR) who were on that drug alone or another drug too 70

Table 4.4: Drug consumption: past-month use, frequency of use, weekly amounts, and monthly spending 74

Table 4.5: Reported Frequency (%) & Types of Criminal activity during the month prior to interview. 77

Table 4.6: Number (%) of drug dealing clients who sold drugs on a daily, near-daily or weekly basis, broken down by four forms of script 78

Table 4.7: Numbers (%) of script-leaking clients who passed on their script on a weekly, fortnightly and monthly basis, broken down by four forms of script 78

Table 4.8: Number (%) of shoplifting clients who stole from shops on a daily, near-daily or weekly basis, broken down by four forms of script 79

Chapter Five - Discussion

Table 5.1: Summary of significant effects (and p. values) 84

Table 5.2: Two-dimensional scheme; Model of drug-related consequences 90

Table 5.3: Model of drug-related consequences: Positive features of prescribing heroin 91

Table 5.4: Model of drug-related consequences: Negative features of prescribing heroin 91

Table 5.5: Daily doses of heroin – UK, Swiss & Dutch trials. 94

Table 5.6: NTA Strategies for improving 4 stages of drug treatment 109

Table 5.7: Annual number of problem drug users in treatment in England, 2001-2005. 110

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Chapter One – REVIEW OF THE LITERATURE

Chapter One – REVIEW OF THE LITERATURE

1.1. Heroin and heroin use

1.1.1 Heroin

“Among the remedies which it has pleased Almighty God to give to man to relieve his sufferings, none is so universal and so efficacious as opium”
Thomas Sydenham (1624-1689)

Known as either “the Shakespeare of medicine” or “the English Hippocrates”, Thomas Sydenham was the founder and first president of the Royal College of Physicians. Sydenham was physician to the King and widely recognized as a founder of clinical medicine and epidemiology, he was also one of opium’s’ earliest supporters. (Encyclopaedia Britannica 2005)

Heroin (derived from ‘heroisch’ the German word for hero) was first synthesized in 1874 from morphine, the main psychoactive ingredient of opium (others include codine). Morphine is reacted with vinegar (diacetic acid) producing diamorphine, or heroin, which has similar pharmacological properties but greater potency. (Gossop et al 2005) Opium is a naturally occurring substance extracted from the seedpod of certain varieties of poppy plants. It was first commercially marketed in 1898 as a new pain remedy, and became widely used in medicine in the early 1900s until it became a controlled substance following the 1917 Defence of the Realm Act. (It was observed that soldiers fighting through the first world war had begun to use heroin and politicians believed that this use could threaten its successful outcome).

When injected, heroin produces a feeling of intense euphoria and pleasure, often followed by happiness and relaxation. Standard doses do not generally impair intellectual or motor ability (after the first 45-60 minutes), although larger doses can lead to light sleep or sedation. Smoking and sniffing heroin provides a milder 'rush', whilst orally, heroin provides no 'rush', hence its unpopularity as a method of consumption.

1.1.2 Heroin use: prevalence

Estimates of the prevalence of heroin are known to be imprecise for a number of reasons including sampling and reporting problems, and clients' reluctance to admit to using 'taboo' drugs associated with more social unacceptability. According to the Drug Misuse Database, which monitored numbers of new problem drug users known to services in Britain from 1993 to 2001, in the six months ending September 1993, 7,700 'new' clients (either presenting for the first time or following a minimum six month break from treatment) reported that heroin was their main drug of use. In the six months ending March 2001, this number had risen to 22,431. (Dept of Health, 2002a) According to the Home Office, the number of notified heroin addicts increased from 14,447 in 1995, to 30,573 in 1996 (Home Office, 1995,1996) (see Table 1.1 below) (the Addicts Index, which focused on opiate and cocaine addicts known to doctors, was ended in 1996)

Table 1.1: Numbers of drug offenders and notified drug addicts in Britain, 1975-2000

	Drug offenders							Notified drug addicts	
	Cannabis	Heroin	Cocaine	Amphet.	LSD	Ecstasy	TOTAL	Heroin	TOTAL
1975	8987	393	379	1501	826	-	11846	812	1458
1980	14912	751	476	827	246	-	17158	1657	2441
1985	21337	3227	632	2946	539	-	26958	8090	8819
1990	42209	1605	860	2330	915	286	44922	14497	17755
1995	76694	4219	2073	10364	1268	3281	93631	24530*	37164*
2000	75985	12297	5451	6637	260	6630	104390		

notes:
* There were 30,573 heroin and 43,372 in total addicts in 1996 (last year of Notified Addicts Index)

Sources: Home Office (1997). Statistics of drug addicts notified to the Home Office, UK 1996. London: Home Office
Home Office (2002). Drug seizure and offender statistics, UK, 2000. London: Home Office

The figures above illustrate the rapid rise in the number of heroin offenders in relation to other drug users; from only 393 in 1975 when heroin offenders were amongst the lowest number, to 12,297 in 2000, second only to cannabis.

In order to try and improve the accuracy of the figures, researchers have estimated the total prevalence of opioid clients from the number of notified opioid clients, by employing a multiplier of five (see Hartnoll et al., 1985, for the London-based study which originally suggested this multiplier). Applying this multiplier to the final count of notified drug addicts in Britain in 1996 (43,372) produced an estimated total prevalence of about 216,000 drug addicts – including about 200,000 addicts of heroin and/or methadone.(Frischer et al. 2001). Estimates for the UK in 1998 put the total number of heroin users at 299,000 (about 1% of the adult population) (Bramley-Harker 2001).

In the case of heroin, prevalence may now (2005) be as high as 300,000, compared with about 200,000 in the mid-1990’s, 50,000 in the mid-1980’s, 10,000 in the mid-

1970's, less than 5,000 in the mid-1960's and less than 1,000 in the mid-50's.

(Newcombe 2006, in press).

1.1.3 Heroin use: consumption

Patterns of heroin consumption have changed considerably over the last 80 years, in terms of users, drug, and form. In the first half of the 20th century it was used mainly by medics and iatrogenic addicts, and by soldiers in the First World War. Heroin developed through the 'hippys' of the 1960's in the South East, into a drug associated with poor/unemployed working class addicts around the country from the 1980's.

Between 1960 and 1980 street heroin was most often injected or sniffed, and came in the form of a pure white crystalline powder, known as 'Chinese White'. The 1980's saw the arrival of a cheaper alternative, originating in Pakistan and Afghanistan, a brown and often heavily adulterated product which could also be smoked – a factor which increased its appeal to a wider audience. Dealers would 'cut' the heroin with a variety of adulterants (to maximise profits) including lactose, glucose, chalk, paracetamol and caffeine (for example, caffeine is added because it increases the 'smokability' of brown heroin). The levels of purity, and in particular the presence of potentially harmful substances in unknown quantities, is a factor in the argument for the controlled prescription of pure unadulterated heroin to reduce the risk of accidental overdose and to address other health issues. The purity of heroin over the last 20 years is shown in Table 1.2. (The purity of 'street' deals is about half the official rate, ie. 15-25%)

In Britain today, users’ slang names for heroin include ‘gear’, ‘smack’, ‘skag’, and ‘brown’. Injecting heroin is called shooting up, cranking, digging and fixing – while smoking heroin is called ‘chasing’ or ‘tooting’

Table 1.2: Purity of illicit powder drugs in England & Wales; Police seizures, 1984-2003

	<u>HEROIN</u>
1984	43-48%
1985	36-43%
1986	30-38%
1987	29-32%
1988	33-41%
1989	35-40%
1990	36-40%
1991	37-47%
1992	41-47%
1993	29-48%
1994	39-44%
1995	40-44%
1996	44-45%
1997	35-36%
1998	34-41%
1999	39-46%
2000	41-51%
2001	43-54%
2002	34-45%
2003	28-42%

Source: Mwenda L. et al (2005).Drug seizures in England & Wales 2003.London:Home Office
(Figures from 1992 based on seizures in E & W only (prior to 1992, figures are for UK)
(figures are ranges for quarterly purity statistics)

Estimates of the average prices of standard retail units (a gram/dose/ounce) and wholesale amounts (kilograms/thousand doses) of drugs are compiled by the National Criminal Intelligence Service (NCIS) from figures provided by local police forces and other experts. National averages are shown in Table 1.3 below. Prices in many cities and towns fluctuate from the national average depending on supply and demand. For

instance, the cheapest heroin can now be purchased in Liverpool and Manchester, where a gram costs around £25-£30 in 2005. (anecdotal)

Table 1.3: Retail price (£) of illicit drugs, UK, 1997-2000

	Cannabis			Heroin	Cocaine
	Skunk	Resin	Herbal		
1997	163	97	95	74	71
1998	154	93	91	74	77
1999	151	100	89	65	63
2000	145	85	82	70	65

Retail units: grams for heroin, cocaine; ounces for cannabis;

Source: Home Office (2002). Drug seizure and offender statistics. London: Home Office.

1.2 The British System; Key changes/influences in the approach to substitution treatment provision in the UK.

It continues to be the case that opioid dependency is an increasing issue in the United Kingdom, with high individual, communal and societal costs. Heroin dependence is perceived by clients, practitioners, researchers, policy makers and law enforcers alike to present major health problems and costs to the individual and to the state. In 2001-2002 the Audit Commission (2002) estimated that the treasury, on drug related problems, spent between three and four billion pounds. Clearly the issue of heroin dependence has high medical, legal, individual, social and criminal costs, and the debate concerning the impact of prescribing heroin and methadone substitution treatments on these respective costs continues to be played out by researchers and policy makers alike. In the often highly charged atmosphere of public health, the

notion of flexible prescribing, tailoring treatment options to the needs of the individual rather than the policy of the service, continues to be a controversial one.

1.2.1 Substitution treatment 1920's – 1960's

The last 80 years have seen the UK response to opioid dependency vary enormously, reflecting changing perceptions regarding the notion of addiction, different political and historical contexts, and power shifts between the legal and medical professions. The option to discuss and implement the prescribing of heroin and other opiate drugs seemed far from the minds of those pushing for the prohibition of opium, heroin, morphine and cocaine in 1920's Britain. (Dangerous Drugs Act). However it soon became clear that rather than purely criminalise heroin dependency, as in the USA, British policy makers and health care providers believed that there was a significant medical aspect to the issue which should be recognised in service delivery and treatment options.

The UK remains distinct in the fact that it is one of the few countries, which incorporates the prescription of pharmaceutical heroin (diamorphine) in the range of treatment options available to those dependant on opiates. In 1926 the government accepted the advice of the Rolleston Committee (Departmental Committee on Morphine and Heroin Addiction, 1926) who published a report establishing the right of medical practitioners to prescribe opiates for the treatment of certain patients, and from this report 'the British System' was born.

"Prescribing opium for addicts is reasonable if: the patient could not be withdrawn without serious withdrawal symptoms; if the patient was undergoing a gradual withdrawal; and if the patient needed the drug to lead a useful and normal life" Rolleston Committee 1926

The treatment for opioid dependency was now (1920's – 1960's) seen as the domain of the medical practitioner, and if that practitioner felt that with a prescription for an opioid drug the patient would be more able to lead a “useful and fairly normal life”, not otherwise possible, then the prescription protocol was met and the drug/s were prescribed. As the quote above detailed, this protocol was broadly divided into three categories; those who could not lead a ‘normal’ life unless a certain minimum dose of an opioid drug was administered; those who would experience unsafe and significant withdrawal symptoms should the opioids be discontinued; and those requesting a managed supervised withdrawal scheme.

Strang (1989) highlighted the fact that one of the main features of ‘the British System’ was its distinct *lack* of any central system, as in practice, the vast majority of prescribing doctors were community based general practitioners. These practitioners were essentially autonomous individuals charged with the development of treatment prescribing programs in accordance with their own professional experience and perceptions of the client needs. Stimson and Metrebian (2003) concluded that on the whole this approach worked well with those clients presenting at the time, most of whom were ‘middle class’ professionals having become dependant through the prescription of opiates for medical treatment (“known as therapeutic or iatrogenic addicts”), or directly because of their exposure to opiates as a result of their position in the medical/nursing profession. The main feature of ‘the British system’ continued to be maintenance and management of the addiction in a medically controlled manner delivered by general practitioners.

Historical commentators would be keen to point out to future policy makers that this system was born at a time when the extent of the opiate dependency issue was minimal in the UK. Praise has been offered to the 'British System' with the fact that there were relatively few dependent users being offered as an indicator of its success. However, others (eg. Strang 1989) believed that the system, (operating at a time when few individuals were dependent on morphine and even fewer on heroin) only worked *because* there were so few dependent users.

In the 1960's the 'British System' began to be challenged because heroin dependence in young people began to be seen as a significant issue. A very different group of clients was formed who initially obtained their drugs from private general practitioners, mainly in London. It was becoming increasingly clear that a 'black market' was being created, made possible by a small number of private practitioners over prescribing (Spear 1994). It was suspected that the 'system' was actually encouraging the rise of the problem, making supplies readily available to those who could afford them, and drug dependency was seen as a socially transferable 'illness' which required treatment. As a direct result of the increasing level of concern regarding the rise of a potential black market, the Brain Committee was first convened in 1961 (Interdepartmental Committee on Drug Addiction, 1961). Although this initial committee concluded that the overall problem was still relatively too small to warrant large scale changes to the policies and practices already in place, it was soon to reconvene in the light of a global increase in recreational drug use and hedonism as the 1960's got into full swing. Stimson and Metrebian (2003) concluded that those doctors who thought they were helping to contain and prevent any illicit heroin

market were in fact fuelling it, by over prescribing to individuals who would then sell part of their 'script' to those seeking (initially) to use heroin for recreational pleasure.

The early 1960's saw another key development with the resurgence in the use and popularity of methadone, a synthetic opiate drug originally invented by the Nazi's during World War Two. According to popular legend in Germany, methadone, invented as a substitute for heroin, was initially christened Dolophine in honour of Adolf Hitler. In reality, the name comes from the Latin dolor, meaning, "pain", and fin, meaning, "end": hence "end of pain". The Allies had managed to stop supplies of heroin reaching the German troops, without effective pain relief the German war effort would soon be over. German scientists were charged with inventing a replacement, and methadone was created. Following the defeat of the Germans, methadone became a largely forgotten drug until 1965 when it was 'rediscovered' by two American doctors, Dole and Nyswander who hailed it as an ideal maintenance treatment option for those individuals presenting with an addiction to heroin, and 'substitute prescribing' was born..(Dole and Nyswander 1965). They highlighted two key advantages methadone held over heroin; the first that it was dispensed in syrup form and therefore able to be administered orally (and not amenable to injecting), and secondly, that it was long lasting (up to 30 hours as compared to up to eight for heroin) and clients could therefore be given single daily doses. A third advantage was that it was far less 'pleasureable' than heroin, though it did stop withdrawals. When it did reconvene, the Brain Committee encouraged practitioners to consider methadone, not just as a form of maintenance, but also increasingly as a drug of withdrawal.

The second Brain report in 1965 also recommended the development of a compulsory notification system for drug clients, the establishment of specialist drug dependency clinics, and maybe most significantly the restriction of heroin prescription to clients to a smaller number of licensed doctors – generally psychiatrists. (Interdepartmental Committee on Drug Addiction, 1965). Drug treatment began moving from GPs to specialist multi-disciplinary drug clinics, and from maintenance on various drugs to maintenance on methadone only – and later toward methadone detoxification only. The Brain report directly resulted in several significant developments leading to the demise of ‘the British system’ and changes in legislation, most notably the Dangerous Drugs Act of 1967, and the establishment of Drug Dependency clinics in 1968. Following the Dangerous Drugs Act (1967) Home Office approval, by way of a specific license, had to be gained by any doctor wishing to prescribe either heroin or cocaine to clients. The establishment of the Drug Dependency clinics represented an important shift in emphasis relating to the response of healthcare professionals. In their first year of operation [mostly in London], Strang (1989) reports that 1,306 clients were registered at the clinics, mostly dependent on heroin. The emphasis was now one of dual aims; to treat the addict with appropriate medical intervention, and to treat the ‘problem’ in terms of the spread/social costs of increased heroin availability. “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” (Stimson and Metrebian 2003, p6)

1.2.2 Substitution treatment 1970’s – 1980’s

In the early 1970’s drug dependency units began moving away from prescribing heroin, favouring oral (and sometimes injectable) methadone. In effect, drug

dependency units were pushing for detoxification and withdrawal regimes, with abstinence rather than maintenance, being the treatment goal. This was echoed in the law enforcement arena, with the introduction of the 1971 Misuse of Drugs Act, which extended prohibition to many more drugs and increased associated penalties. In short, drug services were now there for one purpose: to help people 'get off' drugs, as the sole alternative to being criminalized for them. This new abstinence-only policy lasted for almost two decades. Those who favoured this change in treatment cited two major issues; a generally improving regard for the use and effectiveness of methadone, and the continuing concerns about 'black market' leakage of prescribed heroin. Ashton (1981) supported this latter belief, concluding that maintenance prescribing was not stabilising many users, and that there was evidence of continued criminal activity and 'topping-up' prescriptions with illicit heroin.

It is certainly true to say that some argue this shift in emphasis was neither prompted nor widely supported by research findings. Fazey (1989) stated that the changes in policy, far from being based on sound empirical findings, were in fact the result of a small but influential group of (mainly) psychiatrists who adopted the moral high ground and declared that drug users should not be prescribed drugs of their own choice. In a sense this represented a medical/professional 'fashion'; imposed upon those who were expected to follow. Fazey (1989) pointed out "There is no tradition, in the UK at least, of evaluation of treatments. Research has always been done on the effects of particular drugs and their effectiveness in bringing about physical changes and controlling disease, but not evaluations which look at other variables".

(It should be noted that from the early 1990's there was a sharp increase in the amount of research in most areas of the drugs field, and the conclusions of some of the treatment focused work will be discussed in later chapters).

Those who had not favoured this change in focus argued that by the mid 1970's there was a growing level of disillusionment with this shift in emphasis and its resulting treatment 'options' with medically administered heroin maintenance programs replaced by methadone treatment/reduction programmes, administered through Drug Dependency Units.(Marks 1990)

There was no formal change in policy to support the move away from prescribing heroin, and the findings of the first (and to date, only) randomised control trial comparing oral methadone to injectable diamorphine, proved inconclusive. (Hartnoll et al 1980). This study is presented in more detail in section 1.4.1, however it seems fair to suggest that those who elected to use Hartnoll et als' findings to justify a change in reverting back to methadone and away from heroin were doing so against the aims of the authors;

"It (the Hartnoll and Mitcheson study) has been widely credited with changing treatment policies in the newly established Drug Dependency 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 author's reservations about the results, the research was taken to show that oral methadone maintenance treatment was preferable." (Berridge & Thom 1996, p25)

In 1982 the ACMD produced its report 'Treatment and Rehabilitation' which resulted in many of the mainly methadone detoxification centred Drug Dependency Units

being gradually transformed into Community Drugs Teams. The multi-disciplinary CDT’s involved a wide range of professionals including social workers, probation officers and youth workers, alongside the traditional nurses and psychiatrists. In essence the policy of harm reduction was beginning to emerge (mainly from 1988), and detoxification/abstinence, whilst still on the agenda, were placed firmly behind attracting clients and maintenance in terms of treatment emphasis.

In a landmark article in The Lancet, a prominent psychiatrist and supporter of the prescription of heroin to clients, Dr John Marks, set out his views on the debate surrounding such a treatment option. (Marks 1985) They have remained central to the ongoing and controversial area of prescribing heroin to heroin addicts, and are summarised in the table below;

Table 1.4: The arguments concerning the prescription of heroin.

Against	For
1. It maintains the condition of addiction;	The addict will remain in the condition anyway;
2. It was a public health exercise to protect people from the black market;	A stable supply benefits the addict and provides pure, clean drugs;
3. It is not a doctors job to control the illicit use of drugs;	Doctors are obliged, like anyone else, to help society combat the breaking of the law;
4. Barbiturates and alcohol are not prescribed because they are damaging – why opium?	If alcohol were prohibited, it would be more humane to prescribe a daily dram of whisky than to see someone sell their last possessions for methelated spirits;
5. The illegal use of drugs is not curbed by prescriptions;	There are still insufficient properly controlled clinics;
6. Addicts traffic their prescriptions;	Prescribe less;
7. Addicts supplement their prescriptions	Prescribe more;
8. The efficacy of maintenance is not proven;	The contrast between the USA and England between 1920-1960 suggests otherwise.

Both sides of the argument have been developed over the past twenty years and now include the following three areas of debate in addition to Marks (1985) initial thoughts;

Treatment. In terms of treatment those against prescribing heroin fear that this may dissuade clients from even considering alternatives such as methadone, and encourage them to maintain their addiction longer by making it easier for them to inject their (now free) drug of choice. They also argue that the cost of maintaining large numbers of clients on relatively expensive (as compared to methadone) prescriptions will restrict the number of clients who could be treated, given the fact that any treatment service has finite resources. Those in favour of prescribing argue that offering heroin as a treatment option would attract more clients, and would see them remain in treatment longer, receiving a range of health related and social/educational interventions, thus reducing demands on other areas such as hospital admissions and law enforcement agencies. (Gossop 2000)

HIV/AIDS. Those against prescribing argue that increasing the regularity, with which clients inject, even if they are injecting prescription drugs, still increases the likelihood that they may suffer adverse consequences, including the transmission of HIV and other infectious diseases (eg HBV, HCV). Those in favour argue that the education and advice on injecting techniques and safe practice received by those clients on injectable scripts will in fact reduce the risks associated with injecting. They also argue that levels of purity can be assured by prescribing, and that once attracted and stabilised, clients may be more inclined/empowered to move away from injecting and onto oral methods.

Crime. This involves two areas of crime: acquisitive and drug dealing. First, those in favour of prescribing heroin argue that drug related acquisitive crime would reduce significantly, with the associated positive effects on the criminal justice system from police on the streets right through to the prison service. (Marks 1985) Clearly clients would not have to rely on acquisitive crime to support their drug habit, and this may in turn lead to improved job prospects and family stability. Those against focus their arguments on two key issues; firstly, the potential for leakage/diversion of surplus (high quality) drugs onto the streets, creating new users; and secondly, the relatively small amount of scientific evidence to support the prescribing of heroin (see 1.4.1) as compared to the wealth of evidence surrounding the effectiveness of methadone. Second, Marks (1985) also argued that heroin prescribing would reduce pyramid selling, including street level dealing, and this would reduce the prevalence of heroin use by making heroin harder to obtain.

1.2.3 Substitution treatment; the impact of HIV/AIDS

The Advisory Council on the Misuse of Drugs reviewed the evidence in 'AIDS and Drug Misuse' (1988), which advised the government to prioritise a HIV prevention policy based on risk/harm reduction. The government accepted most of the advice in the report, leading to the setting up of a national network of new and revamped services - notably needle exchange schemes and more flexible methadone prescribing services (though Scotland was slower to respond). The government's official response

to the ACMD report again clearly indicated that harm reduction was to be prioritised over abstinence. It was now a public health priority to attract heroin users into treatment and to keep them in treatment long enough to positively impact on a range of risk behaviours. This policy continued until 1994, when the government announced that abstinence was now the primary goal of drug services, with harm reduction becoming a secondary aim. (Task Force 1994)

1.2.3.1 Flexible prescribing

Flexible prescribing refers to the philosophy and practice of offering a range of treatment options, services and types of prescription, dependant on the individual nature of each client who presents to a service.

In the context of illicit drug use and harm reduction, the option of flexible prescribing was given new impetus in the late 1980's and early 1990's by the rising threat of HIV. In 1988 the Advisory Council on the Misuse of Drugs (ACMD), (established by the Government), highlighted a need to increase awareness of the problems associated with HIV infection, particularly among injecting drug users. The ACMD had firmly moved the focus of service provision for drug users away from abstinence and toward inclusion to treatment and the reduction of HIV related risk behaviour:

“The spread of HIV is a greater threat to public health than drug misuse. Accordingly, we believe that services which aim to minimise HIV risk behaviour by all available means should take precedence in development plans”
(ACMD, “AIDS and Drug Misuse Part 1”, 1988 2.1)

Endorsing a much more flexible approach to drug service provision, the ACMD led the push to encourage service providers to make and maintain contact with those drug users (making up the vast majority) who had previously not been attracted by detoxification / abstinence focused services.

Flexible prescribing would (it was hoped) attract those drug users who wanted to continue to use drugs. Service staff would then be in a position to work with clients on a 'behaviour-change' hierarchy of goals, ranging from the cessation of sharing injecting equipment, through a move from injectable to oral drug use, towards reduction and eventual abstinence. Recognition was made that, as with other behaviour-change focused interventions, information alone was not enough. In a review of the literature concerning HIV and AIDS prevention, Valdiserri (1989) concluded that:

“programs for HIV prevention must not limit themselves to modalities that are purely informational because of the fallacy that healthy behaviours can be induced merely by informing individuals of the dangers of unhealthy behaviours”
(Valdiserri, R. 'Identifying the targets of AIDS prevention' 1989)

The shift towards a harm reduction focused, flexible prescribing approach was accompanied by a growing suspicion that many of the strategies initially adopted to deal with drug use, in fact exacerbated the problem. Prohibition was seen by many to be failing. A new approach to service provision, operating across a wide variety of levels from condom and needle availability, to counselling and non judgmental medical treatment, was seen by many as the only way forward; the only way to realistically address the issues of harm reduction, HIV prevention, reduction of criminal and anti-social behaviour amongst drug users and the wider community.

Reported rates of HIV infection amongst intravenous drug users varied considerably between countries at the time of the ACMD’s first report. Fifty eight percent of intravenous drug users in New York City were antibody positive, 68% in France, 11% in Spain, 76% in Italy, 60% in Scotland and 1.5% in England and Wales. (Terrence Higgins Trust 1988)

1.2.3.2 Injecting behaviour

Table 1.5 presents the bi-annual number of problem drug users who inject, presenting to services (regional drug misuse databases) in Britain between 1993-2001. It also focuses on the percentage of those who share injecting equipment. The percentage of those injecting users rose steadily throughout the 1990’s (with the exception of Sept 95 – Mar 96), as did the overall number of injecting drug users known to services.

Table 1.5: Bi-annual number of PDUs, 1993-2001; and (a) percentage of PDUs who are injecting drug users (IDUs); (b) percentage of IDUs sharing injecting equipment in past month (SIE)

<u>Six months ending:</u>	<u>TOTAL</u>	<u>Overall %</u>		<u>% injecting drug users</u>	
		<u>IDU</u>	<u>SIE</u>	<u>Heroin</u>	<u>Amphets</u>
March 1993	20343	38	..	61	51
Sept. 1993	20221	43	13	69	54
March 1994	21582	42	12	68	54
Sept. 1994	23707	41	12	65	51
March 1995	25440	38	12	59	48
Sept. 1995	27935	37	11	58	47
March 1996	28856	36	11	54	45
Sept. 1996	30292	37	12	52	43
March 1997	31684	37	12	52	42
Sept. 1997	27262	39	15	58	44
March 1998	29765	38	15	58	45
Sept. 1998	34875	39	17	57	47
March 1999	34802	41	17	60	48
Sept. 1999	37681	39	19	58	47
March 2000	39055	40	20	59	41
Sept. 2000	40416	40	21	58	38
March 2001	40181	38	20	54	40

Source: Department of Health (2002). Statistics from the Regional Drug Misuse Databases for six months ending March 2001. London: Government Statistical Service [and previous bi-annual bulletins]

1.2.4 Substitution treatment: the relation to crime

The relationship between drug use/users and crime became the focus for prescribing policy and practice from the 1990’s. The Government viewed drug misuse as an issue directly related to criminal activity, and instructed service providers to expand heroin (and other drug) treatment services to encourage as many clients into treatment as possible. (Gossop 2000) Those in favour of offering heroin on prescription saw this as an opportunity to attract into treatment, and away from crime, those clients previously deterred by the essentially methadone-only clinics; by offering a range of drugs, including injectable diamorphine. However, only about a dozen clinics prescribed heroin to more than one or two clients during the 1990’s (Strang and Gossop 1994).

The UK had seen a steady rise in drug related crime throughout the 1970’s. The 1980’s and in particular the 1990’s saw this rise increase significantly, with the number of heroin related drug offences doubling from 2151 offences in 1987, to 4219 offences in 1995. (see Table 1.6)

Table 1.6: Annual number of drug offences, by heroin and methadone - UK, 1973- 2002

	<u>HEROIN</u>	<u>METHAD.</u>	<u>ALL</u>
1973	435	347	14,977
1974	444	464	12,532
1975	393	484	11,846
1976	464	416	12,754
1977	393	347	12,907
1978	483	369	13,604
1979	520	299	14,339
1980	751	363	17,158
1981	808	445	17,921
1982	966	404	20,356
1983	1,508	379	23,442
1984	2,446	411	25,240
1985	3,227	413	26,958
1986	2,259	280	23,905
1987	2,151	191	26,278
1988	1,856	162	30,515
1989	1,769	172	38,415
1990	1,605	154	44,922
1991	1,466	145	47,616
1992	1,415	191	48,927
1993	2,164	10*	68,480
1994	2,971	10*	85,691
1995	4,219	30*	93,631
1996	5,929	409	95,198
1997	8,892	719	114,640
1998	11,751	790	131,230
1999	12,960	720	121,980
2000	12,430	620	105,190
2001	12,390	570	100,940
2002	11,790	470	110,920

Source: Home Office (2004). Drug Seizure and Offender Statistics, UK, 2001 & 2002 (& Supplementary Tables). London: Home Office [Issue 08/04]

* methadone figures for 1993 to 1995 are for Scotland and N.Ireland only.

The transparency of the link between drug use and crime has led to much discussion amongst UK practitioners, policy makers and politicians alike. In the early 1990's problem drug use, and in particular heroin use, was highlighted by the government as a major crime and public order issue. Introducing his governments white paper 'Tackling Drugs to Build a better Britain' Tony Blair asserted his commitment to *"break once and for all the vicious cycle of drugs and crime which wrecks lives and threatens communities"* (Home Office 1998).

The National Treatment Outcome Research Study (NTORS) was commissioned by the Department of Health in 1994 as a large scale follow up research project to

evaluate the effectiveness of various drug treatment strategies. Gossop et al (1998) reported high rates of criminal behaviour amongst the treatment sample, with 61% reporting a total of nearly 80,000 crimes in the three month period prior to embarking on the treatment programme. The most common of these crimes were shoplifting, burglary and robbery, and clients averaged one crime each per day. (NTORS will be discussed further in 1.4.3)

The government were keen to centre their policies on breaking the links between crime (acquisitive crime in particular) and drug users needing to meet the needs of their habits. The argument being that heroin prescriptions would attract clients into treatment, thereby reducing and/or eliminating their need to commit crime. Bennett (2000) carried out a Home Office study of 506 arrested drug offenders, 29% of whom tested positive for opiates, and found that heroin users spent on average £16,000 per year on their habit, 81% of which came from crime (£13,000)

Links between drug use and crime still play a major part in drug treatment strategy, and will be further examined in the final chapter of this thesis.

1.3 Recent developments in the treatment of opioid addicts

Recent developments in drug treatment policy include the following;

Tackling Drugs to Build a Better Britain. In 1998 the Government published its White Paper ‘ Tackling Drugs to Build a Better Britain 1998-2007, and updated this in 2002 with a 2003-2008 strategy. (Home Office 1998, 2002) The four key aims of the initial 10-year strategy were;

- reducing the supply of illegal drugs
- preventing young people from becoming drug misusers
- reducing drug-related crime
- reducing the use of drugs through increased participation in treatment programmes.

Under each aim were listed several objectives, and more importantly, targets.
(Performance indicators with specified levels of change and amount of change)

In the subsequent updated strategy, specific reference was made to increasing the availability of heroin on prescription; “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” (Home Office 2002), In 2005 this materialised as an injectable heroin prescribing experiment at 3 DDU’s in Britain.

Subutex. Subutex is the trade name for buprenorphine, and is a synthetic opiate similar to methadone, though it is a partial opioid antagonist (ie. It blocks the effects of heroin) It was licensed in 2001 as an alternative drug to be used in detox or maintenance.

Withdrawal management drugs. These reduce residual withdrawal symptoms (eg. Britlofex, clonidine), or block the effects of heroin (antagonists, preventing relapse, eg naltrexone).

National Treatment Agency for Substance Misuse (NTA). The NTA is a special health authority (as opposed to a regional health authority), which was established in 2001 with national responsibility to improve the quality and availability of treatment for drug users in England. The NTA initially set out to do this through;

- monitoring growing annual expenditure, including £200 million on treatment services for 2002/03
- providing guidance on the commissioning of treatment services to local DAT's (Drug Action Teams) & DAAT's (Drug & Alcohol Action Teams)
- improving the availability and skills of staff in the drug treatment sector
- ensuring that users are consulted in the development of services

A major contribution by the NTA is 'Models of Care' (2002), which has three key components: a four tier framework (including tier three which includes maintenance/detoxification programmes), care concepts (including Integrated Care Pathways ICP's, dynamic and flexible individual treatment plans), and monitoring (the delivery, cost and outcomes of services, locally and nationally).

In January 2002, the NTA released a media statement confirming that they were to convene a consensus group of national and international academics and clinicians, to discuss the issue of prescribing heroin;

"Heroin prescribing is already available to specially-licensed clinicians as one of a range of treatment options. It is not the answer to all heroin misusers' problems, but

we believe that it has a role to play within the whole range of treatment options. We want to examine if heroin prescribing may be appropriate for a wider range of users”

Paul Hayes, Chief Executive, NTA (2002)

National Drug Treatment Monitoring System (NDTMS). In 2001 the National Drug Treatment Data Base was established to replace the Drug Misuse Database, which had operated between 1993-2001. Among various changes, the key developments included extending the annual count of PDU's from new clients to all (new and continuing) clients.

These developments will be discussed in relation to the findings of the present study in the concluding chapter.

1.4 Evaluating the effectiveness of heroin/diamorphine substitution prescribing

1.4.1 The evidence base

Very few studies have specifically examined the effectiveness of prescribing heroin to heroin clients. In a landmark thematic review of the literature Ashton and Witton (2003) concluded that worldwide just five key studies hold the answer as to whether such a policy can work. Three of these studies were carried out in the UK.

According to the Home Office Notified Addicts Index (discontinued in 1996), the number of people prescribed heroin in the treatment of drug addiction declined from 437 in 1970 (31% of all notified addicts) to 119 in 1996 (less than 1% of all notified addicts). Though various British studies of opiate clients prescribed heroin have been

published, by 2002 there were only three studies specifically comparing the outcomes of heroin prescribing with those of methadone prescribing: Hartnoll et al. (1980), McCusker et al (1996) and Metrebian et al. (2001).

A pioneering study of heroin prescribing, conducted between 1972 and 1976, involved heroin clients seeking a maintenance prescription of injectable heroin from the University College Hospital, London; they were randomly allocated to receive either injectable heroin or oral methadone. This study remains the only British *randomised* comparison of methadone and heroin prescribing. Participation in the study was restricted to those clients between the ages of 18 and 35, who had a minimum of 3 months history of daily injecting, who had no history of psychiatric illness, who lived in London, and for whom all alternative treatment interventions had failed. Nearly all participants had criminal convictions.

Information was collected on 96% at the outset and at 12 months (whether still attending clinic or dropped out). Significantly, the drop out rate from oral methadone treatment was much greater (71%) compared with the heroin group (26%) at 12 months. The main findings are summarized in Table 1.7 below:

Table 1.7: Summary of Outcome differences between IH and OM clients after 12 months (Hartnoll et al 1980)

<u>AT 12 MONTHS:</u>	<u>Injectable heroin</u>	<u>Oral methadone</u>
Using <5mg heroin daily	10%	32%
Injecting regularly	90%	57%
Attending regularly	76%	29%
Convicted of crime in past year	50%	70%
Use of non-opiates in past year	<i>no difference</i>	
Employment	“	
Health	“	
Mortality rate	“	
<u>IN LAST 3 MONTHS:</u>		
<u>Did not inject for 31+ days</u>	<u>5%</u>	<u>30%</u>

It is clear that a year after starting treatment, those prescribed injectable heroin were more likely than those prescribed oral methadone to report injecting and heroin use - as expected given their prescription. However, overall the main differences after one year in treatment were that, compared with those prescribed oral methadone, those prescribed injectable heroin (1) were over twice as likely to have remained in contact and (2) were less likely to have been convicted of crime - with no differences between the two groups in other drug use, employment, health or mortality. (see table 1.7)

In several key areas there were small but not statistically significant differences between the 2 groups; at 12 months 36% of participants on injectable heroin had reduced illicit opiate use to twice a week or less, as compared with 41% of those on oral methadone. Focusing on the remaining users in each group, 26% of those in the injectable heroin group reported continued ‘heavy’ use, as compared to 37% of those on oral methadone

It was in the area of crime and crime related activity that the two groups differed the most. At 12 months 61% of the oral methadone group reported that criminal activity

remained a major source of their income, compared with 43% of those in the injectable heroin group. 50% of the injectable heroin group had avoided arrest, and 81% had avoided prison, as compared with the oral methadone group who reported figures of 28% and 68% respectively. Ashton and Witton (2003) point out that in relative terms the injectable heroin doses were much less generous than the oral methadone doses, and as a result may have contributed adversely to levels of crime and drug use reported by the injectable group.

Hartnoll et al (1980) concluded that the results did not indicate a clear overall superiority of either approach, and that relative advantages/disadvantages could only be considered according to the priorities assigned to the various outcomes, e.g. health compared with criminal activity. It is also of note that the ethical implications of randomly allocating clients to treatment conditions may in part explain why this study remains the only one of its kind in the UK to date.

McCusker et al (1996) reported the findings of a 1995 community drug team study, looking at 66 long term clients (averaging 10-12 years of opiate use) attending one of three clinics run by the same team in Greater Manchester. Two clinics offered oral methadone maintenance only, whilst the third also offered injectable diamorphine. The 39 oral methadone group members were broadly matched (for age, gender, length of opiate use) with 27 clients in the injectable diamorphine group. When interviewed, again after approximately 12 months, 69% of the methadone group were using illicit heroin, as compared to 22% of the diamorphine group. Those in the diamorphine group also spent less money on illicit drugs, and less time engaging in criminal activity; reporting committing non-drug crimes on two days in the last 30, as compared to an average of six days reported by the methadone group.

In contrast to the relatively low doses of diamorphine prescribed in study reported by Hartnoll et al (1980), the dosing in the community team study was much more flexible, averaging 253mg for the diamorphine group and 72mg for the methadone group. (McCusker et al 1996) However, there was no pre treatment data, and data from those who dropped out of treatment was not collected, making it difficult to conclude with any degree of certainty the relative effects of prescription group over and above a whole range of other factors including the personality of the individual, personal circumstances etc., as well as pre-treatment behaviour patterns.

The third and most recent British study looking at substitution prescribing, reported by Metrebian et al (2001) focused on 58 long-term treatment-resistant opiate clients starting treatment at a London drug clinic between mid-1995 and the end of 1997. To be eligible to take part clients had to be regularly injecting, they had to have experienced various drug-related problems despite receiving relatively high doses of prescribed oral methadone. Clients were asked to choose a prescription of either injectable heroin or injectable methadone – 37 chose heroin and 21 chose methadone. Of the 36% who chose methadone, most did so because it was their primary drug of addiction, and/or they preferred the longer duration of action. Drugs were dispensed on site, with weekend take-home prescriptions, with a maximum daily dose of 200mg for either drug (which again, as with the Hartnoll et al study, saw the heroin group disadvantaged).

Only 57% of the total sample were still in treatment a year later, 59% of those who had chosen heroin compared with 48% of those who had chosen methadone. Ten of the 25 no longer in treatment had been discharged for disciplinary reasons rather than dropping out. Those who remained in treatment had average ending doses of 161mg in

the methadone group and 185mg in the heroin group. The main problems reported were discomfort while injecting in the methadone group, and too low dosage in the heroin group. The discomfort reported by those in the methadone group led researchers to question a previously held belief that a major advantage of prescribing injectable methadone was that clients would only have to inject once per day. This was clearly not the case, with clients reporting splitting the dose into two/three injections to reduce the clear discomfort experienced whilst injecting large amounts of methadone.

At 3 months and 12 months, both groups exhibited major reductions in drug use, injecting and crime, and improvements in mental, physical and social functioning. There were no significant differences in treatment outcomes between the two groups – and any conclusions drawn from comparisons between the two are restricted because clients chose their treatment group rather than being randomly assigned to them. However, it is possible to conclude that as one of the criteria for selection onto the study was a previous failure to comply with oral methadone treatment, those clients who remained on either type of injectable prescription made significant and previously unseen improvements.

The other two relevant studies focusing on heroin prescribing were conducted in Switzerland (1994-2000) and in The Netherlands (1998-2001).

Various reports (Perneger et al 1998; Uchtenhagen 1999; Rehm et al 2001) following eight years of heroin prescribing in Switzerland provide the most detailed and long term perspective on the features of heroin substitution prescribing. In 1994 the

Medical Prescription of Narcotics Programme (PROVE) was started, it began to be evaluated from 1996, and expanded in 1998. By 1998, 1,060 people were being prescribed heroin at 18 locations, including in prison. By 1999, nearly 2000 were being maintained on heroin prescriptions across 21 centres. (Rehm et al 2001) This comprehensive range of reports included double-blind studies (drug not known to either doctor or patient), studies based on treatment assessment and patient choice, and studies involving random allocation to treatment groups. (Perneger et al 1998)

Initial data were collected over three years on a cohort of 1,035 chronic heroin clients who had failed in drug-free or methadone substitution treatment programs, and who were prescribed heroin, morphine or methadone within a comprehensive care program at one of 17 outpatient centres. (Uchtenhagen 1999) Criteria for inclusion were being aged 20 years or older, two years of injectable heroin addiction despite repeated treatments, with marked health damage and social problems. Clients attended their outpatient centre three times a day to inject heroin under clinical supervision. The average daily dose prescribed was 474mg - clients tended to stabilise on 500-600 mgs of heroin per day, with no evidence of increasing tolerance. Indeed, this is similar to the plateau of opiate tolerance suggested by Parry (1992). Nearly a quarter also received methadone, and weekly counselling was compulsory. Retention in treatment was 89% at six months, 76% at 12 months, and 69% at 18 months – most leavers went on to more progressive and less time consuming treatments.

Of 385 clients who started before April 1995, detailed findings were reported for the 237 (62%) who remained in treatment for 18 months. About 80% reported daily use of illegal heroin in the six months before treatment, compared to 3-16% by 1997; and

31% reported income from crime in the six months before treatment, compared to 5-18% by 1997. There were also reductions in use of cocaine and benzodiazepines, reductions in injection-related damage and mental disorder, and improvements in employment, housing and finances. The annual mortality rate was about 1% (many were probably due to pre-existing diseases, and none were overdoses), and only minor problems were reported in the community (eg. occasional diversion of heroin).

These outcomes compare favourably with the outcomes for treatment clients in Britain after two years treatment (who were typically prescribed oral methadone), according to the 2001 NTORS five year follow up study. (Gossop et al 2001) Costs per treatment day were estimated at £20, while benefits (mainly from savings to the criminal justice system) were estimated at £40. It was concluded that heroin maintenance has a positive effect on opiate clients and their social environment due to an improvement in health and social status and a significant decrease in drug-related delinquent behaviour.

The only part of the Swiss study to utilize the random allocation of clients to different treatment options took place in Geneva. This study, randomly assigned 51 opiate clients; 27 to receive injectable heroin maintenance, while randomly assigning another 24 opiate clients into a control group with a six month 'waiting list' (most of whom (19) received oral methadone). (Perneger et al 1998) Clients in the experimental group were occasionally prescribed oral opiates (eg. for night-time withdrawals), and all were still in treatment after six months. (21 of the control group were still on the waiting list receiving oral methadone) It was found that:

- (1) none of the experimental group were using illicit heroin after six months in treatment, compared with half of the controls;
- (2) criminal income and spending on drugs fell to a tenth of pre-treatment levels for the experimental group, but remained at high levels in the control group;
- (3) mental and social functioning in the experimental group improved relative to the controls, though there were no differences in physical health between the two groups.
- (4) heroin was regarded as more 'attractive' than methadone, and had fewer side-effects.

Those clients in the experimental group were offered a comprehensive range of extra services, including counselling and general healthcare. Similar interventions and support were not offered to those on the waiting list receiving oral methadone, and this prevents researchers from attributing with any degree of reliability the various improvements solely to treatment regimes.

The final (and by far the largest) randomised study focusing on heroin prescribing, or more specifically co-prescribing, took place in the Netherlands.

In the Netherlands heroin prescribing was initially piloted on 50 opiate clients in July 1998 - 25 in Amsterdam, and 25 in Rotterdam. In February 1999, the program was extended to include opiate clients in The Hague, Gronigen, Utrecht, and Heerlen. By 1999, 700-800 Dutch opiate clients were being prescribed heroin. (van den Brink et al 1999)

Between 1998 and 2001, The Central Committee on the Treatment of Heroin Addicts (CCBH 2002) selected 549 patients who were chronic treatment-resistant heroin clients previously prescribed methadone. Clients were randomly allocated to either

- (1) none of the experimental group were using illicit heroin after six months in treatment, compared with half of the controls;
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an experimental (heroin plus methadone) or control (waiting list & oral methadone only) group. The study compared the outcomes of 12 months co-prescription of oral methadone plus injectable or inhalable heroin,(the inhalable heroin was provided as powder, like street ‘gear’, not in reefers as in the UK), with the outcomes of 12 months of oral methadone alone. In the co-prescription group, methadone was prescribed to prevent withdrawal symptoms when prescribed heroin was not available. It was found that:

- (1) co-prescription of heroin and methadone was more effective than methadone alone, producing greater health benefits and improved continuation in treatment;
- (2) compared with methadone-only treatment, co-prescription produced no excess of serious medical problems or public order problems.

Some of the clearest benefits to be seen were in the reported reduction in criminal activity, linking the Dutch study to current UK thinking regarding drug policy priorities, and in turn the priorities for attracting clients into treatment.

1.4.2 Summarising the evidence

Any summary of the evidence in favour of prescribing heroin must start by addressing the concerns of those who would seek to discredit it as an effective form of treatment.

The main concerns, presented earlier in section 1.2.2, centre around three key areas:

- Risk of perpetuating the ‘career’ of the opiate user by prescribing heroin rather than methadone

- Risk of leakage/diversion to the illicit market thus creating new users
- Justifying the cost of diamorphine as opposed to methadone prescriptions

Clearly selecting the most suitable clients to receive prescribed heroin is a crucial part of any research trial or resulting treatment programme. The five studies used slightly different recruitment criteria, with the Dutch study operating the strictest criteria including the requirement that clients must be currently in treatment, have had a minimum of five years heroin addiction and a daily injecting habit. The question of perpetuating a heroin habit by offering it on prescription is clearly affected by the dose of heroin available. In the UK studies the heroin dose was capped at the same level as the methadone dose – leading many clients, one third in the case of Metribian et al (1998, 2001) to opt for a methadone prescription. Also in terms of perpetuating an injecting drug habit, the Swiss trials seem to suggest that with the appropriate follow up treatment programmes available, clients choose to leave the heroin programme when stable, to move away from the restrictions imposed including twice daily attendance, counselling, and supervised consumption.

Supervised consumption was a feature of the Dutch and Swiss trials, but not the three UK studies, and it's a issue which may hold the key to convincing the sceptics that prescribing heroin could work for some clients, whilst at the same time not create new ones. The issue of leakage/dispersion is particularly relevant in the UK as it was this which was cited as one of the main reasons for the sharp increase in heroin availability in the 1960's. The evidence is fairly limited regarding dispersion and on-site supervised consumption would pose clear difficulties in some areas/situations, for example rural areas, or for clients who worked or had family responsibilities. Clinical guidelines issued by the Department of Health state that supervised consumption is a

recommenced and necessary precaution, which should be implemented during the early stages of an addicts treatment (DOH 1999). Supervised consumption is common in other countries but varies around the UK, where there is still no formal national policy.

In terms of cost, supervised consumption is identified as one of the areas, which inflate the overall price of prescribing heroin. Stimpson and Metribian (2003) estimate that it costs between £7,717-£9,691 per addict per year to prescribe (a supervised) injectable heroin script, compared to £2,800 for a methadone prescription (excluding supervised consumption) (see Table 1.8 below)

Table 1.8: 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 175mg 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 per day; upper cost inflated pro-rata for three injections of heroin per day

source: Stimpson and Metrebian (2003) Prescribing heroin: what is the evidence?

Any consideration of the relative costs associated with prescribing heroin must also include the potential knock-on effects including costs incurred/saved by the criminal justice and health care systems. The Swiss trials also saw improved employment rates and increased productivity amongst those clients receiving heroin prescriptions.

Two other issues to consider when examining the effectiveness of heroin prescribing are; use of illicit drugs in addition to a heroin prescription, as compared to those receiving methadone; and the actual design of the studies themselves in terms of reliability, validity, random allocation of clients, use of control groups etc.

Each of the five studies found a reduction in the levels of illicit drug use exhibited by those on heroin scripts, however not all the studies involved control groups, or pre-treatment stages, with which to compare this reduction. Illicit use was not eliminated in any of the studies. Only one of the UK studies was randomised (Hartnoll et al 1980), as was the Dutch study – and especially in the case of the Dutch study, it was clear that the pragmatics and ethical considerations associated with allocating clients randomly to treatment groups were extremely complex and time consuming. The control and time constraints associated with clinical trials, in any area of treatment, might not easily translate into large scale ‘real world’ treatment programmes.

1.4.3 NTORS

The National Treatment Outcome Research study (NTORS) was commissioned in 1994 at the request of the Minister of Health. A prospective longitudinal study of clients in a range of treatment programmes across the UK, designed to reappraise the effectiveness of the national drug treatment strategy/ies. Clients (1,075) were recruited during the first six months of 1995, and interviewed at various points including intake, six months, one year, two years, five years etc. NTORS followed clients on residential and community methadone maintenance and reduction

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programmes and did not therefore focus on heroin prescribing as a treatment option. However the methodological and ethical considerations it raises, (including the relative cost of treatments in terms of a reduction in criminal activities, and the difficulties of clients moving between treatment programmes/scripts), gives those interested in heroin substitution treatment and its evaluation valuable bench marks from which to begin to make meaningful comparisons.

NTORS conducted a one year follow up study of 478 clients taking part in drug prescribing programmes in 1996 and found that regular use of opiates had fallen from 86% to 55%, and offending (all crimes) had fallen from 62% to 40%.

Chapter Two – INTRODUCTION TO THE STUDY

Chapter Two – INTRODUCTION TO THE STUDY

This chapter will introduce the study by placing it firstly into a ‘prescription context’(mid 1990’s), and then into a regional context. In many ways the UK still has a rather fragmented approach to drug treatment services,(and this was certainly the case in 1996-98), which can often differ significantly from one region to another. (Although this is changing with the establishment of various national agencies eg the National Treatment Agency).

2.1. Political & Policy context of the study: National prescription patterns

Two key studies examined the prescribing patterns involved in the treatment of problem drug use in Britain in the mid 1990’s. The first of these presented reported on the prescribing of agencies/doctors, the second (in two parts) reports on the dispensing of pharmacies.

Sell et al (1997) reported a survey of all drug treatment agencies providing a prescribing service in England & Wales from March to June 1995 (using SCODA and DOH drug agency listings). Of the 172 treatment agencies surveyed’ 105 (61%) responded. Respondents were typically psychiatrists with addiction specialisms. The table below shows one third of those agencies that responded were currently prescribing heroin to, on average, nine clients per agency.

Table 2.1: Percentage of agencies with Home Office Licences to prescribe opiates, March-June 1995

	<u>HEROIN</u>	<u>DIPIPANONE</u>	<u>COCAINE</u>
<i>Ever applied for license to prescribe</i>	44%	15%	7%
Current license to prescribe	43%	12%	5%
Actually prescribing at present	33%	8%	4%
Median duration	5 years	2.5 years	1 year
Mean number of scripted patients	9.2
Daily dose ranges - min-max	10-1,000mg	10-150mg	..
- median	30-200mg	30-70mg	..

source ; Sell et al (1997) Prescription of diamorphine, dipipanone and cocaine in England and Wales. Drug and Alcohol Review, 16, 221-226.
(note – dipipanone is a synthetic opiate used as a major pain killer, trade name Dicanol)

A large national survey of one in four of the 10,616 community pharmacies in England & Wales was conducted in 1995 (75% response rate – 1,984 pharmacies). Half (50%) were dispensing controlled drugs to an estimated 30,000 problem drug users (PDU's) (mean of 5.9 per pharmacy) – this compared with 23% of pharmacies dispensing to an estimated 7,700 IDUs in 1988 (mean of 3.5 per pharmacy). (Sheridan et al 1996; Strang et al 1997)

Overall, 92% of prescriptions to clients were for methadone, 4% for amphetamines, 2% for heroin, 2% for other opiates, and less than 1% for other controlled drugs. In short, 96% of prescriptions were for opiates (3,486) - of these, 96% were for methadone, 1.7% were for heroin, and 2.3% were for other opiates. The table below shows that the mean dose of methadone prescribed was 47mg – this ranged from a mean 44 mg for oral methadone from NHS doctors, to 118 mg for methadone ampoules from private doctors.

Table 2.2: Mean dose prescribed by UK Community Pharmacies 1995

	<u>HEROIN</u>	<u>METHADONE</u>	<u>AMPHETAMINE</u>
FORMS			
Tablets	16%	11%	73%
Ampoules	75%	9%	3%
Liquid	8%	79%	24%
Reefer	2%	<1%	-
DOSES			
Mean	175 mg	47 mg	
Median	130 mg	40 mg	
Range	10-500 mg	2-300 mg	
Interquar- tile range	60-270 mg	30-60 mg	

source: Sheridan et al 1996; Strang et al 1997

2.2. The North West Region

There have been various changes to the geographical and political make up of the North West Region of England over the last 30 years, including changes to the organisation and delivery of drug services. At the time of this study, the UK Governments Department of Health had delegated control of health services in England and Wales to 15 Regional Health Authorities. The Mersey Regional Health Authority covered the counties of Merseyside and Cheshire, each of which was divided into five health districts. (Newcombe 1989)

(It is perhaps worth mentioning at this point that specially licensed General Practioners (GP's) who worked at drug dependency units could only prescribe opiates under the direction of the consultant psychiatrist. As such, the type of prescribing available across DDU's nationally varied depending on the policies of the individual psychiatrist.)

2.2.1 Prescription Patterns in the North West Region. 1995-2000

As stated above, prescription availability varies across the country according to a variety of factors including the prevailing practices of the consultant psychiatrist responsible for each district health authority. The North West Region of England covers Lancashire, Cheshire, Merseyside, Manchester and Greater Manchester. For the five years 1995 – 2000, the following prescription figures were collated for the Region;

Table 2.3: prescribing action for new clients in north west region, 1995-2000
(drug misuse database)

	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>
Valid episodes	4048	7483	7002	7113	6591	7244
METHADONE	2736	5979	5132	5008	4391	4774
Mixture	2661	5517	4965	4605	4270	4630
Amps	27	140	143	75	87	94
Tablets	11	39	17	24	6	4
Reefers	3	1	7	6	2	1
Unspecified	34	282	79	298	26	45
DIAMORPHINE	22	9	23	24	9	11
Amps	8	0	0	1	3	1
Reefers	5	0	4	0	0	0
Unspecified	9	9	19	23	6	10
OTHER OPIATES	298	119	170	196	214	265
Dihydrocodeine	275	97	161	185	178	211
Buprenorphine	2	2	0	1	25	45
Morphine	3	4	2	2	1	3
Codeine	2	2	2	1	4	1
Opiate compounds ~	13	7	2	4	6	4
Unspecified/other	5	9	3	4	0	1
STIMULANTS	16	61	45	37	27	24
Dexamphetamine	14	55	40	30	27	24
Methamphetamine	1	0	1	1	0	0
Unspecified amphet	1	5	2	6	0	0
Cocaine	0	1	2	0	0	0

sources : University of Liverpool and University of Manchester (1996, 1997); Liverpool John Moores University and University of Manchester (1998, 1999, 2000, 2001)
note ~ such as Distalgesic (dextropropoxyphene)

In terms of prescribing trends, the data in Table 2.3 would suggest the following

- (a) reefer scripts and heroin scripts appear to have been phased out, particularly after 1998 (eg. a total of just 3 reefer scripts - all methadone - were given in 1999 and 2000) - It is presumed, this trend is related to the departure of the consultant

psychiatrist, Dr. John Marks in 1998 (once he had left, the new consultants were not prepared to offer reefers to new clients, and heroin scripts generally dwindled). This trend is clearly illustrated in the clinic data presented in section 2.2.4;

(b) the second most common script, surprisingly, is dihydrocodeine - this was largely due to a 'fashion' at the time among Lancashire treatment agencies to prescribe DF118s instead of methadone to some clients.

Table 2.4 below indicates that at the time of data collection for this study (1995-1997), the region experienced a sharp fluctuation in the numbers of clients presenting at the DDU's, ranging from the lowest in the five-year period to the highest. The mid to late 1990's was a period of significant flux, locally and nationally. With so much control of prescribing policy given to individual consultant psychiatrists, it would always be the case that the departure of John Marks, a strong supporter of flexible prescribing, (including the prescription of heroin) in 1998, would have a 'knock-on effect' on the regions prescription patterns. Nationally, the Labour Party won the 1997 general election, and quickly mobilised its 10-year drugs strategy 'Tackling Drugs to Build a Better Britain'.

Table 2.4: methadone prescribing regime for new clients in north west region, 1995-2000 (drug misuse database)

	1995	1996	1997	1998	1999	2000
Valid episodes	2727	5246	4685	4539	3966	4404
Reducing dose	1219	2943	2651	2457	2118	2156
Maintenance	354	564	470	480	448	680
Not known	603	1739	1564	1422	1400	1568

sources : University of Liverpool and University of Manchester (1996, 1997); Liverpool John Moores University and University of Manchester (1998, 1999, 2000, 2001)

2.2.2 North West of England; Client data 1995-1997

The data for the study reported here were collected between August 1995 and February 1997 at two clinics in Cheshire. The prevailing numbers of clients, new clients, heroin and methadone users, referral sources etc in the North West of England as a whole were recorded over that period and are as follows;

1995

10,429 new agency episodes of presenting problem drug misuse were reported from agencies in the NW. This represented 8,488 individuals of whom 52% (4415) were ‘new’ to services. Fifty seven percent of all episodes were reported by statutory community based drug services. Seventy five percent of those reported were male. Eighty four percent were unemployed. Seventy five percent (6,372) were heroin users, and of those 84% (5,328) were primary, and 16% (1,044) were secondary users. Methadone was the second most commonly reported drug, being used by 3,616 (43%)

individuals, 47% of whom reported using methadone as their primary drug.

(University of Liverpool and University of Manchester, 1996)

1996

(these figures are most relevant to the data presented in this study as most of it was collected during 1996)

During 1996 10,499 new agency episodes of presenting problem drug misuse were reported in the NW. This represented 8,665 individuals of whom 47% were 'new' to services. (These figures were very similar to 1995). (again) Fifty seven percent of all episodes were reported by statutory community based drug services. Seventy four percent of those reported were male. Seventy seven percent were heroin users, and almost half (45%) were using methadone, usually (70%) prescribed. Just under half (48%) of those reported had injected a drug in the previous four weeks. Of these 12% acknowledged that they had also recently shared injecting equipment. The number admitting sharing was 4% greater than in 1995.

(University of Manchester and University of Liverpool, 1997)

1997

Fewer episodes and individual users were reported than in the previous two years.

9,177 new agency episodes of presenting problem drug misuse were reported, relating to 7,897 individuals of whom 46% (3,634) were 'new' to services. Sixty six percent of all episodes were reported by statutory community based drug services. Seventy two percent of those reported were male. Seventy six percent were heroin users, and of those 62% (4,897) were primary, and 38% (1,068) were secondary users. The level of heroin use in 1997 (76%) was very similar to that in 1995 (75%). Most heroin users

were injecting (57%). A total of 3,548 methadone users were reported, 74% of whom were using prescribed methadone.

(University of Liverpool and University of Manchester, 1998)

2.2.3 The clinics; location and services

The two community drug teams involved in this study are located in the Cheshire districts of Widnes and Warrington. The same consultant psychiatrist, Dr John Marks, had overall responsibility for the prescribing of opiates (and other drugs) at both clinics.

Both clinics were located in the community; the Widnes clinic was in the town centre, based in offices above an Insurance company, the Warrington clinic was based in a converted town house close to the railway station. At each clinic the staff included a manager, probation officer, social worker, community nurse, an assistant to the manager and a secretary. A small team of specialist GP's employed on a sessional basis supported the consultant psychiatrist, and each clinic also employed three/four outreach workers/counsellors.

2.2.4 The clinics; prescription trends

Both clinics prescribed the following;

Ampoules – methadone, heroin, morphine, amphetamine, cocaine.

Mixture/Syrup - methadone, dipipanone, amphetamine, cocaine.

Tablets – methadone, morphine, cannabis

Reefers - methadone, heroin, morphine, amphetamine, cocaine

(Marks 1991)

According to client lists produced by the Cheshire Family Health Services Authority in November 1997, there were 132 clients registered and receiving prescriptions from the Widnes clinic and 182 from the Warrington clinic. (314 clients in total)

For the financial year ending April 1996, in-house CDT figures showed the following trends in prescribing for each clinic;

Widnes CDT

Clients receiving methadone only rose from 28.75% in April 1995, to 72% in April 1996. Clients receiving diamorphine only fell from 27% in April '95 to 8% in April '96. Clients prescribed a combination of the two fell from 30.5% in January '96 to 20% in April '96

Warrington CDT.

Clients receiving methadone only, rose from 59% in April 1995, to 94% in April 1996. Clients receiving diamorphine only fell from 11% in April '95 to 1% in April

'96. Clients prescribed a combination of the two fell from 30% in April '96 to 5% in April '96.

2.2.5 Pilot Study; Injectable and Smokable opiates

From 1989, the drug dependency units in Widnes and Warrington began prescribing injectable and smokable alternatives ('reefers'), to those clients registering with a history of long term or injecting drug use. These alternatives included heroin, methadone, (and less frequently) amphetamine and cocaine. The reefers were produced by a local pharmaceutical company in Liverpool and distributed to local pharmacies. Herbal or nicotine cigarettes were injected with a solution of the particular drug (dissolved in chloroform), most commonly diamorphine or methadone hydrochloride. The chloroform would evaporate after a few minutes, leaving only the dissolved drug and a slight green stain on the cigarette paper behind. This green stain would distinguish the reefer from a standard cigarette and help prevent any confusion between the two. Clients were prescribed injectables and/or reefers either in conjunction with other drugs, or as a complete replacement. (see Atlantic Project video, 1991)

It was noted that up to two thirds of the drug in a reefer may be lost due to either poor inhalation techniques or side-stream smoke, and for this reason clients on reefers were prescribed higher doses than those on injectables and oral mixture. For roughly equivalent prescriptions, the relevant prescription costs per year were £100-£200 for oral methadone, £300-£600 for reefers, and £1000-£2000 for injectable opiates. (Marks et al 1991)

Many drug users accepted prescribed ampoules or smokables as an attractive, realistic and sustainable alternative to illicit injecting. Previously, clients not wanting detoxification were almost uniformly offered oral methadone (or occasionally) diamorphine as the only alternative to injecting heroin. For an addict prescribed this oral substitute, the absence of the 'rush' (fast, intense entry into intoxication) associated with injecting often led to dissatisfaction and a search for 'black market' excitement, sometimes financed by selling part or their entire oral substitute. (Marks et al 1991)

Prescribing smokable alternatives resulted in the user experiencing the 'rush' whilst avoiding the transmission of HIV, and risk of potentially fatal poor injecting techniques. It was also suggested that the diamorphine reefers, with a shorter 'half-life', were less addictive (and therefore easier to eventually withdraw from), than the oral methadone syrup previously offered. (Marks, Palombella & Newcombe, 1991)

The driving force behind this initiative was a desire to help clients reduce the risks associated with illicit injecting (particularly H.I.V. infection), and to encourage those illicit drug users (previously not in contact with any agency) to make contact and secure the associated help and support (Marks et al, 1991; Marks & Palombella, 1990).

Based at a drug dependency unit in Cheshire, Newcombe (1989) conducted an initial small scale pilot study involving 20 clients in four different prescription groups. The two IVs were type of drug (heroin or methadone) and form of drug (reefer or mixture), with five clients in each of the four conditions (heroin

reefer, heroin mixture, meth reefer, meth mixture). Initial findings indicated some success, particularly in relation to reefers being a viable alternative for reducing illicit injecting levels and levels of criminal behaviour. A series of follow up interviews with the clients seemed to suggest that certain combined scripts (namely meth mixture and heroin reefers together) were associated with better crime/drug use outcomes than single scripts? (Funding for the main study was not secured) (Newcombe 1989)

2.3 Research Rationale and Aims

Although Britain and ‘the British System’ has played a significant part in the history of diamorphine, there have been surprisingly few UK research studies specifically focused on its viability as a treatment option for problem drug users. Those who question its viability cite three main areas of concern; risk of diversion, increased costs, and risk of prolonging an injecting drug ‘career’. Those who support the use of diamorphine offer examples of good practice to challenge these concerns, and cite findings from (limited) previous research as evidence to support their claims that diamorphine has its place in the treatment range.

It appeared (and continues to appear to be the case) that medical practitioners and government policy makers were at odds in terms priorities; the medics prioritising the need of the individual to be drug free, and the policy makers prioritising the needs of the wider community in terms of the reduction of crime. An effective treatment strategy would need the support of both groups, and would therefore have to address clinical needs and societal needs.

This study explored the effectiveness of diamorphine/heroin as a treatment option for those problem drug users for whom, for a variety of reasons, it may have been better suited than the traditional substitution drug; methadone. “Effectiveness” was assessed across several criteria including use of illicit drugs, self-efficacy, criminal activity and drug-related time demands.

Aims

The project aimed to assess several inter-linked questions within a harm reduction framework. Three key areas and their association with heroin prescribing will be addressed; levels of criminal activity, levels of illicit drug use, and a range of client held perceptions regarding coping/quality of life etc.

Chapter Three - METHODOLOGY

Chapter Three - METHODOLOGY

3.1 Design

Apart from two demographic variables (**gender** and **age**), all variables fall into three categories - i) Type of prescription (**script type**), ii) Drug consumption (**drug use**), and iii) Criminal behaviour (**crime**) - each of which can be divided into *primary* and *secondary* variables, as well as into 'behaviour' and 'perceptions' items.

(Question numbers refer to the relevant item/s on the Research Questionnaire, which can be found in Appendix 1.)

3.1.1 Script Type

Script type is based on three *primary* categorisations of prescription information: **form** (ampoules/mixture/reefers), **drug** (methadone,/heroin/other), and **form&drug** combined (heroin reefers, methadone mixture, heroin ampoules etc).

Excluding various rare/unusual scripts (eg cocaine, methadone tablets) three script-type variables are as follows:

1. Form only: a. Script includes ampoules (yes/no), b. Script includes reefers (yes/no), and c. Script includes mixture (yes/no)
2. Drug only: Script contains methadone only (n=63), heroin only (n=36) and heroin & methadone only (n=16)

3a. Specific script: (3 main script combination types): methadone mixture (MM) (sole & combined), heroin reefers (HR) (sole & combined), and MM with HR (sole & combined)

3b. Specific Script: as (3a), but, due to small numbers, excluding MM&HR (n=10), leaving MM (n=51) and HR (n=25)

Five *secondary* script variables include: **dose** (in milligrams)- question 1, **duration** of time on that particular script (months) – q2, who made the **decision** to receive current script (client +/-or staff) – q4, perceived **satisfaction** with current script (5-point rating scale) – q3, and perceived desire to **change** current script (incl. how & why client would like script to change) – q5.

3.1.2 Drug use

Drug use is based on one *primary* variable – the use/non-use of nine types of drugs – (cannabis, alcohol, nicotine, heroin, diamorphine, methadone, amphetamine, cocaine and benzodiazapines). This variable was re-coded from questions 6&7 which asked about the frequency with which the drug was taken.

‘Drug use’ data is also based on 9 *secondary* variables:

1. amount consumed (x 9 drugs as above) – questions 6&7,
2. frequency with which the drug was taken (x 9 drugs as above) – q’s 6&7,
3. spending per month (x 6 drugs above – not alcohol/cannabis/nicotine) – q10,

4. injecting – drug (what/which drugs injected in the last month) – q8a
5. injecting – frequency (injected how often in the last month) – q8b
6. source – where are illicit drugs acquired from – q9
7. financing – are wages/benefits used to pay/partly pay – q11
8. time-taken – with drug use (including crime) per day – q15
9. perceived causes of use – main factors causing use – q18

Two additional variables are also examined in relation to drug use. These are i) perceived coping with life now (q16), and ii) perceived quality of life compared to one month ago (q17a) (both measured on 5-point rating scale)

3.1.3 Crime

Crime is based on one *primary* variable – whether the user did/didn't do seven acquisitive crimes (burglary, shoplifting, dealing script, dealing street drugs, prostitution, theft from family, and other thefts) – this variable was re-coded from question 12 which asked about frequency of crimes committed.

Three *secondary* crime variables include: frequency (of committing the crime - ranging from every day to not in the past month – q12), perceived causes (why this crime was carried out – q13), and perceived script-crime link (would a change in script affect criminal behaviour – q14)

Using the abbreviated labels explained above, the variables can be summarised in the table below;

Table 3.1: Summary of Variables

	<u>BEHAVIOUR</u>	<u>PERCEPTIONS etc.</u>
SCRIPT	Type (x4) Dose Duration Decision	Satisfaction/Change-script
DRUG USE	Type (9 drugs) Amounts/Frequency/Spending Injecting/Source/Financing/Time-taken	Causes/Coping/Quality
CRIME	Type (7 crimes) Frequency	Reasons/Script-crime

3.1.4 Research Questions

The main research question and source of most statistical comparisons is; does the type of prescription affect illicit drug use, criminal activity, or related perceptions/attributions among treatment clients?

<u>Independent variable</u>	<u>Groups of dependent variables</u>
Script-type	→ Drug consumption
	→ Criminal activity
	→ Perceptions/Attributions about drugs/crime

Due to the limited and conflicting evidence all statistical tests were 2-tailed.

3.2 Participants

One hundred and thirty three registered drug users based at one of two drug dependency units in the North West of England; Warrington and Widnes, were recruited to the study via convenience/opportunity sampling. The average age of the sample was 30, with a range of 20-49 years. Clients were recruited over an 18 month period between August 1995 and February 1997, in three phases; August 1995-October 1995 (50 clients), April 1996-June 1996 (36 clients), and December 1996-February 1997 (47 clients). Data were gathered in three phases for two reasons; 1. the clinics were relatively small and the researcher had to wait for new referrals to be made, and 2. external factors, unconnected with the study, restricted the time available to carry out the (often time consuming) interviews.

Of the one hundred and thirty three clients, 75% were male, 24% were female (in error two clients were not recorded). The drug dependency units had a total of 314 registered clients, 182 at Warrington and 132 at Widnes. (Clinic records November 28th 1996) Of the total registered, 73% were male (229) and 27% were female (85). On the basis of these figures, it was estimated that about 40% of clients registered at the two DDU's during the study period participated in the research.

3.3 Procedure

3.3.1 Pilot Study

Between January 1994 and March 1994, 57 registered drug users, based at the same two drug dependency units, completed a one hour semi-structured, questionnaire-based interview, answering questions relating to their past and current, behaviour and attitudes.

The forty five men and twelve women, (with a mean age of 31), divided into three groups according to the prescription they were receiving; - an exclusively or predominantly smokable prescription (N=23, 40%), exclusively or predominantly injectable prescription (N=16, 28%) and an exclusively or predominantly oral methadone prescription (N=18, 32%). The sample was made up of clients who had been registered for between 3 months and 14 years, with a mean registration period of 4.5 years. Respondents were contacted by opportunistic sampling.

Differences were apparent, both across prescription groups (for example those on injectables compared with those on smokables), and across the time periods of before and after registration at the clinic.

Initial conclusions were drawn in three main areas; Firstly, initial analysis suggests that different prescription regimes did have significant effects on the subsequent prevalence and frequency of unhealthy and anti-social behaviours. Secondly, it is clear that, for the majority of those clients interviewed, registering at a drug dependency clinic had a positive effect on their quality of life across a number of different levels. Thirdly, prescribing practice continues to be heavily influenced by the prevailing political and economic climate of the area/time, and it is this factor in

particular which may prove to be the key to the success or otherwise of future service provision.

Many questions and response formats were also modified as a result of feedback during the pilot study.

(Shortly after the pilot study, the project and degree registration was officially suspended due to a serious road traffic accident, hence the gap between pilot study and main study)

3.3.2 Main Study

After consultations with a number of clients, clinic staff, and a review of the available literature and pilot study methods, it was decided to utilize the self-report method of a questionnaire-based interview to elicit the required information. (see Harrison 1995)

Each client was asked to complete a self-report questionnaire during a forty-minute interview. (Appendix 1.). Each interview was conducted in an environment of the clients choosing, invariably the waiting area of the clinic or a nearby side room. Every effort was made by the researcher to distance herself from the day to day running of the clinic or management of the client's 'script. When working with clients in a manner which assumes a certain amount of risk related disclosure, however minimal in reality, it is clearly important to quickly establish an egalitarian relationship rather than a hierarchical one. (Springer 1991) At no time during the clinic session did the researcher enter the DDU, she remained in the waiting area with any clients arriving to attend various groups/appointments.

It is commonly held that research which utilizes rigorous procedures to protect respondent anonymity and confidentiality produces the best possible estimates of both legal and illicit drug use. With the rules applied in the clinic setting, in particular the immediate cessation of a prescription should 'top-up' illicit use be detected, this confidentiality became doubly crucial. Classical utility theory assumes that respondent's decisions on how accurately to respond to sensitive questions on drug use is based on the perceived risks if they provide truthful responses and the perceived loss associated with possible outcomes if the information were known. (Harrison 1995).

All clients were reassured that none of their responses would be seen or reported to clinic staff, no names were recorded and all completed interview data was taken/posted directly to the university following the session.

3.4 Research Instrument/Materials

The self-report questionnaire is divided into four sections; a) questions about prescriptions, b) questions about drugs used in addition to prescription, c) questions related to criminal activities, and d) questions related to quality of life in relation to current drug use. Specifically, these sections included items related to basic demographic data, current prescription type and form, perceptions/feelings and attributions, illicit drug use history and currently, criminal activities and frequency, injecting behaviour, and additional specific items relating to source and funding of illicit drugs. The questionnaire can be found in Appendix 1.

Questions were formulated according to the four key variable areas: prescriptions, drug consumption, crime, and perceptions/attribution. Whilst the range of possible topics is quite clearly vast, it was decided to maintain focus on these three throughout, to maximise the relevance of the study to the key areas of controversy surrounding the issue of heroin prescribing.

Validity. In general surveys of drug use are often criticised on the assumption that respondents underreport the true extent of their substance use. However validation studies conducted in the early 1990's involving known samples of drug users, correlating self report data with urinalysis techniques showed that drug use was fairly accurately reported. (Harrison 1995)

Response formats included open-ended (13 questions), rating scales (3 questions) and multiple choice (25 questions). Rating scales were 5-point Likert scales, with each point numbered and labelled.

3.5 Methods of Analysis

In analysing the data, the researcher adopted a strict view of all rating scales as ordinal rather than interval measurement: In terms of the rating scales, consistent use of non parametric analysis was employed to avoid ‘forcing’ the issue to ‘create’ significant findings by using parametric equivalents.

Descriptive analyses included measures of central tendency, measures of dispersion, and percentage figures. Inferential analyses focused on tests of differences between script conditions (Mann-Whitney, Chi Square, t-tests, 1-way ANOVA etc) and correlation of some interval variables (eg age, duration on script).

3.6 Ethics

In line with BPS Ethical Guidelines, all the clients were informed about the content of the questionnaires before giving their consent to take part in the study. Clients were also told that the questionnaires would be completed anonymously. For this reason clients were made aware that they were free to withdraw from the study at any time until they submitted their questionnaire, after this time their questionnaire would be untraceable.

Participation was entirely voluntary, and had no bearing on their attendance at the clinic or the prescription they would receive. Approval for the study (pilot and main study) was given by the multidisciplinary management team responsible for both clinics, under the guidance of the Consultant Psychiatrist.

Chapter Four – FINDINGS

Chapter Four - FINDINGS

Findings will be presented in five sub sections as follows; Characteristics of the sample (basic demographic information); Types of prescription (categorised for analysis purposes, and also including duration of 'script' data); Client perceptions and attributions (including self efficacy and quality of life); Illicit drug use (including the use of 'top up' drugs and their cost); and Criminal activity (categorised in terms of type and frequency of crime). Illicit drug use and Criminal activity both focused on reported behaviour in the month prior to interview.

4.1 Characteristics of sample

The sample was made up of 133 clients registered at one of two drug dependency units (DDU's) in the North West of England, and data was collected in three phases between August 1995 and February 1997. One hundred clients were male (75%), 31 female (24%), and the gender of two was not known. The average age of the sample was 30 years, with a range of 20 to 49.

4.2 Types of prescription.

The sample received a total of 29 different types of prescription based on a combination of form (ampoules, mixture, reefers, tablets) and drug type (heroin, methadone etc). The most common of these were methadone mixture 38 (29%), heroin reefers 18 (14%), heroin ampoules 12 (9%), methadone mixture and heroin reefers 8 (6%), methadone reefers 6 (5%), and methadone ampoules 6 (5%).

For analysis purposes the prescriptions were categorised in 3 different ways: (1) three main forms, (ampoules, mixture and reefers); (2) three main types of drugs (heroin, methadone and heroin & methadone together); and (3) three main combinations (methadone mixture, heroin reefers and heroin ampoules).

Twenty three percent of the sample received part/all of their prescription in the form of **ampoules**; 52% were receiving heroin, 32% received methadone, 6% received methadone and heroin, and three were unspecified. Fifty five percent of the sample received part/all of their prescription in the form of **mixture**; 3% were receiving heroin, 83% received methadone, and ten were unspecified. Thirty six percent of the sample received part/all of their prescription in the form of **reefers**; 67% were receiving heroin, 15% received methadone, 6% received methadone and heroin, and six were unspecified. (see Table 4.1 below).

Of the 14 clients who received “other” prescriptions; 43% received benzodiazapines, 29% received methadone tablets, 7% received Dicanol, one person received morphine sulphate, one anti-depressants, and one was unspecified.

The mean time clients had been receiving a prescription was a little under 3 years (35 months), with a range of one month to 21 years.

(As expected) There was a highly significant positive correlation between age and number of months on script. ($r=+.34$, $p < 0.001$, $n = 122$)

When focusing on prescriptions categorised by **type** of drug; 47% received methadone only, 27% received heroin only, and 12% received a combination of methadone and heroin. When focusing on the three main prescriptions by type and

form: 38% received methadone mixture, 19% received heroin reefers, 8% received a combination of methadone mixture and heroin reefers.

The range of prescriptions - based on the drug prescribed and its form (or method of use) - are summarised in Table 4.1 below:

Table 4.1: Numbers (%) of clients getting each of 12 types of script, based on combination of three forms and four drug types

	<u>Ampoules</u>	<u>Reefers</u>	<u>Mixture</u>
Methadone	10 (32)	7 (15)	61 (84)
Heroin	16 (52)	32 (67)	2 (3)
Meth. & Heroin	2 (7)	3 (6)	0 (-)
<i>Unspecified</i>	3 (10)	6 (13)	10 (14)
TOTAL	31	48	73

When interpreting this table, it is important to note that some clients receive more than one script-form, eg. reefers and mixture; while some receive more than one drug (eg. heroin and methadone).

In short, clients prescribed ampoules and clients prescribed reefers are similar on their ‘drug’ profile - most received heroin, some methadone – while those getting mixture were far more likely to be prescribed methadone, and fairly unlikely to be prescribed heroin.

If the ‘unspecified’ and multiple-drug cases are removed from the analysis, there are six remaining categories of prescription - the mean daily doses for each of these is shown in Table 4.2:

Table 4.2: Mean daily doses (mg) involved in each of the six main types of prescription

	<u>Ampoules</u>			<u>Reefers</u>			<u>Mixture</u>		
	Mean	SD	N	Mean	SD	N	Mean	SD	N
Methadone	96	35	10	244	147	7	60	28	54
Heroin	203	157	15	430	196	29	90	14	2

Some clients received more than one drug, or different forms of a drug, and so are represented by more than one script type in Table 4.2. However, it is still possible to examine prescribing trends across the script types; for instance, among those on ampoules, those getting heroin were prescribed twice as much as those getting methadone. There is a similar ratio for reefers (almost 2:1), but this is less pronounced for mixture (1.5:1). This reflects the higher potency of methadone compared with heroin.

As mentioned in the Introduction, it is usual that reefer clients are prescribed doses two to three times higher than those for ampoule clients because it is assumed by clinic staff that up to half of the drug is lost through sidestream smoke etc.

Two of the main specific drug/form prescriptions of interest in this particular study were methadone mixture (MM) and heroin reefers (HR). The following table gives a breakdown of figures for these two types of script, either alone or with others;

Table 4.3: Number (%) of people on two main specific scripts (MM & HR) who were on that drug alone or another drug too

	<u>This script alone</u>	<u>With HR/MM</u>	<u>With other eg. amps</u>	<u>TOTAL</u>
Meth mixture	38 (62)	10 (16)	13 (21)	61
Heroin reefers	18 (51)	10 (29)	7 (20)	35

Focusing on the two main specific script groups above (MM and HR) two statistical tests were carried out for age and gender;

The differences in age between the different script groups were non-significant (mean of 29 and 30 years respectively).

But the gender difference was highly significant – 96% of heroin reefer clients were male compared with 65% of methadone mixture clients. (Chi-Square (YC) = 6.79, df = 1, $p < .01$)

(These figures will be discussed further in relation to section 4.5 ‘Criminal Activity’, and in particular the shoplifting and prostitution results)

This gender bias is apparent when we look at the sample as a whole, 24% of which are female. Thirty five percent of methadone mixture clients are female, compared with just 4% of heroin reefer clients.

4.3 Client Perceptions and attributions.

Of the 131 clients who responded when asked about their perceived quality of life currently as compared with one month ago, 20% replied that it was worse or a lot worse, 47% stated that it was no different, and 23% indicated that it was better or a lot better. (Of the half who indicated “no difference”, many may have been in treatment for several months/years, and improvements may already have occurred). When asked to cite reasons for any changes in life quality, the three main causes were being prescribed methadone (11%), “prescription not large enough/has been reduced” (19%), and “drugs/drug use generally” (11%).

When asked to describe the main cause/causes of their current drug use over half gave one or more of three reasons: 21% cited addiction/dependence, 19% stated that they were unemployed or had nothing to do, and 11% indicated limited clinic treatment policies/practices.

Regarding satisfaction with prescriptions, 39% of the total sample reported being unhappy with their prescription, and 44% reported being happy. In addition, 56% clients indicated that if they had a choice they would like to see their script altered, in the main by either increasing their existing dose of smokable diamorphine (15%), or by changing to a smokable diamorphine prescription (29%).

The three main reasons cited for changing their prescription were to succeed in the treatment programme (24%), to stay off street drugs (37%), and because methadone made them ill (21%).

An assessment was made of whether there were any significant associations between script type and respondents perceptions and attributions, namely; satisfaction with script, self-efficacy/coping etc, and perceived quality of life.

Assumptions for parametric testing were generally not met by the data, so non-parametric (Mann-Whitney) testing was justified. (In each of the following statement of findings, the independent variable is underlined, the dependent variable is presented in italics, and relevant statistics are presented in brackets).

There were 4 significant effects:

1. Clients whose scripts included oral drugs (mixture) were significantly *less happy with their script* compared with other clients (mainly using amps and/or reefers) – 2.7 compared with 3.9 (U = 153.5, $p < .002$)
2. Clients on methadone mixture were significantly *less happy with their scripts* compared with clients on heroin reefers – 2.4 compared with 3.6 (U = 58.5, $p < .02$)
3. Clients whose scripts included injectable drugs (ampoules) perceived themselves as significantly more *able to cope with life* compared with other clients (mainly on mixture and/or reefers) – 3.9 compared with 3.1 (U = 120.5, $p < .02$)
4. Clients whose scripts included injectable drugs (ampoules) perceived their *quality of life*, compared with one month ago, as significantly more improved compared with other clients (mainly on mixture and/or reefers) – 3.6 compared with 2.9 (U = 132, $p < .02$)

Being happy with script, coping with life, and reporting improved life quality (all 5 point scales) were all highly positively inter-correlated, as might be expected - meaning that when a significant effect for one is observed, it tends to be observed for the other two (eg. effects of script type). None of the three psychological variables were correlated with age.

4.4 Illicit Drug use (and nicotine/alcohol)

The sample reportedly spent an average of just over 2 hours per day on drug related activities (illicit and legal activities), and spent an average of £683 per month on illicit drugs (about £22.50 per day). The consumption levels (frequencies and costs) for each main drug consumed are shown in Table 4.4 below:

Table 4.4: Drug consumption: past-month use, frequency of use, weekly amounts, and monthly spending

	Past-month Use	Frequency of use			Weekly amounts Mean (SD)	Monthly spending Mean (SD) [n]
		Daily	Weekly	LTW		
Alcohol	35%	16%	9%	1%	40 (35)	
Nicotine	82%	77%	0	0	124 (52)	
Cannabis	59%	40%	4%	1%	12.2 (8)	
Heroin	61%	31%	13%	3%	4.1 (3.1)	£638 (688) [76]
Diamorphine	9%	4%	2%	1%	1183 (1066)	£184 (285) [9]
Methadone	11%	6%	2%	1%	347 (337)	£91 (133) [12]
Amphetamine	5%	0	2%	0	2.2 (1.6)	£100 (49) [5]
Cocaine	17%	1%	8%	3%	3.6 (4.1)	£268 (283) [16]
1+ illicit drugs	70%				All drugs:	£683 (788) [76]

Notes:
The three figures for frequency of use do not add up to the figure for all past-month use partly because some people indicated that they used but did not indicate the frequency
Amounts: in grams – except: alcohol (standard units), nicotine (number of cigarettes), and pharmaceutical diamorphine and methadone (milligrams)

Significant effects of script type were found for use of speed, cocaine and cannabis:

Clients on mixture scripts were significantly more likely to use speed than clients on reefers or ampoules. (Chi Sq=3.43, df=1, p<.03) (8% and 0%)

Clients on ampoules were significantly more likely to use cocaine than clients on reefers or mixture. (Chi Sq (YC)=5.82, df=1, p<.02) (32% and 12%)

Clients on mixture used significantly less cannabis than those whose scripts include reefers or ampoules. (t=2.2, df=68, p<.03) (9.2g compared to 15.9g)

Ninety three (70%) clients reported using illicit drugs as well as the prescription they received from the clinic, half (48%) injected the drugs. 68% of these injected on at least a daily basis, with heroin being the most common drug for 54%. Fifty one percent cited a dealer as their main source, and 33% cited a combination of other users/dealers as the source for these illicit drugs, 16% reported using wages to pay for them, and 84% reported using social security benefits.

4.4.1 Total monthly drug cost.

Table 4.4: shows the average monthly spending on each of the five main illicit drugs (excluding cannabis). The largest amount is spent on heroin, with one third of clients using daily, and with an overall average consumption of just over 4g per week, followed by cocaine and diamorphine. The least amount spent was for methadone and amphetamine.

Clients whose scripts include mixture spend significantly less on drugs than clients whose scripts include ampoules or reefers. (t=2.04, df=47.9, p<.05)

Mixture = mean of £493, Amps/Reefers = mean of £875

There is a significant positive correlation between age and total monthly drug costs (r = +.34, p < .003, n = 75) – further analyses reveal this overall effect to be based

mainly on a correlation between age and monthly spending on heroin (but not other drugs). Age is also correlated with monthly amount of illicit heroin used in grams (but not amounts of other drugs consumed). In short this shows that heroin users tend to buy and use more heroin, but not other drugs, as they get older (as their habit grows).

Clients whose scripts included injectable drugs (ampoules) allocate significantly less *time to drug-taking activities* compared with other clients (mainly on mixture and/or reefers) – 1.4 hours compared with 2.3 hours (U = 104, p<.005)

4.5 Criminal activities.

Clients were asked to indicate how often they had engaged in a range of criminal activities during the last month; ranging from every day to not at all within the last month.

The table below gives a breakdown of the self-reported types of criminal activities undertaken by the clients along with their frequency. In total 1459 separate crimes were reported in the month prior to interview, ranging from shoplifting to burglary, with 20% of clients reporting criminal activity on a daily basis and 75% reporting criminal activity at least once every week.

Table 4.5: Reported Frequency (%) & Types of Criminal activity during the month prior to interview.

Number (%) of clients committing crime						
	daily	3-4 per week	1-2 per week	1 per fortnight	1 per month	<i>Total incidence per month</i>
Burglary	0	1 (22)	5 (50)	6 (20)	5 (8)	58 (4)
Shoplifting	7 (39)	14 (37)	20 (22)	3 (1)	2 (1)	534 (37)
Dealing [script]	0	2 (39)	5 (42)	5 (14)	4 (5)	72 (5)
Dealing	13 (77)	5 (15)	6 (7)	0	3 (1)	473 (32)
Prostitution	0	0	4 (89)	1 (7)	1 (4)	27 (2)
Theft from family	2 (43)	3 (33)	4 (19)	2 (3)	3 (2)	129 (9)
Other crime/s	5 (84)	1 (9)	2 (7)	0	0	166 (11)
<i>Total freq.of crim. activity</i>	27	26	46	17	18	
<i>Total incidence of crim. activity</i>						1459(100)

The two most common types of criminal behaviour reported are shoplifting and drug dealing, making up 37% and 32% of the total number of incidents respectively.

Ninety eight percent of those who report shoplifting do so at least once every week, with the vast majority (76%) committing offences almost every day. Ninety two percent of those who report drug dealing consist of clients who report dealing every day (77%). ‘Other’ crimes were either theft from or of a motor vehicle. (see Table 4.5 above)

4.5.1 Drug Dealing.

Of those clients who reported drug dealing, those on mixture dealt every day, while drug dealers on other scripts were more likely to be dealing on a non-daily basis.

However, looking at the total sample, only 10% of those on mixture reported dealing, as compared to 16% of those receiving ampoules and 19% of those receiving reefers.

(see Table 4.6)

Table 4.6: Number (%) of drug dealing clients who sold drugs on a daily, near-daily or weekly basis, broken down by four forms of script

	<u>Daily</u>	<u>3-4/week</u>	<u>1-2/week</u>	<u>Total</u>	%of total gp.
Ampoules	1 (20)	1 (20)	3 (60)	5 (21)	16%
Mixture	7 (100)	0	0	7 (29)	10%
Reefers	4 (45)	2 (22)	3 (33)	9 (37)	19%
Combined	1 (33)	2(67)	0	3 (13)	
TOTAL	13 (54)	5 (21)	6 (25)	24 (100)	

As mentioned in the introduction, a major concern raised by many in the discussions surrounding the costs/benefits of flexible prescribing is black-market leakage, and the potentially lucrative market for ampoules and to a lesser extent reefers. The following table summarises reported script dealing across the four groups;

Table 4.7: Numbers (%) of script-leaking clients who passed on their script on a weekly, fortnightly and monthly basis, broken down by four forms of script

	<u>3-4/week</u>	<u>1-2/week</u>	<u>1/fortnight</u>	<u>1/month</u>	<u>Total</u>	group %
Ampules	0	1 (50)	0	1 (50)	2 (12)	6%
Mixture	1 (14)	2 (29)	3 (43)	1 (14)	7 (44)	10%
Reefers	1 (25)	2 (50)	1 (25)	0	4 (25)	8%
Combined	0	0	1 (33)	2 (67)	3 (19)	
TOTAL	2 (13)	5 (31)	5 (31)	4 (25)	16 (100)	

4.5.2 Script-leaking.

In terms of script leaking (dealing part or all of their own prescription), only 6% of those receiving ampoules reported selling/passing on their script, as compared to 8% and 10% for those on reefers and mixture respectively. Amongst those who do report dealing part/all of their scripts, 44% receive mixture (see Table 4.7)

4.5.3 Shoplifting.

Reported shoplifting figures were very similar for those receiving ampoules and those receiving mixture; 29% for the ampoules group and 27% for the mixture group. Those receiving reefers reported much lower levels, with 15% of the group reporting that they had shoplifted, however of these, 29% reported shoplifting on a daily basis. Whereas shoplifters in the other three groups were more likely to be doing it on a weekly basis. (see Table 4.8)

Table 4.8: Number (%) of shoplifting clients who stole from shops on a daily, near-daily or weekly basis, broken down by four forms of script

	<u>Daily</u>	<u>3-4/week</u>	<u>1-2/week</u>	<u>Total</u>	% of total gp.
Ampoules	1 (11)	3 (33)	5 (56)	9 (21)	29%
Mixture	3 (15)	9 (45)	8 (40)	20 (48)	27%
Reefers	2 (29)	2 (29)	3 (42)	7 (17)	15%
Combined	1 (20)	0	4 (80)	5 (13)	
TOTAL	7 (17)	14 (34)	20 (49)	41 (100)	

Significant effects of script type were found only for shoplifting and prostitution.

Clients on reefers are significantly less likely to shoplift compared with other clients (mainly on mixture or ampoules), 23% compared with 41%.

(Chi Sq= 3.75, df = 1, p<.05)

4.5.4 Prostitution

Clients on mixture were significantly more likely to do prostitution than other clients (mainly on ampoules or reefers), 8% compared with 0%.

(Chi Sq = 3.43, df = 1, $p < .03$)

As stated in section 4.2 there are clear gender patterns which almost certainly account for these two significant effects. These effects must be viewed alongside the gender of those clients receiving mixture scripts, who are 33% female, as compared to an overall sample percentage of 24% female. Only 4% of those clients receiving reefers are female. It is widely accepted that the two crimes most frequently carried out by female drug users are shoplifting and prostitution. It therefore seems fair to conclude that these two effects are the product of a gender bias in the make up of the script group, rather than a product of the nature of the script itself.

4.6 Crime and Drug Use

(As expected) There were several significant effects of 'past month crime' (either did no crime in the past month, or did) on overall drug use and overall drug buying:

72% of past month drug buyers had done 1+ crimes

35% of past month non-buyers of drugs had done 1+ crimes

Chi (YC)=13.73, df=1, $p < .001$

Similarly:

76% of past month drug users had done 1+ crimes

33% of past month non-users had done 1+ crimes

Chi (YC)=21.26, df=1, $p<.001$

The latter effect seems to be based largely on two types of drug use: heroin and cocaine, i.e.

75% of past month heroin users had done 1+ crimes

44% of past month non-users of heroin had done 1+ crimes

Chi(YC)=11.84, df=1, $p<.001$

100% of past month cocaine users had done 1+ crimes

56% of past month non-users of cocaine had done 1+ crimes

Chi(YC)=13.54, df=1, $p<.001$

(Raw data/frequencies for Chi Square Calculations can be found in the appendices, p137.)

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DISCUSSION

5.1 Overview

Summary of Key Findings

Key findings can be sub-divided into categories according to the initial aims of the study, which were;

‘...to assess several inter-linked questions within a harm reduction framework. Three key areas and their association with heroin substitution prescribing will be addressed; levels of criminal activity, levels of illicit drug use, and a range of client held perceptions and attributions regarding coping/quality of life etc.’

Each of the three areas were examined according to the type of script an individual client received, with the two primary script variables being *form* (whether the script was injectable, in mixture form, or in the form of smokable reefers), and *type of drug* (whether the script was for methadone or diamorphine/heroin). Significant effects are summarised in Table 5.1 below:

Table 5.1: Summary of significant effects (and p. values)

	Drug use	Crime	Perceptions & Attributions
Prescription includes mixture	- Use significantly <i>more</i> speed than those on reefers/amps (p<.03) - Use significantly <i>less</i> cannabis than those on reefers/amps (p<.03) - Spend significantly <i>less</i> money on drugs than those on reefers/amps (p<.05)	- Significantly <i>more</i> likely to do prostitution than those on reefers/amps (p<.03)	- Significantly <i>less</i> happy with prescription than those on reefers/amps (p<.002)
Prescription includes ampoules	- Significantly <i>more</i> likely to use cocaine than those on reefers/mixture (p<.02)		- Significantly <i>more</i> able to cope with life than those on reefers/mixture (p<.02) - Significantly <i>more</i> improved quality of life than those on reefers/mixture (p<.02) - Significantly <i>less</i> time taken up with drug taking activities than those on reefers/mixture (p<. 005)
Prescription includes reefers		- Significantly <i>less</i> likely to do shoplifting than those on mixture/amps (p<.05)	
Methadone mixture prescription			- Significantly <i>less</i> happy with prescription than those on reefers (p<.02)

5.1.1 Key findings in relation to criminal activity

In relation to criminal activity, two significant effects were found, for shoplifting and for prostitution. Clients receiving reefers were significantly less likely to shoplift compared with those on other scripts. Clients receiving mixture based scripts were significantly more likely to engage in prostitution than those on other scripts. These

effects must however be viewed alongside the gender of those clients receiving mixture scripts, who are 33% female, as compared to an overall sample percentage of 24% female. Only 4% of those clients receiving reefers are female. It is widely accepted that the two crimes most frequently carried out by female drug users are shoplifting and prostitution. It therefore seems fair to conclude that these two effects are the product of a gender bias in the make up of the script group, rather than a product of the nature of the script itself.

Seventy five percent of the sample reported committing a least one crime every week; in the main this was either shoplifting or drug dealing. There were a total of 1459 crimes reported for the month prior to interview, which represented an average of 11 crimes per client. There were some interesting findings in relation to three specific crimes; drug dealing, script leaking, and frequency of shoplifting. Of those clients who reported drug dealing, those on mixture dealt every day. However, looking at the total cohort, only 10% of those on mixture reported dealing, as compared to 16% of those receiving ampoules and 19% of those receiving reefers.

As regards script leaking (dealing part or all of their own prescription), only 6% of those receiving ampoules reported selling/passing on their script, as compared to 8% and 10% for those on reefers and mixture respectively. Amongst those who do report dealing part/all of their scripts, 44% receive mixture. Reported shoplifting figures were very similar for those receiving ampoules and those receiving mixture; 29% for the ampoules group and 27% for the mixture group. Those receiving reefers reported much lower levels, with 15% of the group reporting that they had shoplifted, however of these, 29% reported shoplifting on a daily basis.

5.1.2 Key findings in relation to illicit drug use (and alcohol/nicotine)

There was a significant positive correlation between the age of a client and their monthly level of spending on illicit drugs, this was primarily based on a correlation between age and spending on heroin in particular. On average each client in the sample spent over £680 (£22.50/day) per month on illicit drugs. However, one of the more interesting findings was that clients whose scripts include mixture spend significantly less on drugs than clients whose scripts include ampoules or reefers. An average of £638 per month was spent on 4.1 grams of heroin per client. Cannabis was the second most popular drug, with 59% of the sample consuming an average of 12.2 grams per week.

Clients reported spending, again on average, just over 2 hours per day on drug related activities. The exceptions to this were clients whose script included injectable drugs (ampoules) who spent significantly less time on drug related activities compared with other clients. Those on ampoules spent an average of 1.4 hours per day as compared to 2.3 hours for those on mainly mixture and/or reefers.

There were three significant effects of script type on the use of specific drugs, speed, cocaine and cannabis; Clients on mixture scripts were significantly more likely to use speed than clients on reefers or ampoules, Clients on ampoules were significantly more likely to use cocaine than clients on reefers or mixture, and Clients on mixture used significantly less cannabis than those whose scripts include reefers or ampoules.

More than two thirds (70%) of the sample reported using illicit drugs along with their script, and half of these (48%) injected illicit drugs. Heroin was the most commonly used illicit drug (61% of clients reported using it in the past month), followed by benzodiazepines (17%), cocaine (17%) and methadone (11%). The vast majority (87%) acquired these illicit drugs from either a dealer or other users, and most (84%) reported using social security benefits to pay (at least in part) for them.

Seventy seven percent of the sample smoked daily, with an average of 18 cigarettes per day. Only one third of the sample reported consuming alcohol in the past month, however those who did consume alcohol reported an average consumption of 40 units per week - a far higher figure than the national average (in 2002 the mean weekly consumption for men was 17 units and 8 units for women, ONS 2004).

5.1.3 Key findings in relation to client perceptions and attributions.

In terms of client perceptions and attributions, four significant effects were found; two related to satisfaction with their script, and one each related to perceived self-efficacy and quality of life.

Focusing on the form of the script (ie amps/mixture/reefers), those clients whose scripts included mixture were significantly less happy with their script compared with other clients. (ratings of 2.7 and 3.9 respectively) Focusing on specific drug+form combinations, those clients on methadone mixture were significantly less happy with their scripts compared with clients on heroin reefers. (ratings of 2.4 and 3.6

respectively). It's clear that clients preferred heroin to methadone, and injectables and smokables to mixture.

The rating scale ran from 1 (very unhappy) to 5 (very happy), with 3 representing neutral. The mean for the total sample was 2.95, the mode was 4.0.

The other two significant effects observed both focused on those receiving injectable drugs as part or all of their script; these clients perceived themselves as significantly more able to cope with life compared with other clients (on mainly mixture and/or reefers), and they also perceived their quality of life, compared with one month ago, as significantly more improved compared with other clients. (this may be because injectors have more room for improvement?)

5.1.4 Key findings in relation to Crime and Drug Use in combination

As expected, there were significant effects of past month crime (either committed a crime in the past month or didn't) on overall drug buying, and overall drug use (although this is based largely on specifically heroin and cocaine use). Those who had bought drugs had committed significantly more crime than those who hadn't, and those who had used illicit drugs in the past month had committed significantly more crime than those who had not used illicit drugs. Focusing on heroin and cocaine; 75% of heroin users had committed crime (compared to 44% of non heroin users), and 100% of cocaine users had committed crime (compared to 56% of non cocaine users).

5.2 Interpretation of findings.

In terms of their relevance to the material/studies cited in the Introduction, the findings of this study will address each of the stated concerns regarding the advantages and disadvantages of prescribing heroin in the treatment of opioid dependency. One way of summarising these advantages and disadvantages is as follows:

5.2.1 Two dimensions of drug taking consequences

The findings of this study will be interpreted in terms of Newcombe's two-dimensional scheme, which produces nine categories of drug taking consequences from the three-valued dimensions of type and level. (Newcombe 1991). The development and implementation of a conceptual framework allows practitioners and policy makers to measure the relative effectiveness of specific harm reduction initiatives. Harms and benefits can be organised according to many schemes, depending on the objectives of the classifier and tolerance for complexity. In this two-dimensional scheme the 'type' dimension has three levels: health (including physical and mental health), social (including public order/disorder, social integration etc) and economic (financial factors). The 'level' dimension refers to: individual (the drug user), community (including family, friends, neighbours), and societal (criminal justice/health services, overriding culture). The original scheme, including examples of selected consequences is shown in table 5.2.

Table 5.2: Two-dimensional scheme; Model of drug-related consequences (Newcombe 1991)

	<u>Type of drug related harm</u>		
Level	<i>Health</i>	<i>Social</i>	<i>Economic</i>
<i>Individual</i>	eg. infection due to poor injecting technique		
<i>Community</i>		eg stigmatisation of the relatives of a known problem drug user	
<i>Societal</i>			eg the cost of drug related law enforcement

As stated in the Introduction, in terms of prescribing heroin as an effective substitution treatment, it appears that some medical practitioners and government policy makers are at odds in terms priorities; the medics prioritising the need of the individual to be drug free/healthy, and the policy makers prioritising the needs of the wider community in terms of the reduction of crime/other costs. An effective treatment strategy clearly needs the support of both groups, and will therefore have to address clinical needs and societal needs. In terms of the two-dimensional scheme economic needs will also have to be addressed.

In terms of this two dimensional scheme, the relative advantages and disadvantages associated with prescribing heroin, can be mapped out as per the tables below:

Table 5.3: Model of drug-related consequences: Positive features of prescribing heroin (adapted from Newcombe 1991)

<u>Type of drug related harm</u>			
Level	<i>Health</i>	<i>Social</i>	<i>Economic</i>
	1	2	3
<i>Individual</i>	<i>'clean' unadulterated drugs, measured doses</i>	<i>stabilised – possible to work/meaningfully contribute to society</i>	<i>no need to steal etc to fund habit</i>
	4	5	6
<i>Community</i>	<i>more users attracted Into treatment + off the streets</i>	<i>reduces the need for 'pyramid' selling - reducing demand</i>	<i>reduction in crime will see insurance drop</i>
	7	8	9
<i>Societal</i>	<i>reduced amounts of street drugs around due to less demand</i>	<i>reduced demand on social services/crisis intervention services</i>	<i>reduced costs of drug related law enforcement</i>

(numbers will be used for reference in the text below)

Table 5.4: Model of drug-related consequences: Negative features of prescribing heroin (adapted from Newcombe 1991)

<u>Type of drug related harm</u>			
Level	<i>Health</i>	<i>Social</i>	<i>Economic</i>
	10	11	12
<i>Individual</i>	<i>prolongs the drug using career</i>	<i>potential for↑ in very specific heroin related problems eg pregnancy</i>	<i>no incentive to work, pay tax contribute etc</i>
	13	14	15
<i>Community</i>	<i>more pure heroin around, ↑ risk of diversion</i>	<i>heroin use may be perceived as more normal/mainstream</i>	<i>no illegal income so more reliant on benefits if not in work</i>
	16	17	18
<i>Societal</i>	<i>↑presc. of h at the expense of other drugs/patients</i>	<i>increased need for control and law enforcement to police the programme</i>	<i>increased costs to pay for health & legal services</i>

(numbers will be used for reference in the text below)

5.2.2 Findings in relation to previous research and theoretical issues.

Findings can be grouped into the following broad categories (and will be discussed in relation to previous work and the dimensions illustrated in the previous tables):

Prescription factors – including the form of the prescription, the content (including dose levels) of the prescription, and criteria for prescribing heroin.

Client factors – including perceptions and attributions, the risk of prolonging addiction/injecting, health implications, retention figures, and measures of self-efficacy.

Socio-Economic factors – including the impact on crime and criminal activity, cost implications and the issue of dispersion. (Dispersion crosses all three groups of factors if issues of supervised consumption and/or daily ‘pick ups’ are to be considered in response to concerns about leakage and the creation of a new group of clients).

5.2.2.1 Prescription factors

The finding that those prescribed ampoules spent significantly less time per day on drug related activities (which included committing crime) than those on other scripts, concurs with the findings of McCusker et al (1996). This suggests support for the assertion (*boxes 2+3* above) that in terms of reducing harm in the Social/Individual, and Economic/Individual categories, stabilising clients (on injectables in this case) allows opportunities to spend time more productively and to move away from criminal activity. The findings of the McCusker study are considered particularly relevant to the present study for two reasons: the study was also based in the North West of England (Manchester), with geographical, political and prescribing

similarities, and it was conducted during approximately the same time period (1995/6).

In terms of the impact of prescription factors, the randomised control of treatment regimes is possibly the biggest single influence in terms of securing empirical evidence to support/challenge the effectiveness of prescribing heroin. Clients in the current study were already registered at the clinics, receiving treatment based on clinical prescribing guidelines and individual drug taking histories. It is difficult to imagine another UK trial that would secure ethical approval for a randomised allocation of clients, and as such, Hartnoll et al's (1980) findings will continue to attract attention as the only UK study of its kind.

The other major prescription factor, and one that was frequently mentioned in all of the previous key studies, was dose, and in particular the heroin dose. The fact that the heroin dose was relatively small compared to the methadone dose available was cited as a major confounding variable in both the Metribian et al (2001) and Hartnoll et al (1980) studies. The Swiss and Dutch studies did not restrict dose, but they did enforce supervised consumption. (risk of dispersion was cited as one of the main reasons why Metribian et al (2001) and Hartnoll et al (1980) did cap the heroin doses) In the current study, the mean ampoule dose was 155mg, mixture dose was 64mg, and the mean reefer dose was 360mg (reefers were dispensed in either 60mg or 100mg amounts per cigarette, and larger amounts were prescribed to account for poor inhalation and/or sidestream loss). Overall, both in this study and in the other three UK based studies, prescribed doses of heroin were much smaller than those prescribed in either the Swiss or the Dutch trials. (see Table 5.5)

Table 5.5: Daily doses of heroin – UK, Swiss & Dutch trials.

	UK	Switzerland 3	Netherlands 4
<i>Regulation or guideline.</i>	No upper limit	None	1000mg daily and no single dose greater than 400mg
<i>In practice</i>	Range 5-1,500mg 1	500mg for injectable heroin	Mean 549mg for injectable heroin
	Mean 175mg 2	1,000-1,850mg for smokable heroin	Mean 539-547mg for smokable heroin

notes:
1. Metribian et al (2002), 2. Strang and Sheridan (1997), 3. Uchtenhagen et al (1999), 4. van den Brink et al (2002)

source: Stimpson and Metribian (2003)

In terms of dose, the capped levels of heroin in each of the three main UK trials compromises any conclusions regarding the relative effectiveness of heroin versus methadone in terms of any illicit drug use associated with each script. The current study recorded doses (mean ampoule dose 155mg, mixture dose 64mg), which are approximately in line with current recommendations regarding conversions between oral methadone and injectable heroin doses. The NTA (2004) recommends that a daily dose of injected heroin of between 141-180mg converts to between 50-60mg of oral methadone. Parry (1992) reviewed available evidence and concluded that an optimal daily dose regime of heroin is generally between 300-400mg, and he further argues that any attempts at heroin maintenance with daily doses of no more than 100mg will inevitably lead to ‘topping up’.

Establishing clear criteria for identifying which clients have a clinical need for heroin is a crucial aspect of any treatment programme proposing to prescribe injectable (and/or smokable) opiates. If these criteria are explicit and measurable they will help

clinicians identify those clients for whom heroin is the best option, and go some way to reducing dispersion by ensuring the correct client gets the correct script. In the current study, those receiving injectable/smokable scripts had to comply with the prescribing guidelines issued by the Department of Health, those being; confirmed (using urine samples) physical dependency on heroin and/or, regularly using heroin intravenously, and/or had a minimum of six months regular non intravenous use. The client must also show that they are motivated to change at least some aspects of their drug use. Other considerations included a comprehensive assessment (history, urine toxicology, drug diary) and a doctor/team decision that the client was willing to comply with the requirements of the prescription regime. (DoH 1991)

The admission criteria for the Swiss and Dutch trials were generally stricter than those above. For example, the Swiss trial required clients to have had a heroin dependency for a minimum of two years, to have had a negative outcome on at least two previous treatments, and to have documented health and social deficits as a direct consequence of heroin dependence. The Swiss trial was particularly interesting as it continues to be the only one which addresses the concern that clients might somehow ‘choose’ to fail in methadone treatment to secure a place on a heroin programme. Of the 24 clients who missed out on the initial chance to receive a heroin script (randomly allocated), only nine opted to make the switch from methadone to heroin when offered the chance six months later. (In spite of the fact that all clients had wanted heroin at the onset of the trial) (this also ties in with *box 10* above).

In terms of identifying those clients best suited to heroin substitution treatment, Hartnoll et al (1980) stated that theoretically it should be possible to determine who

will benefit from which type of treatment. However they go on to suggest that individual clients can change in their capacity to respond to clinical intervention, and once an injectable prescription is initiated, it can then prove difficult for the clinician to alter. Hartnoll et al also suggest that the rapid sharing of information which exists in any sub culture inevitably results in the treatment offered to one client raising the expectations of others.

5.2.2.2 Client factors

Ashton and Witton (2003) raised the question that the attraction of prescribing diamorphine may at the same time be one of its major drawbacks. The opportunity to receive safe, high quality and free diamorphine may prove to be a significantly effective motivator to 'fail' in methadone treatment. In addition, it could also be argued that once stabilised on their drug of choice, the prescription of diamorphine could in fact prolong an addict's period of addiction.

The issue of retention rates was not explicitly addressed in the current study, as external factors prevented a longitudinal follow up. However, if the perception/attribution factor of how happy clients report being on particular scripts is taken as a possible indicator of how likely it is that clients would remain in treatment, then the findings that: firstly, those clients whose scripts included mixture were significantly less happy with their script compared with other clients; and secondly, that those clients on methadone mixture were significantly less happy with their scripts compared with clients on heroin reefers, would both support the findings of Hartnoll et al (1980) who found 76% of those receiving diamorphine were still in

treatment 12 months later, compared to 26% receiving oral methadone. Conversely, the Dutch study found that 86% those clients receiving methadone completed the 12 months of treatment as compared to 70% of those prescribed injectable heroin. (van den Brink et al 2002). One possible explanation for this could be the strict demands placed on those clients attending the heroin treatment regime, many of whom were forced to leave for disciplinary rule-breaking reasons. Others may have voluntarily decided to opt into the methadone programme once stabilised on heroin, to eliminate the need for daily pick ups and supervised consumption etc. (this factor may in part relate to *box 10* above, and may hold the key to achieving a balance between treating the clients addiction and prolonging it).

One of the specific health factors, which may be associated with increased harm following heroin prescribing, is pregnancy. This was not investigated as part of the current study however it does warrant some discussion as it featured in one of the key previous trials. Pregnant or breast feeding women were excluded from the Dutch and UK trials. There were 12 pregnancies in the Swiss trials between 1994 and 1996, these resulted in eight live births, three terminations, and one spontaneous abortion during heroin withdrawal. These results were similar to those for women receiving methadone maintenance treatment. (Bammer et al 2003) It would seem fair to suggest that the advantages associated with retaining the pregnant client in heroin treatment in terms of additional health/welfare support, may out weigh the negative effects associated with experiencing pregnancy whilst using heroin illegally, outside of the treatment system. However, in 2004 the National Treatment Agency issued a dosing guidance paper for pilot sites planning to offer IOT (Injectable Opiate Treatment) and concluded that due to a lack of adequate research regarding IOT, (and in recognition of the relatively large amount of evidence regarding oral methadone in pregnancy)

“IOT cannot be routinely recommended in pregnancy” (NTA 2004)

(*box 11*, p 91)

Dr John Marks, the consultant psychiatrist at the two community drug teams at the centre of this study summed up the findings of longitudinal research into heroin use, that the average ‘career’ of a heroin user was approximately 10 years, after which time the user would either stop, switch to methadone, be residing in prison or be dead. (Marks 1991). He suggested that one of the goals of treatment was to minimise the harm experienced by the user during this 10 year period, empowering the individual and keeping them healthy. This belief underpinned his faith in the merits of flexible prescribing, including injectable and smokable heroin. In the current study, clients whose scripts included injectable drugs perceived themselves as significantly more *able to cope with life* compared with other clients, and those clients whose scripts included injectable drugs perceived their *quality of life*, compared with one month ago, as significantly more improved compared with other clients. The findings of the Swiss study also showed positive changes for those prescribed heroin; accommodation situations had improved and employment rates had doubled. (Uchtenhagen et al 1999)

5.2.2.3 Socio-Economic factors

Criminal activity will continue to play a central role in any discussion about drug treatment, heroin based or otherwise. It is clear from this study that criminal activity was present across all script groups/combinations, albeit in slightly differing amounts. With no baseline measure of criminal activity prior to treatment it is not possible to assess the impact of script on subsequent criminal behaviour for this sample. Those

studies, which were able to establish baseline measures of criminal behaviour all, found that crime was reduced but not eliminated. The Dutch study found that only half of the clients receiving heroin were involved in crime after 12 months in treatment, while crime amongst the control group remained high. (van den Brink et al 2002). Hartnoll et al (1980) and Metribian et al (1998) both found that crime was reduced but not eliminated.

In terms of dealing part/all of their script, those receiving essentially mixture form based prescriptions reported very similar (but still relatively low compared to frequencies of other types reported) levels of crime to those receiving reefer-based scripts. In contrast those receiving ampoules reported low levels of script dealing – this has clear implications for concerns raised about dispersion and supervised consumption.

The costs of prescribing heroin are often significantly increased, as they were in the Swiss and Dutch trials, by costs associated with supervised consumption designed to monitor dosing levels, advise on injecting techniques, and prevent dispersion.

As a result of supervised consumption, dispersion was not an issue in the Swiss and Dutch trials, however in the UK heroin is/was prescribed like any other drug; for consumption at home. The practicalities of turning criteria established for a trial into generic treatment practice require a significant amount of planning, not least in terms of establishing a network of accessible locations at which clients could inject. One possible answer, trialed during the Metribian et al (2001) study, would be to require clients to return used ampoules before receiving new ones. (*box 13, p91.*) (recently the use of marker chemicals has also been suggested, they are added to the ampoules and clients are randomly tested for them).

Advocates on both sides of the prescribing heroin debate to support their case cite cost implications. (boxes 9,15+18) Stimpson and Metribian (2003) estimated that it costs between £7,717-£9,691 per addict per year to prescribe (a supervised) injectable heroin script, compared to £2,800 for a methadone prescription (excluding supervised consumption). It is true to say that the differences in cost are often related to the manufacturing process rather than the pharmaceutical process, along with the nature of the script delivery. (eg. frequency of 'pick ups' influences pharmacy related charges). At the time of this study the relevant prescription costs per year were £100-£200 for oral methadone, £300-£600 for reefers, and £1000-£2000 for injectable opiates. (Marks et al 1991)

Strang and Farrell (1992) stated that:

“On any day nearly a quarter of a million clients receive oral methadone worldwide, compared with probably fewer than 1000 who receive injectable methadone, morphine or heroin” (p182)

It is clear that factors other than prescription cost must be established if those who advocate prescribing heroin are to convince the policy makers of its financial merits. In the case of the Swiss study, the calculated comparison of the treatment costs with the economic benefits, showed that there was a total benefit per patient per day of \$26.00. (Treatment costs, including drug, personnel, location, hours of operation etc. were on average \$30.00 per day. The economic benefit, including reduced cost of criminal investigations and imprisonments, were estimated at \$56.00 per day) (Brehmer & Iten 2001)

5.3 Critique of methodological approach

Ashton and Witton (2003) highlighted the fact that “despite its unique history, British evidence on diamorphine’s value is thin... Worldwide there are just five directly relevant studies”. In designing and implementing this study, it became clear as to why there have been so few pieces of empirical work in the area of heroin substitution treatment.

5.3.1 Complexity of design

This study did not include a pre treatment measure, and was in effect a ‘snapshot’ of clients in-treatment behaviour during the month prior to interview. As such, no baseline measures were taken, for example regarding drug use and criminal activity, with which to then compare behaviour whilst receiving a particular script/combination. Baseline factors are also relevant when looking at the time clients had been registered at the clinic. With a range of between 1 month and 21 years (mean three years) its clear that; i) baseline criteria figurers for 20 years ago, the mid 80’s, when treatment practices had different areas of emphasis, would be potentially very unlike those relevant to clients presenting for treatment today. (Indeed, issues relevant at the time of this study, 1995-97, are now moving ‘full circle’ with what was a rather unusual prescribing practice in the mid to late 90’s now being experimented with by senior healthcare policy makers and government ministers).

In a laboratory setting, the ability to control extraneous variables whilst randomly allocating matched participants to experimental and control groups, is clearly one of the most valid methods of evaluating the effectiveness of particular

interventions/treatments. However, when working with problem drugs users this is seldom possible for a variety of practical and ethical reasons. A random allocation of clients (who meet certain criteria for inclusion) as they present at CDT's would of course enable researchers to attribute resulting differences to prescribing regimes rather than client characteristics. The practicalities of this are not quite as straightforward. In the present study, the consultant psychiatrist and his team, with prescription form and drug being decided upon in response to a range of clinical and health related measures, had already assessed clients. It may well be the case that with the recent government statements regarding a possible expansion of the heroin prescribing 'base', future work may well be able to adopt a random allocation policy, possibly with the use of a placebo. The ethical considerations will remain, particularly if results go on to show that those receiving the control/placebo continued to commit crime, do harm etc.

5.3.2 Representativeness of sample.

In the current study, the sample was essentially representative of the population from which they were taken (total number of clients registered at the 2 clinics) in terms of age and gender. However, as cited in the Introduction, prescribing practices vary nationally from region to region, (dependant on a number of factors including the clinical judgement and practices of the consultant psychiatrist), and it is not therefore possible to draw direct comparisons with clients registered at clinics elsewhere. The fact that the government now seems keen to initiate national treatment policies across the country, offering similar services regardless of location, may well address this. The various national treatment agencies, drug data bases and government papers are all contributing to a more coherent nationwide treatment programme, which should help researchers conduct studies, the findings of which will be more representative of the problem drug using population as a whole.

In terms of the five key previous studies, Stimpson and Metribian (2003) suggested it was unclear as to how far the results were generalisable given the different treatment contexts within which each was carried out. They conclude:

“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” (Stimpson & Metribian 2003)

5.3.3 Measuring and reporting ‘effectiveness’

As reported in Chapter two, it would appear to be the case that medical practitioners and government policy makers are at odds in terms priorities; the medics prioritising the need of the individual to be drug free, and the policy makers prioritising the needs of the wider community in terms of the reduction of crime. A third group, the problem drug users, also have a stake in the evaluation and effectiveness of heroin prescribing.

Any research has cost and other resource implications. This current study benefited from the independence associated with academic enquiry, and as such draws conclusions, which may legitimately and without favour support and/or refute the claims of any one or all of the groups above. It is clear that any piece of research in the applied field of drug use will not see positive outcomes in all areas. The current study attempted to address issues relevant to the three key groups, whilst at the same time offering conclusions in a non-hierarchical manner.

When reporting findings it is important to remember that they may well offer contradictory support depending on the focus of the reader. Emphasis may well be placed on free, clean, unadulterated drugs and psychological well-being by the problem drug users, on HIV risk behaviour, illicit drug use and general health levels by the medical practitioners, and on levels of crime and risk of dispersion, by government policy makers.

5.4 Implications for prescribing policy and practice

5.4.1 Government policy for heroin prescribing

In May 2003, the then Home Secretary, David Blunkett, confirmed that guidelines were to be issued to GP's regarding the prescribing of injectable heroin to 'hard-core' problem drug users in an attempt to curb their criminal behaviour and manage their addiction. Blunkett stated:

“we need radical thinking about how we engage them in treatment. Prescribing heroin is all about what is right for the individual. It is about making it available to all those with a clinical need” (Travis, 2003)

Also in May 2003, the NTA produced guidelines for practitioners in drug treatment services on the potential role of injectable heroin and methadone in the treatment of opioid dependency. In these guidelines they made three key recommendations;

- Optimised oral methadone maintenance should be the maintenance treatment for the majority of heroin users
- Injectable heroin and methadone treatments should be considered only for the minority of patients who are genuinely unresponsive to an optimised oral maintenance treatment approach
- Injectable heroin and injectable methadone treatments based on this guidance should be seen as a new drug treatment modality requiring the development of new integrated care pathways

In making these recommendations the NTA was keen to emphasise that injectable prescribing should be seen very much as the exception rather than the rule. They

stressed the importance of eligibility criteria to ensure only appropriate (in terms of age, compliance, and previous treatment failings) clients received heroin, and when they do receive injectables, that maintaining stability on them is paramount. (NTA 2003) (To date, NTA documents and policy make no mention of smokables)

5.4.1.1 Potential problems: GP co-operation

One of the main problems the government face in their plans to offer increased provision for heroin prescribing is from GP's themselves, who's arguments have two main areas of focus; liability and funding.

Some doctors fear that legal action might follow if a patient died as a result of overdosing on heroin prescribed by their GP. The secretary of the Royal College of General Practitioners, Dr Claire Gerada, cautioned against expanding the programme of heroin prescribing in primary care settings until the research base in support of this was clearer. Dr Gerada also pointed out that heroin is an expensive drug, and that once a patient was placed on prescribed heroin it may very likely be for some considerable time, possibly for life. As budget holders, GP's would therefore be reluctant to take on such a commitment without significant financial support from the government in the form of specialist drug treatment contracts. (Travis, 2003)

5.4.2 Implications for policy and services

The biggest implication in terms of policy development seems to centre on the growing recognition that it too needs to be flexible.

In a media statement released on the 15th January 2002, the NTA reiterated its commitment to the full range of treatment options, including heroin prescribing, which it was suggested could be used as a gateway treatment to encourage ‘difficult to reach’ clients into treatment. The NTA stressed the need for a flexible and inclusive regard to service development, based on foundations of research and empirical evidence:

“The NTA is interested in what works best for the users, and for the community as a whole. We do not have ideological barriers and we will look to develop treatment guidance that is based on solid evidence. We will, when necessary, commission research to identify best practice” (NTA 2002)

The NTA are in the middle of a consultation process to set up a trial with around 800 injectable opiate users being prescribed injectable heroin. As yet the exact details are unclear.

5.4.3 Implications for treatment

Regardless of the success or otherwise of heroin prescribing, it is clear that it seems unlikely to replace oral methadone as the drug of choice for service providers. Its widespread introduction would be precluded by a number of factors including expense (mainly those associated with imposing safe guards like supervised consumption,

medical support etc), and the fact that it has a relatively short acting nature. However, even the limited number of studies done to date would suggest that heroin prescribing does have an important supporting role as an adjunct to methadone maintenance, particularly in terms of treating those clients for whom all other forms of treatment have failed. (Bammer et al 1999)

One of the major concerns regarding the prescribing of heroin is the risk of dispersion; this is increasingly held up as one of the most potent and emotive weapons in the armoury of those opposed to flexible prescribing. Possible solutions include supervised consumption, as in the Swiss and Dutch trials, daily pick-ups, and a system of exchange based on returning empty ampoules before receiving new ones (as in the Metribian et al. (2001) trial in the late 1990's). Focusing specifically on the UK, which has a diverse range of problem drug users who are not all city based or living close to clinics, the exchange system may well prove to be the cheapest and least intrusive method of preventing dispersion.

Suggesting a different perspective on the issue of dispersion, John Marks took the opinion that restricting heroin to particular people/small numbers is in fact the *cause* of leakage, because a rare and valuable commodity is made, available in a sub culture where things are constantly bought and sold. He argues conversely, if heroin was really made available to everyone who has a 'need', and all clients who wanted it were given it, then who would be left to buy the leakage? (Marks 1985)

In the 2005 update the National Treatment Agency made some significant changes to the previous 2002 Models of Care in relation to treatment. (see Table 5.6 below)

Table 5.6: NTA Strategies for improving 4 stages of drug treatment

Stage of treatment		Effectiveness indicators
1	Engagement and retention	(a) New client numbers & waiting times (b) 12-week contact rate
2	Delivery	Care/prescribing plans Number of treatment staff
3	Maintenance or completion	(a) number stabilised & (b) number drug-free
4	Reintegration into community	eg. numbers employed, educated, housed, etc.

Whilst not explicitly referring to heroin prescribing, the broadening of the range of available treatments would have clear implications for three of the four stages of treatment; 1. Offering injectable/smokable heroin as a potential option may serve to attract a more diverse range of clients into treatment, 3. clients may stabilise on heroin as their drug of choice, reducing the need to use illicit drugs, and 4. On a stable prescription regime, crime free, clients may feel able to stabilise other aspects of their lives, similar to those patterns seen in the initial heroin trials in the 1990’s. (UK, Swiss and Dutch)

5. 5 Heroin use in the mid 2000’s - prevalence/characteristics

The National Drug Treatment Monitoring System (NDTMS)(run by the NTA), produced the following count of problem drug users for 2001-2005:

Table 5.7: Annual number of problem drug users in treatment in England, 2001-2005

	<u>Completed</u>	<u>Retained</u>	<u>Left treat.</u>	<u>OVERALL</u>	<u>Completed or retained (%)</u>
2001/02	18,100 (12)	57,400 (39)	70,800	146,300	75,500 (52)
2002/03	25,000 (15)	55,700 (34)	85,200	165,900	80,700 (49)
2003/04*	13,000 (10)	77,500 (61)	35,050	125,550 ^	90,500 (72)
2004/05	15,800 (10)	104,900 (65)	39,750	160,450	120,700 (75)

NOTES

~ based on estimation methods employed in 2000/01 to 2002/03 – though the exact comparable figure (not reported by NTDTMS) is based on ‘retained’ plus ‘left treatment’ – i.e. 112,900 in 2003/04

* NDTMS set up in 2000/01, though a new data completion system was introduced in 2003/04, with tighter definitions and methods – leading to adjusted figure of 125,550 people in treatment during 2003/04 (almost 30,000 fewer than overall estimate based on previous methods). Also, numbers exclude people treated in prison (7,500 in 2003/04) or outside of England

Completed: successfully completed treatment during year, including being referred to other agencies. figure is excluded from total annual number (i.e. total based on retained and left treatment cases only)

Retained: remaining in treatment at end of year

Left: dropped out of treatment during the year (not reported from 03/04, but inferred from total (in italics))

^ figure for 2003/04 revised in October 2005 (in report on 2004/05 figures) – from 125,900 (i.e. 350 lower)

Source: www.nta.nhs.uk

Clearly the numbers (and percentages) of those retained in treatment is increasing, however those successfully completing treatment (or being referred to other agencies) has remained static at 10%, and given the ever increasing numbers entering treatment this figure alone suggests alternative approaches need to be investigated.

5.1 Conclusions

In conclusion, empirical evidence seems to be the key to addressing the who, why and how questions associated with prescribing heroin. The gathering of such evidence needs government funding, clinical support and client co-operation, and the successful involvement of all three could potentially lead to unique and mutually beneficial developments in treatment policy and practice.

In one of the very few studies which sought the opinions of drug using clients as to the merits of injectable heroin (and methadone) prescribing, three key features were apparent in terms of client motivation; a desire to obtain a safe drug supply of known dose, to improve family relationships, and to avoid getting into trouble with the police. (Sell & Zador 2004).

It is clear that implementing a research/evidence based coherent strategy to prescribe heroin, or to at least develop a large scale pilot study to look at the feasibility of a genuinely flexible national prescribing policy, needs to be a priority for all involved. Any future decisions regarding the treatment of opioid clients need to be made in a context of transparent and measurable outcomes, based firmly on the commitment, at all levels, to reduce harm.

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APPENDIX ONE - QUESTIONNAIRE

Thank you for agreeing to take part in this
short, confidential study.

THE PURPOSE OF THIS STUDY IS TO FIND OUT WHAT *YOU*
FEEL ABOUT YOUR CURRENT 'SCRIPT, AND HOW IT AFFECTS
YOUR EVERYDAY LIFE.

*ALL OF THE ANSWERS YOU GIVE ARE COMPLETELY
CONFIDENTIAL NO INFORMATION ABOUT ANY INDIVIDUAL
CLIENT WILL BE PASSED ON TO THE CLINIC STAFF,
OR TO ANYONE ELSE.*

AS A PARTICIPANT IN THIS PIECE OF WORK, YOU WILL HAVE
ACCESS TO ITS FINDINGS AND CONCLUSIONS.

WHEN YOU HAVE COMPLETED THE QUESTIONNAIRE,
PLEASE RETURN IT TO ME IN PERSON, OR
IF YOU PREFER POST IT DIRECTLY TO ME IN
THE CONFIDENTIAL, FREEPOST ENVELOPE PROVIDED.

Once again, thank you for your co-operation

Sally Woods
Liverpool John Moores University

Section A: Questions about your 'script.

1 What is your **current** script?
[Please give as much detail as possible e.g. Methadone, diamorphine,
etc? Amps, mixture, reefers etc? How many mg's / ml's?

AMPS: (how much?)

MIXTURE: (how much?)

REEFERS: (how much?)

OTHER: (how much?)

2 Approximately how long have you been on this 'script?

_____ YEARS _____ MONTHS or _____ WEEKS

3 How happy are you with this 'script?
(please circle one number)

1	2	3	4	5
very unhappy	unhappy	neutral	happy	very happy

4 Who decided that you should have the 'script you are now on?
(please tick one response)

You _____

The clinical staff _____

A joint decision between you and the staff _____

5 If you could, would you like to change your 'script?

NO [] (please go on to question 6, on the next page)

YES [] a] **How** would you like to change your 'script?

b] **Why** would you like to change your 'script?

Section B: Questions about drugs you use in addition to your clinic 'script
le, those you use to "top up" the effects of your 'script

THE FOLLOWING QUESTIONS ASK ABOUT YOUR DRUG USE OVER
THE LAST MONTH:

6 On average, during the last month, how much and how often did you
consume any of the following?
(please say how much and how often for each, and leave the line
blank if you didn't use that particular drug)

	HOW MUCH PER DAY / WEEK	HOW OFTEN DID YOU TAKE IT
(e.g. CANNABIS	<u>¼ ounce per week</u>	<u>every day</u>
a)Cannabis	_____	_____
b)Nicotine	_____	_____
c)Alcohol	_____	_____

7 APART from the 'script you receive from the clinic, what other drugs have you taken In the last month?
(for each drug you used, please give an average estimate of **how much** used in a week, and **how often** you used it, if you did not use any drugs, please go to SECTION C)

DRUG	HOW MUCH IN THE WEEK / MONTH	HOW OFTEN DID YOU TAKE IT
(e.g., Heroin	4 grams per week	every day)
A) HEROIN	_____	_____
B) DIAMORPHINE	_____	_____
C) METHADONE	_____	_____
D) AMPHETAMINE	_____	_____
E) COCAINE	_____	_____
F) OTHERS: please state		
_____	_____	_____
_____	_____	_____

8 DURING THE LAST MONTH, have you INJECTED any of the drugs you use to “top up” your ‘script?
(do not include any injectables which you receive as part / all of your ‘script)

NO [] (please go on to question 9)

YES [] a) Which drugs?

b) DURING THE LAST MONTH, how often have you injected “top up” drugs? (please tick one box only)

- 7 or more times per day []
- 3 – 6 times per day []
- 1 – 2 times per day []
- 3 – 6 times per week []
- 1 – 2 times per week []
- 1 – 3 times per month []

9 Where do you get these extra “top ups” from?
(please tick all appropriate boxes, I don’t want any names etc)

- Other registered users []
(i.e., part of someone else’s ‘script)

Family member / Partner []
- Other users (not registered) []
(i.e., drugs from the street)

Dealer []
- GP/ Health Centre []

Other (please specify) []

10 ON AVERAGE, how much do you pay for the drugs you use to “top up” your clinic ‘script? **Please indicate in what form you buy the drug/s e.g., Amps, Reefers etc.** (please leave the line blank if you do not use that particular drug, and add any others you use in spaces g and h)

HOW MUCH DO YOU PAY?

a) HEROIN:

b) DIAMORPHINE:

c) METHADONE:

d) COCAINE:

e) AMPETHAMINES:

f) TRANQUILLISERS:

g)

h)

11 Do you use either of the following to finance your “top up” drug use?
(please tick one box in each row)

	YES	NO
Wages	[]	[]
Social Security / Benefits	[]	[]

SECTION C

12 DURING THE LAST MONTH, please indicate how often, if at all, you engaged in any of the following activities:
(please tick only one box in each row)

HOW OFTEN?

	Every day	3–4 times per week	1-2 times per week	once a fortnight	once a month	not in the last month
Burglary	[]	[]	[]	[]	[]	[]
Shop Lifting	[]	[]	[]	[]	[]	[]
Dealing part/all of your 'script	[]	[]	[]	[]	[]	[]
Dealing street drugs	[]	[]	[]	[]	[]	[]
Prostitution	[]	[]	[]	[]	[]	[]
Theft from family	[]	[]	[]	[]	[]	[]
Other (please specify _____)	[]	[]	[]	[]	[]	[]

13 Why do you / did you engage in any of the above activities?
(please give as much detail as you can)

14 If you were able to receive the 'script you wanted, would this effect your criminal behaviour?

NO [] *(please go on to question 15)*

YES [] a) How would your criminal behaviour be effected?

SECTION D: Questions asking how you feel about your life and about your drug use.
(please circle the number which most closely matches your feelings)

15 How much of your time do you feel is being taken up by drug use?
*(this includes getting to the clinic, collecting your 'script, **and the time it takes to get hold of any "top up" drugs**, e.g., finding the cash, selling stolen goods, prostitution, getting to the dealer, taking drugs etc.)*

- | | | | | |
|------------|-----------|-----------|-----------|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Less than | 2 – 4 | 5 -7 | 8 – 10 | over 10 |
| 1 hour/day | hours/day | hours/day | hours/day | hours/day |

16 How well do you feel you are coping with your new life now?
(for example do you feel you are generally in control of what's going on for you)

- | | | | | |
|----------------------|-----------------|---------------------|----------------|---------------------|
| 1 | 2 | 3 | 4 | 5 |
| coping
very badly | coping
badly | coping
sometimes | coping
well | coping
very well |

17a How does your current quality of life compare to how it was 1 month ago?
(for example do you generally feel any better or worse than you did then)

1	2	3	4	5
a lot worse	worse	no difference	better	a lot better

17b If your quality of life has changed – what do you feel has caused this?

18 What do you feel are the main factors that influence your current drug use?

COULD YOU PLEASE END BY GIVING SOME GENERAL INFORMATION:
(This information will be coded and then this section will be detached from the questionnaire)

Are you male or female? _____

What is your date of birth? ____ / ____ / 19 ____

Thanks for your help, its appreciated.

APPENDIX TWO – CHI SQUARE RAW DATA

Raw data/frequencies for Chi Square Calculations.

Illicit Drug Use.

Clients on mixture scripts were significantly more likely to use speed than clients on reefers or ampoules.

use speed? * Script include mixture Crosstabulation

			Script include mixture		Total
			0	1	
use speed?	no	Count	60	67	127
		% within Script include mixture	100.0%	91.8%	95.5%
	yes	Count		6	6
		% within Script include mixture		8.2%	4.5%
Total		Count	60	73	133
		% within Script include mixture	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.164 ^b	1	.023	.032	.025
Continuity Correction ^a	3.433	1	.064		
Likelihood Ratio	7.431	1	.006		
Fisher's Exact Test					
Linear-by-Linear Association	5.126	1	.024		
N of Valid Cases	133				

a. Computed only for a 2x2 table

b. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.71.

Clients on ampoules were significantly more likely to use cocaine than clients on reefers or mixture.

use cocaine? * Script includes amps Crosstabulation

			Script includes amps		Total
			0	1	
use cocaine?	no	Count	90	21	111
		% within Script includes amps	88.2%	67.7%	83.5%
	yes	Count	12	10	22
		% within Script includes amps	11.8%	32.3%	16.5%
Total		Count	102	31	133
		% within Script includes amps	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	7.233 ^b	1	.007	.012	.010
Continuity Correction ^a	5.824	1	.016		
Likelihood Ratio	6.435	1	.011		
Fisher's Exact Test					
Linear-by-Linear Association	7.178	1	.007		
N of Valid Cases	133				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 5.13.

Criminal Activities

Clients on reefers are significantly less likely to shoplift compared with other clients (mainly on mixture or ampoules).

SHOPLIFT * Script includes reefers Crosstabulation

			Script includes reefers		Total
			0	1	
SHOPLIFT .00	Count		50	37	87
	% within Script includes reefers		58.8%	77.1%	65.4%
	1.00	Count	35	11	46
		% within Script includes reefers	41.2%	22.9%	34.6%
Total		Count	85	48	133
		% within Script includes reefers	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.521 ^b	1	.033		
Continuity Correction ^a	3.750	1	.053		
Likelihood Ratio	4.682	1	.030		
Fisher's Exact Test				.038	.025
Linear-by-Linear Association	4.487	1	.034		
N of Valid Cases	133				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 16.60.

Clients on mixture were significantly more likely to do prostitution than other clients (mainly on ampoules or reefers).

PROSTIT * Script include mixture Crosstabulation

			Script include mixture		Total
			0	1	
PROSTIT .00	Count		60	67	127
	% within Script include mixture		100.0%	91.8%	95.5%
1.00	Count			6	6
	% within Script include mixture			8.2%	4.5%
Total	Count		60	73	133
	% within Script include mixture		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.164 ^b	1	.023		
Continuity Correction ^a	3.433	1	.064		
Likelihood Ratio	7.431	1	.006		
Fisher's Exact Test				.032	.025
Linear-by-Linear Association	5.126	1	.024		
N of Valid Cases	133				

a. Computed only for a 2x2 table

b. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.71.

Crime and Drug Use

Clients who reported buying drugs within the last month were significantly more likely to do 1+ additional crime/s in the past month than clients who had not.

buy illicit drugs (past month) * ACQCRIM Crosstabulation

			ACQCRIM		Total
			no	1+ of 6 crimes	
buy illicit drugs (past month)	no	Count	26	14	40
		% within buy illicit drugs (past month)	65.0%	35.0%	100.0%
	yes	Count	22	57	79
		% within buy illicit drugs (past month)	27.8%	72.2%	100.0%
Total		Count	48	71	119
		% within buy illicit drugs (past month)	40.3%	59.7%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	15.230 ^b	1	.000		
Continuity Correction ^a	13.725	1	.000		
Likelihood Ratio	15.241	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	15.102	1	.000		
N of Valid Cases	119				

- a. Computed only for a 2x2 table
- b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 16.13.

Clients who reported using illicit drugs within the last month were significantly more likely to do 1+ additional crime/s in the past month than clients who had not.

used illicit drug in past month * ACQCRIM Crosstabulation

			ACQCRIM		Total
			no	1+ of 6 crimes	
used illicit drug in past month	no	Count	27	13	40
		% within used illicit drug in past month	67.5%	32.5%	100.0%
	yes	Count	22	71	93
		% within used illicit drug in past month	23.7%	76.3%	100.0%
Total		Count	49	84	133
		% within used illicit drug in past month	36.8%	63.2%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	23.107 ^b	1	.000	.000	.000
Continuity Correction ^a	21.261	1	.000		
Likelihood Ratio	22.854	1	.000		
Fisher's Exact Test					
Linear-by-Linear Association	22.933	1	.000		
N of Valid Cases	133				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 14.74.

Clients who reported using illicit heroin within the last month were significantly more likely to do 1+ additional crime/s in the past month than clients who had not.

use illicit heroin? * ACQCRIM Crosstabulation

			ACQCRIM		Total
			no	1+ of 6 crimes	
use illicit heroin?	no	Count	29	23	52
		% within use illicit heroin?	55.8%	44.2%	100.0%
	yes	Count	20	61	81
		% within use illicit heroin?	24.7%	75.3%	100.0%
Total	Count		49	84	133
	% within use illicit heroin?		36.8%	63.2%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	13.145 ^b	1	.000	.000	.000
Continuity Correction ^a	11.844	1	.001		
Likelihood Ratio	13.119	1	.000		
Fisher's Exact Test					
Linear-by-Linear Association	13.046	1	.000		
N of Valid Cases	133				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 19.16.

Clients who reported using illicit cocaine within the last month were significantly more likely to do 1+ additional crime/s in the past month than clients who had not.

use cocaine? * ACQCRIM Crosstabulation

			ACQCRIM		Total
			no	1+ of 6 crimes	
use cocaine?	no	Count	49	62	111
		% within use cocaine?	44.1%	55.9%	100.0%
	yes	Count		22	22
		% within use cocaine?		100.0%	100.0%
Total		Count	49	84	133
		% within use cocaine?	36.8%	63.2%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	15.377 ^b	1	.000	.000	.000
Continuity Correction ^a	13.538	1	.000		
Likelihood Ratio	22.705	1	.000		
Fisher's Exact Test					
Linear-by-Linear Association	15.261	1	.000		
N of Valid Cases	133				

- a. Computed only for a 2x2 table
- b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 8.11.